

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2065567	(X3) Date Survey Completed 11/25/2019
Name of Provider or Supplier Anycare 24	Street Address, City, State 702 South Cumberland St, Lebanon, 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
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 review of the laboratory procedure manual, employee personnel records for 2018 and 2019, and interview with the laboratory supervisor, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency. The findings include: 1) Review of the laboratory procedure manual revealed the following six criteria were not included in the procedure and competency documentation: 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) Review of the 2018 and 2019 employee personnel records revealed no documentation of competency assessment for the six required criteria for 15 out of 15 testing personnel. 3) Interview on November 25, 2019 at 12:30 p.m. with the laboratory supervisor confirmed the testing personnel competency procedure did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS).</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</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. (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 review of the laboratory's procedure manual and interview with the laboratory supervisor determined the laboratory procedure manual failed to include specimen collection, labeling, storage, processing, specimen acceptability, specimen rejection, reportable range, quality control procedures, corrective action for calibration or control results that fail, limitations in the test, reference ranges, panic or alert values and the laboratory's system for entering results in the patient record and reporting patient results for complete blood count (CBC) in 2019. The findings include: 1. Review of the laboratory's procedure manual failed to have a complete written procedure for the complete blood count (CBC) test in 2019. 2. Interview with the laboratory's supervisor on November 25, 2019 at 12:30 confirmed the laboratory did not have a complete written procedure manual for the CBC test in 2019.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of laboratory Quality Assessment (QA) Plan, QA forms, and interview with the laboratory supervisor determined the laboratory failed to follow the written policy and procedure to assess, monitor and correct problems by conducting monthly assessments for Patient Test Management, Quality Control (QC), Proficiency Testing (PT), Comparison of test results, Errors/complaints and personnel assessment in 2018 and 2019. The findings include: 1. Review of the laboratory QA Plan revealed "each month one of the following systems in the laboratory will be evaluated" patient test management, QC, (PT, comparison of test results, errors/complaints and personnel assessment. 2. Review of the QA forms revealed no monthly assessments for patient test management, QC, (PT, comparison of test results, errors/complaints and personnel assessment. . 3. Interview with laboratory supervisor on November 25,

2019 at 12:45 p.m. confirmed the laboratory QA plan was not followed for monthly QA assessments in 2018, and 2019.

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 2018 and 2019 and interview with the laboratory supervisor, the Technical Consultant (TC) failed to document the six required criteria for assessing personnel competency. The findings include: 1) Review of 15 out of 15 employee personnel records for 2018 and 2019 did not reveal 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 the laboratory supervisor on November 25, 2019 at 12:30 am confirmed 15 of 15 testing personnel evaluated during 2018 and 2019 were not evaluated using the six criteria for competency required by Centers for Medicare and Medicaid (CMS).