



Quality Division Use Only

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|------------------------|------------------|-------------------|------------|
| Quality Tracking #: | 2022-047 Amended | Classification: | Incident |
| Non-Conformance Level: | N/A | Section: | Toxicology |
| Date of Discovery: | 07/26/2022 | Date of Incident: | 07/26/2022 |

This report was amended on 05/11/2023 to include additional cases under Appendix B.

This report was amended for the second time on 08/16/2023 to correct typographical errors in Appendix A. The FCN listed as '2021-20147' has been corrected to '2021-20148' and the FCN listed as '2021-29704' had been corrected to '2021-29705'.

This 08/16/2023 amended report will only be uploaded to the case records in JusticeTrax for FCN 2021-20148 and 2021-29705. All other cases listed in Appendices A and B will have the 05/11/2023 amended report uploaded to their respective JusticeTrax case records.

While researching the correct case numbers, HFSC identified additional 248 batches of cases involved in this nonconformance; however, because this nonconformance did not impact technical results, the additional batches identified will be documented in a memo. The memo will be available on HFSC's eDiscovery site.

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|---|---|
| Forensic Case Number(s), if applicable: | Agency Case Number(s), if applicable: |
| Refer to Appendices A and B for list of affected forensic case numbers. | Refer to Appendices A and B for list of affected agency case numbers. |

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| Description of Non-conformance: |
| There were several instances where the performance check of the Toxicology section pH meter did not meet all of the Toxicology section's required acceptance criteria but were deemed as "passed" by different analysts. |

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| Additional Information/Follow-Up: |
| The performance check for the pH meter is a twofold process that consists of a three-point slope pH check and that these pH readings are within an +0.022 range of the target pH depicted in the buffer solution bottles. The target pH is dependent on the room temperature; it is a pre-established value that is valid within a 10°C temperature range. On instances when the room temperature is between two 10°C temperature ranges, the analyst must average the two target pH values to determine the target pH to determine the acceptable +0.022 passing range. The pH meter is required to be performance checked prior to being used for the in-house preparation of buffers used in drug screening and confirmation analyses. |



On July 26, 2022, a toxicology technician completing a pH meter performance check for training purposes noted that the pH reading was not within the acceptable range for the pH 4 buffer solution. This prompted a review of previously completed performance checks in 2022 where it was discovered that there were four instances where the pH 4 buffer level had failed but had been marked as "passed". Because of this, the section decided to complete a more comprehensive review to include performance checks completed from 2016, when the pH meter was put in service, to present. This comprehensive review also found other instances where the pH 4, 7 and/or 10 buffer level had failed but had been marked as "passed". From reviewing the performance check forms, analysts were not actively looking at the pH values to their acceptable ± 0.022 passing range but were more focused on deeming the check as passed based on the acceptance criteria from the three-point slope. All measured pH values of the buffer solutions agreed to the whole numbers (pH 4, 7, and 10) but the failed checks showed the decimal place outside of the acceptable ± 0.022 range (e.g., pH measured at 4.09 when the acceptable range is 3.978-4.022 for the pH 4 buffer solution).

During the routine toxicology analysis workflow, samples are first analyzed by ELISA drug screening. Screening tests are used for the preliminary screening of blood and urine samples, positive results proceed to the confirmatory testing part of the analysis workflow. A buffer is a solution that is used to maintain the pH constant in a solution to provide the adequate pH environment that is needed when working with biological materials such as blood.

Buffers used in preparation of calibrators and controls of ELISA drug screening analyses can be from different lots from the buffers used for casework samples. Therefore, an additional 3-day verification study was completed to 1) verify the new set of ELISA calibrators and controls made with freshly prepared buffers and 2) compare the ELISA calibrators and controls against the existing calibrators and controls made with affected buffer solutions. Both sets of ELISA calibrators and controls showed comparable and acceptable verification results. There were two active solutions; 100 mM phosphate buffer at pH 6 (lot #: 220531-PB6A) and phosphate buffer saline (PBS) at pH 7.0 (lot #: 220615-PBS7). The pH values of the two solutions were retested. The pH of 220531-PB6A was the same as the original measurement (pH 5.98) and the pH of 220615-PBS7 was slightly different from the original measurement (pH 6.82 vs 6.99). However, this was expected because sodium chloride is added to this solution after measuring the pH value (Analytical Manual v3.8, section 12.3.5). Sodium chloride changes pH of the end product. Within this timeframe, the following external proficiency tests were satisfactorily completed: 21-5671-U2588A, 21-5661-U2588A, 21-5662-U2588A, FTC-A-2022, and DFC-A-2022. In addition, there was a total of 75 blind quality control cases submitted within this timeframe and they all screened positive for the appropriate drug group. Buffers used in drug GC and LC analyses are added not only to the casework samples but to all the calibrators and controls which are of a known concentration. The concentrations of the calibrators and controls must meet the acceptance criteria of being $\pm 20\%$ of the known target concentration to deem a batch satisfactory. In addition, the buffers, controls, and calibrators are verified prior to being used in casework.

Within this timeframe there was a total of 12 blind quality control cases that satisfactorily quantified and confirmed the appropriate analyte.

This incident is being tracked by the Quality Division because staff members were not following the performance review instructions as delineated in their SOP. Although the performance checks requirements were not fully met, because there are additional quality checks implemented in the analytical drug screening and confirmation



processes, and the verification study and retesting of pH values completed for the ELISA drug screening buffers, it was demonstrated that this incident did not have a technical impact on the results reported for the cases involved.

The buffers involved in this incident are summarized in the table below:

| Drug confirmatory solutions | ELISA screening solutions |
|-------------------------------------|---------------------------------------|
| 100 mM Phosphate buffer pH 6.0 | Phosphate Buffer Saline (PBS), pH 7.0 |
| 210625-PB6A | |
| 211102-PB6A | 201119-PBS7 |
| 220107-PB6A | 210104-PBS7 |
| 220317-PB6 | 210513-PBS7 |
| 220531-PB6A | 210528-PBS7A |
| 100 mM Sodium acetate buffer pH 4.5 | 210813-PBS7A |
| 210909-Na4.5 | 220112-PBS7 |
| 220202-Na4.5A | 220615-PBS7 |

Summary of Root Cause Analysis:

Note: Incidents are documented for tracking purposes and trend analysis. Root Cause Analysis is not required for incidents.

N/A

Actions Taken:

New buffer solutions for pH 4,7 and 10 were ordered after discovering this incident. On August 3, 2022, performance checks were performed using all new buffer solutions and these checks met all the acceptance criteria.

To clarify the acceptance criteria, the laboratory form for pH meter performance check (LAB-048) was revised on August 04, 2022. Acceptable ranges for pH 4, 7, and 10 buffer solutions are now listed in the footer of the form for the temperature used in the lab for the past 6 years (20°C) so these ranges are more easily referenced. The part on the pH meter performance check in Analytical Manual v3.8 (issued on 08/04/2022) was revised to use the target pH values closer to the measured temperature rather than taking the average to simplify the procedure.



Houston Forensic Science Center
Incident/Corrective Action Report
Quality Division

Section Manager: Dayong Lee

Date: 08/16/23

Division Director: Amy Castillo

Date: 08/16/23

Incidents or Corrective Actions that involve the Biology/DNA section are reviewed by the Technical Leader and CODIS Administrator.

Technical Leader: N/A

Date: _____

CODIS Administrator: N/A

Date: _____

Quality Director: Jackeline Moral

Date Closed: 08/16/23

Appendix A

| Forensic Case Number | Agency Case Number |
|----------------------|--------------------|
| 2010-06897 | 059136210 |
| 2013-27548 | 109748313 |
| 2019-13655 | 103138719 |
| 2020-06658 | 065209320 |
| 2020-07966 | 076792520 |
| 2020-09873 | 095495020 |
| 2020-10048 | 098396720 |
| 2020-10050 | 098347520 |
| 2020-10060 | 098002720 |
| 2020-10062 | 098387020 |
| 2020-10066 | 098026820 |
| 2020-10084 | 098339020 |
| 2020-10087 | 098357220 |
| 2020-10090 | 097948720 |
| 2020-10093 | 097916120 |
| 2020-10095 | 097970820 |
| 2020-10171 | 098468220 |
| 2020-10179 | 098560220 |
| 2020-10211 | 098917120 |
| 2020-10219 | 099349520 |
| 2020-10221 | 099321920 |
| 2020-10226 | 099295720 |
| 2020-10228 | 099325120 |
| 2020-10230 | 099296620 |
| 2020-10259 | 099398720 |
| 2020-10265 | 099409320 |
| 2020-10267 | 099418020 |
| 2020-10268 | 099378220 |
| 2020-10269 | 099691220 |
| 2020-10302 | 100263520 |
| 2020-10312 | 100320920 |
| 2020-10381 | 100844020 |
| 2020-10588 | 103133620 |
| 2020-10592 | 102778320 |
| 2020-10594 | 102978420 |
| 2020-10595 | 103042620 |
| 2020-10630 | 103511420 |
| 2020-10631 | 103562220 |

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| 2020-10779 | 104293420 |
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| 2020-10783 | 103850120 |
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| 2020-10787 | 104823720 |
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| 2020-10859 | 105023220 |
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| 2020-10896 | 105876320 |
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| 2020-10902 | 105736820 |
| 2020-10937 | 105826420 |
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| 2020-11076 | 107854020 |
| 2020-11089 | 107821520 |
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| 2020-11095 | 107446920 |
| 2020-11097 | 108209920 |
| 2020-11106 | 107808620 |
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| 2020-11124 | 107877520 |
| 2020-11129 | 108279820 |
| 2020-11133 | 106972520 |
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| 2020-11204 | 108787420 |
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| 2020-11213 | 108402120 |
| 2020-11229 | 108516620 |
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| 2020-11279 | 109398120 |
| 2020-11326 | 109963120 |
| 2020-11329 | 110241020 |
| 2020-11333 | 110364720 |
| 2020-11336 | 110324120 |
| 2020-11338 | 110300820 |
| 2020-11362 | 111168320 |
| 2020-11364 | 111355120 |
| 2020-11370 | 111635120 |
| 2020-11372 | 111719020 |

Appendix A

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| 2020-11873 | 115776120 |
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| 2020-11932 | 116521920 |
| 2020-12086 | 117960020 |
| 2020-12089 | 118028020 |
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Appendix A

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Appendix B

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