

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2089973	(X3) Date Survey Completed 10/29/2019
Name of Provider or Supplier Saint Francis Lab-Tulsa Hills	Street Address, City, State 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 10/29/2019. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant, testing person #1, and the laboratory director at the conclusion of the survey.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to maintain records for 1 of 7 quality control lot numbers at least 2 years. Findings include: (1) At the beginning of the survey, the technical consultant stated the following to the surveyor: (a) Hemogram (i.e WBC (White Blood count), RBC (Red Blood count), Hemoglobin, Hematocrit. MCV (Mean Corpuscular Volume), MCHC (Mean Corpuscular Hemoglobin Concentration), RDW (Red Cell Distribution Width), and Platelet count) testing was performed using the Abbott Emerald analyzer; (b) Three levels (Low, Normal, and High) of Cell Dyn 18 Plus quality control (QC) materials were analyzed each 8 hours of patient testing. (2) The surveyor reviewed QC records from 11/01/18 through the date of the survey and identified 7 lot numbers of QC materials had been utilized during the review period. The surveyor could not locate the manufacturer's assay value sheets for 1 of the 7 lot numbers (Lot #9014, used from 02/08/19-04/30/19); (3) The surveyor asked the technical consultant if the manufacturer's assay value sheet for the QC lot number listed above was available for review. The technical consultant stated to the surveyor</p>

the QC assay sheet could not be located; (4) The surveyor reviewed the findings with the technical consultant and explained that all QC records must be maintained at least 2 years.

D5479

CONTROL PROCEDURES

CFR(s): 493.1256(e)(5)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to follow the manufacturer's specifications for establishing ranges for 1 of 7 quality control lot numbers. Findings include: (1) At the beginning of the survey, the technical consultant stated the following to the surveyor: (a) Hemogram (i.e. WBC (White Blood count), RBC (Red Blood count), Hemoglobin, Hematocrit. MCV (Mean Corpuscular Volume), MCHC (Mean Corpuscular Hemoglobin Concentration), RDW (Red Cell Distribution Width), and Platelet count) testing was performed on the Abbott Emerald analyzer; (b) Three levels (Low, Normal, and High) of Cell Dyn 18 Plus quality control (QC) materials were analyzed each 8 hours of patient testing. (2) The surveyor reviewed the manufacturer's assay sheet for the control materials. The assay sheet designated a mean range for each analyte listed above and stated, "The MEAN RANGE does not represent standard deviations (SD)." The range was provided only as a guide to be used by the laboratory for establishing its own mean for each analyte; (3) The surveyor then reviewed the laboratory's QC records from 11/01/18 through the date of the survey. The surveyor identified 7 QC lot numbers had been used during the review period. For 1 of the 7 QC lot numbers reviewed (Lot #8295-used from 11/13/18 to 02/08/19), the laboratory utilized the mean and range of means listed on the manufacturer's assay sheet as the acceptable QC limits for each analyte; (4) The surveyor reviewed the findings with the technical consultant who stated to the surveyor the laboratory had used the manufacturer's assay sheet mean and range of means as the acceptable QC limits for the lot number listed above and failed to establish its own QC mean and limits, as specified by the manufacturer.