

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0910926	(X3) Date Survey Completed 01/24/2024
Name of Provider or Supplier Minnie Hamilton Health Care Center Inc	Street Address, City, State 186 Hospital Hill, Grantsville, 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 as conducted at Minnie Hamilton Health Care Center Inc., by the West Virginia Office of Laboratory Services on January 23-24, 2024. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. 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 written policies and procedures (P&P), laboratory personnel competency records, lack of documentation, and interview the laboratory failed to ensure that the established process to assess employee competency was followed for one of two years reviewed. Findings: 1. Review of P&P identified an established process of assessing testing personnel competency for all methodologies used for patient testing in the laboratory. 2. Review of the laboratory current test menu identified direct antiglobulin testing (DAT) and gram staining as methods utilized by laboratory testing personnel in 2022 and 2023. 3. Review of testing personnel (TP) competency records for 2022 and 2023 revealed a lack of documentation for the assessment of competency in the gram staining process (4 of 4 TP) and DAT (7 of 8 TP) in 2023. 4. An interview with the general supervisor, 1/23/24 at 9:15 AM, confirmed the lack of TP competency documented for gram staining and DAT in 2023.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p>

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on record review, observation, lack of documentation, and interview the laboratory failed to determine the mean normal patient prothrombin time (MNPT) for one of two lots (lot 564624) of Innovin prothrombin time (PT) reagent and verify the accuracy of the INR calculation before putting the lot into use for patient testing.

Findings: 1. Review of the records for lot 564624 (expiry 6/2/25) of Dade Innovin revealed no documentation of the laboratory determined MNPT and no manual verification of the INR calculation. 2. Observation of the coagulation analyzer (Sysmex CA 620) set up menu, 1/24/24 at 10:30 AM, identified the current ISI in use for lot 564624 expiry 6/2/25 to be accurate per Dade Innovin product insert. 3. An interview with the technical consultant and laboratory administration director, 1/24/24 at 10:35 AM, confirmed the lack of documentation for the verification of the required performance specifications for lot 564624 of Dade Innovin PT reagent. 4. An exit interview with laboratory and executive administration, 1/24/24 at 3:30 PM, confirmed the findings.

D5425

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(3)

The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

This STANDARD is not met as evidenced by:

Based on review of written policies and procedures (P&P), lack of documentation, and interview the laboratory failed to establish a process for the validation of statistical parameters for new lots of unassayed quality control (QC) materials in Chemistry for analytes tested on the Vitros 7600. Findings: 1. Review of P&P revealed no established process for the validation of new lots of unassayed QC material used in Chemistry. 2. The technical consultant (TC) stated during an interview 1/23/24 at 1:00 PM that no documentation of the criteria for evaluating the validation of new lots of unassayed QC could be located. 3. An exit interview with the laboratory administration, 1/24/24 at 3:00 PM, confirmed the findings.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on review of written policies and procedures (P&P), quality assurance (QA)

records, and interview the laboratory failed to establish a process for the step by step performance that evaluates and defines the correlation of test results between the Hematology automatic differential and manual differential testing methodologies twice a year. Findings: 1. Review of P&P revealed no established criteria for the performance and evaluation of the intra-laboratory comparison of testing personnel (TP) who perform manual differential testing. 2. Review of P&P revealed no defined criteria for the comparison of test results between the automatic differential and manual differential methodologies. 3. An exit interview with the laboratory technical supervisor (TS) and laboratory administration, 1/24/24 at 3:00 PM, confirmed the findings.