

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0707695	(X3) Date Survey Completed 05/24/2023
Name of Provider or Supplier West End Womens Medical Group	Street Address, City, State 5915 Tyrone Rd, Reno, NV	
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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on May 24, 2023. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D2009	<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 the 2021 American Proficiency Institute (API) Rh Slide Test proficiency testing (PT) attestation forms and an interview with the laboratory manager, the director failed to sign the attestation forms documenting the routine integration of PT samples into the workload. Findings include: 1. Review of the 2021 API Rh Slide Test PT attestation forms revealed that the director failed to sign the attestation form from the third PT event of 2021. 2. An interview with the laboratory manager on May 24, 2023 at approximately 11:00 AM confirmed these findings. The laboratory performs approximately 100 immunohematology tests per year.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on observation and an interview with the laboratory manager, the laboratory failed to ensure that control materials were discarded by their expiration dates. Findings include: 1. Observation of the control materials available for use in the laboratory revealed that Rh positive and negative controls with an expiration date of 5/14/2023 were available for use. 2. The laboratory manager confirmed these findings and indicated the laboratory's procedure was to discard the controls 90 days after collection, in an interview on May 24, 2023, at approximately 11:30 AM. The laboratory performs approximately 100 immunohematology tests annually.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that 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 review of the laboratory's 2022 American Proficiency Institute (API) Rh Slide Test proficiency testing (PT) documentation and an interview with the laboratory manager, the director failed to ensure that all proficiency reports were reviewed. Findings include: 1. Review of the laboratory's 2022 API Rh Slide Test PT documentation revealed that the director failed to ensure that the PT report from the second PT event of 2022 was reviewed. 2. An interview with the laboratory manager on May 24, 2023 at approximately 11:00 AM confirmed these findings. The laboratory performs approximately 100 immunohematology tests per year.