

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0410260	(X3) Date Survey Completed 03/23/2021
Name of Provider or Supplier Phillips County Hospital	Street Address, City, State 311 8th Ave East, Malta, MT	
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
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 personnel files, policy and procedures, and interview with the general supervisor (GS)#1, the laboratory failed to follow their QA/QI Guidelines procedure to perform annual personnel assessments for the technical supervisor (TS) and 1 of 3 testing personnel (TP) in 2019; and for the technical supervisor and 3 of 3 testing personnel in 2020. Findings include: 1. Review of personnel files lacked documentation of annual assessments for TS#1 and TP#1 in 2019, and for TS#1, TP#1, TP#2 and TP#3 in 2020. 2. Review of QA/QI Guidelines states "Asses all personnel at 6 months and 1 year, then annually thereafter, by using unknown specimens in all areas in which a tech performs patient and/or proficiency testing." 3. Interview with GS #1 on 3/23/2021 at 11:00 AM, confirmed the laboratory failed to perform annual assessment for personnel listed above for 2019 and 2020.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:

Based on record review of 2019, 2020 instrument comparison documentation and interview with the general supervisor (GS)#1, the laboratory failed to perform instrument comparison for the analyzers, VITROS 350 and ePOC Blood Gas for basic metabolic panel testing two times a year. Findings: 1. Review of laboratory instrument comparison documentation showed the laboratory failed to perform and document comparison studies twice a year for VITROS 350 and ePOC Blood Gas system analyzers performing sodium, potassium, chloride, ionized calcium, total CO(2), glucose, blood urea nitrogen (BUN) and creatinine analyte testing for 2019 and 2020. 2. Interview with general supervisor GS#1 on March 23, 2021 at 3:00 PM confirmed the laboratory failed to perform twice a year instrument comparison