Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2271428	03/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Las Cruces Women's Health, Organization	2918 Hillrise Dr, Las Cruces, 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 Las Cruces Women's Health, Organization on March 7, 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: 42 CFR, 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant 42 CFR, 493.1250 Condition: Analytic systems
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of CMS form 209, American Proficiency Institute (API) testing records, and staff interview, the laboratory failed to ensure proficiency testing (PT) samples were rotated among all testing personnel for 3 of 3 testing events in 2023. Findings included: 1. Review of the CMS form 209 revealed 5 Testing Personnel (TP) performed Rh testing in 2023. 2. Review of 2023 API Immunology / Immunohematology records revealed the following: a. Event 1 TP 4 tested samples RH 1 through RH 5 b. Event 2 TP 4 tested samples RH 6 through RH 10 c. Event 3 TP 4 tested samples RH 11 through RH 15 TP 3 tested samples RH 11 through RH 15 3. During an interview on 03/07/20024 at 11:30 am, after review of the above records, TP 4 (as listed on the CMS form 209) confirmed the findings. Word Key: CMS = Centers for Medicare and Medicaid Services Rh = Rhesus factor
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 Rh Typing Policy, AB Lab Sheets, and interview, the laboratory failed to document quality control being performed for Rh testing. Refer to D5551
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, review of Anti-D blend ALBAclone package insert, Rh (Rhesus factor) Typing Policy, AB Lab Sheet, and interview, the laboratory failed to document and monitor the temperature of their storage refrigerator, view box, and room temperature for 10 of 10 patients from October 2023 through November 2023 prior to patient testing. Findings included: 1. During a tour of the laboratory on 03/07 /2024 one box of Anti-D blend ALBAclone reagent (Lot#: V243986, Expiration: 05 /18/2024) was found in the storage refrigerator. 2. Review of the Anti-D blend ALBAclone package insert listed the storage conditions as 2Celsius(C) through 8Celsius(C). 3. Review of the Rh Typing Policy, under "Method", listed the following procedure steps for Rh typing. - "1. Verify room temperature is between 20-24 degrees Celsius (64.4-75.2 Fahrenheit (F))" - "3. Check temperature of refrigerator where reagents are stored. Should always be 2-8 degrees Celsius (35.6-45.4 degrees Fahrenheit)" - "10. ...incubate slide at 20-24 degrees Celsius (64.4-75.2 degrees Fahrenheit) ..." 4. Review of AB Lab Sheet, showed the following sections for temperature monitoring to be documented prior to patient testing. - Refrigerator Temperature - (2-8C) =(35.6-45.4F) - View Box Temperature - (20-24 CC) = (64.4-75.2F) - Room Temperature - (20-24 CC) = (64.4-75.2F) 5. Review of AB Lab Sheets from October 2023 through November of 2023 revealed no temperature monitoring was being documented prior to the following patients (P) being tested (see patient alias list): 1. P1 2. P2 3. P3 4. P4 5. P5 6. P6 7. P7 8. P8 9. P9 10. P10 6. Interview on 03/07/2024 at 11:50 am with testing personnel #4 confirmed the findings.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21

	CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (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 review of Rh (Rhesus factor) Typing Policy, AB Lab Sheets, and interview, the laboratory failed to document quality control being performed for Rh testing for 10 of 10 patients from October 2023 through November 2023. Finding included: 1. Review of the Rh Typing Policy, Under "Guidelines for Quality Control", stated "Each day a set of controls is tested and recorded on the daily log.". 2. Review of AB Lab Sheets from October 2023 through November of 2023 revealed QC was not documented as being performed for the following patients (P) tested (see patient alias list): 1. P1 2. P2 3. P3 4. P4 5. P5 6. P6 7. P7 8. P8 9. P9 10. P10 3. Interview on 03/07 /2024 at 12:10 pm with testing personnel #4 confirmed the findings
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of CMS 209 form, Rh Typing Policy, AB Lab Sheets, and interview the technical consultant failed to provide overall management and direction as evidence by: 1. The technical consultant failed to ensure competency assessments were performed twice within the first year of training for testing personnel. Refer to D6053. 2. The technical consultant failed to ensure quality control was being performed prior to patient testing. D6042
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of Rh Typing Policy, AB Lab Sheets, and interview, the technical consultant failed to ensure quality control was being performed for Rh (Rhesus factor) testing for 10 of 10 patients from October 2023 through November 2023. Refer to D5551
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of CMS 209 form, Rh (Rhesus factor) Typing Policy, and interview, the technical consultant failed to ensure a secondary or semi -annual evaluation was performed within the first year of training for 5 of 5 testing personnel in 2023. Findings included: 1. Review of the CMS 209 form revealed 5 testing personnel listed to perform Rh testing. 2. Review of the Rh Typing Policy, under "Guidelines for Personnel" stated, "Evaluations will be done annually". No mention of a semi-annual evaluation being done within the first year after initial training. 4. The laboratory was asked to provide documentation of semi-annual evaluations being done, none were provided. 5. Interview on 03/07/2024 at 11:15 am with testing personnel #4 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 review of CMS 209 form and interview, the laboratory failed to provide education records for 1 (TP #5) of 5 testing personnel (TP). Findings include: 1. Review of CMS 209 form listed 5 moderate complexity testing personnel. 2. Education records were requested for testing personnel #5. None were provided. 3. Interview on 03/06/2024 at 11:15 am with testing personnel #4 confirmed the findings.