

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0945040	(X3) Date Survey Completed 02/21/2024
Name of Provider or Supplier Four Women Health Services Llc	Street Address, City, State 150 Emory Street, Attleboro, MA	
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
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel (TP) competency and American Proficiency Institute (API) proficiency testing (PT) records and staff interview with the nurse manager (NM), the Technical Consultant (TC) failed to ensure TP had yearly competency assessment using all required elements to ensure their ability to perform test procedures accurately in the specialty of Immunohematology. Findings include: 1. Record review on 2/21/2024 of the laboratory's 2023 TP competency records for the 3 TP listed on the CMS form 209 revealed, TP1 did not have documented competency assessment in 2023 for Rh typing. 2. Record review on 2/21/2024 of the laboratory's 2023 API PT records revealed, TP1 participated in API PT Immunohematology 2023 Event 1. 3. Record review on 2/21/2024 of the laboratory's 'Testing of Proficiency Samples Policy' signed by the laboratory director (LD) on 10/23/2015," revealed, "As part of ongoing training and evaluation of staff that routinely perform moderate complexity testing, on patients, the laboratory LD and TC will perform initial, six month, and annual evaluations of staff." 4. Staff interview on 2/21/2024 at 10:00 AM with the NM: a. confirmed TP1 did not have documented Rh typing competency assessment in 2023 for 5 of 6 required elements and only performed PT. b. The NM stated, "The last paragraph of the 'Testing of Proficiency Samples Policy,' pertains to competency assessment of TP. The laboratory's competency assessment policy is contained in the 'Testing of Proficiency Samples Policy' in the last paragraph." 5. The laboratory performs 837 tests annually in the specialty of Immunohematology.</p>