Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2179951	06/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Almat Bio Solutions Llc	3706 Crondall Lane Suite 101b, Owings Mills, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the alternate proficiency testing (PT) policy and PT sample evaluation and interview with the technical supervisor (TS), the laboratory failed to document the procedure followed, the evaluation criteria followed, and the evaluation results for alternate PT performed in April 2021. Findings: 1. The policy titled "Alternate Proficiency Assessment" was reviewed. 2. The "Procedure" section of the document stated that for analytes that are not available from approved PT programs, the laboratory will perform split-sample testing with another accredited laboratory every 6 months. This section further stated that the laboratory will "develop procedures for evaluations of proficiency results including instructions for all relevant stages of the testing event (Pre-analytic, analytic, and post-analytic), reporting format, answer choices, and definition of the "correct" result. The range of acceptability for each quantitative/qualitative analyte, or parameter should be determined prior to initiation of the testing procedure ...Investigate unacceptable performance and initiate corrective action form." 3. The laboratory performed the split-sample alternate PT in April 2021. The documentation included a cover sheet titled "Split Sample Tracking" which listed 7 PT samples, their original identification (ID), the date the laboratory performed testing, the sample IDs sent to the reference laboratory, and the dates samples were sent to and results received from the reference laboratory. 4. The comparative results evaluation of the April 2021 split-sample PT consisted of a spreadsheet listing each analyte tested, the laboratory result, the reference laboratory result, the expected result value, and the percent (%) difference between the results from the two laboratories and between the laboratory's result and the expected result. Selected values under the "% Difference", between laboratories and between the laboratory and the expected value, were highlighted red, but there were no procedures

	instructing how to calculate the % difference nor what the acceptability criteria for evaluation were. Though the cover sheet listed 7 PT samples, there were only comparative results evaluations for 5 samples and none of the 5 samples were identified on the spreadsheets. 5. There were no procedures instructing how to perform testing at all relevant stages (pre-analytic, analytic, and post-analytic), what reporting format to use, what the acceptable answer choices were, the definition of a "correct" result, nor the range of acceptability for each quantitative/qualitative analyte as was stated in the "Alternate Proficiency Assessment" policy. 6. There was no written evaluation of the PT results identifying which analytes had unacceptable performance and what corrective actions were implemented to prevent recurrence. 7. The TS confirmed in an email received on 06/15/2021 at 2:57 PM that the laboratory accepted results that were +/- 25% of the target value, but that this was not written in the current procedure.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview with the technical supervisor (TS), the laboratory's quality assessment system failed to include a system to ensure that each laboratory had a robust policy to ensure proficiency testing (PT) information was not shared between the other laboratories when performing testing on the liquid chromatography with tandem mass spectrometry (LC/MS/MS) analyzer. Findings: 1. The laboratory was located in the same facility as 9 other laboratories. All 10 laboratories performed LC/MS/MS toxicology testing and shared the same testing personnel (TP). 2. According to the memo "Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group", Ref: QSO-18-20-CLIA, dated July 20, 2018, with the subject "Clarification of the Operation of Multiple Laboratories at the Same Location...", "All records (e.g., quality control, procedure manuals, personnel competency) must be kept separate and distinct for each laboratory and must clearly show that each laboratory is operating independently." 3. The laboratory's PT policy did not include a detailed system to ensure that PT was performed independently in each of the laboratories and that the results were not compared prior to submitting the results to the approved PT agency. 4. During a phone conversation on 06/08/2021 at 2: 00 PM, the TS confirmed that the laboratory's PT procedure did not define a system to ensure independent PT testing by each of the laboratories sharing the LC/MS/MS analyzers and TP.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and

	rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the client services manual and validation documentation and interview with the technical supervisor (TS), the laboratory failed to establish the policies and procedures for specimen transportation in non-refrigerated conditions for liquid chromatography with tandem mass spectrometry (LC/MS/MS) testing. Findings: 1. The "Specimen Stability" section of the laboratory's "Client Services User Guide" stated unless "otherwise noted in the test directory, specimens should be kept refrigerated and transported to the Laboratory in a refrigerated cooler." The "Test Directory" at the end of the user guide stated that all analytes should be kept refrigerated. 2. During the initial survey on 05/27/2021 at 1:00 PM, the TS stated that the clients were not required to ship specimens under refrigerated conditions. The furthest client was located in Florida and shipped specimens overnight, but not on ice or in a refrigerated cooler. 3. The laboratory's validation documentation showed that a stability study was performed to verify that each analyte was stable and still detectable under various storage conditions. The storage conditions tested included samples 1) refrigerated for 48 hours, then put into the freezer, 2) left on the bench for 6 hours, then put into the freezer, 3) subjected to 3 freeze/thaw cycles, and 4) immediately stored in the freezer. The stability studies did not include the impact on analyte detection caused by fluctuations at high temperatures that might occur when samples are shipped from Florida in non-refrigerated conditions. 4. During the exit interview on 05/27/2021 at 3:45 PM, the TS confirmed that the laboratory did not perform a study to assess analyte stability at higher temperature fluctuations that could potentially occur during transportation from Florida in non-refrigerated conditions.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: I. Based on review of the procedure manual and interview with the technical supervisor (TS), the laboratory's procedure manual failed to have written instructions for corrective actions to be taken when calibration or quality control (QC) results

failed to meet the laboratory's criteria for acceptability for the liquid chromatography with tandem mass spectrometry (LC/MS/MS) analyzer. Findings: 1. The procedure labeled "AlMat Biosolutions Analytical Procedure: Analysis of Drugs and Metabolites in Human Urine by LC/MS/MS" was reviewed. 2. Number 3 of Section 8.3 Batch Acceptance Criteria stated: "No more than two calibrators may be excluded as outliers. Rerun the calibration curve if more than two calibrators are excluded. The calibrators at the LLOQ [lower limit of quantification] and ULOQ [upper limit of quantification] may not be both excluded for the same analyte. If calibrators are excluded, they must be noted/highlighted on the Daily Curve Record worksheet. No more than one QC may be excluded at each level." 3. During the onsite visit the TS explained that if calibrators 3 and 7 failed, the run would not be acceptable. If calibrators 6 & 7 failed the test could be acceptable, but the patients test result would have to be reported as less than the values of the calibrator that passed. These instructions were not defined in the procedure manual. 4. Number 7 of Section 8.3 Batch Acceptance Criteria stated: "If QC failed, it may be reinjected once. If QC 1 failed, accept values greater than QC 2 and negatives. If QC 2 failed, accept values less than QC 1, greater than QC 3, and negatives. If QC 3 failed, accept values less than QC 2 and negatives. If QC 1 and QC 2 fail, accept negatives and values greater than QC 3. If QC 2 and QC 3 fail, accept negatives. If QC 1 and QC 3 fail, accept negatives. If all QC fail, accept negatives." These statements are inconsistent with the number 3 of Section 8.3 statement that "No more than one QC may be excluded at each level." 5. The procedures failed to include instructions for corrective actions to be taken when each of the failure statements listed in the procedure were encountered, e.g., "If QC 2 failed, accept values less than QC 1, greater than QC 3, and negatives." The procedure didn't clarify if and when to repeat values greater than QC 1 and less than QC 3. 6. During the onsite survey on 05/27/2021 at 3:30 PM, the TS confirmed that the laboratory's batch acceptance procedure failed to explain the corrective actions to be taken and how to document the problems encountered prior to reporting patient test results. II. Based on review of the procedure manual and worksheets and interview with the TS, the laboratory failed to provide written procedures that included all the steps necessary for the completion of the initial validation and verification after relocation of the LC/MS/MS analyzer. Findings: 1. The initial validation documentation showed three days of validation worksheets that listed the identity and the order of testing samples for the validation. The worksheets included sample preparation instructions but did not include written instructions for labeling the specimens, dispensing of the specimens identified on the column listed on the worksheet, and criteria for acceptability. 2. The verification documentation showed that three levels of controls were repeated five times. The following statement was at the bottom of each page "Verification accepted if values fell within +/- 25% of target value on 4 out of 5 injections." 3. Review of the procedure manual showed that the laboratory did not provide step-by-step instructions for the initial validation and verification after relocation of the LC/MS/MS analyzer. 4. During the onsite survey on 05/27/2021 at 3:30 PM, the TS confirmed that the laboratory's procedure manual failed to provide step-by-step instructions for the initial validation and verification after relocation including the criteria for acceptability. 43123 III. Based on review of the procedure manual and interview with the TS, the laboratory's procedure failed to include the storage conditions and expiration dates of reagents used in the LC/MS/MS testing. Findings: 1. The procedure titled "AlMat Biosolutions Analytical Procedure: Analysis of Drugs and Metabolites in Human Urine by LC/MS/MS" was reviewed. 2. The procedure included instructions for the preparation of the Composite Mix Solutions, Quality Control Composite Mix Solutions, Mobile Phase A, Mobile Phase B, and Needle Rinse, but did not specify the storage conditions nor expiration date for each reagent. 3. During the initial survey on 05/27/2021 at 11:00 AM, the TS

	confirmed that the laboratory's testing procedure did not include the storage conditions nor expiration dates for each reagent used in LC/MS/MS testing. IV. Based on review of the procedure manual and interview with the TS, the laboratory's procedure failed to indicate the correct composite mix solution from which to prepare the quality control (QC) standards for the LC/MS/MS testing. Findings: 1. The procedure titled "AlMat Biosolutions Analytical Procedure: Analysis of Drugs and Metabolites in Human Urine by LC/MS/MS" was reviewed. 2. The laboratory used 2 composite mix solutions for reagent preparation. The Composite Mix Solutions A-F (CMS A-F) were used to prepare the calibrators. The Quality Control Composite Mix Solutions A-F (QMS A-F) were used to prepare the QC Composite Spiking Standards (QCC) 1-3. 3. Section 7.1 titled "Preparation of QC Composite Spiking Standards (QCC 1,2,3)" stated "prepare QCC 1 from CMS A-G, and the specified stock standards" and contained a table with columns for "Pool/Stock", "Stock Concentration", and "Spiking Volume (L)." The procedure listed CMS A-F and the spiking volume for each in the table, when it should have been QMS A-F listed in the table. 4. The procedure stated to "prepare QCC 1 from CMS A-G", but the procedure did not include instructions for how to prepare CMS G. 5. During the initial survey on 05/27/2021 at 11:00 AM, the TS confirmed that the testing procedure had a typo and was incorrect. The procedure should read that the QCC was prepared from the QMS and not the CMS as the CMS was used to prepare the calibrators. The TS also confirmed that there were no instructions for how to prepare CMS G. V. Based on review of the procedure manual and interview with the TS, the laboratory's procedure manual failed to include the correct expiration date for one of the reagents used in the LC/MS/MS testing. Findings: 1. The procedure titled "4500 ETG/ETS AlMat Analytical Procedure: Analysis of Ethyl Glucuronide and Ethyl Sulfate in Human Urine by LC/MS/MS" was reviewed. 2. The "Preparation of Reagents" section stated that Mobile Phase A (MPA) should be stored at room temperature and expired after 1 month from the date of preparation. 3. During the initial survey on 05/27/2021 at 11: 00 AM, the TS confirmed that MPA had an expiration date of 1 week, not 1 month. VI. Based on observation, review of the procedure manual, and interview with the TS, the laboratory's procedure failed to include instructions for how to retrieve the data from the LC/MS/MS analyzer for batch evaluation and results release. Findings: 1. While touring the facility, the TS explained that the data from the LC/MS/MS analyzer was not automatically transferred into the laboratory's information management system for analysis and results release. The data was either transferred to another computer via a flash drive or accessed from another computer via a virtual private network (VPN). 2. The laboratory's procedure did not include instructions for how to transfer the data from the LC/MS/MS analyzer to another computer for analysis and results release using either a flash drive or a VPN. 3. During the initial survey on 05/27/2021 at 3:45 PM, the TS confirmed that the procedure did not include instructions for how to transfer the data from the analyzer to another computer for analysis.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: The laboratory director failed to ensure that approved verification procedures were

	used to determine the accuracy and precision of the toxicology analyzer after relocation. Cross refer to D5403 II for details.
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: The laboratory director failed to ensure all split-sample alternate PT results from April 2021 were evaluated for performance and corrective actions were taken for any analytes with unacceptable performance. Cross refer to D5221 for details.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on remote review of the "Validation Results Summary", the laboratory director (LD) failed to ensure that the validation documentation establishing acceptable levels of analytical performance for all testing panels was reviewed and approved. Findings: 1. The laboratory validated 3 different drug panels on the LC/MS/MS analyzer: 1) the main panel, 2) barbituates, and 3) ethyl glucuronide and ethyl sulfate (EtG/EtS). 2. The initial validation records that were received via a shared documents link on 06/04 /2021 included separate pdf documents for each of the 3 drug panel validations. The barbituates and EtG/EtS pdfs both included a "Validation Results Summary" document with the title "Testing Matters Toxicology Analytical Procedure #1 Main Panel: Analysis of Drugs in Human Urine by LC/MS/MS." None of the validation records included a "Validation Results Summary" for barbituates or EtG/EtS testing. 3. The "Validation Results Summary" included with the validation documentation for each of the 3 drug panels was the only validation document that was signed by the LD and all were approved on 07/20/2020. Based on the approval dates and titles of the "Validation Results Summary", it was not apparent that the laboratory director reviewed and approved the validation data for the barbituates and EtG/EtS testing panels.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by:

	The technical supervisor (TS) failed to ensure that approved initial validation and verification procedures were used to determine the accuracy and precision of the toxicology analyzer. Cross refer to D5403 II for details.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: The technical supervisor failed to ensure that the quality control program included specific guidelines for acceptability for the testing being performed. Cross refer to D5403 I for details.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the technical supervisor (TS), the TS failed to document and review quality control (QC) results on a weekly basis. Findings: 1. The procedure labeled "Policy for Quality Assurance" was reviewed. On page 5, the quality assurance schedule stated: "Weekly- Laboratory supervisor will review QC every week. Comments will be added to any outliers." 2. The TS showed the surveyors a worksheet that the TS was developing for documenting review and analysis of the daily QC results that had not been implemented yet. The TS stated that the weekly reviews of QC results were being performed but not documented. 3. During the onsite survey on 05/27/2021 at 3:30 PM, the TS confirmed that the weekly QC review was not being documented.