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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 22D0081111 | (X3) Date Survey Completed 07/19/2023 |
| Name of Provider or Supplier Franey Medical Laboratory | Street Address, City, State 52 Mercantile Way, Mashpee, MA | |
| 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 | A CLIA recertification survey was conducted for the Franey Medical Laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. |
| D5439 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD) and General Supervisor (GS) on 7/19/2023, the laboratory failed to perform calibration</p> |

verifications every six months or, as appropriate, as evidenced by the following: The surveyor reviewed the quality control records for calendar years 2021, 2022, and 2023. The review revealed that calibration verifications of at least three points were not performed once every six months for three (3) out of three (3) analytes requiring calibration verification on the Beckman Coulter AU680 analyzer. Six-month calibration verifications for Ethyl Alcohol, Specific Gravity, and Urine Creatinine were performed on 8/24/2021 and 1/28/2022. The calibration verifications were not performed every six months. The LD and GS confirmed in an interview on 7/19/2023 at 12:00 P.M. that calibration verifications had not been performed every six months for three (3) out of three (3) analytes requiring calibration verification. The laboratory performs 137,800 toxicology tests, 13,000 urinalysis tests, and 26,000 routine chemistry tests annually. This is a repeat deficiency. .

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Laboratory Director (LD) and General Supervisor (GS) on 7/19/2023, the Technical Supervisor (TS) failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: The surveyor asked to review the personnel competency records. The review revealed that a semiannual competency evaluation was not performed and documented for the (1) out of one (1) Testing Person (TP) performing high complexity toxicology testing. The LD and GS confirmed in an interview on 7/19/2023 at 10:48 AM that the TS failed to perform and document a semiannual competency evaluation for one (1) out of one (1) TP in the first year of performing high complexity toxicology testing. The laboratory performs 137,800 toxicology tests annually. .

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Laboratory Director (LD) and General Supervisor (GS) on 7/19/2023, the Technical Supervisor (TS) failed to evaluate and document the performance of individuals responsible for high complexity testing at least annually, after the first year the individual tested patient specimens as evidenced by the following: The surveyor asked to review the personnel competency records. The review revealed that a annual competency evaluation was not performed and documented for one (1) out of one (1) Testing Person (TP)

performing high complexity toxicology testing. The LD and GS confirmed in an interview on 7/19/2023 at 10:48 AM that the TS failed to perform and document an annual competency evaluation for one (1) out of one (1) TP in 2022 after the first year of performing high complexity toxicology testing. The laboratory performs 137,800 toxicology tests annually. .