

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2150121	(X3) Date Survey Completed 06/21/2023
Name of Provider or Supplier Resourceful Clinical Laboratory	Street Address, City, State 8604 Cliff Cameron Drive Suite 116, Charlotte, NC	
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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based upon review of the laboratory's policies and procedures, review of 2023 temperature logs, and interview with the GS (general supervisor) on 6/21/2023, the laboratory failed to perform and document corrective actions when incubator temperatures exceeded the acceptable temperature range for 36 days during 4 of 4 months reviewed (March, April, May, June 2023). Findings: The laboratory's policy "Sample Preparation and Procedure Notes a). Sample Preparation 7)" states "Place plates or vials into incubator 30-40 minutes at approximately 50-55 degrees Celsius..." A review of the laboratory's incubator temperature log revealed the incubator temperature exceeded the acceptable range on the following dates with no corrective action documented: 1. March 2023 - 20, 21, 22, 27, 28; 2. April 2023 - 4, 12, 14, 17, 24, 26; 3. May 2023 - 8, 9, 11, 15, 17, 22, 23, 24, 25, 26, 29; 4. June 2023 - 1, 5, 6, 7, 8, 9, 12, 13, 14, 15, 16, 19, 20, 21. During an interview at approximately 11:55 a.m., the GS stated that an incorrect temperature range was printed on the log used to document incubator temperatures.</p>
D5805	TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based upon review of a random patient test report (Accession #1423F15009) and interview with the TS (technical supervisor) 6/21/23, the laboratory's patient test reports failed to include the lower limit of quantitation for LCMS (liquid chromatography mass spectrometry) toxicology analytes. Findings: Review of a random patient test report (Accession #1423F15009) revealed that LCMS toxicology analytes are reported as "not detected" when they fall below the laboratory's limits of quantitation; however, the laboratory does not disclose its lower limit of quantitation for each analyte on the patient test report. During a telephone interview with the TS at 1:10 p.m., the TS stated she was unaware the lower limit of quantitation for each LCMS analyte was not listed on patient test reports.

D6177

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(b)(3)

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based upon review of the laboratory's procedure manual and interview with the GS (general supervisor) on 6/21/2023, testing personnel failed to follow the steps outlined in the laboratory's procedure manual to prepare the LCMS (liquid chromatography mass spectrometry) quality control materials. Findings: A review of the laboratory's procedure manual revealed that calibration materials and quality control materials are required to be prepared from two different standard stock solutions. Procedure 4.3.2 "Preparation of Quality Control (QC) Materials" states "Quality Control Standard Stock mixes (standard H) are prepared in LCMS grade methanol according to Quality Control Standard Spike tables below ..." The tables displayed a preparation guide for quality control material and a separate guide for calibration material. During a tour of the laboratory at 9:20 a.m. on 6/21/23, the surveyor inquired how calibration and quality control materials are prepared. The GS stated that calibration and quality control materials are prepared from the same standard stock solution.