Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0081111	11/19/2018
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
D0000	A CLIA recertification survey was conducted for Franey Medical Laboratories, Inc. pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) 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) This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish and maintain the accuracy of its testing procedures in accordance with 493.1236(c)(1). Findings include: Review of proficiency testing records from calendar years 2017 and 2018 revealed that the laboratory failed to establish and maintain accuracy of Liquid Chromatography Mass Spectrometery (LCMS) urine confirmation toxicology testing for 2018. Interview with the technical supervisor and laboratory director on 11/19/18 at 10:30 AM confirmed that the laboratory failed to establish and maintain accuracy of LCMS urine toxicology confirmation testing for 2018. The laboratory performs 223,317 LCMS urine toxicology confirmation tests per year.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in

	493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the laboratory failed to meet the the applicable analytic systems requirements in 493.1251 through 493.1283 as evidenced by the following: 1. The laboratory failed to perform testing following the manufacturer's instructions for prothrombin time (PT) testing by not updating the International Sensitivity Index (ISI) with each new lot of PT reagent. (Refer to D5411) 2. The laboratory failed to provide validation studies for the Sysmex CA 620 coagulation analyzer after it was moved. (Refer to D5421)
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation and record review, the laboratory failed to perform testing following the manufacturer's instructions as evidenced by the following: The manufacturer of the Sysmex CA 620 coagulation analyzer indicates that the International Sensitivity Index (ISI) value be changed whenever a new lot of prothrombin time (PT) reagent is used. The technical consultant indicated that the analyzer was discontinued and moved in June 2018 until September 10, 2018. The laboratory began using reagent lot number 549708 on 9/10/18. The ISI value listed on the package insert for the CA 600 system was 1.00. The surveyor observed that the analyzer indicated a lot number of 539305 with an ISI of 0.99. The technical consultant and laboratory director confirmed through interview on 11/19/18 at 4:00 PM that the incorrect ISI value was entered into the analyzer. The laboratory director handed the surveyor a letter stated that the laboratory would cease PT testing effective 11/19/18. Twelve (12) PT tests were performed between 9/10/18 and 11/19/18.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer of a new test system before reporting patient test results as evidenced by the following: The technical consultant indicated that the Sysmex CA 620 coagulation

	analyzer was discontinued and moved in June 2018. The analyzer was moved back into the laboratory and used for patient testing starting 9/10/18. Record review revealed that the laboratory did not perform validation studies prior to patient testing. The technical consultant confirmed through interview on 11/19/18 at 4:00 PM that the laboratory did not demonstrate the Sysmex CA 620 can obtain performance specifications comparable to those established by the manufacturer for prothrombin time (PT) and partial prothrombin time (PTT) prior to reporting patient test results. The laboratory director handed the surveyor a letter stated that the laboratory would cease PT and PTT testing effective 11/19/18. Twelve (12) PT and two (2) PTT tests were performed between 9/10/18 and 11/19/18.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform calibration verifications as appropriate as evidenced by the following: Quality control (QC) record review for calendar years 2017 and 2018 revealed that calibration verifications of at least 3 points were not performed every six months for twenty (20) out of twenty (20) routine chemistry analytes on the Olympus AU 680e. Calibration verifications were performed on 8/15/17 and 8/16/18. The technical consultant and laboratory director interviewed on 11/19/18 at 2:00 PM confirmed that calibration verifications of at least 3 points had not been performed at least once every six months. The laboratory performs a total of 106,869 routine chemistry tests annually.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5)

	Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to have a final report that included the address of the laboratory location where the testing was performed as evidenced by the following: The laboratory unitilizes LabCorp as their reference laboratory. The technical supervisor stated the laboratory results from LabCorp are manually enetered into the laboratory's Orchard laboratory information system (LIS). Record review revealed that the final laboratory reports generated in the LIS do not contain the address of the laboratory location where the testing was performed. The final report indicated "Test performed at LabCorp" as the test performing site. The technical superisor and laboratory director confrimed through interview on 11/19/18 at 5:30 PM that the final test report did not indicate the address of the laboratory where the testing was performed.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant and laboratory director, the laboratory director failed to ensure documentation of proficiency testing review as evidenced by the following: Review of proficiency testing (PT) records for calendar years 2017 and 2018 revealed that the laboratory director did not maintain PT reports received from American Association of Bioanalysts (AAB) and documenation of review by the appropriate staff for the following testing events: Chemistry Testing Events 1 and 2 for 2017 Chemistry Testing Event 2 for 2018 Non Chemistry Testing Events 1 and 2 for 2017 Non Chemistry Testing Events 1 and 2 for 2018 The technical consultant confirmed through interview on 11/19/18 at 10:30 AM that the PT reports from AAB were emailed to the former laboratory director for review and were not available at the time of the survey.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by:

	Based on record review and interview with the technical consultant and laboratory director, the laboratory director failed to ensure documentation of proficiency testing review as evidenced by the following: Review of proficiency testing (PT) records from RTI International for calendar years 2017 and 2018 revealed that the laboratory did not maintain PT reports and documentation of review for oral fluid toxicology confirmation testing by the appropriate staff. 1. The laboratory director did not maintain PT reports for Event 3 from 2017 and Event 2 from 2018. 2. The laboratory director did not document review of PT results from Event 1 in 2018. The technical consultant confirmed through interview on 11/19/18 at 10:30 AM that the PT reports from RTI International were emailed to the former laboratory director for review and were not available at the time of the survey.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview, the technical supervisor failed to evaluate the competency of testing personnel and assuring that the staff maintain their competency to perform the test procedures promptly, accurately, and proficiently as evidenced by the following: A review of personnel records revealed no competency assessments were performed for two (2) out of three (3) testing personnel performing high complexity testing for calendar year 2018. The last competency assessments were performed on 5/11/17. The technical supervisor confirmed through interview on 11/19 /18 at 12:00PM that no competency evaluations were conducted in 2018 to ensure procedures are performed promptly, accurately, and proficiently.