Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0536068	08/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gallup Indian Medical Center	516 E Nizhoni Boulevard 1st Floor South, Gallup, NM	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Full survey 8/20 to 8/24 Based on lack of documentation and interview, the laboratory failed to retain quality control package inserts for Radiometer ABL 800 blood gas instrument as evidenced by: 1. The laboratory was not able to provide the manufacturers instructions with statistical values for quality control for last previously lots from June 2018 until August 2016. 2. On 8/24/2018 @1050 an telephone interview was conducted with the Respiratory Supervisor, the federal surveyor asked if he had the manufacturer's package insert quality control values for the last 2 year. The Respiratory Supervisor stated, "No, I didn't know we need to retain them."
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Full survey 8/20 to 8/24 Based on review of the laboratory's microbiology chart, protocols, and patient test results the laboratory failed to document a step by step process and record the actual biochemical reactions seen as evidenced by: 1. In review of the laboratory's microbiology chart for gram negative it show that one of the differentiation is lactose fermentation. 2. In review of patient #163463 the laboratory identified E. Coli in a clean catch midstream urine. The laboratory did not document the media that was plated, their observations on the MacConkeys agar (lactose positive or negative) or any other biochemical tests performed. The worksheet only had written: "7100 Cs 8/14 " before going into the vitek for ID. 3.In review of patient #3004 the laboratory identified Klebsiella pneumonaie in a clean catch midstream urine. The laboratory did not document their observations on the MacConkeys agar (lactose positive or negative) or any other biochemical test performed. the worksheet only had written "7100 C 101s 8/21 4. In review of patient #32124 the laboratory identified E. coli in a blood culture. The laboratory did not document any of the of the media that was plated, their observation of any other biochemical tests performed. They worksheet only has written "AER GS= GNR ICU 16:15 8/13" 5. In review of patient #5184 the laboratory identified E. Coli in a clean catch midstream urine. The laboratory did not document the media that was plated, their observations on the MacConkeys agar (lactose positive or negative) or any other biochemical tests performed. The worksheet only had written: "7100 Cs 101s 8/14 " before going into the vitek for ID. 6. In review of patient #159459 the laboratory identified E. Coli in a clean catch midstream urine. The laboratory did not document the media that was plated, their observations on the MacConkeys agar (lactose positive or negative) or any other biochemical tests performed. The worksheet only had written: "7100 Cs 101s 8/14 " before going into the vitek for ID. 7. In review of patient #147897 the laboratory identified E. Coli in a clean catch midstream urine. The laboratory did not document the media that was plated, their observations on the MacConkeys agar (lactose positive or negative) or any other biochemical tests performed. The worksheet only had written: "7100 Cs 101s 8/14 " before going into the vitek for ID. 8. In review of patient #148781 the laboratory identified E. Coli in a clean catch midstream urine. The laboratory did not document the media that was plated, their observations on the MacConkeys agar (lactose positive or negative) or any other biochemical tests performed. The worksheet only had written: "7100 Cs 101s 8/14 " before going into the vitek for ID. 9. In interview with the laboratory microbiology supervisor on 8/22 /2018 he stated that they don't document everything concerning the observations and biochemical tests.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results

	within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Full Survey 08/20-24/18 Based on record review, direct observation and interview with staff, the laboratory failed to follow manufacturers instructions for the ACL Top coagulation analyzer by changing the ISI value with lot changes of Hemosil Recomboplastin 2G Protime (PT) Reagents as required. As evidenced by: 1. Direct observation of ACL Top 300 CTS analyzer on 08/22/18 at 1100 reflected an ISI of 0.987 for Lot # N1073129 with Exp. Date 10/2019 saved in the instrument on 02/26 /18@1639. 2. Manufacturers Package insert for Hemosil Recomboplastin 2G Protime (PT) Reagents, Lot # N1073129 with Exp. Date 10/2019 states the ISI for ACL Top Family analyzers is 0.99. 3. In interview with the Hematology Supervisor and the Laboratory Director on 08/22/18 @ 1115, no documentation or explanation as to where the 0.987 ISI value that is in the analyzer came from. 27814 Full survey 8/20 to 8/24 A. Based on review of the manufacturer's instructions, patient testing results, and interview, the laboratory failed to follow the manufacturer's instruction and record incubation times when specimens were plated in microbiology as evidenced by: 1. In review of the Remel MacConkey Agar package insert states, "incubate plates in ambient air at 33-33 degrees C for 18-24 hours" 2. In review of the Remel Blood Agar TSA 5% sheep blood package insert states, "incubate plate aerobically, or in 5-10 CO2 for 18-24 hours at 33-37 degrees C." 3. In review of the Remel Hektoen Agar package insert states, "incubate plates aerobically at 33-37 degree C for 18-24 hours." D. 4. In review of the following patient testing records, the laboratory did not document the incubation time to ensure growth: a. patient #163463 recovered E. Coli , urine culture b. patient #170546 NG 24 hrs, urine culture c. patient #91621 NG 24 hrs, urine culture d patient #16872 NG, urine culture e. patient# 15519 NG, urine culture f. patient # 261120 NG, urine culture 5. In interview with the microbiology supervisor on 8/22/2018 @945 stated the they document the time for blood cultures and body fluids but nothing else in microbiology." B. Based on review of the manufacturer's instructions and daily quality control log from April 2018 to August 2018, the laboratory failed to follow manufacturer's package insert's preliminary needle preparations for the macrovue RPR as evidenced by: 1. In review of the BD Macro-vue RPR card test states under preliminary preparations, "Check delivery of the needle by placing the needle placing the needle firmly on a 1 mL piper or syringe; fill the pipet or syringe with antigen suspension, and holding the pipet or syringe in a vertical position, count the number of drops delivered in 0.5 ml" 2. In review of the laboratory's daily quality control log from April 2018 to August 2018, the laboratory only performed the drop delivery of needle on the following days: Once on August 1st, tests were performed on the 2nd, 6th, 7th, 12th, 18th none in July tests were performed on the 1st and the 27th none in June, tests were performed on the 13th, 15th, 16th none in may, test was performed on the 2nd none in April, test was performed on 20th and 21st
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number

	and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Full survey 8/20 to 8/24 1. Based on review of the laboratory's documentation and interview, the laboratory failed to have in house data established by the laboratory in it own environment for microbiology media plates as evidenced by: a. Based on review of the laboratory's IQCP plan, the laboratory did not have data for prepared media: Blood Agar MacConkey agar Hektoen Enteric Agar MacConkey /Blood Biplate agar Selective Strep Agar, 5% sheep blood CDC Anaerobic blood agar Anerobic Blood Agar w/KV TSA blood Agar, tubed media Columbia CNA blood agar Inhibilitory Mold Agar Tryptic Soy Broth Trptic Soy broth with 15% Gylycerol PRAS Cook meat broth The laboratory did not have data to show that per lot or per shipment that the media was stable to only perform visual checks i.e cracks, dried media etc. 2. Based on review of the laboratory's Individual Quality Control Plan (IQCP) and interview, the laboratory failed to have complete in house data to support their IQCP quality control for the Cepheid Genexpert Infinity and Illunigene pertussis assay as evidence by: a. The laboratory not have data to show that for 30 days that the internal QC was stable to run for 30 days as indicated from their quality control plan. b. In review of the data given to the surveyor they only had a 20-day quality control plan that did not cover the weekends. c. In review of the Genexpert Regents Monthly QC for January 2018 and February 2018 the laboratory performed only two QC tests on 1/19/2018 and 2/20/2018 d.In interview the microbiology supervisor stated on 8/22 /2018 that both the Cephied Genexpert and Illunigene could be run on the weekends if needed.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Full survey 8/20 to 8/24 .Based on review of the manufacturer's specifications, direct observation, the laboratory failed to follow the manufacturer's storage temperature specifications for using Medtox controls as evidenced by: a. In review of the manufacturer's package insert for the Medtox controls states, "store at -20 to 8 degree C" b. In direct observation on 8/23/2018 @1011 the following controls were in freezer @ -38 degree C: 1. 5- vials lot MC 5985 PV Medtox positive control 2. 3 -vials lot N6146 Medtox negative control 3. 1- vial lot N6048 Medtox negative control c. In interview with the chemistry lead, she stated that she was unaware that the controls needed to be stored between -20 and 8 degrees C.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and

	control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Full survey 08/20-24/18 Based on record review, procedure review and interview with staff, the laboratory failed to document quality control(QC) samples are performed in duplicate, and once every 8 hours of testing for hemacytometer body fluid counts. As evidenced by: 1. In review of the Gallup Indian Medical Center Hematology Department CSF/Fluid Cell/Sperm Counts Quality Control Log states, "Controls need to be done ONCE a day" the log does not reflect a time the QC was performed just the date and the analyst that performs the test. The log also reflects only the numerical value of the QC for L1 and L2 not the working data to show that the QC was performed in duplicate as required. No raw data or worksheets were available at the time of the surrey. 2. In review of GSU.CLI.LAB.12b.Body Fluid Quality Controls procedure states:" Once controls are done, it will be good for the day. Any subsequent body fluids received can then be performed without having to do controls again for that day." 3. In interview with the Hematology Supervisor on 08/23/18@1500, She stated:" Body Fluid cell count QC is required every 24 hours and to be done in duplicate.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Full Survey 08/20-24/18 Based on record review, direct observation and interview with staff, the laboratory failed to ensure adequate monitoring of blood and blood product storage continually for 24 hr period. As evidenced by: 1. In review of the Blood Bank Quarterly/Yearly Eminence log it was revealed that alarm checks were performed in February and May of 2018, temperatures were recorded at what temp the alarm sounded. When the continuous monitoring wheels for February and May 2018 were reviewed, no deviations from the required temperature gradient were observed, the monitoring wheels were perfect circles, no lines showing the alarm check temperatures were achieved. 2. In direct observation and interview of the Biomed department on 08/23/18 @1330 they performed an alarm check. The Biomed department did not utilize and was unaware that all probes needed to be used during the alarm checks. During observation Biomed only used the electronic audible alarm, not the monitoring wheel or external temperature monitor, when Biomed did use all the probes, the wheel reflected lines showing the temperature fluctuations and audible alarm sounded. Blood bank policy dictates alarm checks are to be performed quarterly.
D5801	TEST REPORT CFR(s): 493.1291(a)

	The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Full Survey 08/20-24/2018 Based on direct observation, record review and interview with staff the laboratory failed to report test results accurately and reliably from the ACL Top 300 analyzer, entered manually to final report destination RPMS laboratory information system. As evidenced by: 1. Direct Observation on 08/22/18 @ 11300 revealed a testing person performing PTT testing. Observed the PTT reporting process as getting results from the ACL TOP analyzer and manually entering the PTT results into the RPMS lab information system. Analyst took the results off the analyzer as 29.9 seconds for for patient ID 44777, he then entered the result into RPMS system as 30.0 seconds. 2. In interview with the Testing person @ 1300 on 08/22/18, when asked how do you manually enter the PTT results? He stated:"I round PTT's to the whole number, for PT and INR's. I don't know why." 3 In interview with the Lab Director @ 1320 on 08/22/18, when asked if manually entered PTT results were to be rounded? He stated:" Absolutely not, system has the capability to enter results as they come off the analyzer." 4. Random sampling, 3 of 3 PTT results found same rounding issue with the identified testing person: a. Patient ID 180031, 08/22/18, ACL Top report 40.8 seconds and RPMS report 41.0 seconds b. Patient ID 7674, 08/22/18, ACL Top report 37.4 seconds and RPMS report 37.0 seconds c. Patient ID 17086, 08/22/18, ACL Top report 43.9 seconds and RPMS report 44.0 seconds