

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0661133	(X3) Date Survey Completed 12/01/2022
Name of Provider or Supplier Division Of Consolidated Laboratory Services	Street Address, City, State 600 North 5th Street, Richmond, VA	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on lack of supervisory competency assessment records, review of the Division of Consolidated Laboratory Services (DCLS) Competency standard operating procedure (SOP) and interview with the Quality Safety manager, the laboratory failed to establish a competency policy to evaluate personnel that held supervisory position listed on the Laboratory Personnel Report (Form 209) of technical supervisors (TS), general supervisors (GS) and clinical consultant. Findings Include: 1. The DCLS SOP did not state competency guidelines for personnel listed in on the Form 209 as CC, TS and GS. 2. Laboratory Personnel Report (CLIA) Form 209 lists 1 CC, 66 TS and 34 GS. 3. On the day of survey, November 29, 2022, the laboratory was unable to provide competency assessment records for the above personnel that held supervisory position listed on CMS Form 209. 4. The Quality Safety manager confirmed the findings above on November 29, 2022 around 12:00 pm.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.</p>

(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on lack of documentation, record review, and interview, the laboratory failed to include the preparation of calibration and quality control materials in the standard operating procedure for Second Tier Congenital Adrenal Hyperplasia Newborn Screening. Findings: 1. During an interview on 11/29/2022 at about 3:30 PM, TS#1 said that the laboratory used in-house prepared quality control and calibrator material for Second Tier Congenital Adrenal Hyperplasia Newborn Screening. When asked if the preparation steps were available in the standard operating procedure TS#1 said it was not. 2. During a review of the laboratory's standard operating procedure "Second Tier Congenital Adrenal Hyperplasia Newborn Screening," the SOP stated: "Three control levels (LOW, MED, HIGH) are run in duplicate with each assay. If a plate contains more than one assay, quality control specimens should be run with each assay." The SOP also states: "The method uses a full DBS calibration curve in duplicate for each assay. There are five calibration levels with the following concentrations (for all analytes): Calibrator Concentration (ng/mL serum): CAHCAL1 2 CAHCAL2 5 CAHCAL3 20 CAHCAL4 100 CAHCAL5 500 3. The laboratory's standard operating procedure "Second Tier Congenital Adrenal Hyperplasia Newborn Screening," was reviewed in full and did not contain documentation on how to prepare the three control levels or five calibrators used in testing.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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:

Based on lack of laboratory relative humidity records, review of the Illumina MiSeq system site prep guide and interview with technical supervisor (TS) # 49, the laboratory failed to monitor and document daily relative humidity percentage in the SBG laboratory where 4 of 4 Illumina MiSeq systems were located. Findings Include: 1. The Illumina MiSeq system site prep guide, environmental considerations, Humidity states, "Operating conditions: 30-75% relative humidity (non - condensing humidity)". 2. On the day of survey, December 1, 2022, TS# 49 could not provide

documentation for daily recording of relative humidity percentage in the SBG laboratory. 3. TS# 49 confirmed the SBG laboratory did not monitor the relative humidity percentage in the SBG laboratory around 10:30 am.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on review of the Illumina MiSeq and NextSeq 550 comparison studies and interview with Technical supervisor (TS) # 49, the laboratory failed to evaluate the relationship between four of four Illumina MiSeq systems and one of one Illumina NextSeq system used for SARS-Cov-2 Sequencing in 2021 and 2022. Findings Include: 1. On December 1, 2022, review of 4 of 4 Illumina MiSeq systems and 1 of 1 Illumina NextSeq system used for SARS-Cov-2 Sequencing in 2021 and 2022 revealed: - The December 2021 comparison study did not include a comparison of the Illumina NextSeq system against the four Illumina MiSeq systems used for SARS-Cov-2 Sequencing and didn't not evaluate the relations between all 5 systems using the same SARS-Cov-2 Sequencing assay. - The August 2022 comparison study did not evaluate the relations between the five Illumina systems used for the same SARS-Cov-2 Sequencing assay. 2. TS#49 confirmed the findings above on December 1, 2022 around 10:00 am.