Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2004186	01/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
Great Lakes Medical Laboratory	33469 W 14 Mile, Farmington Hills, MI	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . A. Based on record review and interview with Technical Supervisor #1, the laboratory failed to follow its policy for its assessment of personnel competency for 4 (Technical Supervisor #3, Testing Personnel #8, #9, and #14) of 21 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's "Personnel" policy revealed a section stating, "Verify that a formal employee performance appraisal is conducted at the end of the first six months of employment and each year of employment thereafter. Employee performance evaluations consist Of: A review of QC, maintenance, calibration, and proficiency testing (PT) performed. Direct observation of the employee while performing laboratory work. Split-specimen testing. Written tests on instrument theory or laboratory policies and procedures. Having testing personnel not involved in the current PT event test specimens after the cut-off date for filing the report, and the results compared with those returning form the PT program." 2. A review of the laboratory's "Laboratory Competency Assessment Policy and Process" revealed a section stating, "Mandatory elements of competency assessment include: Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing, and testing Monitoring the recording and reporting of test results, including, as applicable, reporting critical results Review of test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records Direct observation of performance of instrument maintenance and function checks Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency

	testing samples Evaluation of problem-solving skills. This can include communication and activities performed when contacting hotline as well as assigned scenarios of laboratory problems." 2. A review of competency assessments revealed the following performed competency assessments lacked the criteria listed above: a. Technical Supervisor #3 failed to have a direct observation of test performance for the urine and oral fluid toxicology testing and instrument maintenance performance for the COVID-19 RT-PCR testing for their 2022 competency assessment dated 7/16/22. b. Testing Personnel #9 failed to have the assessment of test performance through testing previously analyzed specimens for their 2021 competency assessment dated 11/24/21. c. Testing Personnel #8 failed to have monitoring of the recording and reporting of test results and the assessment of test performance through testing previously analyzed specimens for their 2022 competency assessment completed on 12/30/22 for the COVID-19 Taqman assay and the COVID-19 and Flu combo testing. d. Testing Personnel #14 failed to have monitoring of the recording and reporting of test results and the assessment of test performance through testing previously analyzed specimens for their 2022 competency assessment completed on 12/30/22 for urine and urine toxicology and saliva COVID-19 testing. 3. An interview on 1/10/23 at 10:37 am with Technical Supervisor #1 confirmed the staff listed above had required components missing from their competency assessments. B. Based on record review and interview with Technical Supervisor #1, the laboratory failed to establish a policy to assess Clinical Consultant competency for 2 (January 2021 to January 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Personnel" and "Laboratory Competency Assessment Policy and Process" revealed a lack of policy for the assessment of Clinical Consultant competency. 2. A review of the Clinical Consultant's personnel records revealed a lack of competency assessments performed for their duties as a Clinical Consultant. 3. An interview on 1/9/23 at 3:11 pm with Technical Supervisor #1 confirmed the laboratory had not established a policy to assess Clinical Consultant competency.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Supervisor #2, the laboratory failed to verify the accuracy of its proficiency testing when a score had not been received for 1 (OFD-C 2022) of 3 oral fluid for drugs of abuse proficiency testing events reviewed. Findings include: 1. A review of the laboratory's College of American Pathologists Proficiency Testing documentation revealed the following events not evaluated by the proficiency testing provider or the laboratory for quantitative toxicology testing for the OFD-C 2022 (Oral Fluid for Drugs of Abuse) event analyte norfentanyl for specimens OFD-11 to OFD-15. 2. A review of the laboratory's "API Analytes Not Graded" policy revealed a section stating, "Results that state not graded appear in API evaluations. Every analyte that is not graded must be review and self-graded. The lab must determine the acceptability of performance." 3. A review of the laboratory's "Great Lakes Medical Laboratory" policy revealed a section titled "PT Report Review" stating, "If there are results which are ungraded, due to insufficient data, these must be evaluated for acceptability." 4. An interview on 1/9/23 at 2:22 pm with Technical Supervisor #2 confirmed the laboratory had not

	followed its policy to assess analytes not graded by the proficiency provider for the event listed above.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Supervisor #2, the laboratory failed to verify the accuracy of its quantitative urine toxicology testing for 3 (UT-A-C 2022) of 3 urine toxicology events performed in 2022. Findings include: 1. A review of the laboratory's College of American Pathologists (CAP) Proficiency testing documentation revealed analytes tested using the urine toxicology events were evaluated for their qualitative results and did not assess their quantitative accuracy for the following events in 2022: a. UT-A 2022 b. UT-B 2022 c. UT-C 2022 2. An interview on 1/9/23 at 11:12 am with Technical Supervisor #2 confirmed the laboratory had not assessed its urine toxicology testing using the CAP urine toxicology events for its quantitative accuracy.
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: . Based on observation and interview with Technical Supervisor #1, the laboratory failed to ensure reagents used in QuantiFERON TB-Gold tuberculosis testing for 4 of 4 reagent bottles observed. Findings include: 1. The surveyor observed the laboratory's ThunderBolt analyzer performing QuantiFERON TB-Gold tuberculosis testing on 1/9/23 at 9:12 am. The reagent bottles next to the analyzer had a lack of expiration date for 4 bottles to the left of the analyzer. 2. An interview on 1/9/23 at 9: 11 am with Technical Supervisor #1 confirmed the laboratory had not indicated the expiration dates of the reagents.
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 with Technical Supervisor #1, the laboratory failed to perform calibration at least every 6 months for the Sysmex XN-10 analyzer #17768 performing Complete Blood Count (CBC) testing for 1 (10/22/21 to 10/11/22) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Instrument Maintenance and Calibration" policy revealed a section stating, "Instrument maintenance and test calibrations are performed properly at the required frequencies." 2. A review of the laboratory's "Certificate of Calibration" records for its Sysmex XN-10 hematology analyzers revealed a section stating, "Initial calibration is performed during installation by the Sysmex representative. Following installation calibration, the operator is requested to verify the instrument calibration every 6 months or on an 'as needed' basis, and maintain good QC practices, to ensure the accuracy of the system." and revealed a lack of calibration performed for the Sysmex XN-10 serial # 17768 analyzer between 10/22/21 to 10/11/22. 3. An interview on 1/10/23 at 3:12 pm with Technical Supervisor #1 confirmed the laboratory had not performed calibrations at least every 6 months for the Sysmex XN-10 serial # 17768 analyzer.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Supervisor #2, the laboratory failed to establish a system to evaluate the toxicology testing relationship between its Sciex Triple Quad 4500 and ABSciex QTrap 4500 analyzers for 2 (January 2021 to January 2023) of 2 years reviewed. Findings include: 1. The surveyor toured the laboratory on 1/9/23 at 9:12 am and observed a Sciex Triple Quad 4500 and two ABSciex QTrap 4500 toxicology analyzers. 2. A review of the laboratory's toxicology documentation revealed the lack of a system to evaluate its toxicology testing relationship between its Sciex Triple Quad 4500 and ABSciex QTrap 4500 analyzers. 3. An interview on 1/9/23 at 2:22 pm with Technical Supervisor #2 confirmed the laboratory had no system to evaluate the toxicology testing relationship between its Sciex Triple Quad 4500 and ABSciex QTrap 4500 analyzers established.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
. Based on record review and interview with Technical Supervisor #2, the laboratory failed to follow corrective action policies when quantitative toxicology verification of accuracy testing was out of range for 3 (Oral Fluid 2022 Event 1, Urine Split Sample Analysis 2022 Event 1, and Urine Split Sample Analysis 2022 Event 2) of 3 testing events reviewed. Findings include: 1. An interview on 1/9/23 at 11:12 am with Technical Supervisor #2 revealed the laboratory verifies the accuracy of its testing that is not covered by proficiency testing to a reference laboratory and the quantitative results must be within 30% of the reference laboratory result. 2. A review of the laboratory's verification of accuracy documentation revealed the following analytes had not been within 30% of the reference laboratory: a. Oral fluid 2022 Event 1 i. Carisoprodol the percent difference for sample #1 was 53.42%, sample #3 was 61.06%, sample #4 was 56.21%. ii. Meperidine the percent difference for sample #1 was 35.36%, sample #3 was 41.75%. iii. Pregabalin the percent difference for sample #1 was 38.88%, sample #2 was 56.34%, sample #3 was 35.89%, sample #4 was 32.41%. iv. Tramadol the percent difference for sample #1 was 41.85%, sample #2 was 54.16%, sample #3 was 49.96%, sample #4 was 51.21%. v. Tapentadol the percent difference for sample #1 was 52.61%, sample #2 was 55.16%, sample #3 was 56.77%, sample #4 was 66.06%. vi. Ketamine the percent difference for sample #2 was 43.58%, sample #4 was 37.98%. vii. Methylphenidate the percent difference for sample #2 was 35.06%, sample #3 was 37.98%, sample #4 was 35.07%. viii. Zolpidem the percent difference for sample #1 was 35.97%. ix. Amitriptyline the percent difference for sample #3 was 35.68%. b. Urine Split Sample Analysis 2022 Event 1 i. N-Desmethylcitalopram the percent difference for sample #2 was 46.13%, sample #3 was 58.83%, sample #4 was 65.48%, and sample #5 was 30.44% ii. Ritalinic Acid the percent difference for sample #2 was 45.53% iii. Tapentadol the percent difference for sample #4 was 43.98 c. Urine Split Sample Analysis 2022 Event 2 i. N-Desmethylcitalopram the percent difference for sample #2 was 63.62%, sample #3 was 61.39%, sample #4 was 65.47%, and sample #5 was 69.04%. ii. Cotinine the percent difference for sample #4 was 30.92% and sample #5 was 30.91%. iii. Tapentadol the percent difference for sample #4 was 58.40% and sample #5 was 32.73%. 3. A review of the laboratory's summary of the Oral Fluid 2022 Event 1 revealed a section stating, "The % difference between these two labs are found to be to 30% for most of the tested analytes except few outliers are indicated in flag red color in results sheet, we will investigate the discrapenies from ref lab end." 4. A review of the laboratory's summary of the Urine Split Sample Analysis 2022 Event 1 revealed a section stating, "The % difference between these two labs are found to be 25-30% for all the above tested analytes except ritalinic acid in 2022-A2 sample, and N-desmethylcitalopram in samples 2022-A2, A3 & A4 we will investigate further with ref. lab about these outliers." 5. A review of the laboratory's summary of the Urine Split Sample Analysis 2022 Event 2 revealed a section stating, "The %

	difference between these two labs are found to be 25-30% for all the above tested analytes except O-desmethytvenalafaxine and N-desmethylcitalopram in samples 2022-B2, B3, & B4." 6. A review of the laboratory's "Proficiency Testing (PT) and Split-Specimen Testing" policy revealed a section titled "Mechanism of Review: Split-Specimen Testing" stating, "Split-Specimen testing is required on five specimens twice each year for all unregulated analytes not enrolled in PT. This is a quality assurance external comparison, as well." and "The Annual QA review of split-specimen testing should also verify that: Corrective action is teken if results fall outside acceptable limits." 7. The surveyor requested the corrective action from the events listed above on 1/9/23 at 11:12 am and it was not made available. 8. An interview on 1/9/23 at 12:39 pm with Technical Supervisor #2 confirmed the laboratory had not performed corrective action for the verification of accuracy testing results that were outside of the acceptability criteria.
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 record review and interviews with Technical Supervisor #1 and #2, the Laboratory Director failed to ensure the laboratory's corrective action plan was followed when proficiency testing results were unacceptable for 2 (OFD-B 2022 and 2022 Chemistry Core 1st event) of 25 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's "Unsatisfactory PT Results" policy revealed a section stating, "If thre is a PT analyte outside the range of "acceptable values," there is a problem that must be identified and corrected. A failure could be an indication of problems with instrumentation, personnel training, or quality control. Using the COLA Proficiency Testing Corrective Action Checklist, the root cause of the problem should be identified. Upon reviewing the PT results and noting any unsatisfactory results, the following protocol will be followed. 1. The unsatisfactory analyte will be retested using the PT samples that were retained. 2. The technical supervisor will document the PT process on the COLA Testing Check List to determine the scope of the problem. 3. Using the Check List, the technical supervisor will be able to identify where corrective action is needed by documenting the PT procedure through the Pre-Analytical, Analytical and Post-Analytical processes. 4. This documentation will be reviewed with the laboratory staff. 5. The director will review and sign off on the Corrective Action Check List. 6. All documentation will be retained for a period of two years. 7. If required, the documentation will be sent in to COLA." 2. A review of the laboratory's College of American Pathologists Proficiency Testing records revealed the oral fluid toxicology event OFD-B 2022 had unacceptable results for the following analytes: a. Quantitative Hydrocodone b. Quantitative Oxymorphone 3. A review of the laboratory's American Proficiency Institute Proficiency Testing records revealed the laboratory had a self-graded score of 80% for vancomycin. 4. An interview on 1/9/23 at 12:39 pm with Technical Supervisor #2 confirmed the laboratory had not performed corrective action for the unacceptable results for quantitative hydrocodone and quantitative oxymorphone. 5. An interview on 1/10/23 at 3:14 pm with Technical Supervisor #1 confirmed the laboratory had not performed corrective action for the self-graded score of 80% for vancomycin.
D6141	GENERAL SUPERVISOR

	CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interview, the General Supervisor did not meet the qualification requirements of 493.1463. Findings include: 1. The laboratory failed to ensure personnel met the qualification requirements to peform the duties of a General Supervisor. Refer to D6143.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least

	one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m). This STANDARD is not met as evidenced by: . Based on record review and email correspondence with Technical Supervisor #1, the laboratory failed to ensure personnel met the qualification requirements to perform the duties of a General Supervisor for 1 (Testing Personnel #6) of 10 personnel performing the duties of a General Supervisor. Findings include: 1. A review of the laboratory's competency assessment records revealed Testing Personnel #6 had performed the direct observation portion of the competency assessment for Testing Personnel #1 on 12/15/22. 2. A review of the qualification records for Testing Personnel #6 revealed a lack of at least 1 year of laboratory training or experience, or both, in high complexity testing. 3. The surveyor requested documentation of at least 1 year of laboratory training or experience, or both, in high complexity testing for Testing Personnel #6 on 1/10/23 at 3:30 pm and it was not made available. 4. The laboratory was given an additional 7 days to provide the missing documentation and it had not been received. 5. Email correspondence from Technical Supervisor #1 on 1/19/23 at 4:20 pm confirmed Testing Personnel #6 was not qualified to perform General Supervisor duties.