

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D1037480	<b>(X3) Date Survey Completed</b> 03/20/2024
<b>Name of Provider or Supplier</b> Ubmc Vernal Laboratory	<b>Street Address, City, State</b> 405 North 500 West, Vernal, UT	
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>D6076</b>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories performing high complexity testing; laboratory director was not met. The laboratory failed to ensure the physical laboratory space was appropriate for blood bank procedures (see D6083); provide an appropriate environment for the Sysmex CA-600 coagulation analyzer (see D6083); and establish a safe environment for laboratory personnel performing immunohematology testing (see D6084).</p>
<b>D6083</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2)</p> <p>The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.</p> <p>This STANDARD is not met as evidenced by: 1. Based on direct surveyor observation of physical lab space and interview with the technical supervisor (TS), the laboratory failed to ensure the blood bank physical space was appropriate for blood bank procedures. The laboratory performed approximately 127 immunohematology tests annually. The findings include: a) Direct observation of the physical lab space utilized for immunohematology testing on March 20, 2024 at approximately 1:40 PM, revealed there was a lack of counter space to conduct cross-matching, antibody screen, and ABO/Rh testing used for emergency</p>

blood product distribution. b) Direct observation of the physical lab space dedicated for immunohematology testing on March 20, 2024 at approximately 1:40 PM, revealed the lack of physical lab space for two testing personnel to work in the blood bank room. c) In an interview on March 30, 2024 at approximately 1:45 PM, the TS confirmed two laboratory personnel will be in the room during emergency blood distribution procedures and there is a lack of space to appropriately conduct immunohematology testing. 2. Based on laboratory record review and interview with the TS, the laboratory failed to provide an appropriate environment for the Sysmex CA-600 coagulation analyzer. The laboratory performed approximately 6450 coagulation tests annually on the Sysmex-600. The findings include: a) Record review of the Sysmex C-600 instruction manual revealed that the instrument requires an operational environment of 30 - 85% relative humidity. b) Record review on of "Temperature & Humidity Chart" revealed that laboratory humidity was out of range 221 of 305 days from May 1, 2023 - February 29, 2024. c) In an interview on March 30, 2024 at approximately 12:40 PM, the TS confirmed that laboratory humidity was consistently out of range.

**D6084**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:  
Based on direct surveyor observation of physical lab space and interview with the technical supervisor (TS), the laboratory failed to provide a safe environment for laboratory personnel performing immunohematology testing from physical and biological hazards. The laboratory performs approximately 127 immunohematology tests annually. The findings include: 1. Direct observation of physical immunohematology testing space on March 20, 2024 at approximately 1:40 PM, revealed the laboratory sink that was used for hand washing, was also used for laboratory procedures including an instrument drain. 2. Direct observation of physical immunohematology testing space on March 20, 2024 at approximately 1:42 PM, revealed there was less than 12 inches between the back of a laboratory freezer and the hand washing sink. 3. In an interview on March 20, 2024 at approximately 1:44 PM, the TS confirmed that the laboratory does not have adequate space to use the sink and the sink is used for hand washing and laboratory purposes.