Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2291315	(X3) Date Survey Completed 12/06/2024
Name of Provider or Supplier Scylex Inc Dba Scylexlab	**Street Address, City, State** 6994 Columbia Gateway Dr, Columbia, 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
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 procedure and record review and interview with the technical supervisor (TS), the laboratory failed to establish procedures that ensured accurate positive patient identification from specimen receipt through results reporting. Findings: 1. The laboratory performed a molecular pharmacogenetic assay that included logging in the patient information, assigning a patient identification number (sample ID), transferring the specimen to a microcentrifuge tube, then to a 96 well plate for extraction and processing, and then to a BeadChip for analysis. 2. The procedure titled "Quality Control- SOP" (QC SOP) stated to "Log receipt of the sample and documentation into the tracking system (Patient Information Excel Sheet and Lims)." 3. The QC SOP also stated to record the extraction QC results "into the DNA Extraction Log Sheet" which included columns for the date of collection, the date of extraction, the sample ID, the barcode ID, the BeadChip ID, and the extraction QC values. 4. The TS stated that the sample ID number was the last 4 digits of the barcode ID 5. The procedures did not include instructions for assigning patients to wells in the 96 well plate or positions on the BeadChip. 6. Patient number 5915 was randomly selected to review from specimen receipt to results reporting. Testing was performed for patient 5915 and their parent. 7. There were two Excel worksheets containing patient information. The first was the original worksheet in use and the 2nd was just recently transcribed from the original worksheet. 8. The original Excel worksheet included patient 5915's name, but the entry for the sample ID number, 5915, was blank. Sample ID 5915 was assigned to the patient's parent. 9. The 2nd Excel

	worksheet had the parent's correct sample ID number, but listed sample ID 5913 for the selected patient instead of 5915. 10. The extraction log only contained the sample ID which was written in the barcode ID column. All other columns were left blank. 11. All patient information and QC values were correctly entered into a laboratory notebook that was not mentioned in any of the procedures. 12. During the exit interview on 12/06/2024 at 3:00 PM, the TS confirmed that sample ID 5915 was misidentified on the Excel worksheets, that the extraction log was not completed, and that there was no procedure for assigning patients to wells in the 96 well plate or position on the BeadChip to ensure positive patient identification from specimen receipt through results reporting.
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: Based on review of the procedure manuals and interview with the technical supervisor consultant (TS) and laboratory director (LD), the laboratory failed to establish written policies and procedures for assessing the testing personnel as defined in subpart M-CFR 493.1451(b)(8) through (9) for high complexity testing. Findings: 1. The laboratory's approved written procedure manual did not include all the required elements for evaluating the competency of the testing personnel and assuring that they maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to: direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; monitoring the recording and reporting of test results; review of intermediate 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; and assessment of problem solving skills; and evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. 2. During the survey on 12/06/2024 at 3:00 PM, the TS and LD confirmed that the approved policy and procedure manual did not include written training and competency programs to follow when training the testing personnel who perform high complexity testing.
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 review of the policies and procedures and interview with the technical supervisor (TS) and laboratory director (LD), the laboratory failed to have a written

	policy describing the system used for verifying the accuracy and reliability of the analysis of the patient's deoxyribonucleic acid (DNA) to identify genetic variants to help inform medication efficacy, safety, and dosing for which proficiency samples are not available. Findings: 1. The policy and procedure manual did not have a written policy for evaluating the proficiency of the DNA testing at least twice a year. 2. During the survey on 12/06/2024 at 3:00 PM the TS and LD confirmed that the procedure did not have a written policy for evaluating the DNA testing system at least twice a year. The procedure should include, but is not limited to: the details of whom the samples will be exchanged with; how often samples will be exchanged; what the acceptable limits of the comparison and remedial actions to be taken when the results are not within acceptable limits.
D5303	TEST REQUEST CFR(s): 493.1241(b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization. This STANDARD is not met as evidenced by: Based on review of the requisitions, policy and procedure manuals, and interview with the technical supervisor (TS), the laboratory failed to establish written procedures for ensuring that verbal orders are followed up with written or electronic authorization within 30 days of the verbal request. Findings: 1. Review of 9 test requisitions showed that all 9 were missing the authorization signature for ordering the test. 2. The TS confirmed that the laboratory does not have a written procedure instructing the staff to contact the client to procure a written or electronic authorization to perform the test. 3. During the exit survey on 12/06/2024 at 3:00 PM, the TS confirmed that there was no written procedure for obtaining the written authorization signature for the 9 requisitions that were missing the authorization signature.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of the requisitions and interview with the technical supervisor (TS), the laboratory failed to ensure that the collection date was recorded on the requisition

	form. Findings: 1. Review of 9 test requisitions showed that all 9 failed to have the collection date recorded as required on the requisition form. 2. During the exit survey on 12/06/2024 at 3:00 PM, the TS confirmed that the laboratory staff failed to follow up with the client to get the collection date to ensure accurate turnaround time for the specimens tested.
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 procedure and patient test record review and interview with the technical supervisor (TS), laboratory personnel failed to follow procedures when patient consent and testing request forms were received incomplete. Findings. 1. The procedure titled "DNA Sample Collection using Oracollect-DX - OCD-100" stated to "Fill out the Informed Consent: Pharmacogenetic Testing and Pharmacogenetic Testing Request Form" and that the staff receiving the sample should "Ensure all required documentation is included." 2. The procedure titled "Quality Control- SOP" (QC SOP) stated to "Verify that the following required forms are submitted with the sample" and listed "Informed Consent: Pharmacogenetic Testing" and "Pharmacogenetic Testing Request Form." 3. The QC SOP then stated that "If a sample fails the quality check due to incomplete documentation or a damaged/leaky container" the laboratory should 1) "Document the issue in the tracking system", 2) "Notify the submitting entity or individual immediately", and 3) "Follow laboratory policy for sample rejection or request for resubmission." 4. Patient number 5915 was randomly selected to review from specimen receipt to results reporting (see tag D5203 for additional details). 5. Records showed that the Informed Consent form was not signed and that the Testing Request Form only contained the patient's name, date of birth, sex, and address. The provider information, testing information, and provider authorization were missing from the Testing Request Form. 6. There was no documentation that the submitting entity was notified and a request for the resubmission of completed paperwork was made as stated in the QC SOP. 7. During the exit interview on 12/06/2024 at 3:00 PM, the TS confirmed that the Informed Consent and Testing Request forms for patient 5915 were incomplete and there was no documentation that the submitting entity was notified.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on review of the procedure manual and interview with the testing person (TP), the laboratory's procedure manual failed to ensure that written policies and procedures included instructions for the how to use the electronic management system for monitoring reagent quantities available, lot numbers, and expiration dates of the supplies used for laboratory testing. Findings: 1. The TP explained that all the reagents and supplies used in the laboratory are entered into an electronic management system that tracks the quantity available, lot numbers, and expiration dates. The system ensures that supplies are available and reagents and supplies are not used past their expiration dates. 2. During the exit interview on 12/06/2024 at 3:00 PM, the TP confirmed that the policy and procedure manual did not contain written instructions for how to enter and monitor the information entered into the electronic reagent monitoring system. 43123 II. Based on review of the standard operating procedure manual (SOPM) and interview with the technical supervisor (TS), the laboratory's SOPM did not include instructions for instrument maintenance and how to create a final test report. Findings: 1. The SOPM did not include instructions detailing the routine and preventive maintenance requirements for instruments used for patient testing including frequency of maintenance and calibration activities. 2. The TS demonstrated how to create a final test report using patient demographics, instrument results, and software from a 3rd party. The SOPM did not include the written step-by-step instructions that were demonstrated. 3. During the exit interview on 12/06/2024 at 3:00 PM, the TS confirmed that the SOPM did not include procedures for routine and preventive instrument maintenance and did not include instructions for creating the final test report.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on review of laboratory records, manufacturer's instructions for use (IFU), and interview with the technical supervisor (TS), the laboratory failed to monitor and document conditions essential for accurate and reliable test system operation. Findings: 1. The laboratory has two rooms where testing is performed. The Quibit and Smartdrop (chemistry analyzers) are in one room and the iSCAN (chemistry analyzer)

	is in another room. 2. According to the IFU's for each analyzer, the temperature and humidity is to be monitored to ensure the optimal conditions for testing. 3. The laboratory records failed to include documentation of the monitoring of the temperature and humidity in each of the two rooms. 4. During the survey on 12/06 /2024 at 3:00 PM, the TS confirmed that the laboratory was not monitoring temperature and humidity in each of the laboratory's where the testing was being performed. II. Based on review of laboratory records, and interview with the technical supervisor (TS), the laboratory failed to define appropriate reference ranges for storing the reagents in the refrigerator and freezer essential for accurate and reliable test system operation. Findings: 1. The laboratory records that included refrigerator and freezer temperature failed to include limits of acceptability to ensure that the reagents were stored appropriately. 2. During the survey on 12/06/2024 at 3:00 PM, the TS confirmed that the laboratory had not defined limits of acceptability for storage of reagents in the refrigerator and freezer. 43123 III. Based on procedure and record review and interview with the technical supervisor (TS), the laboratory failed to monitor and document the temperature requirements for accurate and reliable test system operation for the molecular pharmacogenetic assay. Findings: 1. The testing procedures included sample incubations at 50 C, 37 C, and 48 C as well as centrifugation at 4 C and verifying the chamber rack temperature of 44 C. 2. During the exit interview on 12/06/2024 at 3:00 PM, the TS confirmed that the laboratory did not document these temperatures when testing was performed to ensure accurate and reliable test system operation.
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: Based on review of validation documentation and interview with the technical supervisor (TS), the laboratory failed to document the evaluation and approval of the validation studies for the molecular pharmacogenetic assay. Findings: 1. The procedure titled "Method Validation Report" explained the studies that were performed to validate the assay for patient testing and the laboratory maintained all the raw data from the studies. 2. There was no documentation that defined the acceptance criteria and showed how the assay met all acceptance criteria and was approved for patient testing. 3. During the survey on 12/06/2024 at 12:20 PM, the TS confirmed that the evaluation of the validation raw data was not documented and there was no documentation stating that the assay had been approved for 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 review of the test report and interview with the technical supervisor (TS), the final test report failed to include the date the report was issued. Findings: 1. An example patient test report was reviewed that did not include the test report date. 2. During the exit interview on 12/06/2024 at 3:00 PM, the TS confirmed that the test report date was not included on the test reports.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the procedure manuals and interview with the technical supervisor (TS) and laboratory director (LD), the LD failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic, and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results. Findings: During the exit interview on 12/06/2024 at 3:00 PM, the TS and LD confirmed that the laboratory's approved procedure manual did not specify in writing the duties and responsibilities of the clinical consultant and technical supervisor.