



**Quality Division Use Only**

Quality Tracking #:	2022-047 Amended	Classification:	Incident
Non-Conformance Level:	N/A	Section:	Toxicology
Date of Discovery:	07/26/22	Date of Incident:	07/26/22

This report was amended on 05/11/23 to add additional cases under Appendix B.

<b>Forensic Case Number(s), if applicable:</b>	<b>Agency Case Number(s), if applicable:</b>
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.

**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.

**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 +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.

Section Manager: Dayong Lee

Date: 01/04/23

Division Director: Amy Castillo

Date: 01/09/23

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: 05/11/23

# 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
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2020-10179	098560220
2020-10211	098917120
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2020-10221	099321920
2020-10226	099295720
2020-10228	099325120
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2020-10259	099398720
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2020-10267	099418020
2020-10268	099378220
2020-10269	099691220
2020-10302	100263520
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2020-10381	100844020
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2020-10592	102778320
2020-10594	102978420
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2020-10630	103511420
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2020-10634	103348320
2020-10640	103292720
2020-10641	103574020
2020-10642	103423820
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2020-10744	103840520
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2020-10773	104076120
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2020-10779	104293420
2020-10780	104332920
2020-10783	103850120
2020-10786	104485920
2020-10787	104823720
2020-10836	104499820
2020-10842	105467020
2020-10843	105416520
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2020-10854	105249020
2020-10856	105302720
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2020-10896	105876320
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2020-11129	108279820
2020-11133	106972520
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2022-03480	035381622
2022-03484	035931722
2022-03493	035387222
2022-03497	035786122
2022-03537	035957222
2022-03541	035058622
2022-03564	036336022
2022-03569	037067922
2022-03575	036402022
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2022-03627	036698622
2022-03632	022032322
2022-03638	037766122
2022-03677	038222422
2022-03729	037814522
2022-03730	037984022
2022-03771	039445322
2022-03783	038864722
2022-03793	036932122
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2022-03799	038472522

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2022-03809	039901522
2022-03811	040233522
2022-03816	040087522
2022-03818	039141322
2022-03819	037456922
2022-03828	039094722
2022-03831	037617622
2022-03839	038692722
2022-03845	039414822
2022-03881	039542222
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2022-04072	041312222
2022-04078	043632422
2022-04080	040885322
2022-04087	043851922
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2022-04402	045469722
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2022-04412	047064422
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2022-04629	048534722
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2022-04747	049987922
2022-04749	050086022
2022-04752	050658122
2022-04755	050254122
2022-04756	048281322
2022-04759	049049322
2022-04763	050527222
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2022-04785	049310522
2022-04786	049840422
2022-04789	050467622
2022-04790	050050522

2022-04795	049559622
2022-04801	050205922
2022-04804	049813822
2022-04806	049706522
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2022-04826	050239722
2022-04828	049868622
2022-04861	049583122
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2022-04868	050979322
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2022-04872	051164722
2022-04897	051860322
2022-04945	052466722
2022-04946	052931122
2022-04950	051991022
2022-05001	053608922
2022-05008	054001122
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2022-05037	051411722
2022-05042	054345422
2022-05055	054412922
2022-05081	053765722
2022-05084	053297222
2022-05090	054465422
2022-05093	053129722
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2022-05110	053425022
2022-05115	050794022
2022-05135	053507022
2022-05140	054919522
2022-05143	054924622
2022-05185	054396622
2022-05289	057047922
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2022-05338	055365322
2022-05355	057380522
2022-05371	056867222
2022-05495	057644222
2022-05500	058900222
2022-05502	058237922
2022-05503	056979722
2022-05505	056838722
2022-06304	067589422
2022-06593	071267822
2022-06596	070441122
2022-06694	072059622
2022-06814	071797822
2022-06816	073355322
2022-06818	073144422
2022-06900	072048322
2022-06901	073291422
2022-06952	074651822
2022-07041	075957622
2022-07042	075608622
2022-07043	076134922
2022-07045	075285922

## Appendix B

Forensic Case Number	Agency Case Number
2022-07050	076070322
2022-07057	076482622
2022-07059	076099322
2022-07195	078069122
2022-07282	079618922
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2022-07324	079369122
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2022-07402	080584322
2022-07404	080633922
2022-07079	076714722
2022-07203	077995922
2022-07208	078167822
2022-07316	079425622
2022-07469	081771422
2022-07474	081586322
2022-07481	081138922
2022-07483	081478622
2022-07485	081504322
2022-07488	080805722
2022-07494	081685922
2022-07495	081324022
2022-07554	082463822
2022-07592	082318422
2022-07596	082184322
2022-07598	082720922
2022-07603	082260222
2022-07605	083341222
2022-07702	083914122