

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number 32D2269356</p>	<p>(X3) Date Survey Completed 03/26/2024</p>
<p>Name of Provider or Supplier Alamo Womens Clinic Of Albuquerque</p>	<p>Street Address, City, State 10151 Montgomery Blvd Ne Bld3, Albuquerque, NM</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D2009</p>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute Proficiency Testing (PT) attestation form and interview, the laboratory failed to have the laboratory director or designee sign and date the PT attestation form for 1 of 3 events in 2023. Findings included: 1. Review of the American Proficiency Institute PT Attestation form for event 2 of 2023 revealed the laboratory director or designee did not sign or date the attestation form. 2. Interview on 3/26/2024 at 10:20 am with the laboratory director confirmed the findings.</p>
<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Rh Factor Procedure, Lab Environment Procedure, and interview, the laboratory director failed to sign off and date procedures for 2 of 2 procedures in 2023. Findings included: 1. Review of the Rh Factor Procedure revealed the laboratory director had not signed off on or dated the procedure. 2. Review of the Lab Environment Procedure revealed the laboratory director had not signed off on or</p>

	<p>dated the procedure. 3. The laboratory was asked to provide evidence the laboratory director had signed off on and dated relevant procedures. None were provided. 4. Interview on 3/26/2024 at 10:50 am with the laboratory director confirmed the findings.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Lab Environment policy, laboratory records, and interview, the laboratory failed to monitor and document room temperature for 2000 of 2000 patients tested in 2023. Findings Included: 1. Review of the Lab Environment policy under the "Procedure" section stated, "Inspect the AcuRite monitor each morning upon arriving at the laboratory facility. Document the temperature displayed in the environmental log, indicate if the room temperature is within expected range, sign or initial." 2. A review of laboratory records revealed and annual volume of 2000 patients for 2023 3. The laboratory was asked to provide documentation of the room temperature being monitored. None was provided. 4. Interview on 3/26/2024 at 10:50 am with the laboratory director confirmed the findings.</p>
<p>D5449</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Rh Factor procedure, Anti D - Control Log, and interview, the laboratory failed to run negative quality control for Rh (rhesus) factor testing for 20 of 25 testing days in March 2023 through May 2023. Findings included: 1. Review of the Rh Factor procedure revealed controls are to be run with every patient sample. 2. Review of the Anti D - Control Log showed the following dates where only positive controls were run, but no negative controls. 1. 3/21/2023 2. 3/22/2023 3. 3/23/2023 4. 3/24/2023 5. 3/25/2023 6. 3/27/2023 7. 3/28/2023 8. 3/30/2023 9. 3/31/2023 10. 4/1/2023 11. 4/02/2023 12. 4/03/2023 13. 4/04/2023 14. 5/18/2023 15. 5/19/2023 16. 5/20/2023 17. 5/22/2023 18. 5/23/2023 19. 5/24/2023 20. 5/25/2023 3. Interview on 3/26/2024 at 10:50 am with the laboratory director confirmed the findings.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of laboratory Rh testing records, competency records, and staff interview, the technical consultant failed to perform competency assessments for 2 of 3 testing personnel in 2022. Findings included: 1. Review of the laboratory's personnel records revealed the following Rh testing was performed from September 2022 through October 2022 (see attached staff and patient identifier lists). a. Staff #1 performed Rh testing for the following patients (P). September 2022: P1, P2 October 2022: P3 through P15 b. Staff #2 performed Rh testing for the following patients (P). September 2022: P16 through P18 October 2022: P19 through P41 2. A request was made to the laboratory for 2022 competency testing records for Staff #1 and Staff #2. No documentation was provided. 3. During an interview on 03/26/2024 at 10:30 am, after review of the above records, Staff #3 confirmed the findings. Word key: Rh = Rhesus Factor