

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2227886	(X3) Date Survey Completed 11/30/2022
Name of Provider or Supplier Chattanooga Men's Clinic	Street Address, City, State 1206 Pointe Center Dr, Chattanooga, TN	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory environmental logs, and interview with the laboratory lead testing person, determined the laboratory failed to document refrigerator temperature for the Endocrinology analyzer Quality Control (QC) and reagents for 15 of 15 months (08/2021 through 11/2022). The findings include: 1. During a tour of the laboratory on 11.30.2022 at 10:15 A.M., the surveyor observed the "LG" refrigerator and the "Hisense" refrigerator in the laboratory. There was no thermometer in the "Hisense" refrigerator that contained Endocrinology analyzer Quality Control (QC) and reagents. 2. Review of laboratory environmental logs revealed laboratory failed to document refrigerator temperature for the "Hisense" refrigerator for 15 of 15 months (08/2021 through 11/2022). 3. Interview with testing person #1 listed on the Centers for Medicare and Medicaid Services Form 209 (CMS 209) at 10:45 am on 11.30.2022 in the laboratory confirmed the above findings.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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</p>

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory's operations manager, the laboratory director failed to ensure proficiency testing results were available and/or reviewed for 3 of 3 proficiency testing performance evaluation reports in 2022. The findings include: 1. Review of the laboratory's API Chemistry proficiency testing performance evaluation reports for 2022 event one, two and three revealed the reports had not been reviewed by the laboratory director. 2. Interview with the laboratory's operations manager on 11.30.2022 at 11:00 AM confirmed the above findings.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of employee personnel records for 2022 and interview with testing person #1 listed on the Centers for Medicare and Medicaid Services Form 209 (CMS 209), the laboratory's technical consultant failed to document the six required criteria for assessing personnel competency for testing person #1 (TP#1) on the CMS 209 in 2022. The findings include: 1) Review of employee personnel records for 2022 for the laboratory TP#1 failed to include documentation of the six required criteria of competency that include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, assessment of problem solving skills. 2) An interview with TP#1 listed on the CMS 209 on 11.30.2022 at 10:45 A.M. confirmed the above findings.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must 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 review of competency assessment for the technical consultant and interview with the laboratory Operations manager, determined the Laboratory Director failed to evaluate the technical consultant listed on the CMS Form 209 in 2021 and 2022. The findings include: 1. Review of 2021 and 2022 competency assessments revealed no documentation of competency assessment for technical consultant for 2021 and 2022. 2. Interview with the laboratory Operations manager on November 30, 2022 at 11:00 A.M. confirmed the above findings.