UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION MATTER NO.

ADMINISTRATIVE LAW JUDGE:

IN THE MATTER OF: JONATHAN WONG

APPELLANT

APPLICATION FOR REVIEW OF FINAL CIVIL SANCTION

Pursuant to 15 U.S.C. § 3051 et seq., 5 U.S.C. § 556 et seq., and 16 CFR § 1.145 et seq., Appellant Jonathan Wong hereby appeals Arbitrator Nancy Holtz's February 9, 2024, decision in JAMS Case No. 1501000584, as corrected, finding that Appellant committed an Anti-Doping Medication Control ("ADMC") Program violation and imposing a multi-faceted final civil sanction ("Decision"). In a letter dated February 13, 2024, the Horseracing Integrity and Safety Authority ("HISA") notified Appellant that the final civil sanction imposed by the Arbitrator "ha[s] been imposed."

Pursuant to 16 CFR § 1.146(b)(2) and (b)(3), Appellant requests a *de novo* review and reversal of the Decision because (1) the Horseracing Integrity & Safety Unit did not carry its burden of establishing that Appellant's alleged acts, practices, or omissions constituted a violation and (2) the Decision was arbitrary, capricious, an abuse of discretion, prejudicial, the result of a conflict of interest, or otherwise not in accordance with law.

First, the Arbitrator erred by ignoring Horseracing Integrity and Safety Authority ("HISA") Rule 5510's requirements for custodial documentation regarding both chain of custody and storage of blood and urine samples collected post-race. The Arbitrator's failure to confirm HIWU's compliance with Rule 5510 is fatal to the Decision, given that Appellant sought dismissal based on Rule 5510 and HIWU failed to introduce any evidence establishing compliance with Rule 5510.

It is worth noting that, due to the absence of Rule 5510 evidence, Appellant made multiple requests for confirmatory DNA testing during the case, which the Arbitrator denied.

Second, the Arbitrator erred in finding that HISA Rules regarding chain of custody were met because "all of the necessary information was recorded somewhere in each of the laboratories' records and that there were no gaps in the chain of custody." (Decision, p. 36-38, attached as **Exhibit A**). The evidence showed—indeed, the Arbitrator found—that "the present mode of record keeping at the laboratories is inadequate" and the B sample laboratory's "documentation would benefit from some improvements." (*Id.*, pp. 37-38). Moreover, the Arbitrator erred in concluding that HISA Rule 6315(b) was satisfied by her finding that "Marc Benoit conducted a technical review" of the B sample laboratory's documentation and that "his signature was found" on a page with personnel's sample signatures. (Id., pp. 11, 38). The record is absent of any evidence of compliance with Rule 6315(b), as the typed initials "MB" do not meet the Rule 6315(b)'s mandate that two certifying scientists conduct an independent review of a laboratory's analysis and attest to the validity of the laboratory's test results. These errors by the B sample laboratory, along with chain of custody gaps and performance method errors, rendered the laboratory's analysis so unreliable that the analysis could not be used as confirmation of the A sample for purposes of HIWU's burden of proof under HISA Rule Series 3000.

Third, the Arbitrator erred in determining that every departure from the HISA Rules—regardless of its nature—is subject to HISA Rule 3122(d). (*Id.*, p. 42). For example, there is no HISA Rule stating that Rule 3122(d) applies to Rule 5510 (which relates to post-collection sample storage, not to a laboratory's internal chain of custody). Beyond lacking plain-text support, the

¹ HISA Rule 1020 ("Certifying Scientists means personnel appointed by a Laboratory to review all pertinent analytical data, Analytical Method validation results, quality control results, Laboratory Documentation Packages, and *to attest* to the validity of the Laboratory's test results.") (emphasis added).

Arbitrator's overly broad view of Rule 3122(d)'s scope is incongruent with *quid pro quo* fairness; that is, HISA Rules imposing strict liability should be strictly adhered to by laboratories conducting analysis that will be used as the factual basis for an alleged ADMC rule violation.

Fourth, the Arbitrator erred in granting HIWU's Motion for Further Analysis over Appellant's valid objection. Contrary to HISA Rule 1010, the Arbitrator permitted Further Analysis solely for retesting purposes by a different laboratory. This error is confirmed by proposed changes to HISA Rule 1010, attached as **Exhibit B**, that would redefine the term "Further Analysis" to comport with the Further Analysis granted by the Arbitrator, which were proposed during this case.² As Appellant argued in opposition, the indiscriminate use of Further Analysis sets the unfortunate precedent that HISA Rule departures by A sample and B sample laboratories are inconsequential when Further Analysis is always available as a do-over.

Finally, even if the Arbitrator's ruling as to whether Appellant committed the charged violation is not reversed, the civil sanction imposed by the Arbitrator should be. (*See* Ex. A, p. 49). The sanction is arbitrary, capricious, an abuse of discretion, prejudicial, or otherwise not in accordance with law.³

The Decision should be reversed. Pursuant to 16 CFR 1.146(c)(4), Appellant requests a hearing to supplement the factual record with Exhibit B, which shows the aforementioned

² See HISA, "Proposed Changes to the Anti-Doping and Medication Control Program," https://hisaus.org/news/proposed-redline-changes-to-the-anti-doping-and-medication-control-program (Redline 1000 - General Provisions).

³ The Decision was the result of error in other respects—all of which were prejudicial to Appellant—including that Appellant was denied due process under the Fifth Amendment and Fourteenth Amendment to present his defense and confront HIWU's charge. These additional grounds are not waived, and Appellant reserves the right to raise them in these proceedings or another forum.

Moreover, the constitutionality of HISA's enabling statute is in doubt. The Fifth Circuit held that the original statute "is facially unconstitutional." *Nat'l Horsemen's Benevolent & Protective Ass'n v. Black*, 53 F.4th 869, 872 (5th Cir. 2022). The amended statue is being challenged in a separate case in which the Fifth Circuit recently heard oral argument. *See Nat'l Horsemen's Benevolent & Protective Ass'n v. Black*, No. 5:21-CV-071-H, 2023 WL 3293298, at *1 (N.D. Tex. May 4, 2023).

proposed changes to the HISA Rules. Further, pursuant to 16 CFR 1.148, Appellant requests a stay, during these proceedings, of the final civil sanction imposed against Appellant as of February 13, 2024.

Respectfully submitted,

Bradford J. Beilly

Beilly & Strohsahl, P.A.

1144 SE 3rd Avenue

Fort Lauderdale, FL 33316

Phone: 954-763-7000 Fax: 954-525-0404

Email: brad@beillylaw.com

Joel B. Turner

Frost Brown Todd LLP

400 West Market Street, Suite 3200

Louisville, KY 40202-3363

Phone: (502) 568- 0392 Fax: (502) 581- 1087 Email: jturner@fbtlaw.com

Darren A. Craig

Frost Brown Todd LLP

111 Monument Circle, Suite 4500

Indianapolis, IN 46204 Phone: (317) 237-3800 Fax: (317) 237-3900

Email: dcraig@fbtlaw.com

Nolan M. Jackson

Frost Brown Todd LLP

20 F Street NW, Suite 850

Washington, DC 20001

Phone: (202) 292-4150 Fax: (202) 292-4151

Email: njackson@fbtlaw.com

Counsel for Appellant Jonathan Wong

CERTIFICATE OF SERVICE

Pursuant to 16 CFR 1.146(a) and 16 CFR 4.4(b), a copy of the forgoing is being served this 14th day of February, 2024, via first-class mail and/or electronic mail upon the following:

Office of the Secretary Federal Trade Commission 600 Pennsylvania Avenue NW, Suite CC-5610 Washington, DC 20580

Hon. D. Michael Chappell
Chief Administrative Law Judge
Office of Administrative Law Judges
Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, DC 20580
(Copies to oalj@ftc.gov
and electronicfilings@ftc.gov)

Allison Farrell 4801 Main Street, Suite 350 Kansas City, MO 64112-2749 <u>afarrell@hiwu.org</u> Counsel for HIWU James Bunting
Carlos Sayao
Tyr LLP
488 Wellington Street West, Suite 300-302
Toronto, ON M5V 1E3
Canada
jbunting@tyrllp.com
csayao@tyrllp.com
Counsel for HIWU

John L. Forgy 830 Vermillion Peak Pass Lexington, KY 40515 johnforgy1@gmail.com Counsel for HISA

Hon. Nancy J. Holtz
JAMS
160 West Santa Clara Street, #1600
San Jose, CA 95113
nholtzjams@gmail.com
Arbitrator

Nolan M. Jackson

0154543.0773827 4878-8741-8018v4

EXHIBIT A

BEFORE THE HORSERACING INTEGRITY AND SAFETY AUTHORITY'S ANTI- DOPING AND MEDICATION CONTROL PROGRAM ARBITRATION PANEL

ADMINISTERED BY JAMS, CASE NO. 1501000584

In the Matter of the Arbitration Between:

HORSE RACING INTEGRITY WELFARE UNIT ("HIWU" or "Claimant"), Claimant

v.

JONATHAN WONG ("Mr. Wong" or "Respondent"), Respondent.

FINAL DECISION (CORRECTED)¹

I, THE UNDERSIGNED ARBITRATOR, having been designated, and having been duly sworn, and having duly heard the allegations, arguments, submissions, proofs, and evidence submitted by the Parties, after a full evidentiary hearing occurring in person at the JAMS Resolution Center in Chicago, Illinois on January 9 and 10,2024, pursuant to the Horseracing Integrity and Safety Act of 2020 and its implementing regulations, do hereby FIND and DECIDE as follows:

¹ On January 31, 2024, HIWU submitted a letter to the Arbitrator, noting a series of non-substantive mistakes in the Final Decision. It further made a suggestion as to a clarification regarding the relief awarded. Mr. Wong does not oppose HIWU's proposed edits and changes. None of these changes is substantive and they have all been made in this corrected Final Decision.

I. INTRODUCTION

- This case involves allegations of an Adverse Analytical Finding ("AAF") and Anti-Doping Rule Violation ("ADRV") for the presence of the Prohibited Substance Metformin found in the urine and blood samples of a single horse. The Respondent was the trainer for the horse.
 - HIWU is the United States government-recognized entity responsible for sample
- 1.2 collection and results management in the anti-doping testing of thoroughbred racehorses in the United States, pursuant to the Horseracing Integrity Act of 2020, 15 U.S.C. secs. 3051-3060. HIWU was represented at the hearing by James Bunting, Esq. of Tyr, LLP, of Toronto, Canada, Allison Farrell, Esq., Senior Litigation Counsel of HIWU, of Kansas City, Missouri, Carlos Sayao, Esq., of Tyr, LLP, of Toronto, Canada and Maria Naimark, Esq.*, of Tyr, LLP, of Toronto, Canada.

- 1.3 Attending the proceedings for purposes of monitoring only, were Lisa Lazarus,* HISA, of Lexington, Kentucky and Sam Reinhardt,** Esq., HISA, of Lexington, Kentucky.
- 1.4 Mr. Wong is a high-level trainer of thoroughbred racehorses based currently in California. Mr. Wong was represented by Bradford Beilly, of Beilly and Strohsahl of Ft. Lauderdale, Florida, Darren Craig of Frost, Brown, Todd, LLC of Indianapolis, Indiana, Joel B. Turner of Frost, Brown, Todd, LLC of Louisville, Kentucky and Nolan Jackson of Frost, Brown, Todd, LLC of Washington, D.C.,
- 1.5 Throughout this Final Decision, HIWU and Mr. Wong shall be referred to individually as "Party" and collectively as "Parties".

II. THE FACTS

2.1 Below is a summary of the relevant facts and allegations based on the Parties' written submissions, pleadings, and evidence adduced at the hearing. Additional facts and allegations found in the Parties' written submissions, pleadings and evidence may be set out, where relevant, in connection with the legal discussion that follows. While the Arbitrator has considered all of the facts, allegations, legal arguments, and evidence submitted by the Parties in the present proceedings, the Arbitrator refers in this Final Award only to the evidence the Arbitrator finds credible and the submissions necessary to explain her reasoning.

A. The Parties' Stipulated Facts

- 2.2 On December 29, 2023, the Parties agreed on and submitted the following "Uncontested Stipulation of Fact":
 - 1. HISA's Anti-Doping and Medication Control (ADMC") Program came into effect on May 22, 2023.
 - 2. On June 1, 2023, Jonathan Wong was the Trainer of Heaven and Earth, a Covered Horse under the ADMC Program.
 - 3. On June 1, 2023, Heaven and Earth competed in Race 7 at Horseshoe Indianapolis in Shelbyville, Indiana. Heaven and Earth finished first in the maiden special weight race and earned a purse of \$21,600.
 - 4. Heaven and Earth was shipped-in to Horseshoe Indianapolis from her home barn in Kentucky. She arrived at Horseshoe at approximately 10:45 AM on June 1, 2023.

3

^{*} These parties attended, remotely, by Zoom.

- 5. While at Horseshoe Indianapolis on June 1, 2023, Heaven and Earth occupied a stall designated by personnel at Horseshoe Indianapolis in the Receiving Barn.
- 6. Following the race, Heaven and Earth was subject to doping control. A blood Sample was collected bearing code #B100231018 and a urine Sample was collected bearing code #U100231018.
- 7. On June 22, 2023, Industrial Laboratories in Denver, Colorado ("Industrial") reported an alleged Adverse Analytical Finding ("AAF") for Metformin in Heaven and Earth's urine #U10023108 and blood #B10023108 samples.
- 8. On July 1, 2023, Mr. Wong was notified that Heaven and Earth's A samples had allegedly returned an AAF for Metformin.
- 9. A Provisional Suspension was imposed on Mr. Wong effective July 2, 2023.
- 10. On July 3, 2023, counsel for Mr. Wong notified the agency that Trainer Wong requested to have the B Samples from Heaven and Earth be sent to a second lab for B sample analysis.
- 11. Pursuant to changes to the ADMC Program announced by the Authority on July 28, 2023, Mr. Wong's Provisional Suspension was lifted pending the B Sample's confirmation of the A sample. Mr. Wong was therefore Provisionally Suspended between July 2, 2023 and July 28, 2023.
- 12. Heaven and Earth's B Sample was sent for analysis at the University of Illinois at Chicago Analytical Forensic Testing Laboratory in Chicago, Illinois ("UIC"). UIC reported the results of the B Sample Analysis on August 10, 2023. UIC reported the presence of Metformin in both the urine and blood Sample, #U100231018 and #B100231018, respectively. Mr. Wong's Provisional Suspension was reinstated effective immediately on August 10, 2023.
- 13. On November 15, 2023, the Arbitrator issued Amended Procedural Order #1, amending the timeline for submission by the Parties and re-scheduling the hearing in this matter for January 9 and 10, 2024.
- 14. On December 13, 2023, HIWU submitted a Motion for Further Analysis. HIWU's motion was granted on December 15, 2023.
- 15. The Kenneth L. Maddy Equine Analytical Chemistry Laboratory at the University of California, Davis (the "UC Davis Lab") conducted Further Analysis on the tube of the A blood sample received from Industrial (#B100231018) and on the remainder of the B urine sample received from UIC (#U100231018).

16. On December 22, 2023, the UC Davis Lab reported the results of the Further Analysis. The UC Davis reported the presence of Metformin in the blood sample received from the Industrial Lab and urine sample received from UIC.

17. Additional Facts, According to HIWU

- 2.3 Petra Hartmann("Hartmann") is the Director of Industrial that conducted the A-Sample analysis on Heaven and Earth's Sample. She is the Director of Drug Testing Services at Industrial Laboratories in Denver, Colorado ("Industrial").
- 2.4 Founded in 1945, Industrial is an independent third-party analytical testing laboratory. Industrial focuses on Banned Substance analysis, microbiology testing, drinking and wastewater analysis, analytical chemistry testing, and custom method development, validation, and verification to international standards. Industrial's clients range from small local operations to large multinational food corporations to state governments.
- 2.5 Hartmann has been the Director of Industrial since 2001, and have been at Industrial since 1987, first as an analyst and then as a manager. She has a Master of Science degree in Pharmacy and Forensic Drug Chemistry from the University of Florida. She is a fellow of the Association of Official Racing Chemists (AORC), an organization devoted to the advancement of drug testing in racehorses. Her curriculum vitae reflects a long, significant body of work in the area of drug testing.
- Organization for Standardization) is an independent, non-governmental organization with a membership of 162 national standards bodies. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories is the international reference for analytical laboratories to demonstrate their capacity and competence to deliver reliable results. This certification is granted biannually by the American Association of Laboratory Accreditation (A2LA). Industrial is also accredited pursuant to the A2LA R203 Competition Animal Drug Testing Laboratory Accreditation Program, which is designed to meet the requirements of the AORC and the International Laboratory Accreditation Cooperation's (ILAC) Accreditation Requirements and Operating Criteria for Horseracing Laboratories (ILAC G7:04/2021). Industrial's current accreditation is valid through to March 31, 2025.
- 2.7 Industrial has also long been accredited by the Racing Medication and Testing Consortium (RMTC) demonstrating that it has met the requirements and operating criteria for horseracing laboratories.
- 2.8 Industrial has contracted with the Horseracing Integrity & Welfare Unit ("HIWU" or the "Agency") to serve as one of the approved laboratories to analyze blood and urine samples under the Horseracing Integrity and Safety Authority's Anti-Doping and Medication Control Program (Protocol) ("ADMC Program").

- 2.9 The blood Sample bearing code B100231018 and the urine Sample bearing code U100231018, and the laboratory identification number 23060537-013 & 23060537-025, was received by Industrial on June 3, 2023.
- 2.10 Based on Hartmann's review of HIWU's EAD Notice of Alleged Anti-Doping Rule Violation dated July 1, 2023, the horse from which sample B100231018 and U100231018 was taken on June 1, 2023 was horse Heaven and Earth and the trainer for this horse is the respondent, Trainer Wong. The samples sent to and analyzed by Industrial were the horse's A samples.
- 2.11 Testing was commenced on June 5, 2023 and concluded on June 22, 2023. Testing resulted in a reported Adverse Analytical Finding (AAF) for Metformin. Industrial wrote a final positive report to HIWU on June 22, 2023, and Hartmann certified the laboratory documentation package on July 25, 2023. A Certificate of Analysis dated June 23, 2023 was sent by Industrial to HIWU.
- 2.12 The laboratory documentation package dated July 25, 2023, that sets out the chain of custody, handling, and analysis of the sample that resulted in the AAF was provided to Wong.
- 2.13 Upon review of the laboratory documentation package, Hartmann was able to confirm that there were no irregularities in the handling and testing of the samples.
- 2.14 In Hartmann's opinion, the samples were received in good condition and their integrity was maintained throughout the testing procedure.
- 2.15 Of the two samples, blood and urine, Industrial sent only the split urine sample (B-Sample) to the University of Illinois at Chicago Analytical Forensic Toxicology Laboratory ("UIC") on July 10, 2023, as reflected in the DTS Sample Release Form signed July 10, 2023. This was done pursuant to an xml file Industrial received from HIWU that listed only the urine sample to be sent to the split lab.
- 2.16 The blood split sample request, however, was noted on the e-mail communication associated with the xml file, but not in the xml file itself. Therefore, the Industrial team initially overlooked it. This oversight was quickly detected and on July 18, 2023, HIWU e-mailed Industrial to advise that UIC had only received the urine B-Sample. HIWU asked that Industrial expedite the shipment of the blood B-Sample to UIC.
- 2.17 As a result of this correction, the blood B-Sample was taken out of secure storage and sent to UIC that same day, as reflected in the DTS Sample Release form signed July 18, 2023.
- 2.18 Consistent with the requirements of the ADMC Program Rules, Metformin is a Banned Substance that is not subject to any testing threshold. Therefore, the presence of Metformin in a sample is an adverse finding regardless of the amount of the drug

- detected. This means that the testing labs are only required to perform a qualitative analysis rather than a quantitative analysis.
- 2.19 A qualitative analysis is a test that confirms the presence of a substance in a sample, but it does not determine exactly how much of the substance is present. The laboratory compares chromatography parameters, such as retention time, and mass spectral characteristics, such as the relative abundance of specific ions, for the test sample and the reference standard. These parameters for the test sample and the reference sample must not differ by more than a pre-determined amount.
- 2.20 In contrast, quantitative analysis is a more complex process. It involves the creation of a calibration curve to permit a precise determination of the amount of a substance found in the test sample.
- 2.21 Where, as here, a qualitative analysis is performed, the applicable lab standards for qualitative analysis do not require the use of an internal standard. Specifically, the ILAC-G7:04 sets out requirements for the use of internal standards only in section 27 under the heading "Regulatory Quantification". This provision deals exclusively with quantitative analysis, not qualitative analysis as was performed by Industrial in this case. There is nothing in ILAC-G7:04 that mandates the use of internal standards for qualitative analysis (or "Regulatory Qualitative Identification" as stated in ILAC-G7:04).
- 2.22 It is worth noting that the implementation of a Harmonized Internal Screening Limit by HISA to ensure some consistency across the laboratories doing testing does not establish a threshold limit.¹ It does not require a quantitative analysis.
- 2.23 To the extent that Industrial has recorded quantitative numbers, they are merely estimations and not intended to be the product of a quantitative analysis.
- 2.24 Having a minimum concentration of a substance is not novel and in fact, the ADMC Rules state that the "Minimum Reporting Level" means the estimated concentration of a Prohibited Substance or its Metabolite(s) or Marker(s) in a Sample below which Laboratories will not report that Sample as an Adverse Analytical Finding. HISL is a means to ensure that the minimum reporting level is the same for all laboratories.
- 2.25 The entries of values on the Confirmation Analysis Worksheet were estimates of the non-threshold substance Metformin and thus not requiring quantification. In fact, a review of the worksheets for both the blood and urine samples reflects that the testing is solely to "confirm" the presence of Metformin.

7

¹ A Protective Order, shielding the actual values of the HISL has been entered on January 9, 2024, orally, with a written Order subsequently entered January 17, 2024. Given that Order and the fact that these Decisions are circulated publicly, the actual values in the present HISL will not be set forth in this Decision. Suffice to say that there is no dispute that as to both blood and urine samples, A and B alike, the HISL was exceeded.

- 2.26 ADMC Program Rule 6314(b)(ii) states that "Appropriate internal standards(s) shall be used for chromatographic methods." For substances that have thresholds under the ADMC Program (which Metformin does not) a quantitative analysis is required to ensure the amount of the drug detected is above the threshold limit before reporting an adverse finding. Rule 6314(b)(1)(ii) applies to the performance of such quantitative analyses. Conversely, for a qualitative analysis done under the ADMC Program like that performed by Industrial in the present case, there is no requirement or need to use an internal standard.
- 2.27 In this case, Industrial performed a proper and appropriate methodology in testing for and establishing the presence of Metformin and its associated retention time. The analysis was confirmed via mass spectrometry, which is a definitive technique. The retention-time window used was commensurate with the resolving power of the chromatographic system performing the spectrometry analysis.
- 2.28 In addition, appropriate run sequences were applied to the urine and the blood sample, confirming the presence of Metformin in both matrices.
- 2.29 Industrial's analysis complied with the applicable requirements set out in ILAC-G7, including those in the section entitled "Regulatory Qualitative Identification."
- 2.30 Industrial's analysis of Heaven and Earth's samples was compliant with all of Industrial's relevant Standard Operating Procedures ("SOPs")
- 2.31 Whether or not Industrial was aware of the HISL at the time of testing or not has no effect on the test itself. Notations made on the worksheets to clarify that the testing being done is qualitative not quantitative did not alter the result either. Thus, to the extent Mr. Wong has sought a comparison of the present worksheet with one in another case, this has no impact on whether or not Metformin was present in the A Sample.
- 2.32 With regard to estimates as to quantity of substances found to be present, changes are being made at Industrial to clarify the entries so there is no misinterpretation: values included on the worksheet are estimates for information purposes only. They are not intended to be considered the result of a validated quantitative process.
- 2.33 Hartmann similarly made changes in the lab packet regarding how chain of custody is memorialized. This includes identifying the name of the person in the document and a comment column, to detail action being taken. The chain of custody was always capable of being followed. But in the earlier version of maintaining a record of the chain, some information was in the system but could not be printed. While Hartmann considered that the data packet was compliant, it was not as easy to access and review and thus the changes have been made. Industrial has continually improved the manner of its recording process.

- 2.34 Brendan Heffron is the Director of the University of Illinois at Chicago Analytic Forensic Testing Laboratory in Chicago, Illinois ("UIC").
- 2.35 UIC is an analytical testing laboratory affiliated with the University of Illinois at Chicago. UIC does a variety of testing and analytical work, including Banned Substance analysis in racehorses.
- 2.36 Heffron has been the Director of Laboratory Operations at UIC since 2017. His role is to supervise the analysis of proficiency samples, ensuring correct results and on-time publication of findings to the testing agencies, as well as to engage in development and validation of methods to improve the testing provided by the laboratory. He has been a laboratory scientist at UIC since 2004, for the duration of his career. He has a Master of Science degree in Forensic Science and a Bachelor of Science degree in biochemistry from the University of Illinois at Chicago. His curriculum vitae reflects significant education and experiential background in the area of analytical testing such as is at issue here.

UIC is an ISO/IEC 17025 accredited laboratory. ISO (International Organization for Standardization) is an independent, non-governmental organization with a membership of 162 national standards bodies. ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories is the international reference for analytical laboratories to demonstrate their capacity and competence to deliver reliable results. This certification is granted and renewed periodically by various accreditation bodies including the ANSI National Accreditation Board (ANAB). UIC is also accredited as meeting the requirements of ANAB Forensic Testing & Calibration AR 3125:2019 (for forensic labs) and the International Laboratory Accreditation Cooperation (ILAC) G7:04/2021 Accreditation Requirements and Operating Criteria for Horseracing Laboratories (the "ILAC Guidance" or "ILAC G7"). UIC's certificate of accreditation is valid through to June 30, 2026.

UIC has also long been accredited by the Racing Medication and Testing Consortium (RMTC) demonstrating that it has met the requirements and operating criteria for horseracing laboratories.

UIC has contracted with HIWU" to serve as one of the approved laboratories to analyze blood and urine samples under the Horseracing Integrity and Safety Authority's Anti-Doping and Medication Control Program (Protocol) ("ADMC Program").

The urine Sample bearing code U100231018, and the laboratory identification number 3060537-013, and the blood Sample bearing code B100231018, and the laboratory identification number 23060537-025 were received by UIC on July 11, 2023 and July 19, 2023, respectively.

2.37 The horse from which samples B100231018 and U100231018 were taken on June 1, 2023 is horse Heaven and Earth and the trainer for this horse is the respondent Mr. Wong. The samples sent to and analyzed by UIC were the horse's B samples.

Testing of both the blood and urine sample was commenced on August 1, 2023 and concluded on August 2, 2023. Testing resulted in a reported Adverse Analytical Finding (AAF) for Metformin. UIC drafted a positive report (Certificate of Analysis) to HIWU on August 9, 2023.

A technical review was conducted on August 14, 2023, by Marc Benoit which did not result in any changes or corrections, and the laboratory documentation package (the "Lab Package") was certified on August 23, 2023

- 2.38 Pursuant to the ADMC Program Rules, Metformin is a Banned Substance which is not subject to any testing threshold. An adverse finding is reportable if the lab detects the presence of Metformin in a sample in any amount. The precise concentration is irrelevant in this regard. Accordingly, the testing labs are only required to perform a qualitative analysis for Metformin and not a quantitative analysis. A quantitative analysis is more complicated than a qualitative analysis as it involves the creation of a calibration curve. This allows for a more precise determination of the amount of the substance in the sample- a determination not required for an AAF in the context of the Presence of a Banned Substance.
- 2.39 In testing for the presence of Metformin using a qualitative analysis, the applicable lab standards do not mandate any internal standard to be used. Specifically, under ILAC's standards for racehorse testing laboratories, ILAC-G7:04/2021, the only requirements for the use of internal standards are found in the section entitled "Regulatory Quantification" and specifically at section 27. This provision deals exclusively with quantitative analysis; and is not relevant to the qualitative analysis done by UIC in this case. The section of ILAC-G7:04 that is relevant to qualitative analysis for Metformin is entitled, "Regulatory Qualitative Identification". There is nothing in that section (or anywhere else in ILAC G7:04) that mandates the use of internal standards when labs are conducting qualitative analysis, as UIC did here.
- 2.40 Further, ADMC Program Rule 6314(b)(1)(ii) states that "Appropriate internal standards(s) shall be used for chromatographic methods." When analyzing for the amount of a substance with a screening limit under the ADMC Program, a quantitative analysis is required so that the lab can reliably determine and report that the amount of the drug detected is above the limit. In such circumstances, an appropriate internal standard should be used pursuant to Rule 6314(b)(1)(ii). As stated above, however, **Metformin does not have a screening limit** under the ADMC Program, such that a qualitative analysis is appropriate. For a qualitative analysis conducted pursuant to the ADMC Program, which like Industrial is what UIC performed to detect the presence of Metformin in this case, labs are not mandated to use any internal standard and the lack of an internal standard does not in any way call into question the validity of the presence results.

- 2.41 Finally, under UIC's Standard Operating Procedure ("SOP") governing the qualitative analysis of basic drug compounds in blood and urine, no use of internal standards is mandated. This reflects ILAC consensus and guidance and accepted scientific methodology. Rather, this SOP requires that "quality controls...be run along with the sample" and that "samples are taken through the entire extraction process alongside the unknown samples," as was done in this case to minimize the risk of erroneous results.
- 2.42 Retention time refers to the amount of time a substance takes to travel through a chromatography column. The samples were tested via mass chromatography, a definitive technique which obviates the need for standardized retention times in sample testing. Rather, the retention-time window must be, and was, commensurate with the resolving power of UIC's chromatographic system.
 - According to UIC's SOP, the presence of Metformin is confirmed if the retention time of the test substance falls within 2% or 12 seconds of the standard retention time, whichever is greater. This criterion is found in the Lab Package at the bottom of the page labelled 7 of 21 under the heading "Acceptance Criteria".
- 2.43 As the retention time for the Metformin standard used by UIC is 0.876 minutes or 52.6 seconds, the maximum retention variance is 12 seconds (as 12 seconds is greater than 2% of 52.6 seconds, or 1.1 seconds).
- 2.44 The Lab Package confirms that the retention time for the blood sample was 0.864 minutes in both runs (or 51.8 seconds) as shown on the page labelled 12 of 21 and the retention time for the urine sample was 0.805 minutes (48.3 seconds) in the first run and 0.793 minutes (47.6 seconds) in the second run as shown on page 14 of 21. As such, the retention time variance was (significantly) less than +/- 12 seconds from the standard in all four runs, and therefore within the acceptable window to report the presence of metformin in both the blood and urine samples. Contrary to the claims of Wong's expert, there were no mathematical errors made in these analysis.

Hydrolysis of the sample was appropriate. The hydrolysis conducted by UIC is explained at page 7 of 21 of the Lab Package under the heading "Description of Extraction." Drugs often undergo extensive metabolism in the body through glucuronidation and/or sulfation, producing conjugated metabolites that are difficult to detect on LC-MS. Hydrolysis is a common technique that removes these conjugates in order to increases drug detection potential. UIC's relevant SOP directs that samples should be hydrolyzed before extraction.

2.45 In response to the question of extraction efficiencies, UIC does not routinely run a non-hydrolyzed sample for urine sample confirmation and there is no requirement to do so pursuant to the laboratory standards under the ADMC Program.

- 2.46 Appropriate run sequences were applied to both the urine and the blood sample, confirming the presence of Metformin in both matrices. Due to inadvertence, only the negative control run for urine (NCU) was included and the negative control run for blood (NCB) was omitted from the Lab Package. The results for the NCB have been provided. There is nothing about this oversight which affected the ultimate result.
- 2.47 UIC's SOP governing minimum criteria for identification and reporting specifies that "chromatographic separation coupled to mass spectrometric detection can be sufficiently specific to be used alone as a confirmatory method provided two tests are run." In keeping with the requirements set out in this SOP, negative controls used by UIC in testing Heaven and Earth's samples "show [] the absence of the drugs of interest," as they are intended to do.
- 2.48 UIC's testing of Heaven and Earth's sample was compliance with its applicable SOPs and with the ILAC Guidance. UIC performed a proper and appropriate methodology in testing for and establishing the presence of Metformin and its associated retention time, as demonstrated at pages 7-17 of the Lab Package.
- 2.49 Each step of the analysis is reflected in the Lab Package as supplemented by the NCB run information and can be clearly attributed to the responsible UIC employee via either typed initials or signature. The concern that no second reviewer signed off on the Lab Package is misplaced, as page 18 of the Lab Package report clearly notes M. Benoit as having completed the technical review and finding no issues, and his signature is found at page 19.
- 2.50 As for sample storage, upon receipt, the samples were stored in a refrigerator kept at 4 degrees Celsius until testing, per UIC's SOP and standard practice. Subsequent to the sample analysis, the samples were re-sealed and moved into long term cold storage at -80 degrees Celsius, also in keeping with UIC's sample handling SOPs.
- 2.51 To further substantiate the chain of custody of the samples, are the courier logs and handwritten sample check-in sheets. The FedEx confirmation numbers for both the urine and blood sample are found on these documents. As far as specific gravity, the specific gravity of the urine sample was recorded in the handwritten check-in sheet for the urine sample.
 - While all of the information necessary to confirm a valid chain of custody exists, it is not all readily available and reviewable which, as with Industrial, has occasioned some changes to be made.
- 2.52 Despite the inadvertent typographical error on pages 3 and 4 of the Lab Package, which checks "serum" for the urine sample and "urine" for the blood sample, the chain of custody was intact for the samples, and there were no deviations from UIC's SOPs. The documentation provided allows for reproducibility and fully demonstrates every step in the analysis, along with the individual responsible for same.

Heffron acknowledges that the Metformin Sequence Table on page 9 of the Lab Package does not match the Data Acquisition date and time stamps on individual runs at pages 10-17. This is due to a technical glitch with the software that autogenerates the Sequence Table. This error did not impact the validity of the run sequences, or the accuracy of the data presented at pages 10-17 of the Lab Package.

- 2.53 Further, a blank and negative controls for both matrices (blood and urine) were run prior to analysis of the samples of interest, as evidenced by the runs shown on pages 10-11 of the Lab Package (blank and NCU) and in Exhibit E (NCB). As part of UIC's method validation, UIC Determines if there is a possibility of carryover or injector memory (i.e., the drug staying on the instrument in between injections). This is done by injecting increasing amounts of a drug and injecting a blank after it and see if any of the drug is in the blank injections.
- 2.54 It is undisputed that UIC received the urine and blood samples on different dates, and each was checked in separately, as shown in the check in sheets referred to above. There is nothing improper or unusual about this, and both the urine and blood samples were properly stored after receipt. The order of sample receipt does not have any bearing on the sample's testing.
- 2.55 On the issue of whether three rather than two ion transitions ought to have been used during the mass spectrometry analysis, Heffron states that the AORC Guidelines for the Minimum Criteria for Identification by Chromatography and Mass Spectrometry are not binding and, in any event, they merely recommended by the use of the word "should" instead of "must" that a minimum of three transitions be used.
- 2.56 Heffron defends the use of two rather than three ion transitions by noting that Metformin is a small molecule and UIC's method optimization found two product ions of sufficient abundance. As such, UIC used two instead of three ions in the analysis. To further ensure that UIC identifies the correct compound, the laboratory performs two separate tests on the samples, as recorded on page 5 of the Lab Package. This is permitted under the AORC Guidelines and has been reviewed by UIC's ISO auditors several times. Heffron specifically points to Paragraph 11 of the AORC guidelines which state that "[f]urther techniques or derivations may be used in combination if a single technique produces less than 3 ions suitable for matching."
- 2.57 No deficiency regarding UIC's transition methodology, or any other aspect of analysis, has been found during any of these audits. UIC now has new equipment which enables it to utilize three rather than two ion transitions.
- 2.58 Based on Heffron's experience as UIC's director, the consistent implementation of UIC's SOPs and compliance with accreditation requirements and laboratory standards, and the data reviewed, there is no scientific, procedural, or substantive reason to doubt the scientific validity of the results of UIC's testing of Heaven and Earth's samples.

- 2.59 Benjamin Moeller ("Moeller") is the Section Head of the Chemistry Section of the Kenneth L. Maddy Equine Analytical Chemistry Laboratory at the University of California, Davis in Davis, California ("UC Davis Lab").
- 2.60 The UC Davis Lab is an analytical testing laboratory affiliated with the University of California, on the UC Davis Campus, which deals exclusively with racehorses. The UC Davis Lab focuses on Banned Substance analysis, analytical chemistry testing, and custom method development, validation, and verification to international standards.

Moeller has been the Section Head of the UC Davis Lab since 2018. He is also Associate Professor at the UC Davis School of Veterinary Medicine and have held that position since 2022. From 2016 to 2022, he was an Assistant Professor.

Moeller has a PhD in Pharmacology and Toxicology from UC Davis, and a Bachelor of Science from UC Davis, in Biochemistry and Molecular biology. While completing his PhD, he conducted his dissertation research on the pharmacokinetics, endogenous production, and metabolism of anabolic steroids in horses. He is certified by the American Board of Toxicology.

2.61 The UC Davis Lab is an ISO/IEC 17025-2017 accredited laboratory. ISO (International Organization for Standardization) is an independent, non-governmental organization with a membership of 162 national standards bodies. ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories is the international reference for analytical laboratories to demonstrate their capacity and competence to deliver reliable results. This certification is granted biannually by the American Association of Laboratory Accreditation (A2LA).

UC Davis is also accredited pursuant to the A2LA R203 – Competition Animal Drug Testing Laboratory Accreditation Program, which is designed to meet the requirements of the AORC and the International Laboratory Accreditation Cooperation's (ILAC) Accreditation Requirements and Operating Criteria for Horseracing Laboratories (ILAC G7:04/2021). UC Davis' certificate of accreditation is valid through to September 30th, 2024.

The UC Davis Lab has also long been accredited by the Racing Medication and Testing Consortium (RMTC), demonstrating that it has met the requirements and operating criteria for horseracing laboratories.

- 2.62 The UC Davis Lab has contracted with the Horseracing Integrity & Welfare Unit ("HIWU" or the "Agency") to serve as one of the approved laboratories to analyze blood and urine samples under the Horseracing Integrity and Safety Authority's Anti-Doping and Medication Control Program (Protocol) ("ADMC Program").
- 2.63 On or around December 15, 2023 Moeller received a request from HIWU that the UC Davis Lab conduct Further Analysis on a blood and urine sample that had already

undergone A and B sample analysis at different testing laboratories under the ADMC Program. Moeller was asked to perform confirmatory analysis for the Banned Substance Metformin. HIWU requested that the analysis be completed on an expedited basis, with the full laboratory document package being delivered by December 22, 2023.

Moeller informed HIWU that the UC Davis Lab had the capacity to do so, and invited them to send the samples to the UC Davis lab as soon as possible.

- 2.64 The A samples were received by UC Davis on December 19, 2023, having been shipped to the laboratory by Industrial Laboratories in Denver, Colorado ("Industrial") on December 18, 2023. UC Davis received a blood Sample bearing code B100231018 and a urine Sample bearing code U100231018 and applied the UC Davis laboratory identification number of 231219-490708.
- 2.65 The B samples were received by UC Davis on December 19, 2023, having been shipped to the UC Davis laboratory by University of Illinois at Chicago Analytic Forensic Testing Laboratory in Chicago, Illinois ("UIC") on December 18, 2023.
 - UC Davis received a blood Sample bearing code B100231018 and a urine Sample bearing code U100231018 and applied the UC Davis laboratory identification number of 231219-490711.
- 2.66 The samples were accompanied by chain of custody forms from Industrial and UIC, respectively.
- 2.67 The samples were opened at the UC Davis Lab on December 20, 2023. Moeller attended the sample opening session with his colleague Medina Matthews. They confirmed the sample identification numbers and checked the seals before Ms. Matthews opened the samples. Due to the limited volume of the blood sample, UC Davis opened only the blood sample sent from Industrial and the urine sample sent from UIC (they identified but did not open the urine sample from Industrial or the blood sample from UIC). Counsel for Mr. Wong, Darren Craig, and two HIWU representatives, Monica Pilarski and Carlos Sayao, attended the sample opening session via Zoom. A recording of the session was preserved by HIWU.
- 2.68 Sample analysis was commenced on December 21, 2023 and concluded on December 22, 2023. Testing of both the blood and urine samples resulted in a reported Adverse Analytical Finding (AAF) for Metformin. UC Davis wrote final positive reports to HIWU, and Moeller certified the laboratory documentation packages, on December 22, 2023.
- 2.69 A laboratory documentation package was created that sets out the chain of custody, handling, and analysis of the blood sample that resulted in the AAF. This package Included the Certificate of Analysis for the blood sample.

- 2.70 There was a laboratory documentation package that sets out the chain of custody, handling, and analysis of the urine sample as well that resulted in the AAF. This too included a Certificate of Analysis for the urine sample. The testing done on the samples described above was qualitative, not quantitative.
- 2.71 Stephanie Jenson ("Jenson") is the Director of Education for the Horseracing Integrity and Welfare Unit (HIWU).

Her day-to-day responsibilities include establishing and implementing educational programs regarding the Horseracing Integrity and Safety Authority (HISA) Anti-Doping and Medication Control (ADMC) Program.

She is familiar with all educational outreach and programming conducted by HISA over the past year, including in the months leading up to the ADMC Program coming into force on May 22, 2023.

2.72 Jenson engaged in a review to determine what educational materials were publicly available to horsemen on the HIWU website prior to June 1, 2023, and which race tracks hard copies of these materials were delivered to; and 2) the racetracks at which HISA's Chief of Science, Mary Scollay, DMV, or HISA's Director of Equine Medical Resources, Patricia A. Marquis, DMV, delivered presentations prior to June 1, 2023.

That review revealed that HIWU posted over twenty separate educational programs on their website (or other online locations such as YouTube) between October 2022 and May 2023, in the form of written articles or videos.

A list of the locations and dates of presentations given by Ms. Scollay and Dr. Marquis is attached to Jenson's statement as HIWU Exhibit 12 D. On May 17, 2023, Jenson sent a follow up email to numerous horsemen's groups, providing links to HIWU educational materials, and encouraging recipients to reach out to her if they had any questions.

Online educational materials posted by HIWU were (and continue to be) freely accessible. Dr. Scollay and Dr. Marquis' presentations were likewise free of charge, and open to any horseman to attend.

Mr. Wong would have been working at locations where these various publications and presentations were being made and would have had access to the online materials.

2.73 Kitten Lee ("Lee") is the Results Manager for the Horseracing Integrity and Welfare Unit. She has held this position since November 2022.²

² Lee's efforts in ascertaining the number of horses testing positive for Metformin on the race day at Horseshoe Indianapolis Racetrack are of no moment given that Mr. Wong now claims the source of the Metformin to have been at his barn, from his groomer, Perez. But since HIWU did not formally withdraw this witness, the evidence will be

Her day-to-day responsibilities include managing the results for all samples tested under the authority of HIWU.

She is notified of all the positive tests (Adverse Analytical Findings) that HIWU accredited laboratories identify.

- 2.74 Lee was asked to determine how many tests were completed on samples collected at the Horseshoe Indianapolis racetrack from May 22, 2023 to October 20, 2023, and how many samples collected from the Horseshoe Indianapolis racetrack have tested positive for Metformin.
- 2.75 Lee determined the following:
 - (a) The number of blood samples taken from Covered Horses that were tested for Metformin at Horseshoe Indianapolis between May 22, 2023, and October 20, 2023 was about 1,327.
 - (b) Only 2 samples taken at the Horseshoe Indianapolis racetrack between the same time period of May 22, 2023 October 20, 2023, have tested positive for Metformin, one of which is the positive test at issue in this case.
- 2.76 On July 2, 2023, Ray Paulick ("Paulick") the publisher of and reporter for the trade publication "The Paulick Report" which addresses issues of interest to the thoroughbred horse racing industry.
- 2.77 On July 2, 2023, Paulick published an article about the suspension of Mr. Wong for the Presence of Metformin in Heaven and Earth.

Paulick is a well experienced, seasoned reporter of many years. In interviewing Wong regarding the suspension, Paulick took detailed notes, rather than recording his discussion with Mr. Wong. With regard to what Mr. Wong said to him, if Paulick published a statement made by Mr. Wong verbatim, he would put it in quotes.

When asking Mr. Wong about how Metformin came to be present in Heaven and Earth, Mr. Wong responded: "I was diagnosed with type 2 diabetes and have been on metformin since last year" Mr. Wong further stated that he had informed HIWU officials that he takes the medication, stating "I told them, but it doesn't matter" he said "They don't care, and that's the problem."

Additional Facts, According to Wong

2.78 Mr. Wong has been in the thoroughbred horsing world since he was nine years old. He started just watching horses at the track being trained and immediately became hooked. He worked through high school and in fact was homeschooled in order to work at the racetrack when he was just sixteen years old. His enthusiasm was so great that he did four years of high school in just three years. He started at the bottom

set forth.

and worked his way up. He has worked as a walker, as a groom and trainer. Part of what Mr. Wong learned was proper care for the horses.

Mr. Wong obtained his training license in 2014 after working under the supervision of several distinguished trainers, including Lonny Arterburn, John Martin, Kristin Mulhall, and Art Sherman. Wong has trained horses for many owners, including Dennis Amaty, Madison Keefer, Gary Madden, Michael Nentwig, Johnny Taboada, and Tommy Town Thoroughbreds.

- 2.79 Mr. Wong was so successful as a trainer that he ultimately grew his business to be a 150 horse barn, between four stables. He is sought after as a trainer and highly regarded by one and all. His colleagues and clients consider him to be caring about the health, welfare and safety of the horses. Many observers have stated that Mr. Wong "puts the horse's safety first.
 - Mr. Wong has entered horses in over 5,000 races. Of those, his trained horses have taken first place finishes in almost 1200 races and otherwise "in the money" i.e. first, second or third, in approximately 3,000 races.
- 2.80 One of the horses Mr. Wong trained for Tommy Town Thoroughbreds was Heaven and Earth, a three-year-old filly. At the time of the events in question here, Mr. Wong had been training Heaven and Earth for about ten months. His employees worked with him in training her, exercising her, grooming her and other activities.
- 2.81 At no time did Mr. Wong or anyone under his supervision administer Metformin to Heaven and Earth. Heaven and Earth's veterinary records support this.
- 2.82 One of his grooms was Luis Perez ("Perez"), who worked for Jonathan Wong since 2022. Typical of grooms, Perez was responsible for the daily care and maintenance of this filly. This included activities such as, in the morning: putting her halter on, tying her to the back of the stall, taking off her bandages, mixing her feed and making sure she ate all of her grain; also cleaning the stall, brushing her, saddling her, bathing her after a race, giving her more food, brushing her and bandaging her post race.

Perez lived at Churchill Downs Training Center in Kentucky in one of the tack rooms. He frequently would urinate in stalls and did not wash his hands after taking his medication. Perez bathed Heaven and Earth, fed her, and prepared her for shipment to Indianapolis on June 1, 2023. Perez is afraid that he may have inadvertently contaminated Heaven and Earth by urinating in the stalls or handling her after taking his medication and not washing his hands. This is the main reason Perez left the racetrack the first week in July and returned to Mexico on July 15, 2023.

2.83 Perez was in physical contact with Heaven and Earth for approximately seven months. According to Mr. Wong, that contact included touching Heaven and Earth

- with his bare hands, putting his hands in the horse's mouth, mixing her feed with his bare hands, putting her blanket on, washing Heaven and Earth with his hand on a sponge, scraping her to wipe off excess water, putting lip chain on under her lip; Perez, being affectionate, also used to pat Heaven and Earth all the time, kissing her on the nose, and side of her face.
- 2.84 On the race day, Heaven and Earth had her picture taken, she was given a shower, drank water and was housed in the place and stall assigned by the racetrack. After winning the race, her blood and urine were collected.
- 2.85 Approximately two weeks later, on June 19, 2023, when the testing was performed, the presence of Metformin in blood and urine was found in very low concentrations. The concentration in blood was found to be 631 picograms per milliliter, and the concentration in urine was found to be 242.5 nanograms per milliliter.
- 2.86 When HIWU notified Mr. Wong of the Adverse Analytical Finding in a letter dated July 1, 2023. the letter provided no information about the concentrations in blood or urine, and no documents from Industrial Labs were provided. Despite the lack of information or documentation, Mr. Wong was subjected to an immediate Provisional Suspension starting July 2.
- 2.87 Mr. Wong promptly requested that HIWU test the B Sample for Heaven and Earth to confirm the results of the A Sample. Despite making that request and paying the required fee on July 5, 2023, the B Sample was not received by UIC Analytical Forensic Testing Laboratory in Chicago, Illinois until July 19, 2023. (Exhibit 8.) The B Sample was not checked in until a week later, on July 26, 2023, and testing did not occur until August 2.
- 2.88 While waiting for the B Sample to be tested, Mr. Wong continued serving his Provisional Suspension until, on July 28, HIWU announced a change in policy allowing a Provisional Suspension to be lifted pending the results of the B Sample testing. HIWU notified Mr. Wong on August 10, 2023, that UIC had confirmed the presence of Metformin in Heaven and Earth and reimposed the Provisional Suspension. (Exhibit 9.) HIWU, however, did not provide the B Sample Laboratory Packet until August 23, 2023.
- 2.89 Mr. Wong voluntarily submitted to a polygraph test in order to dispel the accusation that he had knowledge of the source of the metformin in Heaven and Earth or was somehow responsible for it being in this horse. He selected a polygraph examiner by searching Yelp. The polygraph examiner asked four questions, all of which were crafted by a client of Mr. Wong's who is also an attorney. The questions put to him are set forth in Joint Exhibit 35. The polygraph examiner concluded that Mr. Wong had "No Significant Reactions" to any of the questions.

- 2.90 Mr. Wong observes that others who have had horses test positive for the presence of Metformin have only been subjected to minimal sanctions (2, 3, 4 weeks)
 - Mr. Wong himself has been subjected to some discipline, including for medication violations.
- 2.91 As part of the positive test which occurred, Mr. Wong learned that his place of business was being searched. He started receiving calls from his people at the other tracks where kept horses; he was advised that HIWU was there, conducting searches of the barns. (There is no evidence whether or not HIWU investigators searched the area where Perez was living or whether or not they retrieved any Metformin while searching) Mr. Wong was shocked because he had never in his life given a horse Metformin.
- 2.92 Mr. Wong had never directed any of his employees to administer Metformin. Mr. Wong had procedures in place to ensure that horses under his training comply with all applicable anti-doping and medication rules and in fact he had frequent regular meetings regarding proper horsemanship.
- 2.93 These meetings included admonitions to his staff "countless times" to not urinate in the stalls; if an employee is on medication, they were told to wash hands regularly. Mr. Wong was aware of the severity of the penalties and that even the "slightest bit" of anything can cause a positive.
- 2.94 In December of 2023, Mr. Wong was contacted by a former colleague, Artruro Cortez ("Cortez"). Cortez told Mr. Wong that while he was in Mexico, by happenstance, he had run into Perez. The two got to talking and Cortez mentioned that no one knew why Perez had left in July so abruptly. Cortez told Mr. Wong that Perez told him that he had fled because he was worried that he may have been the cause of the positive finding in Heaven and Earth's blood and urine. He elaborated that he was taking Metformin for a diabetic condition.
- 2.95 Mr. Wong had not had any contact with Perez since the time of the suspension despite his efforts to reach him.
- 2.96 The impact of the present suspension on Mr. Wong and in turn, his family has been powerful and very detrimental. He has experienced monetary loss and emotional harm due to the impact this has had on his marriage as well as his relationship with his children.
- 2.97 Mr. Wong was required to divest himself of all 150 of the horses he was training, dispersing them to other trainers. He has lost clients and training opportunities.

- 2.98 Numerous people have vouched for Mr. Wong's integrity, concern for the wellbeing of the horses, ability, and character.
- 2.99 Francisco Rodriguez ("Rodriguez") has worked for Jonathan Wong for over 4 years as his assistant trainer. Prior to that they worked together for John Martin. Mr. Wong was the assistant trainer and Rodgriguez was a groom. Rodriguez confirms that Mr. Wong has always trained and continuously talked to his employees about the importance of not urinating in the stalls. Also, to always wash hands, if taking any medications.
- 2.100 Dr. Richard Sams ("Dr. Sams") is currently the Scientific Director of KCA Laboratories. His education, experience and credentials, set forth in Joint Exhibit 55, support his ability to opine on the topics at hand.
- 2.101 Dr. Sams major work experience has involved the use of instrumental methods of analysis to analyze substances to determine their identities and to determine the quantity present in various matrices. He has directed analytical toxicology laboratories that test blood, hair and urine samples for the presence of prohibited and regulated drugs and other substances in a variety of animals included racehorses. He has used the results of chemical analysis for pharmacokinetic studies and for determination of compliance with regulatory limits. This work experience in turn includes the use and interpretation of test results from chromatographic and mass spectral analysis as well as immunoassay methods.

As Scientific Director of KCA Laboratories in Nicolasville, Kentucky, Dr. Sams has used multiple analytical methods to identify and determine substances in samples submitted to the laboratory for analysis.

He has significant experience in the area of testing in the context of thoroughbred horse racing, detailed in his curriculum vitae and has been part of advancing the standards of testing of racehorses throughout his career. The depth and breadth of that experience is impressive.

- 2.102 Dr. Sams reviewed all of the relevant submissions, including the Laboratory Data Packets for the three laboratories which performed testing on the samples in question. He offered opinion testimony on three topics:
 - a. whether the testing done by Heffron and Hartmann was violative of ADMC Rule 6314(b)(1)(2) in that neither utilized internal standards.
 - b. whether the testing done by Heffron was violative of AORC Guidelines because Heffron used a two ion transition process rather than three ion process.

- c. whether Heffron's testing was violative of ADMC rules because his aliquoting method did not include the decanting process.³
- 2.103 **The Internal Standards testing.** Dr. Sams opined that although the AORC Guidelines do not mandate the use of internal standards, the HISA rules do so by incorporation of ILAC G-4 into the ADMC rules.
- 2.104 Dr. Sams agrees with HIWU's position that since Metformin is not a threshold substance under the ADMC rules, quantification is not required. Internal standards are only required for quantitative testing. In fact, qualitative testing can be done reliably without the use of an internal standard.
- 2.105 Dr. Sams opined that the failure to utilize these internal standards would not necessarily cause a false positive.
- 2.106 **Transition of Ion Testing**. Dr. Sams opines that AORC Guidelines require that in transition of ions testing, a minimum of three ions should be used. Given that AORC

In the analysis performed for both the A Sample and the B Sample. Industrial Labs, which tested the A Sample, failed to use an internal standard reference compound. The use of such a compound allows for comparisons between analytical runs (now made into relative retention times by its use) as to the actual retention times for the target substance, allowing one to correct for differences. The confirmation of retention time is a primary factor in any confirmation analysis and the failure to provide that data is a technical analytical failure undermining the credibility of the test results.

UIC committed the same error. As seen on page 14 of 21 of the UIC report, the retention times vary from the standards by as much as 14%. UIC's own document regarding criteria for confirmation states on page 7 that "Retention time of sample: Relative retention time +/- 2% or retention time +/- the greater of 2% or 12 seconds." The values seen in the analyses far exceed 2%. Further, there is a math error in their statement; 2% of a minute is not 12 seconds, it's 1.2 seconds. 12 seconds is 20%.

The errors in the B Sample Laboratory Packet also included use of a different method for analysis that may have led to significant differences in the relative amounts of Metformin found in the analyses. (*Id.* at 4.) Further, UIC used only a single negative control run in the analyses of Metformin in blood and urine, which were tested at the same time, and samples were not run in duplicate, but rather single analyses. Proof in science requires a demonstration of reproducibility. Because there are two different matrices, blood and urine, two different analytical negative controls should have been analyz with the samples. The Run Sequence page shows that only one was run and is, supposedly, a Negative Control Urine. That technical error should disqualify the results because there is no proof of possible interference in the analysis from the methodology or the matrix, particularly blood. Finally, estimations of the amounts in blood and urine suggest that there are significant differences in the supposed Metformin between the two labs in both blood and urine, further undermining confidence in the results.

³ There were other failures claimed. They were not pressed at the evidentiary hearing, but neither were they formally withdrawn. Therefore, in the interest of completeness, they will be set forth below.

is incorporated, through the ILAC rules, into the ADMC Rules, Heffron's use of only two and not three ions, constitutes a failure.

Dr. Sams opines, however, that the use of just two ion transmissions could possibly but not likely result in a false positive.

- 2.107 **Aliquot Procedure.** Dr. Sams addressed whether or not Heffron complied with ADMC Rule 6305 which speaks of the requirement to follow a decanting procedure when dealing with aliquots. Instead of using a decanting process, Heffron placed a pipette in the homogenized urine sample twice.
- 2.108 By inserting anything into the homogenized urine as opposed to poring off a portion of it decanting Heffron risked a potential impact to the urine sample: Anything that entered the sample could contaminate it.

Dr. Sams notes the process followed by Heffron, utilizing pipettes instead of decanting, presumably wearing gloves and using only clean pipettes. Assuming this to be the case, Dr. Sams opines that the risk of contamination is very low.

To Dr. Sams, Heffron's inserting of a pipette directly into B sample could have caused false positive if it contaminated the B sample. But while this is possible it is not probable in this case.

2.109 Dr. Sams opines that Metformin was present in both the blood and urine samples.

III. PROCEDURAL HISTORY

- 3.1 On June 1, 2023, Heaven and Earth competed in Race 7 at Horseshoe Indianapolis in Shelbyville, Indiana, finishing first in the maiden special weight race and earning a purse of \$21,600.
- 3.2 Following the race, Heaven and Earth was subject to doping control. A blood Sample was collected bearing code #B100231018 and a urine Sample was collected bearing code #U100231018. Analytical testing on the blood and urine Sample was conducted by Industrial and resulted in a reported AAF for Metformin.15 Under the ADMC Program, Metformin is a S0 category Banned Substance that is not subject to any concentration threshold.
- On July 1, 2023, Mr. Wong was notified that Heaven and Earth's A Sample had returned an AAF for Metformin. Metformin is not a Specified Substance under the ADMC Program's Prohibited List.16 Accordingly, pursuant to Rule 3247(a)(1), a Provisional Suspension was imposed effective immediately.

- 3.4 On July 3, 2023, counsel for Mr. Wong notified the Agency that he wished to schedule a Provisional Hearing18 and to have the B Sample from Heaven and Earth opened and analyzed. Heaven and Earth's B Sample was sent for analysis at UIC and checked in on July 26, 2023.19
- Pursuant to changes to the ADMC Program announced by the Authority on July 28, 2023,20 Mr. Wong's Provisional Suspension was lifted pending the B Sample's confirmation of the A Sample. Mr. Wong was therefore Provisionally Suspended between July 2, 2023 and July 28, 2023.
- 3.6 UIC reported the results of the B Sample Analysis on August 10, 2023, confirming the presence of Metformin in both the urine and blood Sample. Mr. Wong's Provisional Suspension was reinstated effective immediately. Also on August 10, 2023, Mr. Wong opted to forego his right to a Provisional Hearing and instead proceed to a hearing on the merits.22
- 3.7 The hearing on the merits was scheduled for October 16-17, 2023 but Mr. Wong requested a continuance of the hearing in light of a meeting of the ADMC Committee on October 16, 2023. Mr. Wong considered that the decisions taken at that meeting might affect the rules for Metformin under the ADMC Program and therefore potentially impact this case. HIWU did not oppose the continuance, and it was granted by the Arbitrator.
- 3.8 At the October 16 meeting, the ADMC Committee did not vote to reclassify Metformin and it remains a Category S0 Banned Substance.
 - Instead, HIWU decided to establish a harmonized Limit of Detection for Metformin across HIWU-accredited laboratories.23
- 3.9 On November 15, 2023, the Arbitrator issued Amended Procedural Order #1, amending the timeline for submissions by the Parties and re-scheduling the hearing in this matter for January 9 and 10, 2024.24.
- 3.10 On December 1, 2023, Mr. Wong filed his updated Pre-Hearing Submissions, including his Prehearing brief, letters, reports, expert reports, scientific articles and other documents, set forth in detail in the JAMS Access file.
- 3.11 On December 13, 2023, HIWU filed a Motion for Further Analysis.
- 3.12 On December 15, Wong opposed that motion, with supporting documents.
- 3.13 That Motion was allowed on December 15, 2023.
- 3.14 Also on December 15, 2023, Trainer Wong submitted a Motion to Issue Requests for Production of Documents.

- 3.15 The Motion to Issue Requests for Production was denied on December 16, 2023.
- 3.16 On December 18, 2023, HIWU provided opposing counsel and the Arbitrator with an update setting forth the status of the testing further to HIWU's allowed Motion for Further Analysis.
- 3.17 On December 18, 2023, HIWU filed its Prehearing brief, Book of Evidence and Book of Authorities.
- 3.18 On December 19, 2023, Mr. Wong filed a Motion to Reconsider the Order on Further Analysis, which motion was denied.
- 3.19 On December 22, 2023, HIWU sought leave to make two updates to its Prehearing Submissions.
- 3.20 On December 29, 2023 an Order entered that permitting further submissions accepted into the record. In this Order, Mr. Wong was also afforded an opportunity to supplement his submission by including the scientific reports and documents supporting his expert's opinions.
- 3.21 On December 29, 2023, the Arbitrator issued an Order outlining the schedule for the hearing, after both Parties were afforded an opportunity to provide input and propose a joint schedule.⁴
- 3.22 On December 29,2023, HIWU, after conferring with Mr. Wong, filed an Uncontested Statement of Facts; HIWU also filed a witness statement of Benjamin Moeller.
- 3.23 HIWU also presented a Motion for Protective Order, unopposed.
- 3.24 On January 10, 2024 during argument at the close of the evidence, Wong orally renewed his opposition to HIWU's previously allowed Motion for Further Analysis. That Motion was denied.
- 3.25 During argument at the close of the evidence, Mr. Wong also moved that the results of the B sample be vacated as a matter of law because of inadequacies in the chain of custody. That Motion was denied orally on January 10, 2024 and will be discussed further, *infra*.
- 3.26 On January 2, 2024, Mr. Wong filed an Amended Motion to Issue Requests for Production of Documents
- 3.27 On January 4, 2024, an Order entered on Mr. Wong's Request for Production of Documents.

⁴ The need for the chess clock system was obviated by the hard work of all counsel for both parties, who all conducted themselves with a high degree of professionalism and efficiency. Thus, the hearing proceeded to conclusion with no challenges arising from the time limitations.

- 3.28 On January 4, 2024, Mr. Wong filed a Motion to File Supplemental Exhibits (statements from two new witnesses)
- 3.29 On January 4, 2024, Mr. Wong filed a Motion in Limine to Exclude Dr. Dowling.
- 3.30 On January 4,2024, Mr. Wong filed a Motion to Dismiss or alternatively a Motion in limine to exclude Sample evidence.
- 3.31 On January 4, 2024, an Order was entered regarding Mr. Wong's Motion in limine relating to Dr. Dowling.
- 3.32 On January 5, 2024, HIWU filed an omnibus Opposition to three Motions (above) filed by Mr. Wong.
- 3.33 On January 5, 2024 an Order was entered denying Mr. Wong's Motion to Dismiss.
- On January 5, 2024 an Order was entered allowing Mr. Wong's Motion for the introduction of evidence from two witnesses: Perez and Rodriguez.
- 3.35 On January 5, 2024, Mr. Wong filed a Motion to Reconsider the Ruling Denying Motions in Limine filed on January 4, 2024.
- 3.36 On January 5, 2024 both parties submitted their proposed Witness lists.
- 3.37 On January 8, 2024 HIWU filed an updated witness statement from Brendan Heffron, with exhibits.
- 3.38 On January 8, 2024 HIWU, after conferring with Mr. Wong's counsel, sent a letter addressing the HISL, witness issues and a proposed hearing schedule.
- 3.39 On January 8, 2024, HIWU, after conferring with Mr. Wong's counsel, sent a letter updated the Arbitrator with regard to current proposed witnesses, scheduling and disclosure of the HISL (which attached a check in slip for Heaven and Earth)
- 3.40 On January 9, 2024, Mr. Wong introduced his Exhibits 1-57.
- 3.41 On January 9 and 10, 2024, the evidentiary hearing was conducted.
- 3.42 On January 10, 2024,HIWU entered an additional Exhibit, an article published in the Paulick Report.
- 3.43 On January 17, 2024, HIWU' unopposed Motion for Protective Order was allowed and the Order entered.
- 3.44 On January 15, 2024, after conferring, the parties presented a book of Joint exhibits.

3.45 On January 17, 2024, upon receipt of the parties Joint Book of Evidence, the hearing was ordered closed.

IV. JURISDICTION

- 4.1 These proceedings are governed exclusively by the ADMC Program. Preamble Section 3 and Rule 3010(f) expressly state that the ADMC Program pre-empts state laws and Rule 3070(b) provides that the ADMC Program "shall be interpreted as an independent and autonomous text and not by reference to existing law or statutes." Rule 3070(d) provides that the World Anti-Doping Code ("WADC") and jurisprudence interpreting its provisions may be considered when interpreting and applying the ADMC Protocol.
- 4.2 HIWU was created pursuant to the Horseracing Integrity and Safety Act of 2020, 15 U.S.C. secs. 3051-3060 ("Act"), and is charged with administering the rules and enforcement mechanisms of the Horseracing Integrity and Safety Authority's ("HISA") Anti-Doping and Medication Control Program ("ADMC Program"). The ADMC Program was created pursuant to the Act, approved by the Federal Trade Commission on March 27, 2023, and implemented on May 22, 2023. See 88 Fed. Reg. 5084-5201 (January 26, 2023). The ADMC Program sets out the applicable rules that govern this proceeding and ground the jurisdiction of the Panel over all participants. Rule 3020 provides that the anti-doping rules set out in the ADMC Program apply to and are binding on violations by Covered Persons, and Covered Persons are defined under ADMC:

Program Rule 1020:

"(a) The Protocol applies to and is binding on:

. . .

- (3) the following persons (each, a Covered Person): all Trainers, Owners, Breeders, Jockeys, Racetracks, Veterinarians, Persons licensed by a State Racing Commission, and the agents, assigns, and employees of such Persons; any other Persons required to be registered with the Authority; and any other horse support personnel who are engaged in the care, treatment, training, or racing of Covered Horses."
- 4.3 Pursuant to section 3054 of the Act, "Covered Persons" must register with the Authority. However, they are bound by the Protocol by undertaking the activity (or activities) that make(s) them a Covered Person, whether or not they register with the Authority.
- 4.4 ADMC Program Rule 3030(a) further defines a "Responsible Person" to mean: "the Trainer of the Covered Horse."
- 4.5 Wong is a Trainer who is required to be and is registered with HISA. As such, he is both a "Responsible Person" and a Covered Person who is bound by and subject to the ADMC Program.

4.6 The Rule 7000 Series of the ADMC Program sets out the arbitration procedures governing a charged violation of the ADMC Program, providing as follows:

"Rule 7010. Applicability.

The Arbitration Procedures set forth in this Rule 7000 Series shall apply to all adjudications arising out of the Rule 3000 Series.

Rule 7020. Delegation of Duties

- (a) Subject to Rule 3249, Anti-Doping Rule Violations arising out of the Rule 3000 Series and violations of Rule 3229 (together, "EAD Violations") shall be adjudicated by an independent arbitral body (the "Arbitral Body") in accordance with the Rule 3000 Series and these Arbitration Procedures. The Arbitral Body may also adjudicate any other matter referred to it under the Protocol, and any other matter that might arise from time to time under the Protocol that the Agency considers should be determined by the Arbitral Body."
- 4.7 Where HIWU issues a Charge Letter effecting charges on a Covered Person, arbitral proceedings are initiated pursuant to Rule 7060:

"Rule 7060. Initiation by the Agency

- (a) EAD Violations. Unless Rule 3249 applies, if the Agency charges a Covered Person with an EAD Violation, the Agency shall initiate proceedings with the Arbitral Body. If a Covered Person is charged with both an EAD Violation and an ECM or Other Violation, the procedures for EAD Violations apply. The parties to the proceeding shall be the Agency and the Covered Person(s) charged. The Owner and the Authority shall be invited to join in the proceedings as observers and, if accepted as such, receive copies of the filings in the case. In the context of EAD Violation cases, the Owner may be permitted to intervene and make written or oral submissions."
- 4.8 In this case, arbitration proceedings were commenced before JAMS, the designated arbitration provider.
- 4.9 No Party disputed jurisdiction here and all Parties fully participated in the proceedings without objection as to jurisdiction. As consent is the benchmark of arbitral jurisdiction, there is ample evidence of consent and no evidence of objection to arbitral jurisdiction here.
- 4.10 Accordingly, the Arbitrator finds that jurisdiction is proper here.

V. RELEVANT LEGAL STANDARDS

5.1 Rule 3212 of the ADMC Program recognizes "Presence" of a Prohibited Substance as an offense, providing in pertinent part as follows:

- "(a) It is the personal and nondelegable duty of the Responsible Person to ensure that no Banned Substance is present in the body of his or her Covered Horse(s). The Responsible Person is therefore strictly liable for any Banned Substance, or its Metabolites or Markers found to be present in a Sample collected from his or her Covered Horse(s). Accordingly, it is not necessary to demonstrate intent, Fault, negligence, or knowing Use on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3212 Anti-Doping Rule Violation.
- (b) Sufficient proof of a Rule 3212 Anti-Doping Rule Violation is established by any of the following:
- (1) the presence of a Banned Substance or its Metabolites or Markers in the Covered Horse's A Sample where the Responsible Person waives analysis of the B Sample and the B Sample is not analyzed;
- (2) the Covered Horse's B Sample is analyzed and the analysis of the B Sample confirms the presence of the Banned Substance or its Metabolites or Markers found in the A Sample; or
- (3) where, in exceptional circumstances, the Laboratory (on instruction from the Agency) further splits the A or B Sample into two parts in accordance with the Laboratory Standards, the analysis of the second part of the resulting split Sample confirms the presence of the same Banned Substance or its Metabolites or Markers as were found in the first part of the split Sample, or the Responsible Person waives analysis of the second part of the split Sample.
- (c) The general rule is that the presence of any amount of a Banned Substance or its Metabolites or Markers in a Sample collected from a Covered Horse constitutes an Anti- Doping Rule Violation by the Responsible Person of that Covered Horse. (d) As an exception to the general rule of Rule 3212(c), the Prohibited List,
- Standards, or Technical Documents may establish special criteria for the reporting or the evaluation of certain Banned Substances, including a Minimum Reporting Level, Screening Limit, Threshold, or Decision Limit."
- Mr. Wong, as the Trainer of Heaven and Earth, is a Responsible Person under Rule 3030(a) of the ADMC Program, and he does not dispute that status. As a Responsible Person, Rule 3030(a) makes clear that, "The Responsible Person shall be personally liable for his or her Covered Horse(s) as set out under the Protocol." As a Responsible Person, Mr. Wong is also a Covered Person. Rule 3040(a) also makes clear, in pertinent part, that:
 - "It is the personal responsibility of each Covered Person:
 - (1) to be knowledgeable of and to comply with the Protocol and related rules at all times. All Covered Persons shall be bound by the Protocol and related rules, and any revisions thereto, from the date they go into effect, without further formality. It is the responsibility of all Covered Persons to familiarize themselves with the most up-to-date version of the Protocol and related rules and all revisions thereto; . . ."

- 5.3 Pursuant to Rule 3121, the burden of proof is on HIWU to establish that a violation of the ADMC Program has occurred to the comfortable satisfaction of the Panel. "This standard of proof is higher than a balance of probabilities but lower than clear and convincing evidence or proof beyond a reasonable doubt." Rule 3121.
- 5.4 The World Anti-Doping Code ("WADC") provides the framework for a harmonious international anti-doping system and is widely used in international sports, and expressly acknowledged as the basis for the ADMC Program. Rule 3070 provides in pertinent part that:
 - "(b) Subject to Rule 3070(d), the Protocol shall be interpreted as an independent and autonomous text and not by reference to existing law or statutes. . . .
 - (d) The World Anti-Doping Code and related International Standards, procedures, documents, and practices (WADA Code Program), the comments annotating provisions of the WADA Code Program, and any case law interpreting or applying any provisions, comments, or other aspects of the WADA Code Program, may be considered when adjudicating cases relating to the Protocol, where appropriate."
- 5.5 ADMC Program Rule 3040 sets out certain obligations of a trainer such as Mr. Wong, as a Responsible Person, in pertinent part as follows:
 - "Rule 3040. Core Responsibilities of Covered Persons
 - i. Responsibilities of All Covered PersonsIt is the personal responsibility of each Covered Person:
 - (1) to be knowledgeable of and to comply with the Protocol and related rules at all times. All Covered Persons shall be bound by the Protocol and related rules, and any revisions thereto, from the date they go into effect, without further formality. It is the responsibility of all Covered Persons to familiarize themselves with the most up-to-date version of the Protocol and related rules and all revisions thereto; . . .
 - (b) Additional Responsibilities of Responsible Persons In addition to the duties under Rule 3040(a), it is the personal responsibility of each Responsible Person: . .
 - (4) to inform all Covered Persons (including Veterinarians), employees, personnel, agents, and other Persons involved in any way with the care, treatment, training, or racing of his or her Covered Horses of their respective obligations under the Protocol (including, in particular, those specified in Rule 3040(a));
 - (5) to adequately supervise all Covered Persons (including Veterinarians), employees, personnel, agents, and other Persons involved in any way with the care, treatment, training, or racing of his or her Covered Horses, including by (without limitation):
 - (i) conducting appropriate due diligence in the hiring process before engaging their services;

- (ii) clearly communicating to such Persons that compliance with the Protocol is a condition of employment or continuing engagement in the care, treatment, training, or racing of his or her Covered Horses;
- (iii) creating and maintaining systems to ensure that those Persons comply with the Protocol; and
- (iv) adequately monitoring and overseeing the services provided by those Persons in relation to the care, treatment, training, or racing of his or her Covered Horses;
- (6) to bear strict liability for any violations of the Protocol by such Covered Persons (including Veterinarians), employees, personnel, agents, and other Persons involved in the care, treatment, or racing of his or her Covered Horses; . . ."
- Pursuant to ADMC Program Rule 3223, the ineligibility, and financial penalties for a first anti- doping rule Violation of Rule 3214(a) (Presence) is: a. Two (2) years of Ineligibility, and b. A "Fine up to \$25,000 . . . and Payment of some or all of the adjudication costs and [HIWU]'s legal costs."
- 5.7 Where a Violation of the ADMC Program is established, the Respondent may be entitled to a mitigation of the applicable Consequences, only where he establishes on a balance of probabilities, that he acted with either No Fault or Negligence, or No Significant Fault or Negligence. Fault is defined in the ADMC Program as:
 - "any breach of duty or any lack of care appropriate to a particular situation. Factors to be taken into consideration in assessing a Covered Person's degree of Fault include (but are not limited to) the Covered Person's experience and special considerations such as impairment, the degree of risk that should have been perceived by the Covered Person, and the level of care and investigation exercised by the Covered Person in relation to what should have been the perceived level of risk. With respect to supervision, factors to be taken into consideration are the degree to which the Covered Person conducted appropriate due diligence, educated, supervised, and monitored Covered Persons (including Veterinarians), employees, personnel, agents, and other Persons involved in any way with the care, treatment, training, or racing of his or her Covered Horses, and created and maintained systems to ensure compliance with the Protocol. In assessing the Covered Person's degree of Fault, the circumstances considered must be specific and relevant to explain the Covered Person's departure from the expected standard of behavior. Thus, for example, the fact that the Covered Person would lose the opportunity to earn large sums of money during a period of Ineligibility, or the fact that the Covered Person or Covered Horse only has a short time left in a career, or the timing of the horseracing calendar, would not be relevant factors to be considered in reducing the period of Ineligibility based on degree of Fault."
- 5.8 ADMC Program Rule 3224 permits the reduction of sanctions where there is No Fault or Negligence, as follows:

- "Rule 3224. Elimination of the Period of Ineligibility Where There Is No Fault or Negligence
- (a) If a Covered Person establishes in an individual case that he or she bears No Fault or Negligence for the Anti-Doping Rule Violation(s) charged, the otherwise applicable period of Ineligibility and other Consequences for such Covered Person shall be eliminated (except for those set out in Rule 3221(a) and Rule 3620)...
 (b) Rule 3224 only applies in exceptional circumstances..."
- 5.9 No Fault or Negligence is defined by the ADMC Program as:

"the Covered Person establishing that he or she did not know or suspect, and could not reasonably have known or suspected, even with the exercise of utmost caution, that he or she had administered to the Covered Horse (or that the Covered Horse's system otherwise contained) a Banned Substance or a Controlled Medication Substance, or that he or she had Used on the Covered Horse a Banned Method or a Controlled Medication Method, or otherwise committed an Anti-Doping Rule Violation or Controlled Medication Rule Violation. For any violation of Rule 3212 or Rule 3312, the Covered Person must also establish how the Prohibited Substance entered the Covered Horse's system in order to establish No Fault or Negligence."

5.10 ADMC Program Rule 3225 also allows for the reduction of sanctions where there is No Significant Fault or Negligence, as follows:

"Rule 3225. Reduction of the Period of Ineligibility Where There Is No Significant Fault or Negligence Reductions under this Rule 3225 are mutually exclusive and not cumulative, i.e., no more than one of them may be applied in a particular case.

(a) General rule. Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Anti-Doping Rule Violation in question, then... the period of Ineligibility shall be fixed between 3 months and 2 years, depending on the Covered Person's degree of Fault."

5.11 No Significant Fault or Negligence is defined in the ADMC Program as:

"the Covered Person establishing that his or her fault or negligence, when viewed in the totality of the circumstances and taking into account the criteria for No Fault or Negligence, was not significant in relationship to the Anti-Doping Rule Violation or Controlled Medication Rule Violation in question. For any violation of Rule 3212 or 3312, the Covered Person must also establish how the Prohibited Substance entered the Covered Horse's system in order to establish No Significant Fault or Negligence."

VI POSITIONS OF THE PARTIES

6.1 The Parties asserted various arguments in their pre-hearing briefs and at the hearing. The below is an effort to summarize their fundamental positions. To the extent necessary, the Arbitrator will address the various arguments that were made in the Analysis section below.

HIWU'S CONTENTIONS:

- 6.2 HIWU contends, simply, that Mr. Wong is strictly liable, under Rule 3212 of the HISA ADMC Program because the Banned Substance, Metformin, was found to be present in a Sample collected from his Covered Horse, Heaven and Earth.
- 6.3 HIWU contends that Mr. Wong's claims that there were defects in the chain of custody, so called "bad science" and that the B sample ought to be rejected as a matter of law ignores the reality that Mr. Wong has the burden to prove that any such claimed departure from the rules could reasonably have caused the AAF.
- 6.4 Beyond that, HIWU contends that Mr. Wong cannot establish and thus seek any reduced sanction flowing from this ADRV on an account of a finding of No Fault or No Significant Fault, as defined in the ADMC Program. As such, HIWU argues that the evidence supports the imposition of the following consequences:
 - a. A period of Ineligibility of two (2) years for Mr. Wong beginning on July 1, 2023, the date the Provisional Suspension was imposed, with credit for any time served.
 - b. Forfeiture of all distributed purses, prizes, trophies, or other compensation arising from Heaven and Earth's first place finish on June 1, 2023, at Horseshoe Indianapolis in Shelbyville, Indiana, including the purse of \$21,600.
 - c. A fine of USD \$25,000 and payment of some or all of the adjudication costs; and
 - d. Any other remedies which might otherwise be just and appropriate in the circumstances.
- 6.5 HIWU further contends that Mr. Wong has not established the source of the Metformin, which would be a necessary finding in order to entertain a reduced penalty under the No Fault or Not Significant sections of the ADMC rules.
- 6.6 Finally, HIWU contends that even if, *arguendo*, Wong had established the source of the Metformin, he has failed to set forth facts to warrant either a finding of No Fault or No Significant Fault.

WONG'S CONTENTIONS⁵

_

⁵ Mr. Wong had initially raised environmental contamination as the source of the Metformin. Specifically, he contended that there was contamination via water or hay. However, he has abandoned this claim and it will not be addressed further. Mr. Wong also argued that the amount of Metformin could not have affected the result, a argument which was irrelevant and was similarly abandoned.

- 6.7 Mr. Wong contends that there were several specific departures which violate ADMC Rules: failure to use internal standards, use of two instead of three ion transitions, failure in the aliquot procedure, gaps in the chain of custody.
- 6.8 Mr. Wong also contends that the entire manner in which the testing of the A and B Samples were conducted was fraught with errors and deviations from the rules; thus, Wong argues the entire process has been tainted to the point of mandating full dismissal of the charge against him. He argues that given that he is being held to a
- 6.9 standard of strict liability, the rules ought to be applied strictly and any failure, regardless of whether if had any casual impact on the AAF, should warrant dismissal of the charge against him.
- 6.10 Mr. Wong contends that because there is now a uniform, harmonized limit of detection, the HISL, quantitative testing is required.
- Mr. Wong contends that one of his former grooms was the source of the Metformin in Heaven and Earth. He argues that since this groom admitted to urinating in Heaven and Earth's stall, Heaven and Earth must have eaten contaminated hay, which in turn was of sufficiency recency and volume to result in an AAF. Alternatively, Mr. Wong suggests that Perez' physical contact with Heaven and Earth, while taking Metformin as his prescribed medication, may have caused the contamination.
- 6.12 Mr. Wong contends that he has engaged in the utmost care regarding protecting Heaven and Earth from this Metformin contamination; or alternatively, Mr. Wong contends that he acted reasonably under the circumstances and is not at significant fault.
- 6.13 Mr. Wong contends that his past record of excellent performance and good character, together with the fact that others have had much smaller penalties and that he has suffered professionally and financially, supports a reduction in the penalty sought.

VII. ANALYSIS⁶

7.1 While all evidence and legal authorities submitted were considered by the Arbitrator, this section necessarily refers only to the evidence and law that the Arbitrator relied upon in reaching this Final Decision.

Presence

7.2 Mr. Wong is alleged to have breached ADMC Program Rule 3212(a), under which the presence of a Prohibited Substance in a Covered Horse is a strict liability offense

⁶ Each party has set forth a number of disputed facts which require me to make credibility assessments. The facts discussed herein are based on the evidence I find to be credible.

for which the "intent, Fault, negligence, or knowing Use on the part of the Responsible Person" is not required to establish a violation:

- "(a) It is the personal and non-delegable duty of the Responsible Person to ensure that no Banned Substance is present in the body of his or her Covered Horse(s). The Responsible Person is therefore strictly liable for any Banned Substance or its Metabolites or Markers found to be present in a Sample collected from his or her Covered Horse(s). Accordingly, it is not necessary to demonstrate intent, Fault, negligence, or knowing Use on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3212 Anti- Doping Rule Violation."
- 7.3 HIWU has the burden of establishing a Presence Based violation to the "comfortable satisfaction" of the Arbitrator. Under Rule 3212(b), sufficient proof of a Rule 3212 violation is established when "the Covered Horse's B Sample is analyzed and the analysis of the B Sample confirms the presence of the Banned Substance or its Metabolites or Markers found in the A Sample". As set out above, the B Sample Analysis confirmed the A Sample Analysis and Mr. Wong's violation is established under Rule 3212(b)(2).
- 7.4 Under ADMC Program Rules, Metformin is a Banned Substance that is not subject to any testing threshold. As such, its presence in a sample is an adverse finding regardless of the amount of drug detected. As a result, upon receipt of the A and B samples, the laboratories knew that each would only be required to do qualitative testing.
- 7.5 There is no dispute that Metformin was present in Heaven and Earth's blood and urine and A samples and confirmed by the B samples. HIWU's witnesses confirm this finding and Dr. Sams confirms this finding. I am more than "comfortably satisfied" that HIWU has met its burden of proving Presence of Metformin in Heaven and Earth.⁷

Effort to Invalidate the AAF.⁸

7.6 Rule 3122(c) states that laboratories are "presumed to have conducted Sample analysis and custodial procedures in accordance with the Laboratory Standards" which are defined as the ADMC Program Series 6000 rules.

⁷ In applying this standard, I have applied the burden of proof set forth in ADMC Rule 3120: comfortable satisfaction is greater than a mere balance of probability (i.e. preponderance) but less than clear and convincing evidence or proof beyond a reasonable doubt."

⁸ In addition to the claimed errors which are no longer being pressed by Mr. Wong, set forth in Footnote 3, Mr. Wong has also claimed errors such as typographical errors, or samples shipped on different dates. Some claimed departures are truly *de minimus*. Errors such as this are not dispositive. See, e.g. CAS 2014/A/3639, *Muralidharan v. NADA, Indian National Dope Testing Laboratory, Ministry of Youth Affairs & Sports.* They will not be discussed further because in any event, Mr. Wong has not introduced expert opinion as to departures and whether any of these types of errors could reasonably have caused an AAF.

- 7.7 Pursuant to Rule 3122(d), departures from any Standards or provisions of the ADMC program are presumed to not invalidate an AAF:
 - "(d) Departures from any other Standards or any provisions of the Protocol shall not invalidate analytical results or other evidence of a violation, and shall not constitute a defense to a charge of such violation; provided, however, that if the Covered Person establishes that a departure from any other Standards or any provisions of the Protocol could reasonably have caused the Adverse Analytical Finding or other factual basis for the violation charged, the Agency shall have the burden to establish that such departure did not cause the Adverse Analytical Finding or other factual basis for the violation." (emphasis added)
- 7.8 Thus, to invalidate the AAF, Mr. Wong must rebut the presumption that the laboratories complied with ADMC Rules. To do so, he must first establish that there has been a departure from the Rules of the ADMC program, and second, that this departure could reasonably be the cause of the alleged AAF, both on a balance of probabilities. This must be done with proper evidence, and not mere speculation. Third, if and only if Mr. Wong rebuts the presumption does the burden shift to HIWU to establish that the departures did not cause the AAF.
- 7.9 There are a number of areas which Mr. Wong argues constitute departures from the Standards and protocols. Given that there has been no evidence that any departure could reasonably have caused the AAF, the discussion will be brief and limited to some of major ones Mr. Wong has raised.⁹

7.10 The failure to use internal standards.

Mr. Wong has argued that the failure of Industrial and UIC to do internal standards testing constitutes a departure, repeatedly invoking the Accreditation Requirements and Operating Criteria for Horseracing Laboratories ("ILAC")

This argument is unavailing given that Paragraph 15 of ILAC-G7:04 states: "Quantification of a sample component is not necessary for a report of a nonthreshold substance." There is no dispute that Metformin is a non-threshold substance.

Similarly, ADMC Program Rule 6314(b)(ii) only requires appropriate internal standards for substances that have thresholds under the ADMC program. To state the obvious, Metformin is not a threshold substance. The only requirement for internal

Wong called out in the hearing. But for the avoidance of doubt, Mr. Wong has failed to rebut the presumption that the laboratories complied with the ADMC Rules with regard to any of the claimed departures and has failed to show that any such departure, if proven, could reasonably have caused the AAF.

⁹ Wong's original submissions from experts contained a myriad of claims against the testing done at all of the laboratories. The record contains all of the facts relating to them. But since in no instance has Mr. Wong produced any evidence that any of them could reasonably have caused the AAF, I will only speak to those items which Mr.

standards is found in the "REGULATORY QUANTIFICATION" section, at section 27. (emphasis supplied)

I accept Hartmann's testimony that her use of qualitative testing was well within the rules, guidelines and SOPs for the laboratory. I accept that to the extent Hartmann included estimations as to the quantity she found to be present, this was done solely for informational purposes and was not an attempt to do a quantitative analysis.

Dr. Sams prefers the use of internal standards testing but agrees that for qualitative testing, it is not necessary.

Mr. Wong has not proven that not using internal standards constitutes a departure from the ADMC Rules. It would be a meaningless point even if proven because there is no evidence that such a departure could reasonably have caused the AAF.

The use of a two versus three ion transition process.

There is no doubt that the ILAC G-7 states that "[w]here relevant, the AORC Guidelines for the Minimum Criteria for Identification by Chromatography and Mass Spectrometry "should" be followed. three ion transitions "should" be followed.

ILAC also states in Part C of the Introduction that:

"In this document, 'shall' or 'must' indicates a requirement, 'should' indicates a recommendation." (emphasis supplied)

While AORC Guidelines appear to require three rather than two, those guidelines also contain language regarding how to handle less than three ions (implicitly permitting just two):

Paragraph 11 of the AORC guidelines states that "[f]urther techniques or derivations may be used in combination if a single technique produces less than 3 ions suitable for matching." Thus, I find that despite language seemingly requiring three ion transitions, AORC guidelines also appear to make room for Heffron's technique and the use of two transitions.

It seems clear, however, that the preferred method is three ion transitions at a minimum.

The better practice no doubt would have been for Heffron to use three ion transitions – and indeed, he now has new equipment that permits this. But it is questionable whether his use of two ion transitions, together with other confirmatory testing was a departure from the Standards under the above language.

It is a close question, but I am not satisfied that Mr. Wong has met his burden of proving that using two instead of three ion transitions constitutes a departure from the rules taking the totality of the rules into consideration, including Paragraph 11 of the AORC guidelines.

Even if two rather than three ion transitions were a departure, Dr. Sams opined that while possible, he did not believe it likely that the use of just two ion transmissions resulted in a false positive. Thus, even if this were a departure, there is no evidence that it could reasonably have caused the AAF.

The Aliquot Procedure.

Heffron's description of the procedure he followed, together with Dr. Sams' commentary on it, supports the conclusion that the procedure utilized by Heffron was scientifically acceptable.

While ADMC Rule 6305 speaks of a requirement to decant the urine, Heffron utilized a different method: he placed a pipette in the homogenized urine twice. HIWU argues that there is no reason to doubt that Heffron would have taken steps to prevent contamination such as wearing gloves and using clean pipettes.

I credit Dr. Sams opinion that there is a potential impact of contamination. He noted that anything that entered the sample could contaminate it, including inserting a pipette directly into the B sample. But Dr. Sams agreed that if Heffron used clean pipettes and wore gloves, the risk of contamination would have been very low.

Dr. Sams opines since any risk of contamination is very low, it is not likely that this would have caused a false positive.

However, a reading of ADMC 6305 does not appear to give Heffron the latitude to deviate from a requirement to decant the urine. Thus, although I find that Heffron's actions do not appear to run afoul of good laboratory practice, they do run afoul of Rule 6305, and this constitutes a departure from the Rules.

The discussion need go no further, however, since there has been no evidence that this departure could reasonably have caused the AAF.

The Chain of Custody.

Mr. Wong criticizes the chain of custody documentation to one extent or another at all the laboratories. I am satisfied that all of the information necessary to document the chain of custody exists somewhere in the laboratories' documentation. However, Mr. Wong fairly argues that for a Covered Person and his or her expert, who need to

have data more accessible and easily found, the present mode of record keeping at the laboratories is inadequate.

Also, as part of his attack on UIC's chain of custody, Mr. Wong questions whether or not a second technical review was conducted by a second scientist. I am satisfied from Heffron's testimony, together with the exhibits, that Marc Benoit conducted a technical review on August 14, 2023 and thus, UIC complied with the rules.

In recognition of criticisms which have been lodged during this and proceedings regarding other Covered Persons, the laboratories have endeavored to improve their reporting on the chain of custody; Clearly, the documentation would benefit from some improvements, which are fortunately underway. For example, Hartmann is now making changes to the preprinted forms and making sure all of the information relating to chain of custody can be more easily accessed by a subsequent reviewer.

In conclusion, I am satisfied that all of the necessary information was recorded somewhere in each of the laboratories' records and that there are no gaps in the chain of custody. While Mr. Wong has raised many arguments and questions, he has not met his burden to establish a departure.

Even if, *arguendo*, Wong had established any departure from the rules regarding chain of custody, he has not presented any evidence that any such departure reasonably caused of the alleged AAF, on a balance of probabilities.

The B Sample.

In addition to some of the particularized criticisms of the B Sample, discussed above, Mr. Wong also argues that the B Sample ought to be rejected, *in toto*, as a matter of law, because it is "unreliable."

Overall, I find that the results of the B Sample are reliable. Mr. Wong's wholesale attack on the B sample in large part consists of argument of counsel which, albeit eloquent, is no substitute for evidence.

Dr. Sams agrees that none of the claimed departures in how the laboratories handled and tested the samples likely could have caused a false positive.

To be clear, there is one proven departure regarding the aliquoting procedure and an admittedly close question regarding the two versus three ion transitions; and all laboratories would benefit from sharpening their chain of custody paperwork.

But taking the totality of all of the evidence, the opinions of the experts, of the laboratory directors and informed by the ADMC Rules, the AORC guidelines and ILAC G7, I find that Mr. Wong has failed to set forth any basis in law or fact to justify the relief he seeks: rejection of the B Sample in its entirety. As with all Mr.

Wong's other claims, this argument suffers from the fatal flaw that there is no evidence that any of the departures could have reasonably caused the AAF.

7.11 In addition to the arguments above, Wong raises two more arguments:

First, Mr. Wong argues that this Arbitrator erred in allowing HIWU's Motion for Further Analysis. ¹⁰

ADMC Rule 1020 defines further analysis as extra or supplementary analysis. ADMC Rule 3138(b) permits this assistance in definitely establishing whether a laboratory properly detected a Banned Substancewhen the laboratory's methodology is questioned.

In engaging in a further analysis, Moeller conducted testing only the blood sample from Industrial (the A sample) and the urine sample from UIC (the B sample). Moeller did not address the B blood sample because upon receipt of the blood of sample, Moeller discovered that there was inadequate blood from the B Sample to test.

The testing done by Moeller was confirming of that done by Industrial and UIC.

Two points obviate the need to delve deeper into Mr. Wong's opposition to the Motion for Further Analysis. First, I have found that the B sample results at UIC confirmed the A sample results at Industrial. Thus, the UC Davis evidence would at best be cumulative and thus, its introduction into evidence is harmless error. Second, Mr. Wong continues to be plagued by a recurring problem: Mr. Wong has introduced no evidence upon which there could be a finding that any of the departures alleged reasonably could have caused the AAF. To the contrary, there is ample affirmative evidence which supports my conclusion that there was no likelihood at all of a "false positive" caused by any of the claimed departures.

7.12 Wong also argues that HISA's development of a Harmonized Internal Screening Limit ("HISL"), announced in October of 2023, now requires that quantitative testing be done to detect the presence of the non-threshold substance, Metformin.

This HISL is a set a single limit of detection to be used by all of the six laboratories currently doing testing.

The ADMC Rules, Rule 1020, addresses limits of detection and includes *Minimum Reporting Level* which is defined as:

¹⁰ This will be the third time Mr. Wong has pressed this argument. While Mr. Wong has raised no issues warranting revisiting this issue, I will, out of an abundance of caution and fairness to Mr. Wong, address it once more.

"the estimated concentration of a Prohibited Substance or its Metabolite(s) or Marker(s0 in a Sample below which Laboratories will not report that Sample as an Adverse Analytical Finding."

Thus, a minimum limit of detection is authorized in the ADMC Rules, and the setting of this limit is not accompanied by a requirement for quantification. The HISL is simply a logical step: harmonize the limits of detection across all of the laboratories.

ILAC G7:4 addresses the use of harmonized screening limits:

Pharmacologically irrelevant or analytically insignificant levels of certain legitimate therapeutic substances or environmental substances may be present in many test samples. Thus, an authority may require the laboratory to control the detection (and reporting) of such non-threshold prohibited substances through the application of internationally harmonized screening limits (citations omitted)

This new HISL was intended to create a uniform standard as part of HISA's ongoing process to update HISA's ADMC Program. This in turn is in recognition of the reality that each laboratory has its own limit of detection. The goal of creating a harmonized screening limit was to ensure fairness and uniformity regarding these various limits of detection at different laboratories.

7.13 Mr. Wong argues - without factual or scientific support - that "the minute you put a number on something" it must be quantified. His claim that where there is a harmonized screening limit (instead of six different limits), there must be quantification, is bereft of factual, including scientific support or legal support.

A limit of detection is not a screening or threshold limit and no such evidence or authority was cited for Mr. Wong's contrary position.

In addressing harmonized screening limits, nowhere in its guidelines does ILAC, or any other credentialling entity cited in these proceedings, state that the use of a harmonized screening limit carries with it an obligation to quantify the non-threshold substance.

Mr. Wong's argument that the institution of a HISL now requires quantitative testing is sophistry and is rejected.

7.14 Indeed, throughout the hearing, in a variety of ways, Mr. Wong has attempted to impose a quantitative testing obligation to try to require measurement of what is indisputably a non-threshold substance. For example, Mr. Wong points to the fact that Industrial estimated a quantity in its testing; or, UC Davis, used internal standards, although not required, for qualitative testing. As with the creation of a HISL, these gratuitous acts, which exceed the ADMC Rules basic requirements, do not convert Metformin to a threshold substance.

Despite Mr. Wong's herculean efforts, he has not produced any support for the notion testing for a non-threshold substance, here, Metformin, requires quantitative testing.

7.15 Much like Mr. Wong's argument that the B Sample should be rejected in its entirety because there are numerous alleged departures, Mr. Wong also argues that the entire case against him should be dismissed outright because there have been multiple departures from the ADMC Rules. Mr. Wong argues that where there is strict liability imposed on a Covered Person, so should there be strict requirements placed on the enforcement agency, citing *Vadim Devyatovskiy v. International Olympic Comm. (IOC)*, CAS 2009/A/1752, Para.251.

In *Devyatovskiy*, CAS annulled testing results due to B sample failures, noting that "[s]trict application of the rules is the quid pro quo for the imposition of a regime of strict liability for doping offenses."

A comparison of the claimed departures of the laboratories here does not reveal facts at all similar to those in *Devyatovskiy*. In Paragraph 241 of that decision, the Panel noted departures such as instrument malfunction, loss of control over the samples and the failure of quality control procedures. Here, Mr. Wong has not presented any evidence to support that any alternative methods used by any testing laboratory constitute, in the words of his counsel "bad science." There is no evidence that the methods used lacked reliability. And certainly no evidence that any claimed departures caused an AAF. Thus, Mr. Wong's reliance on *Devyatovskiy* to argue that any claimed missteps by the testing laboratories here warrant arbitral nullification is misplaced.

7.16 Devyatovskiy rightly notes the need to hold laboratories to account in how they do their testing by insisting on adherence to rules and standards. The world of laboratory testing demands precision which in turn requires compliance with rules. But balanced against this important principle is the reality that differences in methods and procedures among laboratories is a good thing, leading to improvements. In fact, Mr. Wong elicited from laboratory witnesses repeated instances where, due to lessons learned, the laboratories have made changes, always working toward still further precision and as for documents, better transparency and accessibility. Making changes to systems and procedures does not render the work of any of the laboratories in testing Heaven and Earth's samples questionable, unreliable or invalid.

In its introductory section, ILAC G7:4 states that it provides a set of internationally agreed recommendations for establishing the presence of a prohibited substance, although the concept of "rigid standardization" is rejected.

ILAC G7:4 Preamble states in Paragraph 4:

"4. The guide should not be followed exclusively of other scientific considerations where necessary to establish the presence of a prohibited substance."

5. It is recognized that some laboratories will be able to establish the presence of a wider range of prohibited substances or at lower concentrations of prohibited substances than other laboratories. Such individual capabilities must be allowed to develop, as they will lead to improvements generally." (emphasis supplied)

In sum, Mr. Wong has attempted to invalidate the AAF by a wide-ranging, everchanging attack on the laboratories themselves. His experts have scoured through the laboratory data packets and ADMC rules, searching for a toehold in the mountain of evidence proving the presence of Metformin in Heaven and Earth. But no evidence rebutting the presumption has been introduced. Even Mr. Wong's own expert, Dr. Sams, laudably, refused to sully his own professional credibility by claiming otherwise. The ineluctable fact is that the AAF was not the product of a misstep by any laboratory.

The admonition that enforcement authorities and the laboratories doing the testing must be held strictly to the rules should not be taken in a vacuum. For a demand for adherence to the rules must be tempered by the reality that science is dynamic by nature. Laboratories can and should approach testing in a way that always seeks to improve reliability in methods and accuracy in results. This will, of necessity, result in differences and changes in methodologies.

Simply raising the spectre of *Devyatovskiy* is insufficient to invalidate the fruits the of the A and B testing laboratories. ADMC Rules require a Covered Person to prove a causal link in the event of a departure to overcome the presumption of compliance with the ADMC rules.

Therefore, I reject Mr. Wong's argument that the conduct of the laboratories should be viewed through a procrustean lens leading to the conclusion that dismissal of the case is warranted where there are departures, regardless of whether or not any deviation impacted the AAF.

Lastly, HIWU rightly notes that these rules are designed to favor enforcement, the integrity of sport and the welfare of the horses.

Thus, even if any of the above claimed departures had any purchase, and all but one do not, Mr. Wong did not meet his burden of showing that any of them had any impact whatsoever, let alone could have "reasonably caused" the AAF.

Mitigation of Wong's Sanction Based on Fault

7.17 Where a Violation of the ADMC Program is established, the Respondent may be entitled to a mitigation of the applicable Consequences, only where they establish on a balance of probabilities that they acted with either No Fault or Negligence, or No Significant Fault or Negligence. As explained below, in both cases, as a threshold issue before considering the degree of fault in a particular case, the Covered Person

- must "establish how the Prohibited Substance entered the Covered Horse's system", which is also known as the requirement to prove the source of the AAF.
- 7.18 It is not enough to suggest possibilities or speculate. Mr. Wong has a stringent requirement to offer persuasive evidence of how such contamination occurred. *WADA v CPA & Karim Gharbi*, CAS 2017/A/4962 at para. 80.
- 7.19 I reject Mr. Wong's argument that this defense is illusory. HIWU points out that others have successfully been able to meet the burden of proving source in the *lex sportive*. In fact, in a recent HIWU case, *Horseracing Integrity Welfare Unit v. Dennis VanMeter*, JAMS Case #1 501000594, September 26, 2023, a Covered Person was able to satisfactorily meet his burden of proof.
- 7.20 Wong originally claimed that he, himself, was the source of the Metformin. This claim was made during an interview with Paulick as part of a trade article appearing in the Paulick Report. Paulick is a seasoned, experienced reporter and I am satisfied that he is well familiar with how to take notes and knows the importance of only putting a statement in quotes when certain of the accuracy of the statement. In this case, I am satisfied that Mr. Wong is not being truthful when he says he never spoke to Paulick. Paulick is a disinterested witness whose testimony was corroborated by detailed contemporaneous notes. There is no doubt that Mr. Wong stated that he was the source of the Metformin, even though he never made that a part of his formal defense in the present action. According to the article in the Paulick Report, which I credit as being true and accurate, Mr. Wong also told HIWU officials that he was the source of the Metformin. He has made statements in this hearing that are not consistent with what Mr. Wong has said in the past.

I reject Mr. Wong's efforts to suggest that Mr. Paulick has an interest in the outcome of the case because at some prior unknown time, HISA and/or HIWU may have purchased some advertising in the Paulick.

7.21 Less than a month later, however, Mr. Wong changed course. He now sought out the services of a polygraph examiner, to attempt to establish that he knew nothing about the source of Metformin in Heaven and Earth's blood and urine samples. Mr. Wong answered four questions about whether he had any responsibility in how the Metformin got into Heaven and Earth or knew anything about it. The four questions the polygraph examiner utilized were drafted by a client of Wong's who also happens to be an attorney.

I have been provided with the examiner's report as well as some of the underlying data, but she did not testify or present an affidavit to elaborate on her credentials.

There is no evidence about the polygraph examiner's education, background, training, expertise, or any other credentials except that Mr. Wong found her on Yelp.

There is no evidence about the equipment she used and whether or not it has been calibrated, maintained or is otherwise in proper working order. There is no evidence regarding conversations the examiner may have had with Mr. Wong before, during and after the examination. There is no evidence establishing that the examiner is independent and conducted a proper examination.

The report fails to persuade me first, because of the general lack of reliability of polygraph testing.¹¹ Further, and particular to this case, there is no evidence upon which I can conclude that this polygraph examiner is qualified, that she used the proper equipment and methodology in arriving at her opinion or that she is independent.

I reject the polygraph examiner's opinion as lacking in foundation and any indicia of reliability or credibility.

- 7.22 Mr. Wong has testified that he lectured his employees such as grooms and trainers "countless times" that they must not urinate in the stalls and that they must wash their hands before having contact with the horses if they are on any type of medication. I do not accept this as credible as discussed, *infra*¹².
- 7.23 By his own admission and evidence, Mr. Wong has been disciplined in the past, including for medication violations. During the time when Mr. Wong was supposedly constantly lecturing his employees as he described, Mr. Wong no doubt knew from personal experience as well as the experience of others, that the sanction, if caught, would be minimal. Therefore, Mr. Wong's claim that he lectured his people "countless" times over the years is not likely.

Lastly, there is, unfortunately, the simple fact that Mr. Wong has been untruthful in this proceeding. He has stated that he never even spoke to Paulick. This is a demonstrably false statement. As a result of this testimony, together with other parts of his testimony, I find Mr. Wong's credibility greatly diminished.

7.24 Under all of these circumstances, I do not accept that Mr. Wong had a routine of speaking with his staff let alone doing so "countless times." Even if he did, any such lectures to his employees would be fairly toothless since there is no evidence that such lectures were accompanied by any reinforcing or deterring actions such as spot checks or punishment for violations.

¹¹ The reliability of the polygraph examination as a means to ferret out deception has long been the subject of debate and polygraph test results are generally not admissible in criminal courts in the United States. United States Senator Sam Ervin, who led the Watergate hearings, famously observed that "polygraph tests are 20th century witchcraft." ¹² This evidence of the efforts Mr. Wong claims to have taken to ensure that the horses are not exposed to a substance such as Metformin is of limited value: Mr. Wong has not established the source of the contamination. Thus, I do not reach the issue of whether or not Mr. Wong acted with the utmost care or otherwise reasonably under all of the circumstances.

- 7.25 Wong's final theory as to the source was represented in his Prehearing Brief environmental contamination through surface water or a food source. This position was jettisoned mere days before the evidentiary hearing. This is supposedly because of the discovery of Perez, Mr. Wong's former groom. Perez supposedly cared for Heaven and Earth for the seven months up to and including the day of shipment to the racetrack.
- 7.26 Mr. Wong has claimed that this new witness, Perez, was discovered by a mutual colleague, Garcia who happened upon Perez while visiting family in Mexico in December, shortly before the evidentiary hearing. Garcia and Perez spoke of what was happening with Mr. Wong. While the mechanics of how the statement was obtained are murky, Mr. Wong was able to get an interpreted, sworn statement from Perez, presumably while he was still in Mexico. In his statement, Perez stated that as a diabetic he was prescribed Metformin. He described what sounds like a penchant for urinating in Heaven and Earth's stall as well as his lack of hand washing, covering a period of seven months. He described that he did not wash his hands prior to coming into contact with Heaven and Earth. He expressed his concern that as a result of his actions, he "may have inadvertently contaminated" Heaven and Earth.
- 7.27 Relying on this eleventh hour disclosure, Mr. Wong advanced the argument that the source of the contamination was from Heaven and Earth ingesting hay which contained urine from a groom who urinated in the stall occupied by Heaven and Earth.
- 7.28 This position is rejected because it is not supported by any credible evidence.
- 7.29 I reject the sworn statement attributed to Perez in which Perez claims to have urinated frequently in the barn occupied by Heaven and Earth. It is without any credibility and given its timing, I find that it is a recent contrivance.
- 7.30 I reject the testimony of Rodriguez which essentially mirrors the above testimony of Mr. Wong regarding training being done to the employees. He is a long time colleague of Mr. Wong's and I believe his testimony is borne of that relationship.
- 7.31 In rejecting all of this testimony, I do so based on my assessment of the credibility of the witnesses, their demeanor, their interest in the outcome of the case and the illogic of their testimony.

¹³ Mr. Wong testified that he had not had contact with Perez since the time of his suspension, "despite his efforts to reach him." Given that Mr. Wong knew that Perez was the groom caring for Heaven and Earth at the time of contamination, one would have expected Mr. Wong to have gone to great lengths to find and question him. The record is silent as what Mr. Wong's "efforts" were.

¹⁴ HIWU rightly notes that the relaxed rules of evidence are truly being stretched to their limit in this proceeding regarding what Perez supposedly said. The testimony consisted of Mr. Wong saying what Garcia said that Perez said. I will not exclude this testimony on the basis of it being double hearsay but it certainly goes to the weight of the evidence.

7.32 As to Perez in particular, since that is the only evidence presented by Mr. Wong which might colorably explain how the Metformin got into Heaven and Earth, the Perez account of urinating in the stall and not washing his hands is lacking in any credibility. A review of Perez' own words, raises a host of questions:

"I bathed Heaven and Earth, fed her, and prepared her for shipment...I am afraid that I may have inadvertently contaminated Heaven and Earth by urinating in the stalls or handling her after taking my medication and not washing my hands and that's the main reason I left the racetrack the first week of July and returned to Mexico on July 15, 2023."

No evidence was presented as to when or where in the stall Perez urinated and when and whether Heaven and Earth would even have eaten any hay off the floor which had been urinated on; no evidence — expert or otherwise - was presented as the quantity of urine which would need to be in the hay, or when, in order to trigger a positive finding.

No evidence was presented as to how Perez managed to spend seven months urinating with abandon in the horse stalls, undetected.

How much physical contact did Perez have with Heaven and Earth, when and what parts of the horse's body did Perez touch? When had he last taken Metformin? When had he last washed his hands? Perez's prescription required him to take Metformin at night, so it is questionable how he could have appeared the next morning and touched Heaven and Earth without ever having washed his hands.

Even if the Perez statement were credible, it could only serve as the basis upon which an expert would need to opine: how much contaminated hay was eaten and when in order to have triggered an AAF? Or, how much physical contact with the horse would need to occur to trigger an AAF? Without evidence to answer these questions, Mr. Wong's claim that Perez was the source of the contamination is just that – a claim.

Finally, Perez claims that he left the country upon learning of the contamination. The idea that Perez would leave his job because of an adverse finding of his employer's horse is without credibility.

7.33 Accordingly, I find that Mr. Wong has not met his threshold burden of establishing the source of the contamination and thus there is no mitigation that might possibly be considered for Wong, and his sanction should be two years of Ineligibility.

Punishment- Fine and Arbitration Costs

7.34 Under the ADMC Program, the punishment includes, in addition to a period of Ineligibility, a "Fine up to \$25,000 . . . and Payment of some or all of the adjudication costs and [HIWU]'s legal costs". Rule 3223(b).

In considering what amount of fine is appropriate, I will look to the totality of the record. In so doing, I have considered Mr. Wong's conduct, background and any other circumstances that inform my use of my discretion.

7.35 There is no doubt that Mr. Wong is an experienced, highly successful trainer who has climbed the ranks of this industry from the bottom up. His conduct and performance as a trainer presents a mixed bag: He has submitted numerous letters of support and praise from a constellation of highly regarded people in the horse racing industry.

There is also no doubt that Mr. Wong has suffered financially, professionally, and emotionally from the Provisional Suspension and this will no doubt continue during the balance of the Ineligibility period.

Balanced against these facts, however, is a record which does not support that Mr. Wong did much to prevent this contamination from occurring. If Mr. Wong was engaged in routine, frequent trainings of his staff regarding not urinating in the stalls, keeping hands clean and so on, - which I do not believe - he certainly did not couple this with any level of monitoring, enforcement, or deterrence such as through imposing consequences for violators.

Mr. Wong is no doubt a decent person who, in his own way, has tried to put the safety and welfare of his horses first. But despite his best intentions, the evidence is clear that Mr. Wong has abdicated his obligation as a Covered Person to protect the safety and welfare of the horses under his care consistent with ADMC Rules; and to be blunt, he has not been truthful, as demonstrated in the Paulick interview.

Instead of accepting responsibility for this harmful substance finding its way into Heaven and Earth, Mr. Wong chose to blame the agency charged with the protection of the health, welfare and safety of these horses. The same agency which is charged with protecting the integrity of the very industry so essential to Mr. Wong's own personal and professional wellbeing. When addressing the issue of how the Metformin got into Heaven and Earth, Mr. Wong stated: "I told them, but it doesn't matter" he said "They don't care, and that's the problem."

7.36 There is no doubt that Mr. Wong has every right to defend these serious accusations against him in the best way he and counsel see fit and he has been allowed to do so. In fact, he has been given leeway when needed to defend himself. For example, in recognition that cases evolve, and busy experts can complicate a party's compliance with scheduling orders, Mr. Wong was granted leave early on by this Arbitrator to supplement his disclosures. Similarly, legal claims and defenses, of necessity, can change and as cases develop, defenses can be pared down or completely discarded. Conversely, sometimes, new evidence needs to be introduced. When Mr. Wong sought leave to bring in two witnesses, which completely changed the posture of the case, he was permitted to do so. But much of this could have been avoided by

¹⁵ I take HIWU's point that it appears that some of Mr. Wong's supporters are heartily endorsing him based on the erroneous belief that he has never committed any violations vis-à-vis the horses placed in his care.

- reasonable efforts on Mr. Wong's part to at least try to locate necessary percipient witnesses.
- 7.37 But as a result of these actions, HIWU has had to engage in efforts akin to a game of "whack a mole", retaining one expert after another to respond to the every changing field of play due to Mr. Wong's evolving factual explanation as to how the Metformin got into Heaven and Earth. Perez was supposedly the groom who was inseparable from Heaven and Earth up to and including race day. Yet, I find that Mr. Wong did not expend any effort to find and contact the groom who should have been *the* most important witness if Perez is telling the truth. In having to retool its case mere days before the evidentiary hearing, HIWU has been put to a great deal of needless time and expense, which includes not only its internal expenses but arbitral expenses; much of this was avoidable with any reasonable effort by Mr. Wong.
- 7.38 I find, based on all of the facts and circumstances of this case, including no mitigating facts concerning the contamination, that a fine of \$25,000 is appropriate.
- 7.39 With respect to issues of costs to be assessed, I note that HIWU has not sought reimbursement of or contribution to its legal fees in this case in its claims for relief. HIWU does seek contribution to the costs of the arbitration proceeding, including the compensation of the Arbitrator and the arbitral body's fees.
- 7.40 I have considered the same factual and equitable considerations above in assessing what fine would be appropriate. Based on the circumstances, Mr. Wong should make a significant contribution toward the cost of these proceedings. But I consider the many glowing letters of support submitted on his behalf as well as the fact that Mr. Wong's finances have been severely impacted by having to move 150 horses out of his care. This suspension impacts not just Mr. Wong but his family. I also temper my view of what is fair and reasonable based on accepting the view of one of Mr. Wong's supports that he is "one of the good guys", and the expectation that upon his return to training horses, he will monitor compliance with ADMC Rules at his barns in a robust and meaningful way. Thus, he will be ordered to pay, in addition to his own half of the arbitration, an additional \$8,000 to be paid by the end of his period of ineligibility.

VIII. AWARD

- 8.1 On the basis of the foregoing facts, legal analysis, and conclusions of fact and law, the Arbitrator renders the following decision:
- 8.2 Mr. Wong is found to have committed his first anti-doping rule violation of Presence. As a result, Mr. Wong shall:
 - 1. Be given a period of Ineligibility of two (2) years for Trainer Wong as a Covered Person, beginning on July 1, 2023, the date the Provisional

- Suspension was imposed, with credit for time served;
- 2. Forfeit all distributed purses, prizes, trophies or other compensation arising from Heaven and Earth's first place finish on June 1, 2023 at Horseshoe Indianapolis in Shelbyville, Indiana, including the purse of \$21,600;
- 3. Be fined USD \$25,000.00 and shall pay \$8,000 of HIWU's share of the adjudication costs of this proceeding in addition to paying his share of 50% of the adjudication costs of this proceeding by the end of his period of Ineligibility.

This Decision shall be in full and final resolution of all claims and counterclaims submitted to this arbitration. All claims not expressly granted herein are hereby denied.

IT IS SO ORDERED, AWARDED, AND DECIDED, January 29,2024, as corrected on February 9, 2024.

Hon. Nancy Holtz, Arbitrator

Hanry Holty

EXHIBIT B

1000. General Provisions

Rule 1010. Rules of Interpretation

Unless specified otherwise:

- (a) words in the singular include the plural, and words in the plural include the singular;
- (b) references to any "Rule" or "Rule Series" are references to the rules or rule series approved by the Commission pursuant to section 3053 of the Act;
- (c) any Appendices to a Rule Series form an integral part of such Rule Series;
- (d) any reference to a provision in rules, protocols, policies, standards, guidelines, or similar includes any modifications or successor provisions made or issued from time to time;
- (e) any reference to legislation includes any modification or re-enactment of legislation enacted in substitution of that legislation, and any regulation or other instrument from time to time issued or made under that legislation;
- (f) any term defined in this Rule 1000 Series shall supersede the definition of that term in the Rule 2000 Series;
- (g) a reference to "writing," "write," or "written" includes communications transmitted by email;
- (h) a reference to "may" means "in the sole and absolute discretion of such person or body";
- (i) a reference to a "day" means any day of the week and is not limited to working days;
- (j) any time limits shall begin from the day after which the relevant notification is received (or the day after the relevant notification is sent, if sent by email). Official holidays and non-working days are included in the calculation of time limits. The time Time limits fixed under this Protocol are respected if the communications by the parties are sent before midnight (U.S. Eastern time) on the last day on which such time limits expire. If the last day of the time limit is an official holiday or a non-business day in the state or country from where the notification has been made document is to be sent, the time limit shall expire at the end of the first subsequent business day;
- (k) a reference to a "person" (with no initial capital letter) means a natural person; and
- (I) any words following the terms "including," "include," "in particular," "such as," "for example," or any similar expression, are illustrative only, and do not limit the sense of the words, description, definition, phrase, or term preceding those terms.

Rule 1020. Definitions

Act means the Horseracing Integrity and Safety Act of 2020 (15 U.S.C. 3051-3060), as amended from time to time.

ADMC means the Anti-Doping and Medication Control Standing Committee of the Authority.

Administration means providing, supplying, supervising, facilitating, or otherwise participating in the Use or Attempted Use in a Covered Horse of a Prohibited Substance or Prohibited Method.

However, this definition shall not include the actions of bona fide veterinary personnel involving a Controlled Medication Substance or Controlled Medication Method used for genuine and legal therapeutic purposes or other acceptable justification.

Adverse Analytical Finding ("AAF") means a report from a Laboratory that, consistent with the Laboratory Standards, establishes in a Sample the presence of a Prohibited Substance or its Metabolites or Markers or evidence of the Use of a Prohibited Method.

Agency means the anti-doping and controlled medication enforcement agency known as the Horseracing Integrity and Welfare Unit.

Aggravating Circumstances means circumstances involving, or actions by, a Covered Person that may justify the imposition of one or both of a period of Ineligibility or fine greater than the otherwise applicable standard sanction. Such circumstances and actions include those set forth in Rule 3227 or Rule 3327 (as applicable).

Aliquot means a portion of the Sample obtained from the Covered Horse used in the analytical process.

Analyte means a substance, compound, or measurand that is analyzed or determined in a biological matrix using an Analytical Testing Procedure performed under controlled analytical and laboratory conditions. For anti-doping and controlled medication purposes, an Analyte may be a Prohibited Substance, a Metabolite of a Prohibited Substance, or a Marker of the Use of a Prohibited Substance or Prohibited Method.

Analytical Method has the same meaning as Analytical Testing Procedure.

Analytical Testing means the parts of the Doping Control or Medication Control process performed at the Laboratory, which includes Sample handling, analysis, and the reporting of results.

Analytical Testing Procedure means a Fit-for-Purpose procedure, as demonstrated through method validation, that is used to detect, identify or quantify Analytes in a Sample in accordance with the Laboratory Standards and relevant Technical Document(s), Technical Letter(s), Technical Note(s), or Laboratory Guidelines. Unless the context otherwise requires, Analytical Testing Procedure is also referred to or known as an Analytical Method or Test Method.

Analytical Testing Restriction ("ATR") means a restriction on a Laboratory's application of specified Analytical Testing Procedure(s) or on the analysis of a particular class (esor classes) of Prohibited Substances or Prohibited Methods to Samples, as determined by the Agency.

Anti-Doping Rule Violation ("ADRV") means an anti-doping rule violation under the Protocol, as set forth in Rules 3212 to 3216.

Arbitral Body has the meaning given to it in the Rule 7000 Series.

Arbitration Procedures means the arbitration procedures set forth in the Rule 7000 Series, as amended from time to time.

Arbitrator means an arbitrator who is a member of the Arbitral Body.

Assistant Trainer means a person engaged in the training of Covered Horses, under the direct or indirect supervision of a Trainer.

Associated Person means a Close Relation, assistant, representative, employer, employee, agent, partnership, partner, corporation, business associate, or affiliate of a Covered Person; and any other Person whose relationship (whether financial or otherwise) with the Covered Person in issue would give the appearance that such Person would care for, train, or race one or more Covered Horse(s) or perform veterinary services for Covered Horse(s) for the benefit, credit, reputation, or satisfaction of the Covered Person in issue.

Association Veterinarian means a Veterinarian employed by a Racetrack.

Attempt means purposely engaging in conduct that constitutes a substantial step in a course of conduct planned to culminate in the commission of an Anti-Doping Rule Violation or Controlled Medication Rule Violation; provided, however, that there shall be no Anti-Doping Rule Violation or Controlled Medication Rule Violation based solely on an Attempt to commit a violation if the Covered Person renounces the Attempt prior to it being discovered by a third party not involved in the Attempt.

Attending Veterinarian means a Veterinarian providing treatment or services to Covered Horses hired or otherwise authorized by the Trainer or Owner or his or her respective designee.

Atypical Finding means a report from a Laboratory that requires further investigation in accordance with the Atypical Findings Policy set out at Appendix 1 to the Protocol, prior to the determination of whether or not it is an Adverse Analytical Finding.

Atypical Findings Policy means the policy set out at Appendix 1 to the Protocol.

Authority means the Horseracing Integrity and Safety Authority, <u>Inc.</u> designated by section 3052(a) of the Act.

Banned Method has the meaning given to it in Rule 3111.

Banned Substance has the meaning given to it in Rule 3111.

Batch means a set of Samples processed as a group.

Bias means deviation of a measured result from the expected or reference value when using the complete measurement procedure.

Billing Standards means the standards governing compensation for arbitrators and stewards Arbitrators under the Arbitration Procedures.

Blood Collection Officer ("BCO") means a Veterinarian or—a veterinary technician who has been authorized by the Agency (or its delegate) to collect blood Samples from a Covered Horse in accordance with the Testing and Investigation Standards and related Agency procedures. A BCO is also a Collection Officer (as defined below).

Breeder means a Person who is in the business of breeding Covered Horses.

Certified Reference Material ("CRM") means Reference Material characterized by a metrologically valid procedure for one or more specified properties, which is accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

Certifying Scientists means personnel appointed by a Laboratory to review all pertinent analytical data, Analytical Method validation results, quality control results, Laboratory Documentation Packages, and to attest to the validity of the Laboratory's test results.

Chain of Custody means the sequence of individuals or organizations who have responsibility for the custody of a Sample from the provision of the Sample until the Sample has been delivered to the Laboratory for analysis.

Chaperone means a person authorized by the Agency (or its delegate) to carry out the responsibilities given to Chaperones in the Testing and Investigations Standards or by the DCO.

Charge Letter has the meaning given to it in (as the context requires) Rule 3248 or Rule 3348.

Claim means, in the context of a Claiming Race, the purchase of a Covered Horse for a designated amount.

Claimed Horse Sample has the meaning given to it in Rule 3133(c)(2).

Claimed Horse Testing has the meaning given to it in Rule 3133(c)(2).

Claiming Race means a Covered Horserace in which a Covered Horse after leaving the starting gate may be claimed in accordance with the rules and regulations of the applicable State Racing Commission.

Clearance Sample has the meaning given to it in Rule 3133(c)(2).

Clearance Testing has the meaning given to it in Rule 3133(c)(2).

Close Relation means a spouse, domestic partner, companion (i.e., person who cohabits with or shares living accommodations with the person in issue), or romantic relation; a relative of any spouse, domestic partner, companion, or romantic relation; a former spouse or former domestic partner; or a parent, step-parent, grandparent, child, step-child, grandchild, sibling, step-sibling, cousin, aunt, uncle, niece, nephew, or other family member (whether biological, adoptive, legal, or de facto).

Code of Ethics means the Code of Ethics for Laboratories set forth at Rule 6610.

<u>Collection Assistant</u> means an individual who has been certified by the Agency (or its delegate) to assist the Test Barn Veterinarian, the CO, or the BCO with Sample collection activities in accordance with the Testing and Investigations Standards and any related Agency procedures.

<u>Collection Officer ("CO")</u> means an individual who has been certified by the Agency (or its delegate) to carry out the responsibilities given to COs in the Testing and Investigations

Standards and any related Agency procedures. A CO is not authorized by the Agency (or its delegate) to collect blood Samples from a Covered Horse unless they are a BCO.

Commission means the Federal Trade Commission.

Confirmation Procedure ("CP") means an Analytical Testing Procedure that has the purpose of confirming the presence in a Sample—or, when applicable, confirming the concentration, ratio, or score, or establishing the origin (exogenous or endogenous)—of one or more specific Prohibited Substances, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method.

Consequences means the penalties resulting from the occurrence of one or more violations of the Protocol, as set forth in the Rule 3000 Series. The Consequences for an Anti-Doping Rule Violation or a Controlled Medication Rule Violation may include one or more of the following:

- (1) Disqualification;
- (2) Ineligibility;
- (3) Provisional Suspension;
- (4) financial penalties;
- (5) training or education relating to the requirements and purposes of the Protocol; and
- (56) Public Disclosure.

Contaminated Product means a product other than feed, hay, or water, that contains a Prohibited Substance that (i) is not disclosed on the product label, and (ii) a Veterinarian or TrainerResponsible Person would not otherwise reasonably be aware might be included in the product.

Controlled Medication Method means any method so described on the Prohibited List.

Controlled Medication Rule Violation has the meaning given to it in Rule 3311(a) ("CMRV") means a controlled medication rule violation under the Protocol, as set forth in Rules 3312 to 3314.

Controlled Medication Substance means any substance so described on the Prohibited List or the Technical Document-Prohibited Substances.

Corrective Action Report ("CAR") means a report describing the Root Cause Analysis of a nonconformity and the corrective actions implemented to rectify it. If appropriate, it shall also describe the improvements adopted to minimize the risk of recurrence of the nonconformity.

Covered Horse means any Thoroughbred horse, or any other horse made subject to the Act by election of the applicable State Racing Commission or the breed governing organization for such horse under section 3054(I) of the Act, during the period: (A) beginning on the date of the horse's first Timed and Reported Workout at a Racetrack racetrack that participates in Covered Horseraces or at a training facility; and (B) ending on the date on which the horse is deemed retired pursuant to Rule 3050(b).

Covered Horserace means any horserace involving Covered Horses that has a substantial relation to interstate commerce, including any Thoroughbred horserace that is the subject of interstate off-track or advance deposit wagers.

Covered Person means all Trainers, Owners, Breeders, Jockeys, Racetracks, Veterinarians, Persons licensed by a State Racing Commission, and the agents, assigns, and employees of such Persons; any other Persons required to be registered with the Authority; and any other horse support personnel who are engaged in the care, treatment, training, or racing of Covered Horses.

Decision Limit means the value of the result for a Threshold Substance in a Sample, above which an Adverse Analytical Finding shall be reported.

Designated Owner has the meaning given to it in Rule 3020(c).

Detection Time means the interval after a medication Controlled Medication Substance is administered during which it is detectable in a specific matrix (serum, plasma, urine, or hair) from any member(s) of a group of test horses. Detection times Times are determined from analysis of samples collected at specific time points following an administration of a medicationControlled Medication Substance to a group of, potentially as few as 2, test horses. A detection time Detection Time is not the same as a withdrawal time. The withdrawal time for a medication must be decided upon by a Veterinarian (in consultation with the Responsible Person) and is likely to be based on the Detection Time and an added safety margin. This margin should be determined using professional judgment and discretion to take into account the variability that could be expected to normally occur in a larger population by considering individual differences between horses, such as size, metabolism, fitness, health, or recent illness or disease. The withdrawal interval used for a medication should always be longer than its DetectionWithdrawal Time.

Disqualification means the results of a Covered Horse in a particular Covered Horserace are invalidated, with all resulting consequences, including forfeiture of any purses and other compensation, prizes, trophies, points, and rankings associated with such Covered Horserace.

Doping Control means all steps and processes from test distribution planning through to ultimate disposition of any adjudication and review process pursuant to the Protocol and the Act involving an Anti-Doping Rule Violation and the enforcement of Consequences, including all steps and processes in between, including Testing, investigations, whereabouts programinformation, Sample collection and handling, Laboratory analysis, Results Management, hearings and reviews, and investigations and proceedings relating to Anti-Doping Rule Violations not arising from or related to Testing or relating to violations of Rule 3229.

Doping Control Officer ("DCO") means an official who has been authorized by the Agency (or its delegate) to carry out the responsibilities given to DCOs in the Testing and Investigations Standards and any related Agency procedures.

EAD Notice ("Equine Anti-Doping Notice") has the meaning given to it in Rule 3245.

EAD Violations ("Equine Anti-Doping Violations") means Anti-Doping Rule Violations arising out of the Rule 3000 Series and violations of Rule 3229.

ECM Notice ("Equine Controlled Medication Notice") has the meaning given to it in Rule 3345.

ECM or Other Violations ("Equine Controlled Medication or Other Violations") means Controlled Medication Rule Violations arising out of the Rule 3000 Series, violations of Rule 3329, violations of Rule 3510, or violations of Rule 35103520.

Effective Date means the date that the Commission approves the relevant Rule Series.

Environmental Contamination means substances arising from plants traditionally grazed or harvested as equine feed, and substances in equine feed or bedding arising from contamination during cultivation, processing or treatment, storage, or transportation.

Equibase means the official database for Thoroughbred horseracing.

Equine Constituencies means, collectively, Owners, Breeders, Trainers, Racetracks, Veterinarians, State Racing Commissions, and Jockeys who are engaged in the care, training, or racing of Covered Horses.

Equine Industry Representative means an organization regularly and significantly engaged in the equine industry, including organizations that represent the interests of, and whose membership consists of, Owners, Breeders, Trainers, Racetracks, Veterinarians, State Racing Commissions, or Jockeys.

Expanded Measurement Uncertainty means the multiplication of the coverage factor (q.v.) by the Measurement Uncertainty (q.v.).

External Quality Assessment Scheme ("EQAS") means a program for quality assessment of Laboratory performance, which includes the periodic distribution of urine, blood, hair, or other samples to Laboratories and probationary laboratories by the Agency, to be analyzed for the presence or absence of Prohibited Substances or their Metabolite(s), or Marker(s) of Use of Prohibited Substances or Prohibited Methods. EQAS samples may be open (i.e., educational; in such cases the content may be indicated), blind or double-blind (in such cases the content is unknown to the Laboratories).

Fault means any breach of duty or any lack of care appropriate to a particular situation. Factors to be taken into consideration in assessing a Covered Person's degree of Fault include (but are not limited to) the Covered Person's experience and special considerations such as impairment, the degree of risk that should have been perceived by the Covered Person, and the level of care and investigation exercised by the Covered Person in relation to what should have been the perceived level of risk. With respect to supervision, factors to be taken into consideration are the degree to which the Covered Person conducted appropriate due diligence, educated, supervised, and monitored Covered Persons (including Veterinarians), employees, personnel, agents, and other Persons involved in any way with the care, treatment, training, or racing of his or her Covered Horses, and created and maintained systems to ensure compliance with the Protocol and related rules and procedures. In assessing the Covered Person's degree of Fault, the circumstances considered must be specific and relevant to explain the Covered Person's departure from the expected standard of behavior. Thus, for example, the fact that the Covered Person would lose the opportunity to earn large sums of money during a period of Ineligibility, or the fact that the Covered Person or Covered Horse only has a short time left in a career, or the timing of the horseracing calendar, would not be relevant factors to be considered in reducing the period of Ineligibility based on degree of Fault.

Fit(ness)-for-Purpose means suitable for the intended purpose and in conformity with the ISO/IEC 17025, ILAC-G7, the Laboratory Standards, and relevant Technical Document(s) and Technical Letter(s).

Further Analysis means additional analysis conducted by a Laboratory any laboratory on an A Sample or a B Sample after it has reported an analytical result has been reported by a Laboratory for that A Sample or that B Sample, save that it excludes (and, therefore, there is no limitation on a Laboratory's authority to conduct) repeat or confirmation analysis, and analysis with additional or different Analytical Methods. Such Further Analysis may include (without limitation) analysis for purposes of research, intelligence, monitoring, or evidence in support of a Use charge.

HISA Equine Analytical Laboratory (HEAL) accreditation means the Laboratory accreditation granted by the Agency that is obtained and maintained in accordance with the Laboratory Standards.

IAP member Member means an adjudicator who is a member of the Internal Adjudication Panel-

Immediate Family Member means a spouse, domestic partner, mother, father, aunt, uncle, sibling, or child.

Ineligibility means the Covered Horse or Covered Person is barred for a specified period of time from participating in specified activities, as further particularized in the provisions of the Protocol relating to Ineligibility.

Initial Testing Procedure ("ITP") means an Analytical Testing Procedure whose purpose is used to identify those Samples that may contain a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method, or an elevated quantity of a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method.

<u>Intact Male means a male horse with one or both testicles, whether descended or undescended</u> (i.e., an uncastrated colt, a stallion, or a ridgling).

Interested Party means the Authority, the Owner of the Covered Horse, the Trainer of the Covered Horse, and the relevant State Racing Commission (provided that such State Racing Commission has entered into an agreement incorporating required confidentiality provisions).

Intermediate Precision (sw) means variation in results observed when one or more factors, such as time, equipment, or operator, are varied within a Laboratory, and may also be referred to as inter-batch or inter-run precision.

Internal Adjudication Panel has the meaning given to it in the Rule 7000 Series. The Internal Adjudication Panel shall have the same meaning as the National Stewards Panel in any other rules approved by the Commission.

Jockey means a rider or driver of a Covered Horse in Covered Horseraces.

Laboratory means a <u>HEAL-accredited or RMTC-accredited</u> laboratory approved by the Agency, applying Test Methods and processes to provide evidentiary data for <u>or in relation to</u> the detection or identification of Prohibited Substances, Metabolites, Markers, or Prohibited Methods, and, if applicable, quantification of a Threshold Substance, in Samples of urine, blood, hair, and other biological matrices in the context of Doping Control or Medication Control activities.

Laboratory Director means a person appointed by a Laboratory to be responsible for overseeing the professional, organizational, educational, operational, and administrative responsibilities of the Laboratory's operations in accordance with the Laboratory Standards.

Laboratory Documentation Package ("LDP") means the physical or electronic material produced by a Laboratory upon reporting of an Adverse Analytical Finding or as requested by the Agency to support an analytical result such as an Adverse Analytical Finding or an Atypical Finding or to support a Use violation.

Laboratory Expert Group ("LabEG") means the group of laboratory experts responsible for providing advice, recommendations, and guidance to the Agency with respect to the overall management of Laboratory accreditation, disciplinary action, re-accreditation, approval processes, and monitoring activities.

Laboratory Guidelines ("LGs") means recommendations of Laboratory best practices that may be provided by the Agency to address specific Laboratory operations or to provide technical requirements and guidance on interpretation and reporting of results for the analysis of specific Prohibited Substance(s), Metabolites, or Markers, or Prohibited Method(s), or on the application of specific Laboratory procedures.

Laboratory Internal Chain of Custody means documentation maintained within the Laboratory to record the chronological traceability of custody and actions performed on the Sample and any Aliquot of the Sample taken for Analytical Testing. Laboratory Internal Chain of Custody is generally documented by a written or electronic record of the date, location, action taken, and the person performing an action with a Sample or Aliquot.

Laboratory Standards means the Rule 6000 Series (Equine Standards for Laboratories and Accreditation set forth in the Rule 6000 Series), as amended from time to time.

Laboratory Supervisory Personnel means personnel appointed by a Laboratory to serve as Laboratory supervisors.

Lead Veterinarian means any Veterinarian appointed pursuant to Rule 2134(c).

Limit of Detection ("LOD") means the analytical parameters parameter of assay technical performance. Lowest The LOD is the lowest concentration of an Analyte in a Sample that can be routinely detected, but not necessarily identified or quantified, under the stated Test Method conditions used.

Limit of Identification ("LOI") means the analytical parameter of technical performance for chromatographic-mass spectrometric Confirmation Procedures. The LOI is estimated during method validation to evaluate the rate of false negative results at a certain concentration level. The LOI of a Test Method, at 5% false negative rate, for an Analyte (for which a Reference Material is available) shall be less than the MRPL. Since the LOI is an estimation of the false negative rate, Laboratories may report findings below the estimated LOI as Adverse Analytical Findings or Atypical Findings, as applicable, when the Analyte is reliably identified in the Sample according to the criteria established in a Technical Document.

Limit of Quantification ("LOQ") means the analytical parameter of assay technical performance. Lowest The LOQ is the lowest concentration of an Analyte in a Sample that can be quantitatively determined with acceptable precision and accuracy (i.e., acceptable Measurement Uncertainty) under the stated Test Method conditions.

Management System refers to the Laboratory's quality system to deal with control of management system documents and records and with actions to address risk, test improvements, corrective actions, and ongoing management reviews.

Managing Owner has the meaning given to it in Rule 3020(c).

Marker means a compound, group of compounds, or biological variable(s) that indicates indicates indicates indicates the Use of a Prohibited Substance or Prohibited Method.

Measurement Uncertainty ("MU") means the parameter associated with a measurement result that characterizes the dispersion of quantity values attributed to the measure and provides confidence in the validity of the measured result.

Medication Control means all steps and processes from test distribution planning through to ultimate disposition of any adjudication and review process pursuant to the Protocol and the Act involving a Controlled Medication Rule Violation and to enforcement of Consequences, including all steps and processes in between, including Testing, investigations, whereabouts programinformation, Sample collection and handling, Laboratory analysis, Results
Management, hearings and reviews, and investigations and proceedings relating to Controlled Medication Rule Violations not arising from or related to Testing or relating to-violations of Rule 3329.

Metabolite means any substance produced from a Prohibited Substance by a biotransformation process.

Minimum Reporting Level means the estimated concentration of a Prohibited Substance or its Metabolite(s) or Marker(s) in a Sample below which Laboratories will not report that Sample as an Adverse Analytical Finding.

Minimum Required Performance Level ("MRPL") means minimum analytical criterion of Laboratory technical performance established by the Agency, including the minimum concentration at which a Laboratory is expected to consistently detect and confirm a Prohibited Substance, Metabolite of a Prohibited Substance, or Marker of a Prohibited Substance or Prohibited Method in the routine daily operation of the Laboratory.

Minor means a natural person who has not reached the age of 18 years.

National Stewards Panel means the Internal Adjudication Panel.

Negative Finding means a test result from a Laboratory that, in accordance with the Laboratory Standards and any relevant Technical Document(s) and Technical Letter(s), concludes that no Prohibited Substance(s) or its Metabolite(s) or Marker(s) or evidence of the Use of a Prohibited Method(s), included in the requested Analytical Testing menu, were found in a Sample based on the applied Initial Testing Procedure(s) or Confirmation Procedure(s).

No Fault or Negligence means the Covered Person establishing that he or she did not know or suspect, and could not reasonably have known or suspected, even with the exercise of utmost caution, that he or she had administered to the Covered Horse (or that the Covered Horse's system otherwise contained) a Banned Substance or a Controlled Medication Substance, or that he or she had Used on the Covered Horse a Banned Method or a Controlled Medication Method, or otherwise committed an Anti-Doping Rule Violation or Controlled Medication Rule Violation. For any violation of Rule 3212 or Rule 3312, the Covered Person must also establish how the Prohibited Substance entered the Covered Horse's system in order to establish No Fault or Negligence.

Nominated Person has the meaning given to it in Rule 3040(b)(2)(ii).

No Significant Fault or Negligence means the Covered Person establishing that his or her fault or negligence, when viewed in the totality of the circumstances and taking into account the criteria for No Fault or Negligence, was not significant in relationship relation to the Anti-Doping Rule Violation or Controlled Medication Rule Violation in question. For any violation of Rule 3212 or 3312, the Covered Person must also establish how the Prohibited Substance entered the Covered Horse's system in order to establish No Significant Fault or Negligence.

Nominated Person means a person nominated by a Responsible Person at the time of notification or through a whereabouts filing to assist, consent to, and witness Sample collection from a Covered Horse. If the Responsible Person is not present to nominate a person, or the designated Nominated Person is not present or willing to assist with Sample collection, anyone employed by the Responsible Person or Owner at the stable where the Covered Horse is located shall be the Nominated Person for that Sample collection. If no Nominated Person is promptly identified as described above, the person who has custody or control of the Covered Horse or granted the DCO, BCO, or Chaperone access to the Covered Horse shall be the Nominated Person for that Sample collection. In each case, the Nominated Person shall be 18 years or older.

Non-Threshold Substance means a Prohibited Substance for which the identification, in compliance with any applicable Technical Document(s), constitutes an Adverse Analytical Finding.

Out-of-Competition Sample has the meaning given to it in Rule 3133(a).

Out-of-Competition Testing has the meaning given to it in Rule 3133(a).

Owner means a person who holds an ownership interest in one or more Covered Horses.

Person means a natural person or an organization or other entity.

Possession means actual, physical possession, or constructive possession (which shall be found only if the Covered Person has exclusive control or intends to exercise exclusive control over the Prohibited Substance or Prohibited Method or the premises in which a Prohibited Substance or Prohibited Method exists). If the Covered Person does not have exclusive control over the Prohibited Substance or Prohibited Method or the premises in which a Prohibited Substance or Prohibited Method exists, constructive Possession shall only be found if the Covered Person knew about the presence of the Prohibited Substance or Prohibited Method and intended to exercise control over it. There shall be no Anti-Doping Rule Violation or Controlled Medication Rule violation Violation based solely on Possession if, prior to receiving notification of any kind of any violation that the Covered Person has committed an Anti-Doping Rule Violation or Controlled Medication Rule Violation, the Covered Person has taken concrete action demonstrating that the Covered Person never intended to have possession and has renounced possession by explicitly declaring it to the Agency. Notwithstanding anything to the contrary in this definition, the act of purchasing (including by any electronic or other means) a Banned Substance or Banned Method constitutes Possession by the Covered Person who makes the purchase, whether or not the Banned Substance or Banned Method purchased is ever delivered to the Covered Person.

Post-Race Sample means a Sample collected by or on behalf of the Agency from a Covered Horse where notification of such Sample collection takes place no more than 1 hour after the end of a Covered Horserace in which a Covered Horse participates or is entered, or the end of a Vets' List Workout in which a Covered Horse participates. All Banned Substances and all Controlled Medication Substances are prohibited from being present in a Post-Race Sample has the meaning given to it in Rule 3133(a).

Post-Race Testing has the meaning given to it in Rule 3133(a).

Post-Time means the <u>scheduled (and any rescheduled)</u> start time of a Covered Horserace in which a Covered Horse participates or is entered, or the start time of a Vets' List Workout in which a Covered Horse participates.

Post-Work Sample means a Sample collected by or on behalf of the Agency from a Covered Horse where notification of such Sample collection takes place no more than 1 hour after the end of a Timed and Reported Workout. All Banned Substances and any Controlled Medication Substances specifically identified on the Prohibited List as prohibited during Timed and Reported Workouts are prohibited from being present in a Post-Work Sample has the meaning given to it in Rule 3133(a).

Post-Work Testing has the meaning given to it in Rule 3133(a).

Post-Vets' List Work Sample has the meaning given to it in Rule 3133(c)(2).

Post-Vets' List Work Testing has the meaning given to it in Rule 3133(c)(2).

Presumptive Adverse Analytical Finding ("PAAF") means the status of a Sample test result from the Initial Testing Procedure which represents a suspicious finding, but for which a Confirmation Procedure to render a conclusive test result has not yet been performed.

Program means the anti-doping and medication control program established under section 3055(a) of the Act.

Program Effective Date means the date on which the Commission approves the proposed rule May 22, 2023.

Prohibited List means the list identifying Prohibited Substances and Prohibited Methods set forth in the Rule 4000 Series, as amended from time to time.

Prohibited Method(s) means any method(s) or class(es) of methods so described on the Prohibited List. The term 'Prohibited Method(s)' includes both Banned Substances and Controlled Medication Methods.

Prohibited Substance(s) means any substance(s) or class(es) of substances so described on the Prohibited List or the Technical Document-Prohibited Substances. The term 'Prohibited Substance(s)' includes both Banned Substances and Controlled Medication Methods.

Protocol means the Rule 3000 Series (Equine Anti-Doping and Controlled Medication Protocol), as amended from time to time.

Provisional Hearing means an expedited abbreviated hearing to resolve a challenge to a Provisional Suspension, occurring prior to the adjudication of the violation in issue.

Provisional Suspension means the Covered Horse or Covered Person is barred temporarily from participating in any Timed and Reported Workout-or, Covered Horserace, or other activity in accordance with Rules Rule 3229 or Rule 3329 (as applicable).

Public Disclosure means the dissemination or distribution of information by the Authority or the Agency to the general public.

Quality Manager means the staff member appointed by a Laboratory to perform that role in accordance with the Laboratory Standards.

Race Day means the period commencing at 12:01 a.m. on the day of a Vets' List Workout or Covered Horserace and ending (i) 1 hour after the end of such Vets' List Workout or Covered Horserace or (ii) at the end of any Sample Collection Session conducted at that Vets' List Workout or Covered Horserace when the Covered Horse is released from the Test Barn at the end of any Post-Race Sample Collection Session, whichever is later.

Race Organizer means any Person that arranges, organizes, and has administrative responsibility for a Covered Horserace.

Race Period means the period:

(a) commencing 48 hours prior to the Post-Time of either (i) any Vets' List Workout in which the Covered Horse participates or (ii) any Covered Horserace that the Covered Horse has been entered in, whether or not the Covered Horse actually starts; and

(b) ending:

- (i) <u>if the Covered Horse starts in the Covered Horserace</u>, (A) <u>when the Covered Horse is released from the Test Barn at the end of any Post-Race Sample Collection Session</u>, <u>if applicable</u>; <u>or (B)</u> 1 hour after the end of such Vets' List Workout or Covered Horserace or .
- (ii) atif the end of any Sample collection process conducted at that Vets' List Workout erCovered Horse is scratched from the Covered Horserace when the Covered Horse is released from the Test Barn, (A) when the Regulatory Veterinarian recommends the scratch; (B) when the Responsible Person (or his or her delegate) submits an official documented request to the stewards or race office to make the scratch; or (C) when the stewards or race office order(s) the scratch; whichever is laterearlier.

However, the Prohibited List may specify a Race Period that is shorter or longer in duration than the above period for certain Controlled Medication Substances or Controlled Medication Methods.

Racetrack means an organization licensed by a State Racing Commission to conduct Covered Horseraces.

Racetrack Safety Program means the program set forth in Rule 2000 Series, established pursuant to section 3056(a) of the Actas amended from time to time.

Reference Collection ("RC") means a collection of samples or isolates of known origin that may be used in the determination of the identity of an unknown substance. For example, a well-characterized sample obtained from a controlled administration or from in vitro studies in which the presence of the substance of interest has been established.

Reference Material ("RM") means a Reference Substance or Reference Standard reference substance or reference standard that is sufficiently characterized, homogeneous, and stable with respect to one or more specified properties and that has been established to be fit for its intended use in an Analytical Testing Procedure.

Regulatory Veterinarian means a Veterinarian who is employed, contracted, or appointed by a State Racing Commission, Racetrack, the Authority, or the Agency to monitor the health and welfare of Covered Horses, in addition to any other duties assigned to him or her by the Authority or the Agencypursuant to Rule 2134(b). Any reference to Regulatory Veterinarian in the Rule 1000, 3000, 4000, 5000, 6000 and 7000 Series shall include the Lead Veterinarian, where applicable.

Repeatability (sr) means variability of results obtained within a laboratory using the same method, over a short time, using a single operator, item of equipment, etc. It is also referred to as intra-batch/intra-run precision.

Reproducibility (sR) means variability of results obtained when different laboratories analyze Aliquots of the same Sample. Reproducibility is a property of the results obtained and represents a measurable agreement of analytical results between different laboratories.

Responsible Person has the meaning given to it in Rule 3030.

Restricted Administration Period means an interval specified in the Prohibited List or Technical Document-Prohibited Substances (other than the Race Period) during which Use or Administration of a Controlled Medication Substance or Controlled Medication Method on a Covered Horse is prohibited. To compute the duration of any Restricted Administration Period, the day of administration shall be considered day 1.

Results Management means the process encompassing the timeframe from provision of an EAD Notice or ECM Notice through the charge until the final resolution of the matter, including the end of any adjudication and review process pursuant to the Protocol and the Act.

Revocation means the permanent withdrawal of a Laboratory's Equine Analytical Laboratory accreditation by the Agency.

Risk Assessment means the assessment of risk of doping and controlled medication misuse or other horse welfare concerns conducted by the Agency and used to effectively conduct test distribution planning or Target Testing.

RMTC has the meaning given to it in Rule 6070(a).

Root Cause Analysis ("RCA") means an investigation to identify one or more fundamental causes of a nonconformity based on the collection of objective evidence from an assessment of the likely factors that led to the nonconformity. The removal of a root cause factor prevents the recurrence of the nonconformity; in contrast, removing a causal factor can improve the outcome, but it does not prevent the recurrence of the problem with certainty.

Sample means any biological material collected for the purposes of Doping Control or Medication Control, (including, without limitation, urine, blood, and hair) or for the purposes of research in support of Doping Control, Medication Control, or horse welfare including (without limitation) research to understand and reduce equine fatalities and injuries.

Sample Collection Equipment means A and Bthe bottles, kits, containers, collection vessels, tubes, or other apparatus used to collect, hold, or store a Sample at any time during or after a Sample Collection Session.

Sample Collection Personnel means all qualified officials authorized certified by the Agency to carry out or assist with duties during Doping Control or Medication Control Sample Collection Session, including, but not limited to, Test Barn Supervisors (for Post-Race Testing), Collection Officers, Blood Collection Officers, Doping Control Officers, and Chaperones and Collection Assistants. An individual may be authorized certified by the Agency to carry out one or more roles during Doping Control or Medication Control Sample Collection Session.

Sample Collection Session means all of the sequential activities that directly involve the collection of a Sample from a Covered Horse from the point that initial contact is made with the Responsible Person or Nominated Person until the Covered Horse provides a Sample and is discharged released from the Test Barn (for Post-Race Testing) or other Sample collection obligations location (for all other Sample collections) by the relevant Sample Collection Personnel.

Screening Limit means a concentration to be used by Laboratories when screening for certain Non-Threshold Substances during the Initial Testing Procedure, below which a Laboratory willshall not pursue the possible presence of a Prohibited Substance. When the concentration of an Analyte subject to a Screening Limit exceeds the Screening Limit as determined by the Initial Testing Procedure, qualitative confirmatory analysis by mass spectrometry Confirmation Procedure is required to confirm the presence or absence of the Prohibited Substance.

Quantification is not required. A Screening Limit is not a Limit of Detection, a Limit of Identification, or a Limit of Quantification.

Selectivity means the ability of the Analytical Testing Procedure to detect or identify (as applicable) the substance of interest in the Sample.

Specified Substance has the meaning given to it in Rule 3111(c).

Stacking Violation has the meaning given to it in Rule 3312(ec).

Stakes Race means any race so designated by the Racetrack at which such race is run, including, without limitation, the races <u>comprising</u> the Breeders' Cup World Championships comprises and the races designated as graded stakes by the American Graded Stakes Committee of the Thoroughbred Owners and Breeders Association.

Standard Operating Procedure means a document setting out prescribed methods or procedures to be followed when performing certain routine operations.

Standards means the Testing and Investigations Standards and the Laboratory Standards. Compliance with a Standard (as opposed to another alternative standard, practice, or procedure) shall be sufficient to conclude that the procedures addressed by the Standard were performed properly. Standards shall include any Technical Documents issued pursuant to the Standards.

State Racing Commission means an entity designated by State law or regulation that has jurisdiction over the conduct of horseracing within the applicable state.

Substantial Assistance means, for purposes of Rule 3226(a) and Rule 3326(a), a Covered Person providing the following assistance: (1) fully disclosing in a signed written statement or recorded interview all information the Covered Person possesses in relation to violations of the Protocol; and (2) fully cooperating with the investigation and adjudication of any case or matter related to that information, including, for example, by providing an affidavit and presenting testimony at a hearing if requested to do so by the Agency or adjudication body. Further, the information provided must be credible and must comprise an important part of any case or proceeding which is initiated or, if no case or proceeding is initiated, must have provided a sufficient basis on which a case or proceeding could have been brought.

Tamper Evident means to have one or more indicators or barriers to entry included with or incorporated into the Sample Collection Equipment, which, if breached, missing, or otherwise compromised, can provide visible evidence that Tampering or Attempted Tampering of Sample Collection Equipment has occurred.

Tampering means intentional conduct that subverts the Doping Control or Medication Control process, but that would not otherwise be included in the definition of Prohibited Methods. Tampering includes, without limitation, offering or accepting a bribe to perform or fail to perform an act, preventing the collection of a Sample, affecting or making impossible the analysis of a Sample, falsifying documents submitted to the Agency (or a committee or adjudication body), procuring false testimony from witnesses, committing any other fraudulent act upon the Agency (or committee or adjudication body) to affect Results Management or the imposition of Consequences, and any other similar interference or attempted interference with any aspect of Doping Control or Medication Control. However, this definition shall not include the actions of bona fide veterinary personnel involving a Controlled Medication Substance or Controlled Medication Method used for genuine and legal therapeutic purposes or other acceptable justification.

Target Testing means selection of specific Covered Horses for Sample collection based on criteria set forth in the Testing and Investigations Standards.

TCO2 Sample has the meaning given to it in Rule 3133(a).

TCO2 Testing has the meaning given to it in Rule 3133(a).

Technical Document ("TD") means a document adopted and published by the Authority from time to time containing requirements or guidance on specific anti-doping or medication control topics.

<u>Technical Document-Prohibited Substances means the Technical Document set out at Appendix 1 to the Rule 4000 Series.</u>

Technical Letter ("TL") means a document published by the Agency or Authority from time to time containing mandatory technical requirements provided by the Agency from time to time to address particular issues on the analysis, interpretation, and reporting of specific Prohibited Substance(s), Metabolites, Markers, or Prohibited Method(s), or on the application of specific Laboratory procedures.

Technical Note ("TN") means technical guidance provided by the Agency to Laboratories on the performance of specific Laboratory methods or procedures.

Test Barn means the location where Sample collection is conducted enfor Post-Race Day Testing.

Test Barn Supervisor means a Collection Officer or certified Blood Collection Officer appointed by the Agency to supervise Post-Race Testing at a Test Barn, including by managing all Agency-certified Sample Collection Personnel and other persons authorized by the Agency and all Sample collection activities, in accordance with the Testing and Investigation Standards and related Agency procedures. The Test Barn Supervisor is certified by the Agency to oversee and perform all parts of a Sample Collection Session except blood collection, unless he or she is also a BCO.

Test Barn Veterinarian means a Veterinarian who is employed, contracted, or appointed by a State Racing Commission, Racetrack, the Authority, or the Agency to monitor the health and welfare of Covered Horses subject to Sample collection in the Test Barn.

Testing means the parts of the Doping Control or Medication Control process involving Sample collection, Sample handling, and Sample transport to the Laboratory (or other laboratory approved by the Agency), for the purposes of Doping Control or Medication Control or for the purposes of research in support of Doping Control, Medication Control, or horse welfare including (without limitation) research to understand and reduce equine fatalities and injuries.

Testing and Investigations Standards means the <u>Rule 5000 Series</u> (Equine Testing and Investigations Standards set forth in the Rule 5000 Series), as amended from time to time.

Test Method has the same meaning as Analytical Testing Procedure.

Thoroughbred means a horse that is registered in The American Stud Book or in a foreign stud book approved by the Jockey Club or the International Stud Book Committee.

Threshold means the maximum permissible level of the concentration, ratio, or score for a Threshold Substance in a Sample. The Threshold is used to establish the Decision Limit for reporting an Adverse Analytical Finding or Atypical Finding for a Threshold Substance.

Thresholds may only be adopted for (i) substances endogenous to the horse or (ii) substances arising from plants traditionally grazed or harvested as equine feed.

Threshold Substance means a Prohibited Substance, or Metabolite or Marker of a Prohibited Substance, for which the identification and quantitative determination, including, for example, concentration, ratio, or score, in excess of a pre-determined Decision Limit, or, when applicable, the establishment of an exogenous origin, constitutes an Adverse Analytical Finding.

Timed and Reported Workout means an officially timed and published running of a Thoroughbred horse over a predetermined distance that is not a horseracerace, as reported by Equibase or any official supplier of racing information and statistics recognized by the Authority. Official timed workouts shall have the same meaning as Timed and Reported Workouts. Any official timed workout by a Thoroughbred horse in any other jurisdiction shall be deemed a Timed and Reported Workout upon the earliest to occur of the following: (i) the horse is brought to the United States for purposes of participating in any Covered Horserace; or (ii) the horse is nominated for a Covered Horserace.

Trafficking means a Covered Person selling, giving, transporting, sending, delivering, or distributing by any means a Banned Substance or Banned Method to any other Person, or Possessing a Banned Substance or Banned Method for any such purpose; provided, however, that Trafficking shall not include the actions of Veterinarians or other licensed medical personnel involving a Prohibited Substance used for genuine and legal therapeutic purposes or other acceptable justification.

Trainer means an individual engaged in the training of Covered Horses.

Training Facility means a location that is not a Racetrack licensed by a State Racing Commission that operates primarily to house Covered Horses and conduct Timed and Reported Workouts.

Transfer Sample has the meaning given to it in Rule 3133(c)(2).

Transfer Testing has the meaning given to it in Rule 3133(c)(2).

Use means the utilization, application, ingestion, injection, or consumption by any means whatsoever of any Prohibited Substance or Prohibited Method in relation to a Covered Horse.

Veterinarian means a licensed veterinarian who provides veterinary services to Covered Horses.

Veterinarians' List (or "Vets' List") has the meaning given to it in Rule 2000 Series (Racetrack Safety Program).

Vets' List Workout means an officially timed running of a Covered Horse over a predetermined distance that is not a Covered Horserace ace but is overseen by a Regulatory Veterinarian or Racetrack steward.

WADA Code Program has the meaning given to it in Rule 3060(d).

Whereabouts Failure means a failure by the Responsible Person to do any of the following: (i) provide notice to the Agency that his or her Covered Horse has been moved from a Racetrack or Training Facility to a private facility (i.e., a facility not under the jurisdiction of the Authority/Agency) before such move occurs; (ii) provide whereabouts information about his or her Covered Horse(s) upon request by the Agency; (iii) provide sufficient information about the Covered Horse's whereabouts to enable the Agency to Test the Covered Horse at any time; or

(iv) update any whereabouts information provided to the Agency if it changes. Whereabouts Failure has the meaning given to it in Rule 3510(b).

Withdrawal Time means the Detection Time for a Controlled Medication Substance plus an added safety margin, determined by a Veterinarian in consultation with the Responsible Person. The added safety margin should be determined using professional judgment and discretion taking account of individual differences between horses, such as size, metabolism, fitness, health, or recent illness or disease. The Withdrawal Time used for a Controlled Medication Substance should always be longer than its Detection Time.

Without Prejudice Agreement means a written agreement between the Agency and a Covered Person that allows the Covered Person to provide information to the Agency in a defined time-limited setting with the understanding that, if an agreement for Substantial Assistance or a case resolution agreement is not finalized, the information provided by either party may not be used by the other party in any Results Management proceeding under this Protocol. Such an agreement shall not preclude the parties from using any information or evidence gathered from any source.

Workout means a timed running of a horse over a predetermined distance not associated with a race or its first qualifying race, if such race is made subject to the Act by election under section 3054(I) of the Act of the horse's breed governing organization or the applicable State Racing Commission.