Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2151501	06/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
Eml Group Llc	3706 Crondall Lane Suite 105, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on observation, procedure manual review, and interview with the general supervisor (GS), the laboratory failed to ensure that there was an approved procedure for calibrating the scale used to measure reagents for urine toxicology testing. Findings: 1. During a tour of the laboratory at 9:30 AM, it was observed that the laboratory was using a "OHAUS" scale to measure reagents used for urine toxicology testing. Documentation of the scale's calibration is recorded in a binder. 2. A review of the binder showed that a procedure for calibrating the scale was placed on the outside of the binder. This procedure was not signed and approved by the laboratory director. 3. During an interview on 06/05/2023 at 11:30 AM, the GS stated that there was no book or instructions available which described how to operate the scale so they wrote a procedure. Procedure manual review confirmed that the laboratory did not have an approved procedure for how to operate the scale.
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 daily patient workload, instrument maintenance log, policy and procedure manuals, and interview with the testing person (TP), the laboratory's procedure manual failed to include an interpretation of the abbreviations used when documenting information on the daily patient log. Findings: 1. The laboratory's daily patient workloads and instrument maintenance logs included abbreviations such as "ext", "MPA", "MPB", "MP" and "NRB." Neither the worksheet nor the policy and procedure manual identified the meaning of the abbreviations. 2. During the survey on 06/05/23 at 4:30 PM, the TP confirmed that the abbreviations used on the daily workload and instrument maintenance log were not identified in the policy and procedure manuals. II. Based on review of the policy and procedure manuals and interview with the TP, the laboratory's procedure manual failed to include the expiry date for the "Needle Rinse" reagent once it was prepared. Findings: During the survey on 06/05/23 at 4:30 PM, the TP confirmed that the policy and procedure manual failed to include the expiry date of the prepared "Needle Rinse" reagent used for testing in the toxicology laboratory. III. Based on review of the policy and procedure manuals, and interview with the laboratory director (LD), the laboratory's procedure manual failed to include instructions for preparing alternate proficiency testing (PT) samples to be sent to the laboratory as a blind sample for the evaluation of analytes not included in the approved PT programs. Findings: 1. The approved "Alternate Proficiency Assessment" procedure failed to include instructions for preparing alternate PT samples to be sent to the laboratory as a blind sample for the evaluation of analytes not included in the approved PT programs. There were no instructions for corrective actions to be documented when the PT results were unacceptable. 2. During the survey on 06/05/23 at 4:30 PM, the LD confirmed that the policy and procedure manual failed to include instructions for preparing alternate PT samples to be sent to the laboratory as a blind samples and corrective actions to be documented when the PT results were unacceptable. IV. Based on review of the policy and procedure manual, and interview with the GS, the laboratory's procedure manual failed to include written instructions of labeling the red, pink, yellow and blue racks that held microcentrifuge tubes, and identifying the reagents stored in the microcentrifuge tubes for patient testing. Findings: 1. During a tour of the laboratory at 9:30 AM, it was observed that the laboratory stored reagents in the "R1" refrigerator. The reagents are aliquoted into plastic microcentrifuge tubes. The microcentrifuge tubes are stored in red and pink racks labeled "ETC"; yellow racks labeled, "Avalon/EML"; and blue racks labeled, "East Coast." 2. During an interview at 9:30 AM, the GS stated that the racks contained two different reagents which are used for performing urine toxicology testing. The laboratory marks the caps of one set of reagents and leaves the other set blank in order to determine which reagent is stored in the tubes. The GS also stated

	that the reagents expire one week after being made. 3. Upon inspection, it was observed that the microcentrifuge tubes had no other identifiable markings. Neither the racks nor the tubes were labeled with the name of the reagents or the date of preparation or expiration. 4. Record review showed that there were no batch sheets available, documenting the lot numbers and expiration dates of the components used to make the reagents stored in the "R1" refrigerator. 5. During an interview on 6/05 /2023 at 4:15 PM, the GS confirmed that the laboratory failed to have written instructions for labeling and identifying what was stored in the colored racks and microcentrifuge tubes. V. Based on review of the policy and procedure manual, "Instrument Maintenance Log", and interview with the GS, the laboratory's procedure manual failed to include written instructions defining the acceptable limits of the "Injections on the column (Kinetex)", "Injections on column (Luna)", and corrective actions to be taken when the valued fall outside of those limits. Findings: 1. The "Instrument Maintenance Log" worksheets from January 2022 through July 2022 and September 2022 through March 2023 were reviewed. August 2022 was missing. 2. The "Instrument Maintenance Log" requires the TP to document an injection number on the worksheet for the two injection columns (Kinetex and Luna). According to the GS when the recorded values are greater than 5,000 the column is to be changed. 3. During an interview on 6/05/2023 at 4:30 PM, the GS confirmed that the laboratory failed to have written instructions for defining the acceptable limits of the injections columns and corrective actions to be taken when the valued fall outside of those limits. VI. Based on review of the policy and procedure manual, and interview with the GS, the laboratory's procedure manual failed to include written instructions defining the comments documented on the chromatography on the worksheet and corrective actions to be taken and documented on the worksheet. Findings: 1. The worksheet labeled "Instrument: Raptor" is used for documenting whether the chromatography is "Acceptable/Unacceptable." The worksheets from 01/24/23 to 02 /17/23 were reviewed. Under the "Acceptable/Unacceptable" the following comments were recorded: "good", "etg good", "mp good", and "bad." These comments were not defined in the policy and procedure manual and corrective actions be be taken when the comments indicate a problem. 2. During the survey on 06/05/23 at 4:30 PM, the GS confirmed that the policy and procedure manual failed to include written instructions defining the comments documented on the chromatography on the worksheet and corrective actions to be taken and documented on the worksheet. 38127 VII. Based on review of the policy and procedure manual, and interview with the general supervisor (GS), the laboratory's procedure manual failed to include the target value for the revolutions per minute (RPM) when calibrating the centrifuge. Findings: 1. The procedure, "Centrifuge Calibration Acceptability and Log" states, "Each centrifuge is tested quarterly to assess acceptability of function. The acceptability range of the centrifuge RPM is 10%." 2. The procedure describes how to perform the calibration but does not state the target RPM or the laboratory's established limits for the centrifuge. 3. During an interview on 06/05/2023 at 4:15 PM, the GS stated that the centrifuge was calibrated quarterly, but confirmed that the acceptable range was not defined in the procedure.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: I. Based on observation and interview with the general supervisor (GS), the laboratory did not ensure that toxicology reagents used for urine drug testing are labeled with the date that they expire. Findings: 1. During a tour of the laboratory at 10:30 AM, it was observed that the opened and in-use bottle of Beta Glucuronidase enzyme in the laboratory refrigerator ("R1") was labeled with the date that it was opened but was not labeled with the expiration date. 2. During an interview on 06/05/2023 at 10:30 AM, the GS stated that the bottle of Beta Glucuronidase enzyme expires 30 days after it is opened. The GS confirmed that the bottle of in-use enzyme was not labeled with the new expiration date. II. Based on observation, record review, and interview with the GS, the laboratory did not ensure that toxicology reagents used for urine drug testing are labeled with the date that they are prepared or when they expire. Findings: 1. During a tour of the laboratory at 9:30 AM, it was observed that the laboratory stored reagents in the "R1" refrigerator. The reagents are aliquoted into plastic microcentrifuge tubes. The microcentrifuge tubes are stored in red and pink racks labeled "ETC"; yellow racks labeled, "Avalon/EML"; and blue racks labeled, "East Coast." 2. During an interview at 9:30 AM, the GS stated that the racks contained two different reagents which are used for performing urine toxicology testing. The laboratory marks the caps of one set of reagents and leaves the other set blank in order to determine which reagent is stored in the tubes. The GS also stated that the reagents expire one week after being made. 3. Upon inspection, it was observed that the microcentrifuge tubes had no other identifiable markings. Neither the racks nor the tubes were labeled with the name of the reagents or the date of preparation or expiration. 4. Record review showed that there were no batch sheets available, documenting the lot numbers and expiration dates of the components used to make the reagents stored in the "R1" refrigerator. 5. During an interview on 6/05/2023 at 4:15 PM, the GS confirmed that the laboratory did not ensure that toxicology reagents are labeled with the date that they are prepared or when they expire.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the policy and procedure manuals and "Mobile Phase A Form", and interview with the testing person (TP), the laboratory's procedure manual and "Mobile Phase A Form" worksheet failed to include the expiration date of the formic acid used to prepare the Mobile Phase A (MPA) reagent. Findings: 1. The "Mobile Phase A Form" from July 2022 through May 2023 were reviewed and did not include the expiration date of the formic acid used to prepare the MPA reagent. 2. During the survey on 06/05/23 at 4:30 PM, the TP confirmed that the policy and procedure manual and the "Mobile Phase A Form" worksheet failed to include the expiration date of the formic acid used to prepare the Mobile Phase A reagent to ensure that.
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 observation, procedure manual and record review, and interview with the general supervisor (GS), the laboratory failed to perform and document the calibration of pipettes used for urine toxicology testing. Findings: 1. During a tour of the laboratory at 9:30 AM, two pipettes were observed on a work bench where testing is performed. An "Eppendorf Research Plus" 200 ul [microliter] pipette (K161911) was labeled with a sticker which stated, "Cal 11/03/2021" and "Next Cal 11/03/2022" and an "Eppendorf Repeater M4" (N76442K) which was labeled with a sticker which was illegible. 2. A review of the procedure manual showed that the laboratory did not have a procedure for pipette calibration. Record review showed that there was no documentation that pipette calibrations had been performed. 3. During an interview on 06/05/2023 at 11:00 AM, the GS stated that to their knowledge, pipette calibrations had not been performed in the last two years and confirmed that there were no calibration records for the pipettes used for laboratory testing.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on procedure manual review and interview with the general supervisor (GS), the laboratory failed to define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. Findings: 1. The laboratory uses a centrifuge for urine toxicology testing. The procedure, "Centrifuge Calibration Acceptability and Log" states, "Each centrifuge is tested quarterly to assess acceptability of function. The acceptability range of the centrifuge RPM [revolutions per minute] is 10%." 2. The procedure describes how to perform the calibration but does not state the target RPM or the laboratory's established limits for the centrifuge. 3. During an interview on 06/05/2023 at 4:15 PM, the GS stated that the centrifuge was calibrated quarterly, but confirmed that the acceptable range was not defined in the procedure.
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:
I. Based on review of the policy and procedure manual, "Instrument Maintenance Log", and interview with the general supervisor (GS), the laboratory records failed to include document of corrective actions taken when the injection values were unacceptable for the "Injections on the column (Kinetex)" and "Injections on column (Luna)." Findings: 1. The "Instrument Maintenance Log" worksheets from January 2022 through July 2022 and September 2022 through March 2023 were reviewed. August 2022 was missing. 2. The "Instrument Maintenance Log" requires the TP to document an injection number on the worksheet for the two injection columns (Kinetex and Luna). According to the GS when the recorded values are greater than 5,000 the column is to be changed. 3. On 01/01/22 the Luna column recording was recorded as 5734 and the column was not documented as being changed until 01/11/22 when the recorded value was 6839/0. There was no explanation as to why the column wasn't changed until the value was 6839. 4. On 04/27/22 the injection value was recorded as 3181 and the Luna column was changed on 04/28/22. There was no explanation as to why the column was changed prior to reaching 5,000. 5. On 04/30/22 the injection value was recorded as 452 for the Kinetex column and 362 for the Luna column. There is a lot number and validation date recorded but the records are illegible and the surveyor could not determine if this was a new lot number nor the reason for the change. 6. On 07/15/22 the injection value was recorded as 3860 and the Luna column was changed. There was no explanation as to why the column was changed prior to reaching 5,000. 7. On 09/19/22 the injection value was recorded as 964 for the Kinetex column and 1987 for the Luna column. A lot number and validation date was recorded. The next day, 09/20/22, the injection value was recorded as 964 for the Kinetex column and 2117 for the Luna column. Neither column went back to "0" and there was no explanation for why the column changed prior to reaching 5,000. 8. On 10/24/22 the injection value was recorded as 4530 and the Luna column was changed on 10/25/22. There was no explanation as to why the column was changed prior to reaching 5,000. 9. On 12/27/22 the injection value was recorded as 3317 and the Luna column was changed. There was no explanation as to why the column was changed prior to reaching 5,000. 10. On 12/30/22 the injection value for the Kinetex column was 1428 and then on 12/31/22 the value was recorded as 428. There was no explanation for the drop in the injection value from 1428 to 428 and if the column was changed. On 01/01/23 and 01/02/23 the injection value was at 428. 11. On 01/18/23 the injection value was recorded as 662 for the Luna column and the injection value for the Kinetex column was illegible and crossed out. On 01/19/23 the Kinetex value was recorded as 53. There was no explanation as to why the column was changed prior to reaching 5,000. 12. On 03/29/23 the injection value was recorded as 1834 for the Luna column and a column was documented as changed. There was no explanation as to why the column was changed prior to reaching 5,000 and the date validated was not recorded. 13. On 03/31/23 the injection value was recorded as "0" for the Kinetex column and there was no documentation of the column being changed. 14. During the survey on 06/05/23 at 4:30 PM, the GS confirmed that the laboratory records failed to include documentation of corrective actions taken when the injection values were unacceptable for the injections columns.

	38127 II. Based on temperature log record review and interview with the laboratory director (LD), the laboratory failed to document corrective action when laboratory refrigerator and freezer temperatures and room humidity is out of range. Findings: 1. The laboratory stores reagents used for urine toxicology testing in the "R1" refrigerator and the "F1" freezer. A review of temperature logs from January through May, 2023 showed that "Acceptable Range Refrigerator" was "2 - 8C[Celsius] (+/- 1)" and the "Acceptable Range Freezer" was "-15 - -40C (+/- 1)." 2. During an interview at 4:45 PM on the day of the survey, the LD stated that they had added the "(+/- 1)" C to widen the acceptable temperature range because refrigerator and freezer temperature were noticed to be out of range. The LD stated that the refrigerator range should be "2 - 8C" and the freezer range should be "-15 - -40C" to ensure proper storage of reagents. 3. Refrigerator temperature log review showed that temperatures for "R1" were out of the acceptable range of "2 - 8C" for 13 out of 16 days recorded in 01/2023; eight out of 24 days in 02/2023; 10 out of 26 days in 03/2023; 12 out of 25 days in 04/2023; and 13 out of 26 days in 05/2023. 4. The column labeled "Corrective Action" on the temperature log showed the comments "Reset Max" or "Reset Hi" written for five of eight out of range event in 02/2023 and for two out of 10 out of range events in 03/2023. There was no other documentation of corrective actions taken when refrigerator temperatures were out of acceptable range. 5. Freezer temperature log review showed that temperatures for "F1" were out of the acceptable range of "-15 - -40C" for 16 out of 24 days recorded in 02/2023; 16 out of 25 days in 03/2023; and one out of 26 days in 05/2023. 6. The column labeled "Corrective Action" on the temperature log showed the comment "Reset Hi" written for two of 16 out of range events in 02/2023. There was no other documentation of corrective actions taken when freezer temperatures were out of acceptable range. 7. The laboratory also documents the humidity level of the room where testing is performed on the "Raptor" "Room Temperature and Humidity" log. The logs states that the "Acceptable Humidity Range" is "20-80%." Humidity log review showed that the level of humidity in the testing area was out of acceptable range three out of 24 days recorded in 02/2023. There was no corrective action documented for the days that humidity was outside the laboratory's acceptable range. 8. During an interview on 06 /05/2023 at 4:45 PM, the LD confirmed that there were no corrective actions documented for the days that the refrigerator and freezer temperatures and room humidity were out of range.
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 review of patients final reports and interview with the general supervisor (GS), the laboratory failed to ensure that the final test report listed the correct suite number of the laboratory performing the tests. Findings: 1. Final patient reports were pulled for review. The final reports that were reviewed listed the suite identification

	number (ID#) as "100D" which was the suite ID# of the lab prior to moving to the new location over two years ago. The laboratory is currently located in suite 105A. 2. During the survey on 06/01/2023 at 4:45 PM, the GS confirmed that the final reports did not include the correct suite ID# of the laboratory performing the tests.
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 review of the alternate toxicology proficiency testing (PT) records and interview with the general supervisor (GS) and laboratory director (LD), the LD failed to investigate the PT failure and implement a corrective action plan for unacceptable PT testing results. Findings: 1. Review of the alternate toxicology PT records that were received on 05/17/2023 showed that the laboratory failed to accurately quantify Naloxone in specimens "ALT PT 03" and "ALT PT 06" and Dihydrokavain in specimen "ALT PT 06." 2. During the survey on 06/05/2023 at 4:45 PM, the GS and LD confirmed that the PT failures had not been investigated and corrective actions implemented.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 policy and procedure manuals, quality assurance (QA) records, and interview with the current laboratory director (LD), the previous LD failed to ensure that the established quality assurance (QA) procedures were maintained to monitor the overall operation of the laboratory were maintained. Findings: 1. The QA procedure requires the LD to review the documentation of the monthly "QA Huddle." The records from June 2021 to May 2023 were reviewed and 16 of the 23 records failed to include documentation showing that the LD had review the monthly documents. 2. The QA procedure requires the LD to review the "Monthly Report Check." The records from February 2022 to February 2023 were reviewed and 13 of the 13 records failed to include documentation showing that the LD had review the monthly documents. 3. During the survey on 06/05/2023 at 4:45 PM, the LD confirmed that the "QA Huddle" and "Monthly Report Check" documentation had not been reviewed by the LD as required.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

	This STANDARD is not met as evidenced by: Based on procedure manual and record review and interview with the general supervisor (GS), the testing person (TP) failed to follow written procedures for performing maintenance on laboratory refrigerators and freezers. Findings: 1. Procedure manual review showed that the laboratory had a form for documenting "Refrigerator Maintenance," which lists duties to be performed every six months and annually, and a form for documenting "Freezer Maintenance" which lists duties to be performed annually. 2. Record review showed that there were no completed forms, showing that the laboratory had performed the maintenance listed on the forms. 3. During an interview on 06/05/2023 at 12:00 PM, the GS stated that to their knowledge the refrigerator and freezer maintenance had not been performed in the "last two years" and confirmed that the TP was not following the laboratory's procedure for maintenance.