Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2084863	01/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Jessie Crawford Recovery Center Inc	1925 Washington Ave, Racine, WI	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory did not retain quality control assay sheets or instructions for use of the Drugs of Abuse Total (DOAT) control materials, manufacturer's instructions for the eight toxicology assays performed in the laboratory, or lot number and expiration date records of reagents used in the laboratory. Findings include: 1. Review of laboratory records showed no evidence of DOAT quality control assay value sheets or instructions for use, manufacturer instructions for toxicology assays, or records documenting the reagent lot numbers used in the laboratory and their expiration dates. 2. Interview with the technical consultant on January 25, 2021 at 11: 45 AM confirmed the laboratory had not retained control instructions or assay sheets, toxicology reagent instructions, or reagent records.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor review of laboratory procedures, records, and reports, observation

	of the facility, and interview with the facility and laboratory staff, the laboratory had not met the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. Findings include: 1. Written instructions for specimen collection and handling were not available for referring clients. See D5317. 2. Individual procedures or instructions were not available for the toxicology assays performed in the laboratory. See D5401. 3. Storage temperatures were not documented. See D5413. 4. Expired reagents were available for use. See D5417. 5. Required maintenance was not documented. See D5429. 6. Calibration records were not available. See D5437. 7. Corrective actions were not documented when quality control results were unacceptable. See D5783. 8. Test records were not available and test reports were not filed in patient medical charts. See D5803. 9. Test reports did not include the required elements. See D5805.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the Chief Executive Officer (CEO), the laboratory had not made written instructions available to the laboratory's clients for patient preparation or for specimen collection, labeling, storage, transportation, processing, acceptability or rejection. Findings include: 1. Review of laboratory policies and procedures showed no evidence of instructions for clients submitting samples to this laboratory for testing. 2. Interview with the CEO (staff A) on January 25, 2021 at 10:30 AM confirmed the laboratory received specimens from other organizations but did not have written instructions for specimen collection and handling available for these clients.
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 surveyor review of laboratory procedures and a patient test report, and interview with the technical consultant, the laboratory did not have available procedures for eight of the eight individual toxicology assays performed in the laboratory. Findings include: 1. Review of the laboratory procedure manual showed no evidence of procedures for each individual toxicology assay performed in the laboratory. Manufacturer's instructions for the assays were not available in the procedure manual. 2. Review of a patient test report showed the laboratory performed eight toxicology assays including amphetamine, benzodiazepine, buprenorphine, cannabinoid, cocaine, ethyl alcohol, methadone, and opiate. 3. Interview with the

	technical consultant on January 25, 2021 at 11:45 AM confirmed the laboratory did not have individual procedures for the eight toxicology assays performed in the laboratory.
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 surveyor observation of reagent storage, review of laboratory records, and interview with testing personnel, the laboratory did not document the temperature of the refrigerator used for reagent storage. Findings include: 1. Observation of testing reagents in the laboratory refrigerator on January 25, 2021 at 11:15 AM showed the manufacturer required storage temperature for the reagents was two to eight degrees Celsius. 2. Review of laboratory records showed no records of temperature documentation. 3. Interview with testing personnel (staff B) on January 25, 2021 at 11: 15 AM confirmed staff B did not document storage temperatures and was not aware of any documented temperature records in the laboratory.
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 of reagents in the refrigerator and interview with testing personnel, the laboratory did not ensure testing personnel did not use 4.5% Washing Solution after the expiration date of December 31, 2020. Findings include: 1. Observation of reagents stored in the laboratory refrigerator on January 25, 2021 at 11: 15 AM revealed nine boxes of 4.5% Washing Solution. Five of the boxes showed the manufacturer's expiration date was December 31, 2020, four boxes showed an expiration date of March 31, 2021. 2. Interview with testing personnel (staff B) on January 25, 2021 at 11:15 AM confirmed the five boxes of Wash Solution available for use expired on December 31, 2020.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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.

	This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with testing personnel and the technical consultant, the laboratory did not document all required maintenance for the Indiko Plus analyzer since March 2020. Findings include: 1. Review of laboratory records revealed one "Indiko Plus Maintenance Checklist" completed in February 2020. The form showed the following required maintenance procedures: Daily maintenance: Check and/or fill DI water reservoir, Empty solid waste and wastewater reservoirs, Load TenCell cuvettes, Perform Start Up and check water blank, Clear daily files, and Wipe analyzer surfaces with cloth and mild detergent. Weekly maintenance: Run Stand-by procedure, Wash liquid and solid waste reservoirs, wipe up condensed water from reagent storage, Clean reagent/sample racks, Clean and check probes and mixing paddle, Clean the wash wells, Restart computer, Back-up database on USB flash drive, Weekly LJ Check. Monthly maintenance: Decontaminate all reservoirs and tubing, and Clean cuvette incubator. Review of the form showed daily maintenance completed on February 11, 14, and 20, and weekly maintenance completed on February 20. The report shows no documented monthly or occasional maintenance and no evidence of review. 2. During an interview with testing personnel at 11:00 AM on January 25, 2021, staff B stated staff document maintenance in the Indiko Plus analyzer information system. 3. Review of a "Maintenance report" from the Indiko Plus analyzer information system showed maintenance records from thirteen days from December 26, 2020 through January 25, 2021. The report included records from December 26 and 31, 2020 and January 8, 9, 10, 11, 14, 15, 16, 17, 21, 22, and 23, 2021. Six of the nine maintenance items on the report were only documented on January 22 and 23. The report showed completion of the following maintenance procedures: Check the water container, completed on two days, January 22 and 23. Check the waste water container competed on two days, January 22 and 23. Empty the cuvette waste bin completed on two days, January 22 and 23. Add cuvettes completed on two days, January 22 and 23. Start-up completed on ten days, December 26, 2020, January 8, 9, 11, 14, 15, 16, 17, 22, and 23, 2021. Clear daily files completed on six days, January 8, 9, 10, 15, 16, and 22 (twice). Stand-by completed on seven days, January 9 (four times), 11, 15, 16, 17 (twice), 22 and 23. Save DB completed on two days, January 22 and 23. Remove racks completed on two days, January 22 and 23 (twice). 4. Comparison of the maintenance form with the analyzer records showed the two records sets did not correlate exactly, the analyzer records did not include all required maintenance tasks and did not document the acceptability of the water blank function check. 5. Interview with the technical consultant on January 25, 2021 at 11:30 AM confirmed the laboratory had no maintenance checklists after the February checklist, and confirmed records in the analyzer information system were not complete and that the laboratory had not documented all required maintenance since March 2020.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as

	acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with testing personnel, the calibration records for eight of eight toxicology analytes were not available during the survey. Findings include: 1. Review of laboratory records showed no documented evidence of calibrations performed for the eight toxicology tests on the Indiko Plus analyzer. 2. Interview with testing personnel (staff B) on January 25, 2021 at 10:00 AM, revealed testing personnel calibrate each toxicology analyte at least weekly. Further interview at 11:45 AM confirmed the laboratory had not retained printed records of calibration and attempts to retrieve calibration records from the Indiko Plus analyzer information system during the survey were unsuccessful.
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 surveyor review of laboratory records and interview with testing personnel, the laboratory had not documented corrective actions taken when control results were not acceptable. Findings include: 1. Review of laboratory records showed no evidence of documented corrective actions taken when controls were not acceptable. 2. Interview with testing personnel (staff B) on January 25, 2021 at 11:15 AM confirmed testing personnel have not documented corrective actions taken when controls were not acceptable.
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: Based on surveyor requests for and review of patient test records and reports and interview with the Chief Executive Officer (CEO), test reports were not readily available during the survey. Findings include: 1. Surveyor requests for testing records to identify patients tested on a given day did not result in receipt of the requested records during the survey. 2. Interview with testing personnel (staff B) on January 25, 2021 at 11:00 AM revealed testing personnel print one copy of each patient's test report for the medical record after completion of testing. Interview also revealed personnel electronically archive the testing records each day after testing and stated the records were not available without reloading a back-up file. Instructions for

	loading a back-up file were not available. 3. Surveyor requests to review patient medical record charts with previously performed test reports resulted in access to a group of unfiled patient test reports from January 15, 2021. 4. Interview with the CEO (staff A) on January 25, 2021 at 12:30 PM confirmed testing records and medical charts with patient test reports were not available.
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 surveyor review of test reports and interview with the Chief Executive Officer (CEO), five of five test reports did not indicate the name and address of the laboratory, the reports identified eight of eight toxicology tests performed as abbreviations, and the report showed quantitative results. Findings include: 1. Review of patient test reports showed the reports did not indicate the name and address of the laboratory. Further review showed the report identified the tests performed with the following abbreviations: DRI THC5Qu, DRI Opi3Qu, DRI MetdQu, DRI EtOH, DRI Coc1Qu, DRI Ben2Qu, DRI Amp5Qu, and CDA Bup. The test report included quantitative results for each test. 2. Interview with the CEO (staff A) on January 25, 2021 at 9:30 AM revealed the laboratory reported qualitative test results for the eight toxicology tests performed. Interview on January 25, 2021 at 12:30 PM confirmed the test reports include quantitative results, did not indicate the name and address of the laboratory and the tests performed were only indicated with abbreviations.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) 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 surveyor review of verification records for the Indiko Plus analyzer performed in February 2020 and interview with the laboratory director, the director did not evaluate the results of the verification procedures to determine whether the accuracy and precision of the test system was adequate to provide quality results. Findings include: 1. Review of the verification records for the Indiko Plus analyzer showed no evidence of review or acceptance for use. 2. Interview with the laboratory

	director on January 25, 2021 at 9:45 AM confirmed the laboratory director had not approved, signed, or dated the verification records for the Indiko Plus analyzer to show accuracy, precision, and other performance characteristics of the test system were acceptable for use.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of test parameters and laboratory records and interview with testing personnel, the laboratory director did not establish and maintain a quality control program to ensure the laboratory tested a positive and negative control material for three of four toxicology assays reviewed to ensure quality of results. Findings include: 1. Review of "Test parameters" reports from the Indiko Plus analyzer information system show: Drug / Cut-off value for positive or negative interpretation Drugs of Abuse Total (DOAT) control material: acceptable range based on two standard deviations from the mean / qualitative interpretation Cocaine / 150 ng /mL (nanograms per milliliter) DOAT4: 64.6 - 119.4 / negative DOAT5: 124 - 252 / negative or positive Benzodiazepines / 200 ng/mL DOAT4: 82 - 218 / negative or positive DOAT5: 144 - 356 / negative or positive Ethyl Alcohol / 100 mg/dL (milligrams per deciliter) DOAT5: 46 - 94 negative DOAT6: 208 - 392 positive Buprenorphine / 20 ng/mL DOAT4: 8.8 - 21.2 / negative or positive DOAT5: 11.2 - 38.8 / negative or positive 2. Review of laboratory records showed no evidence of instructions or the manufacturer's assay sheet with expected control values for the DOAT control materials used. 3. Interview with testing personnel (staff B) on January 25, 2021 at 11:45 AM confirmed the laboratory did not have the manufacturer's assayed control target values and confirmed the acceptable ranges in the Indiko Plus analyzer would not ensure a positive and negative control result for each analyte.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on surveyor review of patient test reports and interview with the chief executive officer (CEO) and the laboratory director, the director had not ensured the test report included cut-off values for interpretation of eight of the eight toxicology assays tested in the laboratory. Findings include: 1. Interview with the CEO (staff A)

	on January 25, 2021 at 9:30 AM revealed the laboratory reported qualitative test results for eight toxicology tests using the Indiko Plus analyzer. 2. Review of test reports from January 15, 2021 showed quantitative results listed for each drug tested. Further review showed the report did not identify what cut-offs were used to determine the provided interpretation for any of the eight tests. 3. Interview with the laboratory director on January 25, 2021 at 12:30 PM confirmed the test report included quantitative results from the Indiko Plus analyzer and did not identify the cut-off values used to interpret the assay results.