| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 22D0081111 | 07/16/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Franey Medical Laboratory | 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 |
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| **D0000** | A CLIA recertification survey was conducted for the Franey Medical Lab, Inc laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. |
| **D2003** | ENROLLMENT<br>CFR(s): 493.801(a)(2)(ii)<br><br>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview on 7/16/21 with the technical supervisor (TS) and laboratory director (LD), the laboratory failed to establish and maintain the accuracy of its testing procedures in accordance with 493.1236(c)(1). Findings include: The surveyor reviewed proficiency testing (PT) records from calendar years 2019, 2020, and 2021on 7/16/21. The review revealed that the laboratory failed to establish and maintain accuracy of Ethylglucuronide (EtG) on the Olympus AU680 analyzer. The TS and LD confirmed in an interview on 7/16/21 at 11:15 AM that the laboratory failed to establish and maintain accuracy of EtG on the Olympus AU680 urine drug screen analyzer. The laboratory performs approximately 3,353 EtG screens annually. . |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>. Based on record review and interview on 7/16/21 with the technical supervisor (TS) and laboratory director (LD), the laboratory failed to follow policies and procedures in place for all tests, assays, and examinations performed by the laboratory as evidenced by the following: The surveyor reviewed the "Basic Operation of LC-MS Instruments" standard operating procedure (SOP) on 7/16/21. The SOP states "Maintenance: Semiannually (or on need basis): Preventative maintenance (P.M.) will be performed by Waters field service engineers under the terms of our service contracts." The surveyor asked to review the terms of their service contract with Waters for preventative maintenance (PM). The TS and LD were not able to produce a service contract. The surveyor toured the laboratory space on 7/16/21. The surveyor observed 4 Liquid Chromatography-Mass Spectrometers (LC/MS) utilized for urine toxicology confirmation testing. Each LC/MS was equipped with a sticker indicating when the next PM is due. 3 out of 4 LC/MS were overdue for their PM indicating "Next PM due" 8/2020, 9/2020, and 10/2020. The TS and LD confirmed in an interview on 7/16/21 at 2 PM that PMs on 3 out of 4 LC/MS were overdue and the laboratory did not have a current service contract per their SOP. . |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview on 7/16/21 with the technical consultant (TC) and laboratory director (LD), , the laboratory failed to perform calibration verifications as appropriate as evidenced by the following: The surveyor reviewed quality control (QC) records for calendar years 2019, 2020, and 2021 on 7/16/21. The review revealed that calibration verifications of at least 3 points were not performed every six months for specific gravity, urine creatinine, and alcohol on the Olympus |

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| | AU 680 urine drug screen analyzer. The TC and LD confirmed through interview on 7 /16/21 at 11:45 AM that calibration verifications of at least 3 points had not been performed at least once every six months. This is a repeat deficiency. . |
| **D6084** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(2)<br><br>The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation, record review, and interview on 7/16/21 with the technical supervisor (TS) and laboratory director (LD), the LD failed to ensure that the physical plant and environmental conditions provided a safe environment in which employees were protected from physical, chemical, and biological hazards as evidenced by the following: The surveyor toured the laboratory space on 7/16/21. The surveyor observed maintenance documentation for the eye wash station. The documentation stated "Need to check each week." The latest documented eye wash check was 3/9/21. The TS stated that the person who checked the eye wash each week is no longer employed at the laboratory and no one took over the responsibility. The TS and LD confirmed in an interview on 7/16/21 at 1:30 PM that LD failed to ensure a safe environment. . |