

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0663536	(X3) Date Survey Completed 11/20/2025
Name of Provider or Supplier Louisiana Office Of Public Health Laboratory	Street Address, City, State 1209 Leesville Ave, Baton Rouge, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey conducted November 18, 2025 through November 20, 2025. The laboratory was found in compliance with standard-level deficiencies cited.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, final test reports, and interview with the TS of Newborn Screening (NBS), the laboratory failed to follow its own policy for the turnaround time (TAT) of UNSAT (Unsatisfactory) specimens for 32 of 661 UNSAT specimens from January 1, 2025 to March 31, 2025 (random review). Findings Included: 1) Review of the laboratory's policy #4679 titled 'Louisiana Department of Health Office of Public Health Laboratory NBS Dried Blood Spot Specimen Sorting Protocol' revealed the following on page 4 of 5: "Unsatisfactory Sample Protocol I. Any submitter sending unsatisfactory samples to the lab will receive a fax and/or phone call from a NBS staff member on the day the sample is accessioned in the laboratory. -Facilities that have opted out of phone notifications: fax sent with unsatisfactory reason -Non-courier facilities: phone call with unsatisfactory information and fax if the fax number is available. -All other submitters: fax sent with unsatisfactory reason and phone call to confirm the fax was received. II. The NBS staff will record in the Add Notebook section in Neometrics - MSDS the date and time the submitting facility was contacted, to whom they spoke and the nature of the phone call. III. If the NBS staff is unable to speak with someone from the submitting facility on the day of the initial phone call then, they will make a follow-up call on the next business day. IV. If after a second call, the NBS staff is unable to speak with</p>

someone regarding the sample, a notation will be made in the Add Notebook section in Neometrics - MSDS and dated. In these instances, the NBS staff will notify the OPH Lab Medical Director with the sample information. V. The final lab report stating the sample was unsatisfactory will be released within 3 business days." 2. A random sample review of UNSAT final lab reports from January 1, 2025 to March 31, 2025 revealed 32 out of 661 UNSAT specimens failed to meet the laboratory's policy requirement of a three day TAT to the provider. 3. In an interview on November 20, 2025 at 10:54 AM in the NBS meeting room, the TS of NBS confirmed the findings of UNSAT lab reports sent beyond the laboratory's policy of a three business day TAT. Word Key: OPH - Office of Public Health (LA) TS - Technical Supervisor NBS - Newborn Screening MSDS - Material Safety Data Sheet TAT - Turnaround Time UNSAT - Unsatisfactory

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

I. Based on direct observation during a laboratory tour, review of room temperature records, review of the manufacturer's instructions for use (IFU), and an interview with the General Supervisor (GS) for specimen accessioning, the laboratory failed to define the proper storage temperature requirements for Aptima specimen collection kits and urine transport tubes consistent with the manufacturer's recommendation for 17 of 17 months. 1. During a tour of the laboratory's specimen accessioning storage room, A-195, on 11/20/2025 at approximately 11:00 AM, the following collection kits and transport tubes were observed stored on open shelves: a. Aptima Multitest Swab Specimen Collection Kit Lot # 922105, Expiration Date: 12/31/2026 Quantity: 62 boxes (50 collection tubes per box) Temperature requirement printed on the kit: 15-30C. b. Aptima Urine Specimen Transport Tube Lot #925911, Expiration Date: 07/31/2027 Quantity: 54 boxes (50 transport tubes per box) Temperature requirement printed on the kit: 15-30C 2. A review of the room temperature log sheets for room A-195 revealed the acceptable room temperature range was set at 10-35C from 07/2025 to 11/2025 (17 months). 3. A review of the IFU's for the Aptima collections kits revealed the following storage requirements: a. Aptima Multitest Swab Specimen Collection Kit Store collection kit at room temperature (15C to 30C) b. Aptima Urine Specimen Transport Tube Store urine specimen transport tubes at room temperature (15C to 30C) 4. During an interview on 11/20/2025 at approximately 11:05 AM, the General Supervisor for Specimen Accessioning confirmed the identified Aptima specimen collection kits and transport tubes were stored in room A-195 where the temperature log sheets from 07/2024 to 11/2025 had an acceptable room temperature range between 10-35C. 47107 II. Based on direct observation, review of the laboratory's policy, temperature records, test volumes, and interview with the Technical Supervisor (TS) of the Newborn Screening Section (NBS), the laboratory failed to monitor and document temperatures for 2 of 2 Inheco Shaker/Incubators

during testing of T-cell receptor excision circles (TREC) for the screening of Severe Combined Immunodeficiency (SCID). Findings Included: 1) During a tour of the laboratory on November 18, 2025 at 9:15 AM, two Inheco Shaker/Incubators (Serial Numbers #5143 & #5638) were observed in use within Room A107 of the NBS SCIDS testing area. 2) Review of the laboratory's policy #7724 titled 'Louisiana Department of Health Office of Public Health Laboratory TREC and SMN1 Testing Using NeoMDx and QuantStudio Dx' revealed the following on page 5 of 17: "15. Remove the plate from the Integra. Incubate and shake the plate for 8 minutes on the Inheco shaker at 25 degrees C (+/- 2 degrees C) and 700 rpm (+/- 100 rpm)... 18. Place the plate on the Inheco shaker and change the temperature setting to +70 degrees Celsius. 19. Once the shaker temperature reaches +70 degrees Celsius (+/- 2 degrees C), remove the plate and place on the Integra Pipettor. 20. Return plate to the +70 (+/- 2 degrees C) Inheco shaker and shake for 30 minutes at 700 rpm (+/- 100 rpm). 21. Stop the shaker and change the temperature settings to 25 degrees Celsius. Let the plate cool down to at least +35 degrees Celsius on the shaker..." 3) Review of the laboratory's temperature records revealed no documentation or monitoring of temperatures for the Inheco shaker/incubators. 4) Review of the laboratory's test volumes revealed an annual test volume of 46,375 for TREC. 5) In an interview on November 20, 2025 at 9:34 AM, in the NBS meeting room, the TS of NBS confirmed the findings the laboratory did not have a mechanism to document and monitor temperatures of the two Inheco shaker/incubators.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on direct observation during a laboratory tour, review of the manufacturer's instructions for use (IFU), review of the 2019 verification of performance for the Gold Standard Diagnostics(GSD) AIX1000 Rapid Plasma Reagin (RPR), an interview with the Sexually Transmitted Infections (STI) Testing Personnel (TP) and Technical Supervisor (TS), the laboratory failed to verify performance specification of the GSD AIX1000 RPR automated test system when utilizing the retry sample option for insufficient sample volume for one of one AIX1000 automated test system. 1. During a tour of the laboratory's RPR room, B105.02, on 11/20/2025 at approximately 1:30 PM, the following instrument was observed, used for Automated RPR testing. Gold Standard Diagnostics (GSD) AIX1000 Rapid Plasma Reagin Automated Test System Serial Number: 181267-119AG 2. A review of the GSD AIX1000 RPR automated test system IFU revealed a warning for the "retry sample" option available for insufficient sample volume. Although the option was available in the AIX1000 software, the feature had not been evaluated by the manufacturer. 3. In an interview on 11/20/2025 at approximately 1:35 PM, the STI TP was asked to describe the process in resolving

an insufficient sample volume when using the GSD AIX1000 RPR automated test system. The STI TP stated in cases when insufficient sample volume is suspected, the system will give an error message on the instrument screen with an option to retry sample. The option to retry is selected and that resolves the error message and the testing proceeds. If the same error message occurs on the retry, the sample is not test and is reflected in the final test report as not tested due to insufficient sample volume. 4. A review of the 2019 verification of performance specification for the GSD AIX1000 RPR automated test system revealed verification of performance specific to the use of the retry sample due to insufficient sample volume was not completed. 5. In a telephone interview on 11/24/2025 at approximately 2:45 PM, the STI TS confirmed the verification of performance specification completed in 2019 for the GSD AIX1000 RPR automated test system did not include the verification of performance specific to the use of the retry sample option for insufficient sample volumes. 6. Annual test volume for Syphilis = 13,791

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on direct observation, review of quality control (QC) records, laboratory policy, test records, and confirmed in an interview with the Technical Supervisor (TS) of Newborn Screening (NBS), the laboratory failed to take corrective action(s) necessary to ensure the evaluation of all patient test results obtained since the last acceptable test run after QC failures requiring recalibration, on the Revvity Genetic Screening Processors (GSP), for 457 of 40,988 patients tested for Immunoreactive trypsinogen (IRT), Congenital adrenal hyperplasia (CAH) and Thyroxine (T4), between July 15, 2025 and October 29, 2025 (random review). Findings Included: 1. During a tour of the laboratory on November 18, 2025 at 9:15 AM, two Revvity GSP analyzers (Serial Numbers #20210456, #20210449) were observed in the NBS section of the laboratory. 2. Review of the laboratory's QC records between July 15, 2025 and October 29, 2025 revealed the following failures with subsequent recalibration where evaluation of patient test results since the last acceptable test run was not performed: Immunoreactive Trypsinogen (IRT) a. 10/9/2025, Batch #5, Westgard Rule Failure 1 (3s) Total Plates on Run - 2, Plate that failed - Plate #2 Initial Run Instrument - S/N #20210456 Re-run Instrument - S/N #20210456 # Patients no patient evaluation - 81 Congenital adrenal hyperplasia (CAH) a. 7/30/2025, Batch #85, Westgard Rule Failure 1(3s) Total Plates on Run - 2, Plate that failed - #2 Initial Run Instrument - S/N #20210449 Re-run Instrument - S/N #20210456 # Patients no patient evaluation - 81 b. 7/31/2025, Batch #87, Westgard Rule Failure 1(3s) Total Plates on Run - 2, Plate that failed - #2 Initial Run Instrument - S/N #20210456 Re-run Instrument - S/N #20210449 # Patients no patient evaluation - 81 Thyroxine (T4) a. 6/06/2025, Batch #35, Westgard Rule Failure 1(3s) Total Plates on Run - 2, Plate that failed - #2 Initial Run Instrument - S/N #20210449 Re-run Instrument - S/N #20210449 # Patients no patient evaluation - 81 b. 7/28/2025, Batch #82, Westgard Rule Failure 1(3s) Total Plates on Run - 3, Plate that failed - #3 Initial Run Instrument - S/N #20210456 Re-

run Instrument - S/N #20210449 # Patients no patient evaluation - 81 c. 9/08/2025, Batch #23, Westgard Rule Failure 6(1s) Total Plates on Run - 2, Plate that failed - #2 Initial Run Instrument - S/N #20210449 Re-run Instrument - S/N #20210456 # Patient no patient evaluation - 52 3. Review of the laboratory's policy titled 'Louisiana Department of Health Office of Public Health Laboratory GSP SOP' stated on page 12 and 13 of 29: "Quality Control Calibration Curve - A new calibrator is opened daily. A calibration curve in duplicate is on the first assay plate of each batch daily. A calibration curve is valid for up to 24 hours, or until a new calibration curve is run... Assay Controls: -17 OHP, IRT & IRT - Run 3 levels of kit controls in singlicate on each plate... -Accept the assay run only if the controls meet the QC acceptance criteria. - If the Mult-rule is violated the software will reject the run. -All rejected assays due to QC violations or instrument failures are repeated..." 4. Review of laboratory test volume records revealed 13,737 IRT, 13,737 CAH, and 13,514 T4 patient tests run between July 15, 2025 and October 29, 2025. 5. In an interview on 11/20/2025 at 11:30 AM, the TS of NBS confirmed the laboratory's failure to perform patient evaluations to the last acceptable test run, when QC failures with subsequent recalibrations were performed on either the same or secondary instrument.