Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0536068	05/11/2018
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
D0000	Complaint Survey The Laboratory complaint was found substantiated and out of compliance with the following CONDITIONS: 493.1217 Condition: Immunohematology 493.1240 Condition: Preanalytic systems 493.1403 Condition: Laboratory Director; Moderate Complexity testing 493.1441 Condition: Laboratory Director; High Complexity testing
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on Proficiency Testing record review, laboratory policy review and interview with staff, the laboratory failed to examine proficiency testing samples it receives from the proficiency testing (PT) program in the same manner as it tests patient specimens. As evidenced by: 1. Laboratory policy GSU.CLI.LAB15b Proficiency Testing states in Procedure section: a. #4. Perform testing directed by the kit. All PT samples analyzed are to be integrated into the normal workflow. Further, whenever possible, samples are to be handled and analyzed exactly as patient samples. Don't repeat testing on samples unless the assay's procedure indicates that this should be done for patient testing. 2. Review of CAP PT event HBF-A2017 Fetal RBC Detection Survey showed that samples were analyzed by multiple testing persons

	prior to submitting results to PT agency: a. Attestation statement signed by 6 testing personnel and by laboratory director attesting to specimens tested in the same manner as patients. b. Kit #1 raw data showed 6 testing personnel(TP) performed the testing on this event and documented results. 5 TP documented results on 5/17/17 and one TP on 5/23/17. Event was submitted on 5/23/17 to CAP. c. Kit #2 raw data showed 4 testing personnel(TP) performed the testing on this event and documented results 2 TP documented results 5/15/17 and one TP on 5/18/17 and one TP 5/19/17. Event was submitted on 5/23/17 to CAP. 3. Review of CAP PT event ABT-A2017 Antibody Titer Survey showed that samples were analyzed by multiple testing persons prior to submitting results to PT agency: a. Attestation statement signed by 2 testing personnel and by laboratory director attesting to specimens tested in the same manner as patients. b. Kit #30339982 raw data showed 2 testing personnel(TP) performed the testing on this event and documented results 1 TP documented results 6/23/17 and one TP on 6/19/17. Event was submitted on 6/23/17 to CAP. 4. Review of CAP PT event DAT-A2017 Direct Antiglobulin Testing Survey showed that samples were analyzed by multiple testing persons prior to submitting results to PT agency: a. Attestation statement signed by 2 testing personnel and by laboratory director attesting to specimens tested in the same manner as patients. b. Kit #30342624 raw data showed 2 testing personnel(TP) performed the testing on this event and documented results 2 TP documented results 3/17/17. Event was submitted on 3/21/17 to CAP. 5. Interview with Lab Manager and Lab Director on 05/08/18@1130 stated that it is not laboratory policy to have multiple TP perform PT events or immunohematology testing patient samples unless there are issues with reactions or interpretation. "We use PT for competency but not intended to be done prior to submission to CAP.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on record review and interview with staff, the laboratory failed to investigate a potential transfusion related death and report to Center for Biologics Evaluation and Research (CBER) FDA as required by FDA and laboratory policy. As evidenced by: 1. Laboratory identified patient death from 11/17/17. The patient expired within 72 hours of blood component transfusion and did not investigate for transfusion reaction. See D-5559 2. In interview with Laboratory Director on 05/09/18@1500, "We were not notified of the potential transfusion reaction by ED medical staff or that the patient expired while blood products were transfused, had we known, I would have worked this up and reported to FDA as required. The Blood Bank supervisor identified patient only as expiring within 72 hours of receiving blood products in normal QA review. not having a transfusion reaction. I never received that review form from Blood Bank Supervisor."
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.

	1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on record review and interview with staff, the laboratory failed to meet the requirements of If the the specialty of Immunohematology as evidenced by: 1. The laboratory failed to investigate and report potential transfusion related death to FDA as required. See D-3025 2. The laboratory failed to promptly investigate identified transfusion reaction and death within 72 hours of blood product administration as required by policy. See D-5559
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on interview, the laboratory's policies, testing records, and manufacturer's instructions, the laboratory failed to evaluate overall quality in the preanalytic system as evidenced by: 1. The laboratory failed to follow their policy and manufacturer's instructions to ensure patients specimens were processed within 20-30 minutes for Ammonia (see D5311-A) 2. The laboratory failed to follow manufacturer's instruction to ensure patients specimens were processed within 15 minute timeframe for lactic acid (see D5311-B) 3. The laboratory failed to have written instruction for each client that sends specimens to their laboratory (see D5317)
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: A. Based on review of laboratory testing records, manufacturer's package insert, and laboratory policy, the laboratory failed to follow their policy and manufacturer's instructions to ensure patients specimens were processed within 20-30 minutes timeframe for Ammonia from April 5 to May 6, 2018 as evidenced by: Ammonia Specimens 1. In review of the manufacturer's instructions states, "Perform analysis within 20-30 minutes of venipuncture or freeze separated plasma immediately" 2. In review of the laboratory's policy Specimen requirements chart states, "Place immediately on ice after collection. Spin and analyze within 20-30 minutes." 3. In review of the laboratory testing records, the following patients tests for Ammonia

	were past the 20-30 minute time frame: a. patient #37715 collected 4-18-2018 @ 2236 received in lab @2319, 43 minutes b. patient #175256 collected 4-30-2018 @2220 received in lab @2332, 1 hour 12 minutes c. patient # 273477 collected 5-3-2018@ 1320 received in lab @1402, 42 minutes d. patient # 10914 collected 5-3-2018@ 1651 received in lab @ 1739, 48 minutes e. patient #231405 collected 4-23-2018 @ 1530 received in lab @ 1614, 44 minutes f. patient #123715 collected 4-30-2018@ 2300 received in lab @2344, 44 minutes g. patient #67672 collected 5-6-2018@ 0648 received in lab @ 0744, 56 minutes B. Based on review of laboratory testing records, manufacturer's package insert, and laboratory policy, the laboratory failed to follow manufacturer's instruction to ensure patients specimens were processed within 15 minute timeframe for lactic acid April 5 to May 6 2018 as evidenced by: Lactic Acid specimens 1. In review of the manufacturer's instructions states, "Centrifuge within 15 minutes of collection the specimen" 2. In review of the laboratory's policy specimens requirements chart states, " 8 hours RT" The laboratory policy was not the same as the manufacturer instructions. 3. In review of the laboratory testing records, the following patient were tested for lactic acid past the 15 minute time frame: a. patient # 66001 collected 4-8-2018 @ 1532 received in lab @1626, 53 minutes bipartite #76986 collected 5-4-2018@ 1655 received in lab @1719, 24 minutes c. patient # 24962 collected 5-4-2018@ 0700 received in lab @0736, 36 minutes d. patient #1416 collected 4-7-2018 @ 0110 received in lab @ 0319, 2 hours 9 minutes e. patient #94431 collected 4-18-2018@1040 received in lab @1106, 26 minutes f. patient # 43267 collected 4-26-2018@1455 received in lab @ 1523, 28 minutes g. patient # 22242 collected 4-12-2018 @ 0630 received in lab @ 0652, 22 minutes h. patient #178368 collected 4-08-2018 @ 1633 received in lab @1659, 26 minutes i. patient #45208 collected 4-30-2018 @ 1135 received in lab @ 1256, 1 hour 26 minutes j. patient #180421 collection 4-28-2018 @ 1055 received in lab @1131, 34 minutes k. patient #37493 collection 5-4-2018 @ 1945 received in lab @ 2035, 50 minutes l. patient #139553 collection 4-19-2018 @ 0905 received in lab @ 0951, 46 minutes
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing records, direct observation, lack of documentation, and interview, the laboratory failed to have written instruction for each client that sends specimens to their laboratory as evidenced by: 1. The laboratory could not provide documentation to show that they had written instructions for specimens being sent to the laboratory. They did not have: Collection, preservation, storage, transport, and temperature requirements 2. In interview with the laboratory supervisor on May 7th he stated that they typically receive specimens from nursing homes, a Federal Indian health laboratory, and a cancer center. When asked about a client service manual, the supervisor stated, "To be honest we may have anything like that." @1022 May 7th, 2018 3. In direct observation on May 7 @ 1022 the laboratory received an EDTA tube specimens from a Cancer center. 4. The following patients were received from another laboratory: a. 4/18/2018 @ 1140 patient #243362 b. 4/1 /2018 @1552 patient #244409 Platelet Poor Plasma from Sister Health Clinic 5. In review of the laboratory's policy for prothrombin time test (GSU.CLI.LAB.12C), states to "Refer to H21-A5 for further instructions on specimen collection, handling

	and storage." 6. In review of H21-A5 states under 6.2 Processing suitable Specimens for Plasma-Based Coagulation Assay, "While it is crucial that an essentially platelet-free sample is obtained if the specimen will be frozen for subsequent testing, APTT, prothrombin/time /international normalized ratio (PT/INR)...." 7. In interview with laboratory supervisor at a sister health clinic on May 9th @ 1428 she stated that for prothrombin time (PT) tests that they spin tubes down and separate the serum and ship the specimen on ice. The laboratory supervisor from the health clinic stated that she did not check the number of platelets before they frozen the plasma. 8. The laboratory supervisor could not provide documentation to show that PT specimens were platelet poor upon being frozen.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on patient medical record review, transfusion reaction workup review, and interview with staff, the laboratory failed to promptly investigate identified transfusion reaction and death within 72 hours of blood product administration as required by policy. As evidenced by: 1. In review of patient chart #69459 on 05/08/18 it documents; a. Patient was transferred from Gallup Indian Medical Center ED to Gallup Medical Flight Crew at 1945 on 11/17/17 for transfer to Presbyterian tertiary facility for higher level of care with 2 units Packed RBC's(PRBC) and 2 units Fresh Frozen Plasma(FFP) for transfusion. b. On 11/17/17 at 2115 "patient was brought back to the ED by flight crew for suspected transfusion related reaction upon arrival to the airport. Patient had PRBC and FFP, 1 unit each fully infused. Patient had diffuse arm and back pain, as well as C/O hot flashes and acute malaise. No respiratory issues or rash." Signed by ED provider. c. GIMC ED Nurses note stated"11/17/17@2125 FLT. crew return with PT. R/T "possible allergic reaction" stated PT given Benadryl /pepcid infusing" upon arrival ER physician ordered Solumedrol and ordered plasma /ffp infusion stopped. d. Pt coded at 2138 and code was called at 2151. Patient expired on 11/17/17@2151 at the ED department at Gallup Indian Medical Center. 2. Laboratory policy approved August 6th, 2014 "Criteria for Transfusion Review" Section IV. #5. states Any patient who expires within 72 Hours of receiving any blood component requires transfusion review. 3. Interview with Blood bank Supervisor on 05 /09/18@1400 stated; " I perform a medical record review of all blood transfusion tags that are returned to the laboratory to see if any meet criteria for transfusion review. For this particular case I did see that patient expired within 72 hours of receiving blood products and made a transfusion review form, however I just found the form I made stuck behind some paperwork and it was never given to the pathologist for transfusion review." 4. Transfusion record review sheet date of incident 11/17/17 Med Rec#69459 provided by Blood Bank supervisor on 05/09/18 @ 1430 stated indication

	for review as; Any patient who expired within 72 hours of receiving any blood products is automatically reviewed. This form did not have the pathologist review or any comments and the form was incomplete. 5. Interview with Laboratory Director on 05/09/18@1500, "We were not notified of the potential transfusion reaction by ED medical staff or that the patient expired while blood products were transfused."
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory testing records, interviews, the laboratory's policy, and manufacturer's instructions, the Laboratory Director failed to provide overall management and direction of the laboratory as evidenced by: 1.The Laboratory Director failed to oversee overall operation in the preanalytic phase of testing (see D6007)
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of laboratory testing records, manufacturer instructions, and interview, the Laboratory Director failed to oversee overall operation in the preanalytic phase of testing as evidenced by: 1. The laboratory failed to follow their policy and manufacturer's instructions to ensure patients specimens were processed within 20-30 minutes for Ammonia (see D5311-A) 2. The laboratory failed to follow manufacturer's instruction to ensure patients specimens were processed within 15 minute timeframe for lactic acid (see D5311-B) 3. The laboratory failed to have written instruction for each client that sends specimens to their laboratory (see D5317)
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by:

	Based on review of laboratory testing records, interviews with staff, and the laboratory's policy review, the Laboratory Director failed to provide overall management and direction of the laboratory as evidenced by: 1. The Laboratory Director failed to oversee overall operation and ensure compliance with the regulations. See D-6089
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory testing records, policies and procedures review, and interview with staff, the Laboratory Director failed to oversee overall operation and ensure compliance with the regulations, as evidenced by: 1. The laboratory failed to investigate and report potential transfusion related death to FDA as required. See D-3025 2. The laboratory failed to promptly investigate identified transfusion reaction and death within 72 hours of blood product administration as required by policy. See D-5559