

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 53D0662186	<b>(X3) Date Survey Completed</b> 10/20/2021
<b>Name of Provider or Supplier</b> Hot Springs County Memorial Hospital Laboratory	<b>Street Address, City, State</b> 150 E Arapahoe St, Thermopolis, WY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6117</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(4)</p> <p>The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.</p> <p>This STANDARD is not met as evidenced by: Based on quality control (QC) record review, lack of documentation, review of the patient testing log, policy and procedure review, and staff interview, the technical supervisor failed to ensure a quality control program was established to assure the quality of laboratory services provided. The findings were: 1. Review of the QC records showed the laboratory performed a positive and a negative control for the Biofire respiratory panel 2.1 on 8/31/21, 9/1/21, 9/2/21, 9/3/21, 9/7/21, 9/9/21, 9/16/21, 9/20/21, and 10/20/21. 2. Review of the patient testing log showed 27 respiratory panels and 225 SARS-CoV-2 patient tests had been performed between 8/30/21 and 10/20/21. There was no evidence QC had been performed each day prior to patient testing for 18 of the respiratory panels and 164 of the SARS-CoV-2 tests performed during that timeframe. 3. Review of the BioFire Quality Control for Respiratory Panel 2.1 policy signed by the laboratory director on 9/17/21 showed "Respiratory Panel 2.1 QC, both positive and negative must be run every 30 days or when a new lot of cartridges is put into use...COVID-19 is part of this QC group and cannot be run by itself..." 4. There was no evidence an IQCP (individualized quality control plan) had been developed for the BioFire respiratory panel 2.1. 5. Telephone interview with the technical supervisor on 10/20/21 at 11:41 AM revealed she was unaware the laboratory was not performing QC on the BioFire respiratory panel every day prior to patient testing. The technical supervisor confirmed an IQCP had not been developed for the respiratory panel.</p>