

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1064042	(X3) Date Survey Completed 06/21/2023
Name of Provider or Supplier Upper Cumberland Cancer Care	Street Address, City, State 707 S Main Street, Crossville, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, the Centers for Medicare and Medicaid Services form 209 Laboratory Personnel Report (CMS-209) and interview with the laboratory's lead testing person (TP#1), the laboratory failed to test proficiency testing samples by routine testing personnel in 2021 and 2022. The finding include: 1. Review of the laboratory's PT records revealed that testing personnel number two and three did not participate in six of six Hematology PT events (2021 events one, two, and three; 2022 events one, two, and three). 2. Review of the CMS-209 revealed four personnel who perform patient testing. 3. Interview with the laboratory's lead testing person (TP#1) at approximately 11:30 am on June 21, 2023 confirmed that testing personnel number two and three did not participate in six of six Hematology PT events, resulting in the laboratory failing to test proficiency testing samples by the same personnel who perform patient testing in 2021 and 2022.</p>
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>

This STANDARD is not met as evidenced by:
 Based on review of the Centers for Medicare and Medicaid Services form 209 Laboratory Personnel Report (CMS-209), the laboratory's policies, the testing personnel (TP) records, and interview with the laboratory's lead testing person (TP#1), the laboratory failed to follow their policy for personnel competency assessment for four of four testing personnel in 2021 and 2022. The findings include: 1. Review of CMS 209 report revealed four testing personnel performing moderately complex patient testing for complete blood counts (CBCs). 2. Review of the laboratory's "Competency Verification Policy" stated, "Each year an annual evaluation form will be completed per employee (employees that perform lab testing only). This form will be placed in the employee file." 3. Review of testing personnel competency assessments revealed no annual competency assessments for testing personnel one, two, three in 2021 and 2022 and no annual competency assessment for testing personnel four in 2022. 4. Interview with the laboratory's lead testing person (TP#1) at approximately 11:30 am on 06.21.2023 confirmed the laboratory failed to follow their policy for personnel competency assessment in 2021 and 2022.

D5403

PROCEDURE MANUAL
 CFR(s): 493.1251(b)

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 direct observation, review of the laboratory's procedure manual, and interview with the laboratory's lead testing person (TP#1), determined the laboratory's procedure for the Cell Dyn Emerald instrument for Complete Blood Count (CBC) testing did not include a procedure for platelet clumping recollection. The findings include: 1. Observation of the laboratory at approximately 10:00 am on 06.21.2023 revealed a Cell Dyn Emerald instrument in use for CBC patient testing. 2. Review of the laboratory's "Emerald Procedure" revealed the procedure did not include a procedure for platelet clumping recollection. 3. Interview with the laboratory's lead testing person (TP#1) at approximately 11:30 am on 06.21.2023 revealed "We will recollect in a blue top (sodium citrate) and rerun the specimen but we do not multiply the new platelet count by 1.1." When asked if there was a procedure, TP#1 stated, "No", confirming that the laboratory's procedure for the Cell Dyn Emerald CBC instrument did not include a procedure for platelet clumping recollection.