

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D2073142	<b>(X3) Date Survey Completed</b>  10/07/2020
<b>Name of Provider or Supplier</b>  Preferred Laboratory Llc	<b>Street Address, City, State</b>  1071 Worcester Road, 4th Floor, Framingham, MA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A CLIA recertification survey was conducted for Preferred Laboratory, LLC pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Due to repeat deficiencies being cited herein, the following Condition level regulations were deemed to be not met: Condition 42 CFR 493.1441 - Laboratory Director. Condition 42 CFR 493.1447 - Technical Supervisor. .
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform complete validation studies for fourteen (14) of fourteen (14) newly implemented test systems not subject to FDA clearance prior to reporting out patient testing results as evidenced by the following: Accuracy: A review of validation studies for the Beckman AU 680 chemistry analyzer revealed that accuracy studies (correlation) were not performed as part of the validation for pH and ethanol. The technical supervisor interviewed on 10 /67/20 at 9:50 AM confirmed that accuracy studies had not been completed prior to reporting out patient test results at the beginning of September 2020. Day to day precision: A review of validation studies for the Routine Chemistry and Toxicology analytes performed on the Beckman AU 6800 chemistry analyzer. revealed that the laboratory failed to include day to day precision studies as part of the validation for all fourteen (14) of the test analytes being performed (creatinine, urinary pH, oxidant,</p>

	<p>amphetamine, benzodiazepine, buprenorphine, cocaine, methadone, opiate, oxycodone, cannabinoid (THC), and ethanol). The technical supervisor stated in an interview on 10/7/20 at 9:00 AM that the day to day precision studies were in process of being performed and had not been completed. The laboratory performs 14,400 Routine Chemistry and Toxicology assays annually. This deficiency was cited at the last two CLIA recertification surveys performed on 5/8/18 and 6/22/16. .</p>
<p><b>D5429</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform maintenance of equipment defined by the manufacturer and with at least the frequency specified by the manufacturer as evidenced by the following: Laboratory thermometers: a) Review of the 2 laboratory refrigerator thermometers revealed that the laboratory failed to perform calibration checks as required. For refrigerator number 3 the thermometer calibration was required to be performed on 2/22/12 and for refrigerator number 4 the thermometer calibration was required to be performed on 10/10/19. b) The technical consultant confirmed in an interview on 10/7/20 at 9:19 AM that calibration checks for the two thermometers had not been performed. .</p>
<p><b>D5791</b></p>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory follow procedures for an ongoing mechanism to monitor and ensure reliable and accurate test results as evidenced by: a) A review of quality control records for testing performed between 9/2 /20 and 10/3/20 (10 days of testing) revealed that here was no documentation to verify that testing personnel were monitoring and assessing quality control and calibration results on a daily basis. b) The technical supervisor confirmed in an interview on 10/7 /20 at 10:12 AM that the calibration and quality control results were being reviewed for acceptability but these reviews were not being documented. .</p>
<p><b>D5805</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>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</p>

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 record review and interview, the laboratory failed to ensure that the final report contained all required information for interpretation as evidenced by the following: a) Record review conducted on 10/7/20 of twelve (12) final patient test reports for testing performed between 9/3/20 and 10/2/20 revealed that all twelve (12) (laboratory accession numbers 179299, 179416, 179445, 179523, 179531, 179638, 180174, 180324, 180326, 180351, 180516, and 180724) of the final reports did not include the test report date. b) The technical supervisor confirmed in an interview on 10/7/20 at 10:00 AM that the final report did not include the test report date. .

**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 the fact that one of the deficiencies cited during this CLIA recertification survey had been cited at two previous CLIA surveys (refer to D5421), the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart and did not ensure that deficiencies cited were corrected and remained corrected through the implementation of appropriate monitoring mechanisms. \* The laboratory director failed to ensure that verification procedures used were adequate to determine the accuracy and precision and other pertinent performance characteristics of new test methodologies. Refer to D 6086.

**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 record review and interview, the laboratory director failed to ensure that verification procedures used were adequate to determine the accuracy and precision and other pertinent performance characteristics of new test methodologies as evidenced by the following: Refer to D5421. .

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated

that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on an interview, the laboratory director failed to ensure that documentation was maintained to verify that newly hired personnel were appropriately trained for the type and complexity of the services offered as evidenced by the following: a) One (1) new laboratory technologist, the sole person performing testing in the laboratory, had been hired since the last CLIA survey performed. There was no documentation maintained to verify that the technologist had received training in all aspects of the laboratory operation prior to performing specimen processing, testing, and reporting procedures. b) Interview on 10/7/20 at 8:30 AM with the technical supervisor confirmed that there was training performed off site at the corporate laboratory in Indiana but the documentation was not available on site for review at the time of the survey.

**D6108**

**LABORATORY TECHNICAL SUPERVISOR**  
CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:  
Based on the nature of the deficiencies cited herein, the laboratory technical supervisor failed to provide technical supervision in accordance with 493.1451 of this subpart as evidenced by the following: a) The technical supervisor failed to ensure: 1) the establishment of the laboratory's test performance characteristics, and, 2) that the verification of the test procedures performed were adequate for accuracy and precision when applicable, prior to implementing new test methodologies or instrumentation for patient testing and reporting. Refer to D6115. .

**D6115**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:  
Based on record review and interview the technical supervisor failed to ensure the establishment of the laboratory's test performance characteristics and that the verification of the test procedures performed were adequate for accuracy and precision when applicable, prior to implementing fourteen (14)of fourteen (14) test procedures for patient testing and reporting: a) The technical supervisor failed to ensure that validation studies were performed for accuracy and precision prior to implementing the test for patient testing and reporting. Refer to D5421. b) Based on a review of the validation documentation on 10/7/20 for the fourteen (14) test methods the technical supervisor failed to document a review and approval of the validations that had been completed. .