

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 32D2120728	<b>(X3) Date Survey Completed</b> 05/11/2018
<b>Name of Provider or Supplier</b> Gallup Indian Medical Center	<b>Street Address, City, State</b> 2018 College Drive, Gallup, NM	
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>D0000</b>	Federal Complaint Survey The complaint was found unsubstantiated with standard level deficiencies cited
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and interview, the laboratory failed to monitor and define the proper storage temperature of reagents according to manufacturer's instructions in the Internal Medicine Clinic as evidenced by: 1. The laboratory could not provide documentation that they had define criteria for storage condition of reagents. 2. In direct observation on May 10th in exam room #1 the following reagents were stored without being temperature monitored: a. 15 Genexpert swabs GC/CL lot# 170925000 expires 1/2019. The manufacturer's label requires 2-30 degrees C b. 24 thin prep container lot # 717AA 2019-6-26The manufacturer's label requires 5-25 degree C 3. In direct observation on May 10th in treatment room #2 the follow reagents were stored without being temperature monitored: a. 2 Bottle of BD blood culture bottles lot# 7361855 exp: 2018-10-31. The manufacturer's label requires 2-25 degrees. 4. In interview with a traveling nurse on May 10th @1055 she stated that she was unaware that they ( the other nurses) were taking temperatures for reagents daily.</p>

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:

Based on direct observation, the laboratory failed to discard supplies that have exceeded their expiration date in the Internal medicine clinic as evidenced by: 1. In direct observation @1005 in treatment room #1 the following laboratory supplies were expired: a. 3 Vacuette Grey top tubes, NaFl lot#A16104D2 expired 4-13-2018 2. In direct observation @1006 in exam room #10 the following laboratory supplies were expired: a. 3-Gene Xpert swabs lot 159007 05H025 expired date 02/2018