

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0117904	(X3) Date Survey Completed 12/19/2024
Name of Provider or Supplier Cherry Hill Women's Center	Street Address, City, State 502 Kings Highway North, Cherry Hill, NJ	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with Laboratory Administrator (LA), Testing Personnel (TP) failed to sign attestation statements for ABO and Rh Factor Proficiency Testing events provided by American Association of Bioanalysts (AAB) from 5/26/23 to 12/11/24. The finding includes: 1. Review of PT records revealed TP did not sign the attestation statements for the following PT events for ABO and RH factor: a) 2nd event of 2023 b) 3rd event of 2023 c) 1st event of 2024 d) 2nd event of 2024 2. The LA confirmed on 12/19/24 at 11:45 am TP did not sign the attestation statements for the above listed PT events.</p>
D5551	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f)</p> <p>(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</p>

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 surveyor review of the Procedure Manual (PM) and interview with the Laboratory Administrator (LA), the laboratory lacked a procedure specifying when testing for weak D must be performed from 8/22/23 to 12/19/24. The finding includes: 1. The PM states "Slide techniques are not recommended for the detection of weak D or partial RhD samples. If the detection of antigens exhibiting weakened or modified expression is required, negative slide tests should be confirmed by tube testing." 2. The laboratory lacked a procedure specifying when testing for weak D must be performed. 3. The laboratory lacked a procedure to perform tube testing for the detection of weak D or partial RhD samples. 4. The LA confirmed on 12/19/24 at 11:38 am, the laboratory did not have the above procedures.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on surveyor review of Testing Personnel (TP) files and interview the Laboratory Administrator (LA), the Laboratory Director (LD) failed to ensure that all TP who performed Immunohematology testing had all education records from 9/1/24 to 12/19/24 . The findings include: 1. There were no education records for TP #4 as listed on the CMS 209 form. 2. The LA confirmed on 12/19/24 at 11:40 am, the LD failed to ensure TP had all education records.