

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2140476	(X3) Date Survey Completed 10/29/2024
Name of Provider or Supplier Cardiovascular Specialty Care Center Of Covington	Street Address, City, State 71070 Highway 21, Covington, 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 Validation survey was performed at Cardiovascular Specialty Care Center of Covington, CLIA ID 19D2140476, on October 29, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's quality control records, and interview with personnel, the laboratory failed to retain the i-STAT cartridge lot number in use for patients tested for two (2) years. Findings: 1. Observation by surveyor during the laboratory tour on October 29, 2024 at 9:48 a.m. revealed the laboratory utilized two (2) i-STAT 300 instrument for Activated Clotting Time (ACT) testing. 2. Further observation during the laboratory tour revealed the laboratory had one i-STAT in each room (Cath Lab A and Cath Lab B) where testing was performed. 3. In interview on October 29, 2024 at 1:50 p.m., Personnel 3 stated the cartridge lot number in use in one room could differ from the cartridge lot number in use in the other room. 4. Review of the laboratory's quality control (QC) records revealed the laboratory documented the lot numbers of cartridges for monthly and new lot QC, but did not document the in use date of cartridges. 5. In interview on October 29, 2024 at 1:54 p. m., Personnel 3 stated the laboratory did not document when a lot was put into use. She further stated the laboratory did not utilize a printer with the i-STAT analyzer. The Technical Consultant stated the cartridge lot number utilized with each patient was retained in i-STAT analyzer but was unable to retrieve the lot information.</p>

<p>D5209</p>	<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 review of the laboratory's policy and personnel records as well as interview with laboratory personnel, the laboratory failed to establish a written competency assessment policy for Technical Consultant. Findings: 1. Review of the laboratory's CMS-209 form revealed Personnel 2 served as Technical Consultant. 2. Review of the laboratory's policy "Performance Evaluations and Competency Assessments" revealed the laboratory did not include performance of competency assessment for Technical Consultant. 3. In interview on October 29, 2024 at 10:20 a.m., the Technical Consultant stated competency assessments for Technical Consultant were performed annually. 4. Review of personnel records for the Technical Consultant revealed a competency assessment was performed in 2022 and 2024 but not in 2023. 5. In interview on October 29, 2024 at 10:25 a.m., the Technical Consultant confirmed the laboratory's policy did not include competency assessment of the Technical Consultant.</p>
<p>D5431</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions and maintenance records, as well as interview with personnel, the laboratory failed to perform the thermal probe check every six (6) months as required by the manufacturer in 2023 and 2024 for four (4) of four (4) checks reviewed. Findings: 1. Observation by surveyor during the laboratory tour on October 29, 2024 at 9:48 a.m. revealed the laboratory utilized the i-STAT 300 instrument for Activated Clotting Time (ACT) testing. 2. Review of the manufacturer's instruction manual for the i-STAT 300 section "Quality Control" revealed "Ensure the thermal probe check is performed every 6 months on each handheld reader." 3. Review of the laboratory's maintenance records revealed the laboratory did not have documentation of performance of thermal checks in 2023 and 2024. 4. In interview on October 29, 2024 at 1:32 p.m., the Technical Consultant confirmed the laboratory did not perform thermal probe checks as identified above.</p>
<p>D5479</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:
 Based on observation, review of manufacturer's instructions and laboratory quality control logs, and interview with personnel, the laboratory failed to ensure the temperature of ISTAT cartridge shipments was satisfactory as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on October 29, 2024 at 9:48 a.m. revealed the laboratory utilized the i-STAT Kaolin Activated Clotting Time (ACT) cartridge for ACT testing on the i-STAT 300 instrument. 2. Review of the i-STAT 300 user manual section "Quality Control" revealed "Check Temperature Strip for a New Shipment of Cartridges" and "Verify that the transit temperatures were satisfactory by reading the temperature strip included in each shipping container." 3. Review of the laboratory's quality control logs revealed the laboratory did not document temperature strip checks for shipments of cartridges. 4. In interview on October 29, 2024 at 1:40 p.m., Personnel 3 stated that the temperature strips were checked for acceptability but not documented.

D5781

CORRECTIVE ACTIONS
 CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
 I. Based on review of the laboratory's policy and temperature logs as well as interview with personnel, the laboratory failed to perform corrective actions when the room temperature was not maintained between 20 - 24 degrees Celsius as required by the laboratory for twenty-nine (29) of two hundred twenty (220) days reviewed. Findings: 1. Review of the laboratory's policy "Environmental Monitoring" section "Temperature" revealed "Any unacceptable temperature will have a notation and the corrective action taken noted on the Corrective Action form ...When laboratory personnel are not present, the temperatures of the reagent and specimen refrigerators are recorded using a Hi-Low Thermometer. This device automatically records the highest and lowest temperatures of the refrigerators during the time frame. If temperatures are unacceptable an investigation and corrective action must be documented." 2. Review of the laboratory's "R/Humidity Temperature Log" and "CVSCC Daily Room Checklist" logs revealed the acceptable room temperature range defined by the laboratory was 20 - 24 degrees Celsius. 3. Further review of the laboratory's temperature logs revealed the temperature was documented as outside of the acceptable limits but no corrective action was performed on the following dates: a) "Cath Lab: B CVSCC Daily Room Checklist" 1/2/2024: 25.0 degrees Celsius 3/1/2024: 25.2 degrees Celsius 3/20/2024: 24.3 degrees Celsius b) "Cath Lab: B R /Humidity Temperature Log" 5/4/2024: Maximum Temp documented as 26.4 degrees Celsius 5/16/2024: Maximum Temp documented as 24.3 degrees Celsius 5/17/2024: Maximum Temp documented as 25.2 degrees Celsius 5/20/2024: Maximum Temp

documented as 25.2 degrees Celsius 5/21/2024: Maximum Temp documented as 25.2 degrees Celsius 5/22/2024: Maximum Temp documented as 25.2 degrees Celsius 5/28/2024: Maximum Temp documented as 25.5 degrees Celsius 6/3/2024: Maximum Temp documented as 25.2 degrees Celsius 6/5/2024: Maximum Temp documented as 24.5 degrees Celsius 6/6/2024: Maximum Temp documented as 24.2 degrees Celsius 7/8/2023: Maximum Temp documented as 26.3 degrees Celsius; Current Temp documented as 26.1 degrees Celsius 7/10/2024: Maximum Temp documented as 26.4 degrees Celsius 7/16/2024: Maximum Temp documented as 26.1 degrees Celsius 7/17/2024: Maximum Temp documented as 24.1 degrees Celsius 7/23/2024: Maximum Temp documented as 24.1 degrees Celsius 7/24/2024: Maximum Temp documented as 24.4 degrees Celsius 7/27/2024: Maximum Temp documented as 24.6 degrees Celsius 7/31/2024: Maximum Temp documented as 24.6 degrees Celsius 8/1/2024: Maximum Temp documented as 24.1 degrees Celsius 8/26/2024: Maximum Temp documented as 24.3 degrees Celsius 9/12/2024: Maximum Temp documented as 25.1 degrees Celsius 9/14/2024: Maximum Temp documented as 26.1 degrees Celsius 9/15/2024: Maximum Temp documented as 26.1 degrees Celsius 9/16/2024: Maximum Temp documented as 26.1 degrees Celsius 9/17/2024: Maximum Temp documented as 26.1 degrees Celsius 9/18/2024: Maximum Temp documented as 25.2 degrees Celsius 4. In interview on October 29, 2024 at 12:25 p.m., Personnel 3 confirmed no corrective action was performed when temperatures were outside of acceptable limits as identified above. II. Based on review of the laboratory's policies and temperature logs as well as interview with personnel, the laboratory failed to perform corrective actions when the humidity was not maintained between 30 - 60% as required by the laboratory for seven (7) of ninety-three (93) days reviewed. Findings: 1. Review of the laboratory's policy "Environmental Monitoring" section "Humidity" revealed "1. If the humidity is out of range high, notify the manager, who will check the system. 2. If the humidity reading is still out of range high, it may be necessary to reduce the room temperature to condense additional moisture out of the air. 3. If these corrective actions do not resolve the issue, the manager will contact the heating and air condition company. 4. Any malfunction with the barometers must be addressed with the manufacturers." 2. Review of the laboratory's "CVSCC Daily Room Checklist" log revealed the acceptable humidity range defined by the laboratory was 30 - 60%. 3. Further review of the laboratory's temperature logs revealed the humidity was documented as outside of the acceptable limits but no corrective action was performed on the following dates: a) "Cath Lab: B CVSCC Daily Room Checklist" 1/2/2024: 27% 1/3/2024: 25% 1/4/2024: 28% 1/17/2024: 27% 1/18/2024: 27% 1/19/2024: 26% 1/22/2024: 27% 4. In interview on October 29, 2024 at 12:25 p.m., Personnel 3 confirmed no corrective action was performed when humidity was outside of acceptable limits as identified above.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

	<p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall direction and management to the laboratory. Refer to D3031.</p>
<p>D6014</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to perform the thermal probe check every six (6) months as required by the manufacturer in 2023 and 2024 for four (4) of four (4) checks reviewed Refer to D5431. 2. The laboratory failed to ensure the temperature of ISTAT cartridge shipments was satisfactory as required by the manufacturer. Refer to D5479.</p>
<p>D6024</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective action by the laboratory was taken when the temperature and/or humidity was not maintained within the laboratory's acceptable range. Findings: 1. The laboratory failed to perform corrective actions when the room temperature was not maintained between 20 - 24 degrees Celsius as required by the laboratory for twenty-nine (29) of two hundred twenty (220) days reviewed. Refer to D5781 I. 2. The laboratory failed to perform corrective actions when the humidity was not maintained between 30 - 60% as required by the laboratory for seven (7) of ninety-three (93) days reviewed. Refer to 5781 II.</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure procedures for assessing personnel competency were established and maintained. Findings: 1. The laboratory failed to establish a written competency assessment policy for Technical Consultant. Refer to D5209. 2. The Technical Consultant failed to ensure competency assessment for testing personnel performing Activated Clotting Time (ACT) testing on the i-STAT 300 instrument included review of quality control records one (1) of ten (10) testing personnel. Refer to D6049.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on observation by surveyor, review of manufacturers' storage requirements, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to perform the thermal probe check every six (6) months as required by the manufacturer in 2023 and 2024 for four (4) of four (4) checks reviewed Refer to D5431. 2. The laboratory failed to ensure the temperature of ISTAT cartridge shipments was satisfactory as required by the manufacturer. Refer to D5479.

D6044

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(6)

(b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Findings: 1. The laboratory failed to perform corrective actions when the room temperature was not maintained between 20 - 24 degrees Celsius as required by the laboratory for twenty-nine (29) of two hundred twenty (220) days reviewed. Refer to D5781 I. 2. The laboratory failed to perform corrective actions when the humidity was not maintained between 30 - 60% as required by the laboratory for seven (7) of ninety-three (93) days reviewed. Refer to 5781 II.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel records and interview with personnel, the Technical Consultant failed to ensure competency assessment for testing personnel performing Activated Clotting Time (ACT) testing on the i-STAT 300 instrument included review of quality control records one (1) of ten (10) testing personnel.

Findings: 1. Review of personnel competency assessment records for 2023 and 2024 revealed the laboratory did not include documentation of review of quality control records for the 6 month assessment of Personnel 11. 2. In interview on October 29, 2024 at 11:14 a.m., Personnel 2 confirmed the laboratory did not have the documentation as identified above.