

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0409929	(X3) Date Survey Completed 12/18/2024
Name of Provider or Supplier Prairie Community Hospital	Street Address, City, State 312 South Adams, Terry, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a record review of quality control (QC), manufacturers' instructions, and an interview with the Laboratory Director (LD) #1, the laboratory failed to follow the manufacturer's instructions and perform two levels of external quality control for each new lot, shipment, or new user for Xpert Xpress SARS-CoV-2 (CoV-2), influenza (Flu) A, influenza B, and respiratory syncytial virus (RSV) plus cartridge performed on the Gene Xpert Xpress system from May 2, 2024, to December 18, 2024. Findings: 1. A review of the CoV-2/Flu/RSV Plus test's QC records lacked documentation of a positive and negative external QC for each new lot, new shipment, or new user per the manufacturer's instructions (lot #19220 used to perform patient testing on 9/24/2024). 2. An interview with the LD #1 on December 18, 2024, at 10:50 AM confirmed the laboratory failed to perform a positive and negative external QC per the manufacturer's instructions for the CoV-2/Flu/RSV plus cartridge performed on the Gene Xpert Xpress system from May 2, 2024, to December 18, 2024.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p>

This STANDARD is not met as evidenced by:

Based on observation, manufacturers' instructions, and interviews with the testing personnel (TP) #1 and the laboratory director (LD) #1, the laboratory failed to update the new assay definition file (ADF) version 2 for the Xpert Xpress SARS-CoV-2 (CoV-2), influenza (Flu) A, influenza B, and respiratory syncytial virus (RSV) plus assay as required by the manufacturer from December 18, 2023, to December 18, 2024. Findings: 1. Observed in the laboratory on December 18, 2024, at 11:05 AM, two kits of Xpert Xpress CoV-2/Flu/RSV plus which contained the manufacturer's instructions to "Read Before Using This Kit: New Assay Definition File (ADF) indicating "Cartridges from this lot (and all subsequent lots) of Xpert Xpress CoV-2 /Flu/RSV plus require the import of ADF version 2." 2. An interview with testing personnel TP #1 and LD #1 at 11:07 AM revealed the new ADF file had not been uploaded to the GeneXpert System. 3. A review of the test volume sheet revealed 47 patients had been tested using the Xpert Xpress CoV-2/Flu/RSV plus cartridges from December 18, 2023, to December 18, 2024.