Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0537796	09/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Union County General Hospital	300 Wilson St, Clayton, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: Successful [Proficiency Testing] Participation was not met. The laboratory failed to achieve an overall testing score of satisfactory performance (80% or greater) for the analyte blood gas pH for two out of three consecutive events in 2024 resulting in unsuccessful proficiency testing performance (See D2096).
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f)

	Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency testing record review and interview with the laboratory manager on September 17, 2024 at 10:00 am, the laboratory failed to achieve satisfactory performance (80% or greater) for the analyte blood gas pH for two out of three consecutive proficiency testing events in 2024 resulting in unsuccessful proficiency testing performance. Findings included: a, A review of the laboratory's 2024 API proficiency testing scores indicated the following unsatisfactory proficiency testing events for the analyte blood gas pH: - 2024 Proficiency Testing Event 1 = 60% - 2024 Proficiency Testing Event 2 = 40% b. An interview on 09/17/2024 at 10:00 am with the laboratory manager confirmed the above findings.
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 the number and severity of the deficiency cited herein, the Condition: Immunohematology was not met. The laboratory failed to review all immunohematology policies and procedures to assure they are adequate to ensure the safety of individuals being transfused (See D5559).
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: Based on laboratory manager interview and preanalytic systems policies and procedures record review on September 17, 2024 at 10:30 am, the laboratory failed to establish written policies and procedures for the laboratory informations system (LIS) used to process patient specimens. Findings included: a. According to the laboratory manager and referenced in the laboratory's written protocol, the laboratory used an electronic laboratory informations system (LIS) to process patient specimens. The laboratory used the LIS to record and document the collection, receipt, and testing of patient specimens, and reporting of patient test results. b. The laboratory manager

	confirmed that the laboratory did not maintain a written policy and procedures for the laboratory's LIS. c. According to laboratory CLIA records, the laboratory performed approximately 99,999 patient test annually.
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 and interview with the laboratory manager on September 17, 2024 at 11:00 am, the laboratory failed to ensure microbiology culture media were not in use past the expiration date for three of three packages of Columbia Nalidixic Acid (CNA) culture media. Findings included: a. During a tour of the laboratory on 09 /17/2024 at 11:00 am, three packages of CNA culture media, lot number 140221, expiration 8/31/2024, were found in use for patient testing. b. Additional observations determined that the following patient specimens were cultured using this expired CNA culture media: 907036 and 907016. c. Interview on 09/17/2024 at 11:00 am with the laboratory manager confirmed the above findings.
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 hospital administrator and laboratory manager interviews and immunohematology record review on September 17, 2024 at 09:00 am, the laboratory, which issues fresh frozen plasma (FFP) for patient transfusion, failed to review all immunohematology policies and procedures to assure that they are adequate to ensure the safety of individuals being transfused with FFP. Findings included: a. On May 28, 2024, for patient #904678, a type and screen, and two units of packed red blood cells (pRBC) and two units of FFP were ordered by the patient's physician. i. Laboratory records indicated that the type and screen testing results showed that patient #904678 was AB positive with a negative antibody screen. ii. Laboratory records indicated that laboratory testing personnel set up two units of compatible A positive pRBC that were fully crossmatched for transfusion to patient #904678. That is, laboratory testing personnel compatibly crossmatched the two pRBC units using immediate spin and anti-human globulin (AHG) techniques. iii. Laboratory records indicated that laboratory testing personnel set up to units of O positive FFP for transfusion to patient

	#904678. NOTE: O positive FFP is incompatible for transfusion to AB positive patients. b. On May 28, 2024 at 19:10, laboratory records indicated that the laboratory issued the first unit of compatible A positive pRBC to nursing staff. This first unit of A positive pRBC unit was transfused to patient #904678 without incident. c. On May 28, 2024 at 20:34, laboratory records indicated that nursing staff #1, per laboratory written protocol, issued the second unit of compatible A positive pRBC to nursing staff #2. This second unit of A positive pRBC was transfused to patient #904678 without incident. Typically, it was the practice of the hospital to staff the laboratory with laboratory testing personnel from 06:00 to 18:00 daily. When laboratory personnel were not available, nursing staff were permitted to enter the laboratory using two nurses to issue blood products set up by laboratory testing personnel to themselves. d. On May 28, 2024 at 21:53, laboratory records indicated that nursing staff #2, per laboratory written protocol, issued the first unit of incompatible O positive FFP to nursing staff #1. This first unit of O positive FFP was transfused to patient #904678 without incident. e. On May 28, 2024 at 22:12, laboratory records indicated that nursing staff #2, per laboratory written protocol, issued the second unit of incompatible O positive FFP to nursing staff #1. This second unit of O positive FFP was transfused to patient #904678 without incident. f. On June 3, 2024, the laboratory manager was reviewing blood product transfusion records from the previous seven days and discovered that on May 28, 2024 two units of incompatible FFP was set up by laboratory testing personnel for transfusion to patient #904678. These two incompatible FFP units were issued on May 28, 2024, and transfused to patient #904678 without incident. g. Hospital records indicate that patient #904678 was transfer to a different facility on May 30, 2024. h. Although the laboratory maintained written policies and procedures for the issuance of blood products to nursing staff, these policies and procedures were not adequately reviewed and revised to ensure that hospital patients were transfused when blood products, including FFP, were compatible.
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 the number and severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing, Laboratory Director was not met. The laboratory director, high complexity testing, failed to ensure that: - methodologies selected have the capability of providing the quality of results required for patient care (see D6085); - laboratory personnel were following the laboratory's written protocols as required (see D6087); - proficiency testing samples are tested as required under subpart H of this part (see D6089); - all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action (see D6091); and, - policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills (See D6103).

D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on hospital administrator and laboratory manager interviews and immunohematology record review on September 17, 2024 at 09:00 am, the laboratory director, high complexity testing, failed to ensure that all methodologies selected have the capability of providing the quality of results required for patient care. The laboratory failed to review all immunohematology policies and procedures to assure that they are adequate to ensure the safety of individuals being transfused with FFP. See D5026.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on laboratory manager interview and immunohematology testing records review on September 17, 2024 at 09:45 am, the laboratory director, high complexity testing, failed to ensure that laboratory testing personnel were following the laboratory's procedures for the utilization of fresh frozen plasma (FFP) as required. See 6175.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on 2024 American Proficiency Institute (API) proficiency testing record review, and interview with the laboratory manager, the laboratory director, high complexity testing, failed to ensure that proficiency testing samples were tested as required under subpart H of this part. The laboratory failed to achieve successful proficiency testing participation for the analyte blood gas pH (see D2016).
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by:

	Based on American Proficiency Institute (API) proficiency testing (PT) record review and interview with the laboratory manager on September 17, 2024 at 12:10 pm, the laboratory director, high complexity testing, failed to ensure that all microbiology proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings included: a. A review of the laboratory's 2024 API PT performance records for microbiology proficiency testing events 1 and 2 showed the following tested analytes as ungraded: 2024 Event 1: 1. Microbiology: Blood Culture MIC Zone Diameter Value - All results = "Not Graded" 2. Microbiology: Blood Culture Susceptibility Interpretation - All results = "Not Graded" 3. Microbiology: CSF Culture MIC/Zone Diameter Value - All results = "Not Graded" 4. Microbiology: CSF Culture Susceptibility Interpretation - All results = "Not Graded" 5. Microbiology: Urine Culture MIC/Zone Diameter Value - All results = "Not Graded" 2024 Event 2: 1. Microbiology: Blood Culture MIC Zone Diameter Value - All results = 'Not Graded' 2. Microbiology: Blood Culture Susceptibility Interpretation - All results = "Not Graded" 3. Microbiology: Urine Culture MIC/Zone Diameter Value - All results = "Not Graded" b. The laboratory maintained no documentation to indicate that these ungraded proficiency testing results were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problem that require corrective action. c. Interview on 09/17/2024 at 12:10 pm with the laboratory manager confirmed the above findings.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on laboratory manager interview and competency policies and procedures record review on September 17, 2024 at 11:45 am, the laboratory director, high complexity testing, failed to ensure that procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings included: a. Laboratory records indicated that the laboratory routinely documented laboratory personnel competency in accordance with 42 CFR 493.1451(b)(9). b. However, although the laboratory maintained a written policy describing the laboratory's intent on establishing and maintaining laboratory personnel competency, the laboratory maintained no written procedures detailing the laboratory's competency procedure that included the items listed under 42 CFR 493.1451(b)(8). c. According to laboratory CLIA records, the laboratory performed approximately 99,999 patient test annually.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1)

	Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on laboratory manager interview and immunohematology testing records review on September 17, 2024 at 09:45 am, each individual performing high complexity testing failed to follow the laboratory's procedures for the utilization of fresh frozen plasma (FFP). Findings included: a. The laboratory written protocol titled "Blood Products: Fresh Frozen Plasma & Thawing" states: "The unit [of FFP] must be ABO compatible." In addition, this written protocol indicates that group AB patients are provided group AB FFP only. b. On May 28, 2024, two units of incompatible group O FFP was set up by laboratory testing personnel for transfusion to a patient whose ABO blood type was AB. These two incompatible FFP units were issued on May 28, 2024, and transfused to patient #904678, whose ABO blood type was AB, without incident. See D5559. c. On May 28, 2024, laboratory testing personnel, high complexity testing, failed to follow the laboratory's written protocol "Blood Products: Fresh Frozen Plasma & Thawing."