

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0474552	(X3) Date Survey Completed 03/06/2025
Name of Provider or Supplier Saint Francis Lab - Warren Clinic Springer	Street Address, City, State 6160 South Yale Avenue, Tulsa, OK	
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	The recertification survey was performed on 03/05,06/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and the technical consultant at the conclusion of the survey.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the technical consultant, the laboratory failed to have a written policy to assess the competency of the clinical consultant, based on the job responsibilities as listed in Subpart M, for one of one persons. Findings include: (1) On 03/05/2025, a review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the clinical consultant, including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of March 2023 through the current date identified competencies, based on job responsibilities, had not been performed for one of one person listed as the clinical consultant after 06/26/2023; (3) The findings were reviewed with the technical consultant who stated on 03/05/2025 at 12:45 pm, a policy was not available and competencies had not been performed for the position as stated above.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing</p>

performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant, the laboratory failed to review and evaluate proficiency testing results for one of six Hematology/Coagulation proficiency testing events reviewed in 2023 and 2024. Findings include: (1) On 03/05/2025, a review of Hematology/Coagulation proficiency testing records for 2023 (first, second, and third events) and 2024 (first, second and third events) identified the following ungraded results tht had not been evaluated by the laboratory: (a) API Hematology/Coagulation 2023 third event (i) Educational blood cell identification (aa) Sample DIF-03 (ii) Immature Cells - Reported Result 70, expected results 0 - 1; (iii) Lymphocytes - Reported Result 9, expected results 44 - 90; (iii) Neutrophils - Reported Result 21, expected results 12 - 38; (iv) Platelet estimate - Reported Result normal, expected result Decreased. (2) There was no evidence in the records to prove the reported results had been identified and addressed; (3) The records were reviewed with the technical consultant who stated on 03/05/2025 at 01:40 pm, the results that did not agree with the expected results had not been identified and addressed.

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a review of records, policies and procedures, and interview with the technical consultant and testing person #1, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly during the review period of March 2023 through the current date. Finding include: (1) On 03/05/2025 at 11:00 am, the testing person #1 stated the following: (a) Urine sediment examinations were performed; (b) The specimens were processed in the Horizon 642 VES centrifuge at a speed of 1500 rpm (revolutions per minute) for 5 minutes. (2) A review of the centrifuge function check policy titled, "Centrifuge Function Check Procedure" stated, "To ensure the centrifuge is functioning properly in an acceptable standardized manner, its speed and timer is being checked annually"; (3) A review of centrifuge records from 03/01/2023 through the current date identified the speed and timer checks had not been documented as performed prior to 06/10/2024; (4) The records were reviewed with the technical consultant who stated on 03/05/2025 at 02:25 pm, the laboratory had not followed their policy.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for two of 11 testing persons during the review period of March 2023 through the current date. Findings include: (1) On 03/05/2025, a review of personnel records for 11 persons performing moderate complexity testing during 2023 and to date in 2025 identified no evidence an annual competency evaluation had been performed for two 11 testing persons as follows: (a) Testing Person #5 - Prior to 10/23/2024 (b) Testing Person #11 - Prior to 10/14/2024 (2) The records were reviewed with the technical consultant who stated on 03/05/2025 at 01: 55 pm, the annual evaluations had not been documented as performed.