Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2073142	05/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Preferred Laboratory Llc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	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 regulation was deemed to be not met: Condition 42 CFR 493.1441 - Laboratory Director. .
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: Based on procedural review and interview, the laboratory failed to have a procedure manual which included all procedures as evidenced by the following: The laboratory

	implemented two (2) new synthetic cannabinoid procedures (AB-Pinaca and UR144) on 3/1/18. A review of laboratory procedures on 5/8/18 revealed that the procedures had not been included in the procedure manual. The manufacturer's package inserts were available, but were not included in the laboratory's procedure manual, did not include quality control and calibration procedures and did not reflect a documented review and approval by the laboratory director (refer to D5407). The technical supervisor confirmed in an interview on 5/8/18 at 10:36 a.m. that the procedure for AB-Pinaca and UR-144 had not been included in the procedure manual. .
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 procedure manual review and interview, the laboratory director failed to approve, sign, and date new test procedures as evidenced by the following: a) A review of the laboratory manufacturer's procedures for three (3) new tests performed (AB-Pinaca, UR-144 and Ethyl Gluconuride (EtG)) revealed that the laboratory director did not review and approve the three new procedures prior to use. b) Interview with the technical supervisor on 5/8/18 at 10:36 a.m. confirmed that the laboratory director had not reviewed and approved the above procedures prior to implementation. The tests were implemented and patient testing began on 3/1/18 for AB-Pinaca and UR-144 and on 3/30/17 for EtG. This deficiency was cited at the last CLIA recertification survey performed on 6/22/16. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation and record review, the laboratory failed to ensure laboratory reagents were not used when they had exceeded their expiration date as evidenced by the following: During a tour of the laboratory on 5/8/18 at 11:45 a.m. the surveyor observed the following expired item: A bottle of Cedia Buprenorphine 75 ng/mL calibrator, lot number 124840, expiration date 3/31/18 was stored in the laboratory refrigerator. Review of the calibration log revealed that a buprenorphine calibration had been performed, utilizing this expired calibrator, on 4/5/18. .
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 record review and interview, the laboratory failed to establish performance specifications of three (3) of three (3) newly implemented test systems not subject to FDA clearance as evidenced by the following: 1. Cedia AB-Pinaca assay (synthetic cannabinoid) Specificity: A review of validation studies for the Cedia AB-Pinaca Assay revealed that the laboratory failed to perform specificity studies as part of the validation. The technical supervisor stated in an interview on 5/8/18 at 10:06 a.m. that specificity studies had not been included as part of the validation. The laboratory performs 1,847 AB-Pinaca assays annually. 2. Cedia UR-144 Assay (synthetic cannabinoid) Accuracy: A review of validation studies for the Cedia UR-144 Assay revealed that accuracy studies were not performed as part of the validation. The technical supervisor interviewed on 5/8/18 at 10:04 a.m. stated that he was unable to obtain positive samples to perform the accuracy studies. Specificity: A review of validation studies for the Cedia UR-144 Assay revealed that the laboratory failed to perform specificity studies as part of the validation. The technical supervisor stated in an interview on 5/8/18 at 10:06 a.m. that specificity studies had not been included as part of the validation. The laboratory performs 1,847 UR-144 assays annually. 3. Ethyl Glucuronide (EtG) Assay (alcohol metabolite) Day to day precision: A review of validation studies for the Cedia UR-144 Assay revealed that the laboratory failed to include day to day precision studies as part of the validation. The technical supervisor stated in an interview on 5/8/18 that the studies had been performed but were not documented. He printed out the day to day precision data on the day of the survey. The laboratory performs 17,179 EtG assays annually. This deficiency was cited at the last CLIA recertification survey performed on 6/22/16. .
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on procedural review and interview, the laboratory failed to have policies and procedure which outlined the ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems as evidenced by the following: A review of laboratory procedures on 5/8/18 revealed that there were no specific procedures for the postanalytic portion in the case where corrected reports needed to be issued. . A review of corrected reports issued for calendar year 2018 revealed that there were three corrected reports issued (accession numbers 661427 - reported on 3/31/17, 661428 - reported on 3/31/17, and 669795 - reported on 7/25/17). There was no documented investigation into the cause of the reports needing to be corrected and no indication of corrective action instituted to prevent future occurrences. In addition there was no documentation maintained as to whether the reports had been issued to the authorized individual ordering the tests and whether

	there was communication to the authorized individual advising them of the corrected test results. The technical supervisor confirmed in an interview on 5/8/18 at 11:35 a. m. that there were no written policies or procedures addressing the issuance of corrected reports and no mechanism for documenting an investigation and corrective action related to corrected reports being issued.
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 two of the deficiencies cited during this CLIA recertification survey had been cited at the previous CLIA survey (refer to D5407 and D5423) as well as additional deficiencies cited herein, 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 D6086. .
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 D5423. .
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, precision, sensitivity and specificity, when applicable, prior to implementing three (3) of three (3) new test procedures for patient testing and reporting. a) A review of validation

	studies for three (3) of three (3)newly implemented test procedures (AB-Pinaca, UR-144 and Ethyl Glucuronide (ETG)) revealed no documented review and approval by the technical supervisor. The technical supervisor confirmed in an interview on 5/8/18 at 10:36 a.m. that he had performed the studies and had reviewed them but had not documented a review. b) The technical supervisor failed to establish all performance specifications for three (3) of three (3) newly implemented test systems. Specifically, accuracy, day to day precision, and specificity. Refer to D5423.