

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D0969131	(X3) Date Survey Completed 08/13/2025
Name of Provider or Supplier Fort Bayard Medical Center	Street Address, City, State 41 Fort Bayard Rd, Santa Clara, 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	A recertification survey was conducted on 08/13/2025. The facility was found to be not in compliance with the following standard-level deficiencies.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory personnel competency records and interview with the Technical Consultant (TC) the laboratory failed to establish and follow written policies and procedures to assess competency for one of one consultant. 1. A review of personnel competency records revealed there was no record of training or initial competency assessment for the TC. 2. During an interview conducted on 08/13/2025 at approximately 12:10 PM, the Technical Consultant confirmed the laboratory failed to establish written policies and procedures for competency assessment of the TC and there was no record of training or initial assessment for the TC.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test</p>

reports.

This STANDARD is not met as evidenced by:

I. Based on laboratory tour observation, review of the BD Vacutainer package inserts, the laboratory temperature/humidity log and interview with the Technical Consultant (TC), the laboratory failed to ensure the room temperature acceptable range was within the manufacturer's storage specifications for four of four vacutainer types. Findings included: 1. During a laboratory tour on 08/13/2025 at approximately 2:45 PM, the following BD Vacutainer tubes were observed in storage in a cupboard in room F-43: 4 ml K2EDTA Lot Number: B240934K Expiration Date: 2026-01-01 Quantity = 12 Trays of 50 Tubes Storage Temperature Requirement on Label = 4-25C 5 ml Serum Sep Clot Activator Lot Number: B2412343 Expiration Date: 2026-04-02 Quantity = 8 Trays of 50 Tubes Storage Temperature Requirement on Label = 4-25C 3.5 ml Coagulation Sodium Citrate 3.2% High Altitude Lot Number: B25023C6 Expiration Date: 2026-02-05 Quantity = 1 Tray of 50 Tubes Storage Temperature Requirement on Label = 4-25C 4 ml Sodium Floride Potassium Oxalate Lot Number: A25033CS Expiration Date: 2026-07-07 Quantity = 1 Tray of 50 Tubes Storage Temperature Requirement on Label = 4-25C 2. A review of the BD Vacutainer package inserts for K2EDTA, Serum Sep Clot Activator, Coagulation Sodium Citrate, and Sodium Floride/Potassium Oxalate revealed a storage temperature requirement of 4-25C (39-77F). 3. A review of the laboratory temperature/humidity log for room F-43 revealed an acceptable room temperature range of 18C to 30C with the following dates where the temperature exceeded 25C: Date Temperature 01/27/2025 25.4C 01/28/2025 25.6C 01/29/2025 25.9C 01/30/2025 25.4C 01/31/2025 25.3C 4. In an interview on 08/13/2025 at approximately 3:00 PM, the TC confirmed the mentioned findings above. II. Based on laboratory tour observation, review of Chemistry reagent and Hematology Quality Control (QC) package inserts, the laboratory temperature /humidity log and interview with the Technical Consultant (TC), the laboratory failed to define and store reagents and QC material in temperatures consistent with the manufacturer's specifications for 43 out of 68 days. 1. During a tour of the laboratory, room F-43, on 08/13/2025 at approximately 1:20 PM, a refrigerator (State of NMDOH #19534) was observed storing the following items: Medica EasyRA Chemistry Test Reagents Alkaline Phosphatase (ALP), 2 boxes Alanine Aminotransferase (ALT), 2 boxes Aspartate Aminotransferase (AST), 2 boxes Blood Urea Nitrogen (BUN), 2 boxes Total Calcium (CA), 2 boxes Creatinine (CREA), 2 boxes Glucose-Hexokinase (GLU-H), 1 box Total Bilirubin (TBIL), 2 boxes Hematology Quality Control Cell-Dyn 22 Plus Control 2 Trays 2. A review of the manufacturer's package inserts for all the reagents and QC mentioned above revealed the following statements: Medica EasyRA test reagents, "Unopened reagent is stable until the expiration date listed on the label if stored at 2-8C. Cell-Dyn 22 Plus Control, "Cell-Dyn 22 Plus Control ... tightly capped and stored at 2-10C (36-50F). Protect containers from overheating and freezing." 3. A review of the laboratory temperature /humidity log for room F-43 revealed an acceptable temperature range for the refrigerator (State of NMDOH #19534) was 2C to 15C. A three-month random sample review of the refrigerator temperature recordings revealed the following dates when the temperature was outside the manufacturer's specified temperature ranges: Date Temperature 01/06/2024 1C and 8.7C 01/08-11/2024 1C 01/13/2024 1C 01/17-20/2024 1C and 8.3C 01/22/2024 1C and 8.3C 01/23-24/2024 1C and 8.9C 01/26/2024 1C 01/27/2024 1C, 8.3C, and 9.3C 01/29-31/2024 1C and 9.3C 01/06-07/2025 8.7C 01/10/2025 No Temperature Recorded 01/14-17/2025 9.4C 01/21/2025 9.4C 01/22-24/2025 13.1C 01/28-29/2025 17.9C 01/30/2025 13.1C 01/31/2025 17.9C 05/01/2025 1C 05/08-09/2025 1C 05/13-14/2025 1C 05/16/2025 1C 05/22-23/2025 No

Temperature Recorded 05/28-29/2025 15.0C 4. In an interview on 08/13/2025 at approximately 1:30 PM, the TC confirmed the mentioned findings above.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on direct observation during a laboratory tour, review of laboratory temperature /humidity log, and interview with the Technical Consultant (TC), the laboratory failed to document corrective actions taken when the refrigerator temperature readings fell out of the laboratory's acceptable range for 29 out of 93 days. Findings included: 1. During a tour of the laboratory, room F-43, on 08/13/2025 at approximately 1:20 PM, a refrigerator (State of NMDOH #19534) was observed storing Chemistry test reagents and Hematology controls. 2. A four-month random sample review of the laboratory temperature/humidity log for room F-43 revealed there was no documentation of corrective actions taken when the refrigerator (State of NMDOH #19534) temperature readings were out of the laboratory's established acceptable range of 2C to 15C and when no temperatures were recorded for the following dates: Date Temperature 01/06/2024 1C 01/09/2024 1C 01/11/2024 1C 01/13/2024 1C 01/17-20/2024 1C 01/22/2024 1C 01/24/2024 1C 01/26-27/2024 1C 01/29-31/2024 1C 07/10/2024 1C and 16.9C 07/29-30/2024 1C 01/10/2025 No Temperature Recorded 01/29/2025 17.9C 01/31/2025 17.9C 05/01/2025 1C 05/08-09/2025 1C 05/13-14/2025 1C 05/16/2025 1C 05/22-23/2025 No Temperature Recorded 3. In an interview conducted on 08/13/2025 at 1:30 PM, the TC confirmed there was no documentation of corrective actions taken on days when the refrigerator (State NMDOH #19534) temperature was out of the laboratory's established acceptable range and when the refrigerator temperature was not recorded.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

(e)(12) 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 a review of laboratory personnel competency records, Laboratory Director responsibility policy, and an interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure policies and procedures were established to monitor and maintain competency for one of one laboratory consultant role. Findings included: 1. A review of laboratory personnel competency records revealed there were no records of training or initial competency assessment completed for the TC. 2. A review of the Laboratory Director's responsibilities revealed the statement, "Employ competent personnel," but there was no written requirement to establish and maintain a competency assessment policy and procedure for the laboratory TC. 3. During an

interview conducted on 08/13/2025 at approximately 12:10 PM, the Technical Consultant confirmed the Laboratory Director failed to establish policies and procedures for competency assessment for the Technical Consultant.