Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0218865	07/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Friends Medical Laboratory	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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the laboratory director (LD) and testing personnel, the laboratory failed to ensure that the attestation worksheet was printed and signed by the appropriate laboratory personnel and the final results were reviewed by the appropriate staff. Findings: 1. The College of American Pathology (CAP) chemistry (C) PT records for 2022 (three events) were reviewed. The attestation worksheet for two of three events had not been signed and dated by the appropriate laboratory personnel. 2. The CAP urine toxicology (UT) PT records from 2022 and the first event of 2023 (four events) were reviewed. The "Attestation/Use of Other Form" for UT-A 2023 included the typed initials, "DD", for the LD/designee and three sets of typed initials, "SH", "DD", and "DM" for the testing personal (TP). The "Internal Chain of Custody" form had one set of initials which was "SH." The "Urine Toxicology Survey" attestation form has the signature of the LD /designee and the signature of one TP which was "TF". 3. The lead TP for screening urine toxicology specimens stated that "TF" had prepared the specimens for testing but had not tested and verified the test results. 4. The American Association of

	Bioanalysts (AAB) Urine Drug Screening PT records for 2022 were reviewed (three events). Two of three events, AAB events Q-1 and Q-2, failed to show that the designee had documented a review of the reports with a signature and date. 5. During the survey on 07/14/2023 at 3:30 PM, the LD confirmed that the attestation worksheets had did not have the signatures of the appropriate laboratory personnel, that one signature was of a person who prepared the specimen but not actually verified the test results, and the final results for AAB events Q-1 and Q-2 had not been documented as being reviewed and acceptable.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the maintenance charts for the Quantis (toxicology analyzer) and interview with the laboratory director (LD), the laboratory failed to provide the manufacturers acceptable reference ranges for the N2 Pressure, Check Vacuum Pressure level, and Pump Initial Pressure Daily Run on the "Quantis Maintenance Sheet" on the worksheet. Findings: 1. The "Quantis Maintenance Sheet" for the months of February, November, and December 2022 and March and May 2023 were reviewed. 2. The "Quantis Maintenance Sheet" worksheet failed to provide and acceptable reference range for N2 Pressure, Check Vacuum Pressure level, and Pump Initial Pressure Daily Run. Values were recorded each day of testing but with no reference ranges there was no way to ensure that the values recorded were within acceptable limits. 3. During the exit survey on 07/14/2023 at 3:30 PM, the LD confirmed that the "Quantis Maintenance Sheet" and the procedure manual did not include limits of acceptability for N2 Pressure, Check Vacuum Pressure level, and Pump Initial Pressure Daily Run.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on humidity log record review and interview with the laboratory director (LD), the laboratory failed to document corrective action when laboratory humidity was out of range. Findings: 1. A review of room temperature and humidity logs for the "Olympus AU640 Room" for 2022 showed that in January and February 2022 the

	acceptable humidity range for the laboratory was "40% - 80%." 2. In January 2022 laboratory humidity was out of range 19 of 19 days recorded and in February 2022 laboratory humidity was out of range 20 of 20 days recorded. 3. There were no corrective actions documented for these dates. 4. During an interview on 07/14/2023 at 3:30 PM, the LD confirmed that there were no corrective actions documented for the days that the laboratory humidity was out of range.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the technical supervisor (TS), the laboratory director (LD) failed to investigate PT failures and implement corrective actions to prevent unacceptable test results in the future. Findings: 1. The second PT event for Urine Drug Confirmation testing UDC-B from 2020 was reviewed. Specimen identification numbers UDC-19 and UDC-20 had "Directed Challenge" listed as the result. The "%Maximum Possible Score" was listed as 49% and "Your Performance" was listed as "Unacceptable." 2. At the time of the survey the investigation of the failure was not available. Seven days later the TS submitted documentation of a PT failure that did not include the investigation on the UDC-B 2022 failure. 3. During the survey on 07/14/2023 at 3:30 PM, the LD agreed to email the UDC-B 2022 investigation, but the documentation that was received did not include the investigation of the "%Maximum Possible Score" was listed as 49% and "Your Performance" was listed as "Unacceptable."
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on competency assessment record review and interview with the laboratory director (LD), the LD failed to ensure that the policies for monitoring the laboratory staff included the evaluation of the technical consultant (TC), general supervisor (GS), and technical supervisor (TS). Findings: 1. A review of competency assessment records from 2021 through 2023 showed that the documentation did not include an annual evaluation of the TC, GS, or TS for the duties they perform in the laboratory. 2. During an interview on 07/14/2023 at 3:15 PM, the LD confirmed that there were no annual evaluations of the TC, GS, and TS for 2021 through 2023.