Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D2172074	**(X3) Date Survey Completed** 08/24/2021
Name of Provider or Supplier National Laboratory Corporation	**Street Address, City, State** 5805 E 15th St, Ste 104, 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 08/24/2021. The findings were reviewed with the technical supervisor at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the technical supervisor, the laboratory failed to follow written policies and procedures to ensure the optimum integrity of patient specimens from the time of collection through the reporting of results for 6 of 8 patient specimens. Findings include: (1) On 08/24/2021 at 10:25 am, the technical supervisor stated to surveyor #2 the laboratory performed urine drug confirmation testing using the Sciex Triple Quad 4500 analyzer; (2) Surveyor #2 reviewed the "Laboratory Policies and Procedure Manual" under the section of stability studies titled, "10. Stability Studies" it stated "Specimens are stable for up to 2 weeks at room temperature or in the refrigerator."; (3) Surveyor #2 reviewed 8 patient reports tested between 06/03/2020 and 04/02/2021 and identified the following for 6 of 8 patient reports: (a) Patient report #1- Specimen was collected on 05/14/2020, received into the laboratory on 05/28/2020, and analyzed on 06/03/2020 (17 days after collection); (b) Patient Report #2 - Specimen was collected on 05/14/2020, received into the laboratory on 05/28/2020, and analyzed on 06/03/2020 (17 days after collection); (c) Patient #3 - Specimen was collected on 05/16/2020, received into the laboratory on 05/28/2020, and analyzed on 06/03/2020 (19 days after collection); (d) Patient #4 - Specimen was collected on 09/14/2020, received into the

	laboratory on 09/16/2020, and analyzed on 10/01/2020 (17 days after collection); (e) Patient #5 - Specimen was collected on 02/19/2021, received into the laboratory on 02/27/2021, and analyzed on 03/07/2021 (16 days after collection); (f) Patient #6 - Specimen was collected on 03/08/2021, received into the laboratory on 03/12/2021, and analyzed on 04/02/2021 (23 days after collection). (4) Surveyor #2 reviewed the reports with the technical supervisor. The technical supervisor stated on 08/24/2021 at 12:25 pm the patient specimens were tested beyond the laboratory's specimen stability as indicated above.
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 a review of records, written policy and procedure manual, and interview with the technical supervisor, the laboratory failed to follow written procedures for patient reporting for 3 of 4 patient reports. Findings include: (1) On 08/24/2021 at 10:30 am, the technical supervisor stated to surveyor #2: (a) Urine drug confirmation testing was performed in the laboratory; (b) Six calibrators were run at least twice with each batch of patient testing; (c) Three levels of QC (quality control Level A, Level B, and Level C) were run at least twice with each batch of patient testing. (2) Surveyor #2 reviewed written "Laboratory Policy and Procedure Manual". The procedure titled, "Reporting Qualitative Only Results" stated, "If two or more Quality Control samples (QCs) from one level meet identification criteria but are outside the allowed 30% accuracy, then the analyte may be reported as qualitative only."; (3) Surveyor #2 reviewed 4 patient reports between 12/20/2020 and 05/11/2021 and identified the following for 3 of 4 patient reports: (a) Patient #1 analyzed on 06/16/2020 - Level A QC met the identification criteria to report only qualitative results for Norbuprenorphine. The patient report included both qualitative and quantitative results; (b) Patient #2 analyzed on 03/07/2021- Level A QC met the identification criteria to report only qualitative results for Amitriptyline. The patient report included both qualitative and quantitative results; (c) Patient #3 analyzed on 04/17/2021- Level B QC met the identification criteria to report only qualitative results for Norhydrocodone. The patient report included both qualitative and quantitative results. (4) The surveyor reviewed the findings with the technical supervisor who stated on 08/24/2021 at 01:26 pm, the laboratory did not follow the laboratory's written procedure for patient reporting as indicated above.
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 the technical supervisor, the laboratory failed to verify the acceptable performance of the laboratory computer system. Findings include: (1) On 08/24/2021 at 10:25, the technical supervisor stated to surveyor #1 the laboratory began performing patient urine drug testing on 12/26 /2019, which included installing the SchuyLab laboratory information system (LIS); (2) Surveyor #2 asked the technical supervisor for documentation to prove the laboratory ensured the LIS performed acceptably before it was put into use; (3) The technical supervisor was not able to locate records and stated to surveyor #2 on 08/24 /2021 at 12:30 pm there was no documentation to substantiate the laboratory had determined the acceptable performance of the new LIS when it was installed.
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 a review of records, policies and procedures, and interview with the technical supervisor, the laboratory failed to follow their written protocol for ensuring the urine centrifuge and pipettes were functioning properly. Findings include: THERMOFISHER LEGEND MICRO 21 CENTRIFUGE (1) On 08/24/2021 at 10:30 am, the technical supervisor stated to surveyor #2, urine drug confirmation testing was performed in the laboratory. The specimens were processed in the Thermofisher Legend Micro 21 centrifuge at a speed of 13000 rpm (revolutions per minute) for 10 minutes; (2) Surveyor #2 reviewed the "Laboratory Policy and Procedure Manual" policy titled "Centrifuge Procedure & Calibration Check". Under the section titled, "Purpose" it stated, "A calibration check should be performed one yearly, or after maintenance, using a tachometer and a stopwatch." (3) Surveyor #2 ask the technical supervisor for the centrifuge maintenance records. The technical supervisor stated on 08/24/2021 at 12:52 pm, the centrifuge had not been checked since patient testing began on 12/26/2019. MICROPIPETTING PROCEDURE AND MAINTENANCE (1) On 08/24/2021 at 10:32 am, the technical supervisor stated to surveyor #2, urine drug confirmation testing was performed in the laboratory. The specimens were processed using VWR pipettes; (2) On 08/24/2021 at 10:38 am surveyor #2 observed the following pipettes in the laboratory: (a) VWR 100 l serial number 19L0188 serviced 01/29/2020; (b) VWR 200 l serial number 19M0405 serviced 01/29/2020; (c) VWR 20 l serial number 19L0484 serviced 01/29/2020; (d) VWR 50 l serial number 19K0423 serviced 01/30/2020. (3) Surveyor #2 reviewed the "Laboratory Policy and Procedure Manual" policy titled "Micropipetting Procedure and Maintenance". Under the section titled, "Maintenance" it stated, "2. Annual Maintenance: Every year, all micropipettes will require Quality Assessment testing and, if necessary, calibration. A professional calibration service or gravimetric analysis may be used to verify accuracy

	of pipettes. Annual maintenance may be performed off-site." (4) Surveyor #2 ask the technical supervisor for the 2021 pipette maintenance records. The technical supervisor stated on 08/24/2021 at 12:50 pm, the pipettes had not been checked in 2021.
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 the Technical Supervisor, the laboratory failed to ensure that test reports included the name and address of the laboratory location. Findings include: (1) On 08/24/2021 at 10:25 am, the technical supervisor stated to surveyor #2 the laboratory performed urine drug confirmation testing using the Sciex Triple Quad 4500 analyzer; (2) On 08/24/2021 at 10:30, the technical supervisor stated to surveyor #2 the laboratory sent Ethyl Glucuronide (EtG) and Ethyl Sulfate (Et5) to a reference laboratory; (2) Surveyor #2 then reviewed 1 patient report that included Ethyl Glucuronide (EtG) and Ethyl Sulfate (Et5) . For 1 of 1 report the following was identified: (a) 06/08/2020 - Patient report did not include the name and address of the reference laboratory where the Ethyl Glucuronide (EtG) and Ethyl Sulfate (Et5) were tested. (3) The surveyor reviewed the report with the technical supervisor who stated on 08/24/2021 at 10:40 am the report did not include the name and address of the laboratory location where the testing had been performed as indicated above.