

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0474552	(X3) Date Survey Completed 03/09/2021
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 March 08, 2021 through March 09, 2021. The findings were reviewed with the technical supervisor and testing person #14 during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, patient reports, and interview with the technical supervisor and testing person #14, the laboratory failed to follow the manufacturer's instructions for waived testing for 5 of 10 reports. Findings include: (1) On 03/09/2021, the technical supervisor and testing person #14 stated the following at 10:00 am to the surveyor: (a) COVID-19 testing was performed on 4 Abbott ID-NOW analyzers (serial number C345D91C, serial number F543D91C, serial number G857D91C, and serial number CF3ED91C); (b) Patient specimens were routinely collected in the urgent care patient rooms and transported to the laboratory. (2) The surveyor then reviewed the manufacturer's instructions which stated, "ID NOW (Trademark) COVID-19 is a rapid (13 minutes or less), instrument-based isothermal test for the qualitative detection and diagnosis of SARS-CoV-2 from nasal, nasopharyngeal and throat swabs." (3) The surveyor reviewed 10 patient COVID-19 nasopharyngeal specimen reports received and tested in the laboratory and identified the following: (a) For 3 of the 10 reports, the time of collection was the same as the time of receipt into the laboratory: (i) Testing performed 11/24/2020- The collection and laboratory receipt time was 9:47 am; (ii) Testing performed 11/24/2020- The collection and laboratory receipt time was 10:14 am; (iii) Testing performed 12/18</p>

/2020- The collection and laboratory receipt time was 08:10 am. (b) For 2 of 10 reports, the time of receipt into the laboratory was the same or within one minute of the verified results: (i) Testing performed 11/19/2020 - The receipt and verified time was 04:20 pm. (ii) Testing performed 12/21/2020 - The receipt time was 03:09 pm and verified time was 03:10 pm. (4) The surveyor reviewed the findings with the technical supervisor and testing person #14 who stated on 03/09/2021 at 11:10 am the collection time, receipt time and verified result time were not accurate as indicated above.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the technical supervisor and testing person #14, the laboratory failed to perform quality control as stated in the IQCP for 3 of 24 months. Findings include: (1) On 03/08/2021, the technical supervisor and testing person #14 stated at 02:15 pm the following to the surveyor: (a) Three Abbott iSTAT 1 analyzers (serial number 304488, serial number 383654, and serial number 347704), were used to perform BNP (Brain Natriuretic Peptide) and Troponin I testing; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system and external QC (quality control) was performed monthly and with new lot numbers of cartridges. (2) The surveyor reviewed QC records from January 2019 through January 2021 and identified that QC had not been tested monthly, as stated in the IQCP. QC had not been tested between: (a) BNP (i) 10/25/2019 and 12/13/2019 (ii) 11/25/2020 and 01/22/021 (b) Troponin I (i) 11/13/2020 and 01/07/2021 (3) The surveyor reviewed the records with the technical supervisor and testing person #14, and asked if QC had been performed monthly. Both stated to the surveyor QC on 03/09/2021 at 11:30 am QC had not been performed monthly as indicated above.

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 supervisor, testing person #7, and testing person #14, the laboratory failed to follow the manufacturer's quality control instructions. Findings include: (1) On 03/09/2021, at 10:15 am, the technical supervisor and testing person #14 stated the

following to the surveyor: (a) CBC (Complete Blood Count) testing was performed using the Abbott Cell Dyn Ruby analyzer; (b) Three levels of Cell-Dyn 26 Plus quality control (QC) materials were performed each day of patient testing. (2) On 03/09/2021, the surveyor reviewed the following manufacturer's instructions: (a) The QC package insert stated, "The mean range does not represent standard deviations (SD)"; (b) Product information sheet provided by the manufacturer titled, "Establishing Quality Control Means and Limits" provided instructions to the laboratory for establishing laboratory means and limits for new lot numbers of control materials. (3) The surveyor then reviewed QC records for testing performed from January 10, 2020 through December 31, 2020. It was identified the laboratory had used the package insert ranges, instead of laboratory established ranges, to determine acceptability of QC results for 2 of 7 lot numbers: (a) Low, Normal, and High control lot #0055 used from 03/11/2020 through 03/29/2020 (b) Low, Normal, and High control lot #0083 used from 05/01/2020 through 05/26/2020 (4) The surveyor reviewed the findings with the technical supervisor, testing person #7, and testing person #14 who stated on 03/09/2021 at 03:00 pm the laboratory had used the package insert ranges instead of laboratory established ranges for determining acceptability of QC results as indicated above.