

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0985015	(X3) Date Survey Completed 09/20/2023
Name of Provider or Supplier Cancer And Blood Disorders Treatment Center	Street Address, City, State 3261 Old Washington Rd #1030, Waldorf, MD	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory procedure manual and competency assessment record review and interview with the technical consultant (TC), the laboratory did not ensure that the written procedure for conducting competency assessments on testing personnel (TP) is followed. Findings: 1. The procedure, "170 - Lab Personnel Training and Competency Testing" states, "Competency checklists must be performed by lab supervisor and or lab director" and "See competency checklist for task to be performed, how task was measured (via direct observation or test), and if task was achieved." 2. The laboratory currently has 5 TP listed on the "Laboratory Personnel Report" (CMS-209). A review of competency assessment records from 2022 and 2023 showed that 1 out of 5 TP had their competency assessment performed using a "Training Competency Assessment Criteria" form (checklist). The remaining 4 TPs' records included copies of instrument printouts, proficiency testing records, and instrument maintenance logs but did not include the checklist. 3. During an interview on 09/20/2023 at 2:00 PM, the TC confirmed that the laboratory did not follow the established procedure for documenting competency assessments.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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</p>

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 on review of patient test report printouts, and interview with the technical consultant (TC), the laboratory failed to ensure that the final test report included the correct address of the laboratory where hematology testing is performed. Findings: 1. The laboratory performs hematology testing. The instrument printout with each patient's test results is scanned into the laboratory's electronic medical record system as an attachment. 2. During a tour of the laboratory at 10:15 AM, a testing person notified the TC that the address of the laboratory on the instrument printouts was incorrect. The laboratory moved to its current location in July 2022. 3. Random review of patient test report printouts showed that as of the day of the survey, the address on the instrument printouts was the laboratory's former location, not the current location. 4. During an interview on 09/20/2023 at 2:00 PM, the TC confirmed that the address of the laboratory where testing is performed was not correctly documented on patient test reports.