Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2089973	02/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Saint Francis Lab-Tulsa Hills	7858 S Olympia Ave, 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 02/10/2026 through 02/11/2026. Standard-level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the technical consultant, the laboratory failed to follow their written policy for verifying the stated values of control materials prior to implementation for three of six lot numbers used during the review period of 09/06/2025 through the current date. Findings include: (1) On 02/10/2026 at 11:19 am, the technical consultant stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Beckman Coulter DxH 520 analyzer; (b) Three levels of Beckman Coulter 500 Series control materials were tested each eight hours of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of the policy titled, "Saint Francis Outreach Laboratory - New Lot Quality Control Ranges Beckman Coulter" revealed the new lot of quality control materials were to be analyzed twice a day for at least three days to establish correlation prior to the old lot expiration date. (3) A review of records for six lot numbers used from 09/06/2025 through the current date identified no evidence the laboratory followed their policy for verifying three of six lot numbers prior to implementation as follows: (a) Abnormal low level - Lot #352618111, Normal level - Lot #362618112, and Abnormal high level - Lot #372618113 were used from 11/06 /2025 through the current date (all tested one time on 11/06/2025). (4) The findings

	were reviewed with the technical consultant who stated on 02/11/2026 at 10:00 am, the laboratory did not follow their written policy.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to perform positive and negative control materials for one of one day of patient mononucleosis testing reviewed from January 2026 through the current date. Findings include: (1) On 02/10/2026 at 01:50 pm, the technical consultant stated the laboratory performed qualitative mononucleosis testing using the Remel Colorslide II test kit on serum samples; (2) A review of QC (Quality Control) and patient testing records for testing performed from January through the current date identified positive and negative QC materials had not been performed for one of one day of patient testing (01/04/2026); (3) The records were reviewed with the technical consultant who stated on 02/10/2026 at 01:54 pm, QC materials had not been performed each day of patient testing as stated above.