Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2232889	03/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Santa Fe County Adult Detention Facility	28 Camino Justicia, Santa Fe, 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	An onsite initial survey conducted at Santa Fe County Adult Detention Facility on 03/28/2024, found the laboratory to be out of compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with the following condition not met: D2000 - 493.801 Proficiency Testing enrollment and testing of samples D5400 - 493.1250 Analytic Systems
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the laboratory test menu and staff interview, the laboratory failed to enroll in a CMS-approved proficiency testing program (PT). Refer to D6015.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in

	493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and staff interview, it was revealed that the laboratory failed to meet analytical requirements, as evidence by: 1. The laboratory failed to have any approved procedure manuals for any aspect of patient testing. Refer to D5401 2. The laboratory failed to have an approved quality assessment procedure. Refer to D5793
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, the laboratory failed to provide approved procedure manuals for 1300 of 1300 patient tests in 2023. Findings included: 1. The laboratory was asked to provide approved procedure manuals available to staff for any aspect of the testing process. No procedures were provided. 2. A review of laboratory records revealed an annual volume of 1300 tests performed. 3. Interview on 03/28/2024 at 10:00 am with the technical consultant confirmed the findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (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. This STANDARD is not met as evidenced by: Based on direct observation, laboratory temperature logs, and staff interview, the laboratory failed to monitor proper storage conditions of CELL-DYN Emerald 22 reagents for 3 of 3 months, from January 2024 through March 2024. Findings included: 1. During a tour of the laboratory on 03/28/2024 at 1:30 pm, the following reagents were stored at room temperature: a. CELL-DYN Emerald 22 Easy Cleaner Lot number 2314109815 Expiration date 05/21/2024 Manufacturer's storage requirements = 15 Celsius (C) - 30 C b. CELL-DYN Emerald 22 Lyse Lot number 2332 Expiration date 08/06/2025 Manufacturer's storage requirements = 2 Celsius (C) - 25 C 2. A request was made for documentation of room temperatures being monitored from January 2024 through March 2024. No documentation was provided. 3. During an interview on 03/23/2024 at 1:30 pm, after review of the above records, the Technical Consultant number 1 confirmed the findings.

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, manufacturer's instructions, and interview, the laboratory failed to ensure laboratory supplies and reagents were not in use past expiration dates for 50 of 50 CAT Serum Sep Clot Activator tubes, 13 of 13 BD Vacutainer tubes, and 4 of 15 Piccolo Lipid Panel cartridges from April 2023 through March of 2024. Findings included: 1. During a tour of the laboratory area on 3/28/2024 at 1:40 pm the following expired items were found: - 50 CAT Serum Sep Clot Activator tubes: Lot number: B220333D, Expiration 09/10/2023 - 13 BD Vacutainer tubes: Lot number: 112315, Expiration 04/30/2023 - 4 Piccolo Lipid Panel cartridges: Lot number: 3122AA7, Expiration 03/14/2024 2. Interview on 03/28/2024 at 2:03 pm with the Technical Consultant number 1 confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the CELL-DYN Emerald 22 product user manual, Event Log Report, and interview, the laboratory failed to follow manufacturer's instructions for performing required weekly maintenance on the CELL-DYN Emerald 22 instrument for 14 of 16 weeks in 2023. Findings included: 1. Review of the CELL-DYN Emerald 22 product user manual under "Preventive Maintenance Schedule", listed bleach cleaning as a required weekly maintenance. 2. Review of the Event Log Report revealed the following weeks bleach cleaning was not performed: 1. 08/23/2023 - 08 /25/2023 2. 08/28/2023 - 09/01/2023 3. 09/04/2023 - 09/08/2023 4. 09/18/2023 - 09/22 /2023 5. 09/25/2023 - 09/29/2023 6. 10/02/2023 - 10/06/2023 7. 10/09/2023 - 10/13 /2023 8. 10/16/2023 - 10/20/2023 9. 10/23/2023 - 10/27/2023 10. 10/30/2023 - 11/03 /2023 11. 11/06/2023 - 11/10/2023 12. 11/13/2024 - 11/17/2023 13. 11/20/2023 - 11 /24/2023 14. 11/27/2023 - 12/01/2023 3. Interview on 03/28/2024 at 12:00 pm with the Technical Consultant number 1 confirmed the findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, the laboratory failed to provide an approved quality assessment procedure manual for 1300 of 1300 patient tests in 2023. Findings included: 1. The laboratory was asked to provide an approved quality assessment procedure manual. No procedure was provided. The laboratory was unable to provide evidence of monitoring and correction of problems to prevent their recurrence. 2. A review of laboratory records revealed an annual volume of 1300 tests performed. 3. Interview on 03/28/2024 at 10:00 am with the technical consultant confirmed the findings.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of laboratory test menu and staff interview, the laboratory director failed to ensure the laboratory was enrolled in an approved proficiency testing program for 11 of 11 months from May 2023 through March 2024. Findings included: 1. A review of the laboratory's test menu revealed the laboratory performed moderate complexity hematology testing using the CELL-DYN Emerald 22 instrument (serial number 1022-001767). 2. A request was made to the laboratory for documentation of enrollment in a CMS-approved PT program for regulated, non-waived hematology analytes. No documentation was provided. 3. During an interview on 03/28/2024 at 10: 00 am, after review of the above records, Technical Consultant number 1 (as listed on the CMS form 209) confirmed the findings.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the CMS form 209 and staff interview, the laboratory failed to provide education records for 1 of 11 Testing Personnel (Testing Personnel number 6) in 2023 and 2024. Findings included: 1. A review of the CMS Form 209 revealed

	Testing Personnel number 6 (as listed on the CMS form 209) performed moderate complexity testing. 2. The laboratory was asked to provide education records for the above personnel. No records were provided. 3. During an interview on 03/23/2024 at 2:30 pm, after review of the above records, Technical Consultant number 1 confirmed the findings.