

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0218865	(X3) Date Survey Completed 11/04/2021
Name of Provider or Supplier Friends Medical Laboratory	Street Address, City, State 5820 Southwestern Boulevard, Baltimore, MD	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the daily "LC/MS [Liquid Chromatography Mass Spectrometry] Run Code Batch Summary Form", Levy-Jennings (L-J) quality control (QC) graphs, "Weekly/Monthly QC Review Acknowledgement Form", procedure manuals, and interview with the general supervisor #1 (GS1) and testing person #1 (TP1), the previous laboratory director failed to provide written instructions for preparing the in-house "trailing" QC materials, validating the in-house "trailing" QC materials along with the expired QC materials, evaluation of the in-house "trailing" and assayed QC materials and corrective actions to be taken when failures occurred. Findings: 1. The</p>

"LC/MS Run Code Batch Summary Form" from 08/11/2021 was reviewed. The form included documentation of the results for the unextracted calibrator, six calibrators, three levels of QC (QC1, QC2, and QC3), morphine glucuronide (hydrolysis QC), blank, blind internal proficiency sample, patient samples, and two trailing QC labeled "Trailing QC Low" and "Trailing QC Cutoff." On 10/15/2021 at 9:10 AM, TP1 confirmed that the specimens labeled QC1, QC2, and QC3 were the expired QC materials and the specimens labeled "Trailing QC Low" and "Trailing QC Cutoff" were the QC materials prepared in-house. TP1 also stated that the laboratory did not monitor the "trailing" QC results for acceptability by printing L-J QC graphs. 2. Via a phone conversation on 10/15/2021 at 9:10 AM, TP1 confirmed that the procedure manual did not include step-by-step instructions for preparing the in-house "trailing" QC materials, validating the in-house "trailing" QC materials along with the expired assayed QC materials, evaluating the in-house "trailing" and assayed QC materials and corrective actions to be taken when failures occurred. 3. The monthly L-J QC graphs for January through March 2021 were reviewed. The graphs did not differentiate between the expired QC and in-house QC materials that were in use for patient testing. On 10/15/2021 at 9:10 AM, TP1 confirmed that the monthly L-J graphs that were printed were for the expired QC materials and the laboratory did not monitor the "trailing" QC results for acceptability. 4. The "Weekly/Monthly QC Review Acknowledgement Form" summary form is used to evaluate the Shimadzu 8040 Liquid Chromatography Mass Spectrometry (LC/MS/MS), Quantis LC/MS/MS, and GC [gas chromatography]/MS analyzers. The form required the reviewer to enter an "X" in the appropriate box to indicate that 10 of the QC data points were above or below the mean. 5. On 11/04/2021 at 9:20 AM, the GS1 explained that the two untitled worksheets along with the "Weekly/Monthly QC Review Acknowledgement Form" were trend analysis worksheets. The trend analysis worksheets are a summary of the 8040, Quantis and GC/MS toxicology analyzers. Specific tests are performed on each analyzer. a) 8040 assays are- OPT, 6-MAM, BENZO, PCP, AMPH, GABA, WELLBN, NALT, Cocaine, Cotinine, and SOMA/MEPRO. b) Quantis assays are- ETS/ ETG, Methadone, Fentanyl, and Buprenorphine c) GC/MS assays are- THC, BARBITURATES, and Meperidine 6. The trending analysis worksheet does not include a corresponding procedure that identifies the worksheet and the purpose for the documentation of the information. 7. During a phone interview on 11/04/2021 at 9:20 AM, GS1 confirmed that the procedure manual did not include written and approved procedures for using the trending analysis worksheet.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of the quality control (QC) records, "LC/MS [Liquid Chromatography Mass Spectrometry] Run Code Batch Summary Forms", "Weekly/Monthly QC Review Acknowledgement Form", monthly trending analysis worksheet, procedure manuals, and interview with the general supervisor #1 (GS1) and testing person #1 (TP1), the previous laboratory director (LD) failed to provide the GS1 and TP1 with an established QC program to follow to ensure the quality of the patient test results when the QC materials in use had expired and when QC values had 10 data points above or below the established mean. Findings: 1. According to the

GS1, the previous LD recognized that the laboratory had an excessive amount of QC materials that were going to expire on 10/20/2020. In October 2020 the LD provided the GS1 and TP1 with electronic instructions for the preparation of two levels of in-house QC materials. The in-house QC materials, identified as "trailing QC" (Trailing QC Low" and "Trailing QC Cutoff") on the "LC/MS Run Code Batch Summary Forms", were tested along with the expired QC (QC1, QC2 and QC3). 2. Via a phone conversation on 10/15/2021 at 9:10 AM, TP1 confirmed that there were no written and approved procedures to follow for evaluating the expired QC along with the "trailing QC." The LD failed to ensure that the QC program included the evaluation of the "trailing QC" along with the expired QC materials. 3. On 11/04/2021 at 9:20 AM, the GS1 explained that the two untitled worksheets along with the "Weekly/Monthly QC Review Acknowledgement Form" were trend analysis worksheets. The trend analysis worksheets are a summary of the three toxicology analyzers- Shimadzu 8040 Liquid Chromatography Mass Spectrometry (LC/MS/MS), Quantis LC/MS/MS, and GC [gas chromatography]/MS analyzers. The specific toxicology tests performed on each analyzer are listed below. a) 8040 assays are- OPT, 6-MAM, BENZO, PCP, AMPH, GABA, WELLBN, NALT, Cocaine, Cotinine, and SOMA/MEPRO. b) Quantis assays are- ETS/ ETG, Methadone, Fentanyl, and Buprenorphine c) GC/MS assays are- THC, BARBITURATES, and Meperidine 4. The "Weekly/Monthly QC Review Acknowledgement Form" along with the monthly summary of the 8040, Quantis and GC [gas chromatography]/MS (toxicology analyzers) for January 2021 were reviewed. The weekly/monthly form indicated that there were no issues with the QC results during each of the four weeks in January. The monthly trending analysis worksheet summary for 1/1/2021-1/31/2021 indicated that QC1, QC2, and QC3 for "ETG" and "ETS" had "10 Data Above the Mean." The monthly trending analysis worksheet summary for 1/1/2021-1/31/2021 indicated that QC1 for "NORBUP", "AMPH MDMA", and "BZE" had "10 Data Below the Mean." The monthly trending analysis worksheet summary for 1/1/2021-1/31/2021 indicated that QC2 for "BENZO 7-AMINO" and "EDDP" had "10 Data Below the Mean." The monthly trending analysis worksheet summary for 1/1/2021-1/31/2021 indicated that QC1 and QC2 for "METHADONE" had "10 Data Below the Mean." The monthly trending analysis worksheet summary for 1/1/2021-1/31/2021 indicated that QC1, QC2, and QC3 for "BENZO LOR", "BENZO OX", "BENZO AA", "BENZO NOR", and "BENZO TEM" had "10 Data Above the Mean." These QC violations were not mentioned on any of the four weeks listed on the "Weekly/Monthly QC Review Acknowledgement Form" for January 2021 and there was no documented follow-up. 5. The "Weekly /Monthly QC Review Acknowledgement Form" along with the monthly summary of the 8040, Quantis and GC/MS for March 2021 were reviewed. The weekly/monthly form indicated that there were no issues with the QC results during each of the four weeks in March. The monthly trending analysis worksheet summary for 3/1/2021-3/31/2021 indicated that QC1 for "METHADONE" had "10 Data Below the Mean." The monthly trending analysis worksheet summary for 3/1/2021-3/31/2021 indicated that the "GLUC" hydrolysis control for "THC" had "10 Data Above the Mean." The monthly trending analysis worksheet summary for 3/1/2021-3/31/2021 indicated that QC1 for "OPT MOR", "AMPH MDA", and "AMPH MDMA" had "10 Data Below the Mean." The monthly trending analysis worksheet summary for 3/1/2021-3/31/2021 indicated that QC3 for "BENZO TEM" had "10 Data Below the Mean." The monthly trending analysis worksheet summary for 3/1/2021-3/31/2021 indicated that QC1 and QC2 for "OPT COD" had "10 Data Below the Mean." The monthly trending analysis worksheet summary for 3/1/2021-3/31/2021 indicated that QC1 and QC3 for "AMPH MAMPM" had "10 Data Below the Mean." The monthly trending analysis worksheet summary for 3/1/2021-3/31/2021 indicated that QC2 and QC3 for "BENZO 7-AMINO", "OPT OM", and "OPT HC" had "10 Data Below the Mean."

The monthly trending analysis worksheet summary for 3/1/2021-3/31/2021 indicated that QC1, QC2, and QC3 for "OPT HM" had "10 Data Below the Mean." These QC violations were not mentioned on any of the four weeks listed on the "Weekly /Monthly QC Review Acknowledgement Form" for March 2021 and there was no documented follow-up. 6. During a phone interview on 10/15/2021 at 9:10 AM, TP1 confirmed that the previous LD did not evaluate the expired and "trailing" QC materials. 7. During a phone interview on 11/04/2021 at 9:20 AM, GS1 confirmed that the previous LD did not follow-up when the monthly trending analysis worksheet indicated that 10 consecutive QC data points were above or below the mean.

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 review of personnel records and interview with the general supervisor #1 (GS1), testing person #3 (TP3), and laboratory director (LD), the technical supervisor (TS) failed to perform annual competency evaluations on all personnel performing testing. Findings: 1. Personnel records for the GS1, who was a supervisor and TP for toxicology testing, were missing annual competency evaluations for 2019, 2020, and 2021. 2. Personnel records for TP3, who was a supervisor and TP for thin layer chromatography, were missing annual competency evaluations for 2019, 2020, and 2021. Records for TP3 showed a document titled "Performance Review" that was performed on 03/21/2021 by the quality manager, who is not qualified as a TS for thin layer chromatography. 3. During the survey on 09/24/2021 at 5:00 PM, the GS1, TP3 and LD confirmed that annual competency evaluations were not performed in 2019, 2020 and 2021 for GS1 as a TP for toxicology testing and TP3 for thin layer chromatography. At 5:30 PM, the LD confirmed that the "Performance Review" for TP3 was not comparable to an annual competency evaluation.