

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D0884506	<b>(X3) Date Survey Completed</b> 01/31/2020
<b>Name of Provider or Supplier</b> Ubmcc Clinic Duchesne	<b>Street Address, City, State</b> 50 East 200 South, Duchesne, 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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on Emerald complete blood counter reagent's record review, lack of documentation and interview with the director, the laboratory failed to ensure blood counting lyse reagent was not expired prior to testing patient samples for 11 of 24 months of testing reviewed (January 2018 to January 2020). The laboratory performed approximately 85 complete blood counts per year. Findings include: 1. Reagent records review included Lyse reagent documentation that lot number 7201 was in use on 3/22/2018 and expired on 06/30/2018. A new lot number was not recorded as placed in use until 06/03/2019. 2. In an interview conducted on 01/31/2020 at approximately 12:45 P.M. staff stated the laboratory did not record each time lyse reagents were changed.</p>
<b>D6070</b>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1)</p> <p>Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on patient test records reviewed, patient instrument printouts reviewed, and interview with staff, the laboratory failed to ensure they followed their procedure to</p>

perform instrument start up and three levels of quality control each day of patient complete blood cell count (CBC) testing for 1 of 11 patient's test reports reviewed (patient 68278) on 09/23/2019. Findings include: 1. Patient chart records include the instrument print out as documentation of the test report. 2. Patient test records instrument printouts include documentation the laboratory performed a CBC for patient #68278 on 09/23/2019, reporting a Red Blood Cell count of 4.96/ cubic millimeter x one million, Hemoglobin of 11.1 grams/deciliter, Hematocrit of 36.0%, and a mean corpuscular volume of 72.5 femtoliters. 3. In an interview with the laboratory director on 01/31/2020 at approximately 12:15 P.M. the director confirmed the patient was tested and the results were reported and that the laboratory failed to document they performed instrument start up, three levels of controls or recorded the environmental testing and storage temperatures or humidity on 09/23/2019.