

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0235176	(X3) Date Survey Completed 07/21/2021
Name of Provider or Supplier St Mary's Medical Center Himg Campus	Street Address, City, State 5170 U S Route 60 East, Huntington, WV	
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
D0000	An announced, on site, recertification survey was conducted at St Mary's Medical Center HIMG Campus on July 21, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. The specific deficiencies are explained below.
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 record review and interview the laboratory failed to assess and document the competency of 1 (TP1) of 7 laboratory testing personnel for 2020. Findings: 1. Review of personnel competencies revealed no annual testing personnel competency for TP1 for 2020. 2. An exit interview with the general supervisor, administrative laboratory director, and vice president, on 7/21/21 at approximately 12:45 PM, confirmed the findings.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p>

This STANDARD is not met as evidenced by:

Based on review of policies and procedures (P&P) and interview the laboratory failed to establish the criteria for Hematology peripheral smear to be (8) referred for review.

Findings: 1. Review of P&P identified a lack of defined criteria for referral of a peripheral smear. 2. An exit interview with the general supervisor, administrative laboratory director, and vice president, on 7/21/21 at approximately 12:45 PM, confirmed the findings.