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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 37D2089973 | (X3) Date Survey Completed 11/22/2021 |
| 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 on 11/22/2021. The findings were reviewed with the technical consultant at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited. |
| D5445 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with testing person #6 and the technical consultant the laboratory failed to follow written quality control policies for 3 of 3 test systems. Findings include: (1) On 11/22/2021 at 09:45 am, testing person #6 stated the following to the surveyor: (a) PT/INR (Prothrombin Time /International Normalized Ratio) testing was performed in the laboratory using the PT /INR cartridge and iSTAT 1 analyzer (serial number 373929); (b) Troponin testing was performed in the laboratory using the CTnl cartridge and iSTAT 1 analyzer (serial number 373929); (c) BNP (B-type Natriuretic Peptide) testing was performed in the laboratory using the BNP cartridge and iSTAT 1 analyzer (serial number 373929); (d) An IQCP (Individualized Quality Control Plan) had been developed for the above test systems. (2) The surveyor reviewed the IQCP that had been developed for each test system. The QCP (Quality Control Plan) portion of the IQCP required 2 levels of external quality control materials be tested once every 30 days; (3) The</p> |

surveyor reviewed QC (quality control) records for 22 months (January 2020 through October 2021) and identified the laboratory failed to follow the written QCP of performing quality control testing every 30 days. Quality control testing had not been performed as follows: (a) PT/INR (i) Between 03/06/2020 and 05/09/2020 (b) Troponin (i) Between 03/06/2020 and 05/09/2020 (c) BNP (i) Between 03/06/2020 and 05/09/2020 (ii) Between 03/25/2021 and 05/06/2021 (4) The findings were reviewed with the technical consultant who stated on 11/22/2021 at 12:45 pm, the laboratory had not performed quality control testing as required by the QCP.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (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 testing person #6 and the technical consultant, the laboratory failed to perform negative and positive control materials 2 of 2 days of patient qualitative serum pregnancy testing; and failed perform a negative and positive control materials 2 of 10 days of patient mononucleosis testing. Findings include: (1) On 11/22/2021 at 09:45 am, testing person #6 stated the following to the surveyor: (a) The laboratory performed qualitative serum pregnancy testing using the Beckman Icon 25 HCG test kit: (i) Positive and negative serum quality control (QC) materials were performed each day of patient testing. (b) The laboratory performed mononucleosis testing using the Remel Colorslide II test kit: (i) Positive and negative serum QC materials were performed each day of patient testing. (2) The surveyor reviewed QC and patient testing records between 10/03/2021 through 10/31/2021. The review showed that negative and positive QC materials had not been performed as follows: (a) Beckman Icon 25 HCG (i) For 2 of 2 days of patient testing reviewed. The specific days were 10/11/2021 and 10/27/201. (b) Remel Colorslide II (i) For 2 of 10 days of patient testing reviewed. The specific days were 10/06/2021 and 10/14 /2021. (3) The surveyor reviewed the records with the technical consultant, who stated on 11/22/2021 at 02:25 pm, negative and positive QC materials had not been performed as indicated above.