Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2183993	06/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Heavens Place Recovery Center	11 E Lexington St, Baltimore, 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
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 review of the standard operating procedure manual (SOPM) and interview with the technical consultant (TC), the laboratory's SOPM did not include procedures that defined the frequency of analyte calibration, defined the acceptability criteria for humidity, and described requirements for performing maintenance on the urine drug screen (UDS) toxicology analyzer. Findings: 1. The laboratory used a Diatron P500 analyzer for patient UDS testing. 2. The "Standard Operating Procedure for Drug Screening in Urine" described the different calibrators used for each UDS analyte tested for, but did not define the frequency with which each analyte calibration should

	occur. 3. The "Temperature Log" procedure stated "Open Air Temp: Daily: Record the temperature and humidity of the lab on the corresponding temperature log." The laboratory documented the room temperature and humidity on the "Humidity /Temperature Chart." Neither the "Temperature Log" procedure nor the "Humidity /Temperature Chart" defined the acceptable humidity ranges for operating the P500 analyzer. 4. The laboratory recorded instrument maintenance on the "Diatron P500 Maintenance" log. Neither the "Equipment Maintenance" procedure nor the "Standard Operating Procedure for Drug Screening in Urine" described the requirements for performing maintenance on the Diatron P500 analyzer. 5. During the exit interview on 06/06/2024 at 1:45 PM, the TC confirmed that the SOPM did not define the frequency of analyte calibration, did not define humidity requirements, and did not describe maintenance requirements for the P500 toxicology analyzer.
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: Based on review of the toxicology analyzer's brochure and temperature records and interview with the technical consultant (TC), the laboratory failed to record humidity in the laboratory where patient testing was performed and failed to record the temperature of the refrigerator that stored reagents for urine drug screen (UDS) toxicology testing. Findings: 1. The laboratory used a Diatron P500 analyzer for patient UDS testing. The P500 brochure located on the Diatron website stated that operating "Environmental Conditions" were "Humidity 40 to 80% noncondensing." 2. The laboratory began reporting patient results on 04/02/2024. 3. The "Humidity /Temperature Chart" for 2024 included columns to record room temperature and humidity values for January-May and then hand drawn columns to record values for June. All values for humidity for April-May were recorded as "NA" and the June hand drawn columns did not include a column to record humidity. 4. At 11:35 AM, the TC confirmed that reagents used for patient testing were stored in refrigerator #2. The 2024 "Temperature Record Log" for refrigerator #2 included columns to record refrigerator temperature values for January-June. The first record occurred on 06/05 /2024. The temperature for refrigerator #2 was not recorded in April-May. 5. During the exit interview on 06/06/2024 at 1:45 PM, the TC confirmed that humidity was not recorded from April-June and that the temperature for refrigerator #2, where reagents for patient testing were stored, was not recorded until 06/05/2024 when patient testing began on 04/02/2024.
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 review of the verification documentation and interview with the technical consultant (TC), the laboratory did not have a procedure stating how the verification was performed and what the acceptability criteria were or a data summary that stated whether the laboratory's results were comparable to the performance specifications established by the manufacturer for the urine drug screen toxicology assay. Findings: 1. The laboratory's verification documentation included the raw data as well as the results summarized in the EP Evaluator software. 2. There was no procedure describing how the verification studies were performed and defining the acceptance criteria. 3. There was no data summary stating whether the laboratory's results met the acceptance criteria and were comparable to the performance specifications established by the manufacturer. 4. At 12:20 PM on 06/06/2024, the TC confirmed that there was no procedure describing how the verification studies were performed and no summary stating whether the laboratory's results met acceptability criteria and were comparable to the performance specifications established by the manufacturer.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the procedure, the final report, and quality control (QC) records and interview with the technical consultant (TC), the laboratory failed to document corrective actions when negative QC results for opiates failed to meet acceptability criteria in one of seven days tested in April 2024. Findings: 1. The "Opiate Assay" section of the "Standard Operating Procedure for Drug Screening in Urine" stated "Control results must fall within established ranges determined by the laboratory and package inserts. If results fall outside of established ranges, assay results are invalid." 2. The "Quality Control Program" procedure stated "Out-of- control Results: Out of control results must be recorded together with repeat results. Corrective Action Records should also briefly indicate: A. Any changes made in the test system e. g. fresh control material, new standard, instrument reset. Etc. B. Cause of test going out-of-control. If the cause cannot, as is often the case, be pinpointed then a question mark should appear." 3. The final report showed that a negative result for opiates was a value less than 300 ng/mL indicating that a positive result was equal to or greater than 300 ng/mL. 4. The printed QC records for April 2024 did not include a result for the negative QC performed for opiates on 04/04/2024. 5. At 12:55 PM, the TC confirmed that the negative QC value from 04/04/2024 was missing from the QC records because the value was 300 ng/mL which was rejected by the analyzer for not meeting

	acceptability criteria. 6. The unacceptable QC was not repeated on 04/04/2024 and no corrective actions were documented. 7. During the exit interview on 06/06/2024 at 1: 45 PM, the TC confirmed that the negative QC result for opiates was unacceptable on 04/04/2024 and no corrective actions were documented.
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 consultant (TC), the laboratory's test report did not list the current name of the laboratory. Findings: 1. The laboratory's name on the CLIA Certificate of Registration was "Heavens Place Recovery Center." 2. The laboratory's name on the test report was "Mighty Behavioral Health Services." 3. During the exit interview on 06/06/2024 at 1:45 PM, the TC confirmed that the laboratory had recently changed names and the test report had not been updated to reflect the current laboratory name.