Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2177137	09/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Olympia Neurological Institute	6130 E 81st St, Tulsa, OK	

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
D0000	The initial survey was performed on 09/21/2023. The laboratory was found out of compliance with the following CLIA Conditions: 493.1213; D5022: Toxicology 493.1403; D6000: Laboratory Director, Moderate Complexity 493.1441; D6076: Laboratory Director, High Complexity The findings were reviewed with the regional manager and testing person #2 during an exit conference performed at the conclusion of the survey.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, laboratory policy and procedure, and interview with testing person #2, the laboratory failed to ensure the requirements were met for the subspecialty of Toxicology for 22 of 22 months of patient testing. Findings include: (1) The laboratory failed to verify the accuracy of Urine Drug Screen and Specimen Validity testing at least twice annually. Refer to D5217; (2) The laboratory failed to follow the manufacturer's instructions and laboratory procedure on specimen storage stability for the Urine Adulterant Strip testing. Refer to D5311; (3) The laboratory failed to ensure the procedure manual had been approved and signed by the laboratory director. Refer to D5407; (4) The laboratory failed to demonstrate the performance specifications for a new analyzer. Refer to D5421; (5) The laboratory failed to establish the performance specifications for analytes not subject to FDA clearance or approval (labeled as for forensic /toxicology use only). Refer to D5423; (6) The laboratory failed to perform calibration verification procedures at least once every 6 months for the Urine Drug Screen and Specimen Validity testing performed on the Siemens Viva Pro E EMT analyzer. Refer

	to D5439; (7) The laboratory failed to perform two levels of quality control materials each day of patient Urine Adulterant Strip testing. Refer to D5447; (8) The laboratory failed to ensure patient test reports included the address of the laboratory location where the testing was performed. Refer to D5805; (9) The laboratory failed to ensure test reports for Urine Drug Screen and Adulterant testing included information required for interpretation. Refer to D5805.
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 a review of records and interview with testing person #2, the laboratory failed to verify the accuracy of Urine Drug Screen and Specimen Validity testing at least twice annually during the review period of December 2021 through August 2023. Findings include: (1) On 09/21/2023 at 09:20 am, testing person #2 stated the laboratory began performing Urine Drug Screen testing (Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, and Methadone) and specimen validity testing (pH, Specific Gravity) using the Siemens Viva-ProE EMT analyzer on 12/01 /2021; (2) A review of records from December 2021 through August 2023 identified the testing had not been verified for accuracy at least twice annually; (3) The records were reviewed with testing person #2 who stated on 09/21/2023 at 10:05 am, the laboratory had not verified the accuracy of the testing twice annually during the review period, however they enrolled in proficiency testing on 09/15/2023.
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 a review of patient test record, manufacturer's instructions, laboratory policy and procedure, and interview with testing person #2, the laboratory failed to follow the manufacturer's instructions and laboratory procedure on specimen storage stability for the Urine Adulterant Strip testing for one of one test report reviewed. Findings include: (1) On 09/21/2023 at 09:30 am, testing person #2 stated the following: (a) The laboratory performed pH Urine Adulteration testing using the ADU-6T Reagent Strips; (b) Specimens were typically stored refrigerated (2-8 degrees Centigrade (C)) one to two days prior to testing. (2) A review of the manufacturer's package insert and procedure manual identified: (a) The package insert under the section titled, "Specimen Storage" stated "Urine specimens maybe stored at 2-8 degrees C for up to 48 hours before testing"; (b) The procedure titled "Urine Adulteration Strip Testing" under section 4 titled "Specimen Storage" stated "Urine specimens may be stored at 2-8 degrees C for up to 48 hours before testing". (3) A review of the urine adulteration

	test report for pH performed on 09/12/2023 identified the following for one of one test report: (a) Patient #2518 - The collection date was on 09/12/2023 and the result date was on 09/20/2023 (eight days later). (4) The findings were reviewed with testing person #2 who stated on 09/21/2023 at 02:00 pm, the laboratory had not followed the specimen storage requirement.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with testing person #2, the laboratory failed to ensure the procedure manual had been approved and signed by the laboratory director. Findings include: (1) On 09/21/2023 at 09:20 am, testing person #2 stated the laboratory began performing Urine Drug Screen testing (Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, and Methadone) and specimen validity testing (pH, Specific Gravity) using the Siemens Viva-ProE EMT analyzer on 12/01/2021; (2) A review of the manual titled, "Laboratory Policies and Procedures" identified no evidence it had been signed and dated as approved by the laboratory director; (3) The manual was reviewed with testing person #2 who stated on 09/21/2023 at 10:00 am, the policy and procedure manual had not been approved and signed by the laboratory director.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #2, the laboratory failed to demonstrate the performance specifications for one of one analyzer. Findings include: (1) On 09/21/2023 at 09:20 am, testing person #2 stated the following: (a) The laboratory performed Qualitative Urine Drug Screen testing (Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, and Methadone) and specimen validity testing (pH and Specific Gravity) using the Siemens Viva-ProE EMT analyzer; (b) The laboratory began using the analyzer on 12/1/2021. (2) A review of records from December 2021 through the current date identified no evidence the performance specifications (i.e., accuracy, precision, reportable range) had been demonstrated for the analyzer; (3) The findings were reviewed with testing person #2 who stated on 09/21/2023 at 01:25 pm, the laboratory had not demonstrated the performance specifications for the analyzer; (4) A review of patient records identified Urine Drug Screen testing had been reported for three patients on 09/07/2023 (Patient ID #96, Patient ID #3437, and Patient ID #10949).

D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's package inserts, and interview with testing person #2, the laboratory failed to establish the performance specifications for two of two new analytes not subject to FDA clearance or approval (labeled as for forensic/toxicology use only). Findings include: (1) On 09/21/2023 at 09:20 am, testing person #2 stated the laboratory began performing Urine specimen validity testing (pH, Specific Gravity) using the Siemens Viva-ProE EMT analyzer on 12/01 /2021; (2) A review of the manufacturer's package insert for the tests stated under the heading, "Intended Use" stated "This test is for forensic/toxicology use only" which confirmed the tests were not subject to FDA clearance or approval; (3) A review of records from December 2021 through the current date identified no evidence the performance specifications (i.e., accuracy, precision, reportable range, analytical sensitivity, and analytical specificity) had been established for the test system; (4) The findings were reviewed with testing person #2 who stated on 09/21/2023 at 01:25 pm, the laboratory had not established the performance specifications for pH and Specific Gravity; (5) A review of patient records identified pH and Specific Gravity testing had been reported for three patients on 09/07/2023 (Patient ID #96, Patient ID #3437, and Patient ID #10949).
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 a review of records and interview with testing person #2, the laboratory failed to perform calibration verification procedures at least once every 6 months for the Urine Drug Screen and Specimen Validity testing performed on the Siemens Viva Pro E EMT analyzer for 22 of 22 months reviewed. Findings include: (1) On 09/21 /2023 at 09:20 am, testing person #2 stated the laboratory began performing Urine Drug Screen testing (Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, and Methadone) and specimen validity testing (pH, Specific Gravity) using the Siemens Viva-ProE EMT analyzer on 12/01/2021; (2) A review of 2023 calibration records identified calibration procedures had been performed using one or two data points; (3) A review of records from December 2021 through the current date identified no evidence calibration verification procedures had been performed at least once every six months; (4) Interview with testing person #2 on 09/21/2023 at on 06/15 /2023 at 01:27 pm confirmed the laboratory had not performed calibration verification at least once every six months during the review period.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, written procedure, and interview with testing person #2, the laboratory failed to perform two levels of quality control materials each day of patient Urine Adulterant Strip testing for one of one day reviewed. Findings include: (1) On 09/21/2023 at 09:30 am, testing person #2 stated the laboratory performed pH Urine Adulteration testing using the ADU-6T Reagent Strips; (2) A review of the procedure titled, "Urine Adulteration Strip Testing" under the heading "8. Quality Control" stated, "Regularly verify the accuracy and realiabiligy of the urine adulteration strip tests by suing control samples with known values"; (3) A review of laboratory records and a patient pH Urine Adulteration test report for Patient ID #2518 performed on 09/20/2023 identified no evidence two levels of quality control materials had been tested on the day of patient testing; (4) The records were reviewed with testing person #2 who stated on 09/21/2023 at 01:35 pm, the laboratory had not performed two levels of quality control testing on the day of patient testing.
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 a review of records and interview with testing person #2, the laboratory failed to ensure patient test reports included the address of the laboratory location where the testing was performed for three of three reports reviewed. Findings include: (1) On 09/21/2023 at 09:30 am, testing person #2 stated the laboratory performed Qualitative Urine Drug Screen testing (Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, and Methadone) and specimen validity testing (pH and Specific Gravity) using the Siemens Viva-ProE EMT analyzer; (2) A review of patient reports identified they did not include the address of the laboratory location where testing was performed for the following: (a) Patient ID # 96 testing performed on 09 /07/2023; (b) Patient ID #3437 testing performed on 09/07/2023; (c) Patient ID #10949 testing performed on 09/07/2023. (3) The findings were reviewed with testing person #2 who stated on 09/21/2023 at 01:30 pm, the laboratory address had not been included in the patient test reports. 48517 Based on a review of records, urine drug assay package inserts, and interview with testing person #2, the laboratory failed to ensure test reports for Urine Drug Screen and Adulterant testing included information required for interpretation for three of three patient reports. Findings include: URINE DRUG SCREEN DISCLAIMER (1) On 09/21/2023 at 10:05 am, testing person #2 stated Urine Drug Screen testing, which included the analytes Amphetamines, Barbiturates, Benzodiazepines, Buprenorphine, Cannabinoids, Cocaine, Opiates, Oxycodone, and Methadone was performed using the Viva Pro E analyzer; (2) A review of the manufacturer's instructions contained in the assay package inserts for each analyte stated, "The Emit II Plus assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used"; (3) A review of three patient reports with Urine Drug Screen test results reported on 09/07/2023 identified the reports did not include a disclaimer with the manufacturer's statement that the results were preliminary and guidance on obtaining a confirmed analytical result; (4) The findings were discussed with the testing person #2 who stated on 09/21/2023 at 10:05 am, the patient reports did not include the disclaimer. ADULTERANT DISCLAIMER (1) On 09/21/2023 at 10:05 am, testing person #2 stated Urine Adulterant testing, which included the analytes pH and Specific Gravity was performed using the Viva Pro E analyzer; (2) A review of the manufacturer's instructions contained in the assay package inserts for each analyte stated, "The Syva Validity test is intended for use as a measurement of Specific Gravity and pH as an indicator of adulteration in human urine. This test is for forensic/toxicology use only"; (3) A review of three patient reports with pH and Specific Gravity test results reported on 09/07/2023 identified the reports did not include a disclaimer with the manufacturer's statement that the results were for forensic/toxicology use only; (4) The findings were discussed with the testing person #2 who stated on 09/21/2023 at 10:05 am, the patient reports did not include the disclaimer.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, policy and procedure manual and interview with testing person #2, the laboratory director failed to provide overall management and direction for 22 of 22 months of patient testing. Findings include: (1) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (3) The laboratory director failed to ensure test reports included pertinent information required for interpretation. Refer to D6026; (4) The laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for the testing process. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) 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: Based on a review of records and interview with testing person #2, the laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the performance specifications had been demonstrated for a new analyzer. Refer to D5421.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #2, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to

	ensure the accuracy of Urine Drug Screen testing performed on the Siemens Viva Pro E had been verified at least twice annually. Refer to D5217; (2) The laboratory director failed to ensure calibration verification procedures had been performed at least once every 6 months for the Urine Drug Screen testing performed on the Siemens Viva Pro E EMT analyzer. Refer to D5439.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with testing person #2, the laboratory director failed to ensure test reports included pertinent information required for interpretation. Findings include: (1) The laboratory director failed to ensure patient test reports for Urine Drug Screen testing included the address of the laboratory location where the testing was performed. Refer to D5807; (2) The laboratory director failed to ensure test reports for Urine Drug Screen testing included information required for interpretation. Refer to D5807.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with testing person #2, the laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for the testing process. Findings include: (1) The laboratory director failed to ensure the procedure manual had been approved, signed, and dated by the laboratory director before use. Refer to D5407.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by:

	Based on a review of records, written procedure, and interview with testing person #2, the laboratory director failed to meet the qualification requirements for high complexity testing and failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure verification procedures were adequate to determine the performance characteristics. Refer to D6086; (2) The laboratory director failed to ensure quality control programs were established and maintained. Refer to D6093.
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: Based on a review of records, manufacturer's instructions, and interview with testing person #2, the laboratory director failed to ensure verification procedures were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the performance specifications establish the performance specifications for two of two analytes not subject to FDA clearance or approval (labeled as for forensic/toxicology use only). Refer to D5423.
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 a review of records, written procedure, and interview with testing person #2, the laboratory director failed to ensure quality control programs were established and maintained. Findings include: (1) The laboratory director failed to ensure the accuracy of Specimen Validity testing performed on the Siemens Viva Pro E had been verified at least twice annually. Refer to D5217; (2) The laboratory director failed to ensure calibration verification procedures had been performed at least once every 6 months for the Specimen Validity testing performed on the Siemens Viva Pro E EMT analyzer. Refer to D5439; (3) The laboratory director failed to ensure two levels of quality control materials had been performed each day of patient Urine Adulterant Strip testing. Refer to D5447.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with testing

	person #2, the laboratory failed to ensure test reports included pertinent information required for interpretation. Findings include: (1) The laboratory director failed to ensure patient test reports included the address of the laboratory location where the testing was performed for pH and Specific Gravity reports reviewed. Refer to D5805; (2) The laboratory director failed to ensure test reports for pH and Specific Gravity testing included information required for interpretation for three of three patient reports. Refer to D5805.