

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0235176	(X3) Date Survey Completed 06/24/2025
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	A routine recertification survey was conducted at St. Mary's Medical Center HIMG Campus on June 24, 2025, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficiencies cited 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 review of laboratory policies and procedures, testing personnel (TP) competency records, lack of documentation, interview with the general supervisor (GS), and exit interview with the laboratory director (LD) and administrative team, the laboratory failed to document the assessment of problem solving skills for 8 of 8 TP for initial, six month, and annual competency assessments (CA) in 2024 and 2025. Findings: 1. Review of laboratory policies identified "Personnel Competency and Assessment" stating "All documentation for training, proficiency testing participation, QC verification, and evaluation of critical documentation will be maintained in the Technical Personnel Individual Folders in the supervisor's office." 2. Review of the 11 CAs performed in 2024- 4 initial CAs (TP5, TP6, TP7, TP8) three semiannual CAs (TP4, TP5, TP6, TP8) four annual CAs (TP1, TP2, TP3, TP4)- revealed no documented assessment of problem solving skills. 3. Review of the two CAs performed in 2025 (one semi annual for TP7 and one annual for TP8) revealed no documented assessment of problem solving skills. 4. During an interview with the GS /TP8, 6/24/25 at approximately 10:00 AM, the GS agreed that no documentation for</p>

the assessment of problem solving skills could be located for the CAs performed in 2024 and 2025. 5. An exit phone interview, 6/24/25 at approximately 5:15 PM, with the LD and the laboratory administration team confirmed the findings.

D5807

TEST REPORT

CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, performance verification records for the Beckman chemistry analyzers, validation records of the CERNER laboratory information system (LIS), CERNER LIS patient reports, interview with the general supervisor (GS), and exit interview with the laboratory director and administration team, the laboratory failed to ensure accurate reference intervals were available on the test report for one of 45 chemistry analytes from March 2025 thru date of survey. Findings: 1. Review of performance verification records for two Beckman DxC 700 AU analyzers and one Beckman Dxi 600 analyzer (put in use December 2023) and the CERNER LIS validation records (put into use March 2025) revealed reference intervals for all 45 analytes were validated. 2. Review of "Chemistry Procedure Manual" revealed written policies for all 45 analytes that included reference intervals. 3. Review of CERNER patient reports from date of survey (MRN 00039632, MRN 01020290, MRN 33024940) compared with the written policy reference intervals for each analyte revealed an inaccurate reference interval for one of 45 chemistry analytes (creatinine). The CERNER patient reports state the following reference interval for creatinine: 0.70-1.30 for the two reports for male patients (69 years old and 68 years old) 0.60-1.20 stated for the female patient (67 years old) The approved policy for creatinine states the following reference interval for creatinine: 0.70-1.30 for female patients >1 year old to 150 years old 0.60-1.20 for male patients >1 year old to 150 years old 4. During an interview with the GS, 6/24/25 at approximately 2:30 PM, the GS stated that the reference interval discrepancy for creatinine was possibly a transcription error in the policy. 5. An exit phone interview with the LD and administration team, 6/24/25 at 5:15 PM, confirmed the finding.