Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2163391	09/30/2020
Name of Provider or Supplier	**Street Address, City, State**	
Access Behavioral Care	24714 Michigan Avenue, Dearborn, MI	

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 observation and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure specimen aliquot tubes were labeled with positive identification for 1 of 1 patient testing event observed. Findings include: 1. An observation by the surveyor on 9/30/20 at 10:22 am revealed TP1 aliquoted a urine specimen from the specimen cup to a smaller aliquot tube to be loaded on the analyzer without labeling the tube with patient information prior to analysis. 2. A review of the laboratory's established "Internal Quality Control" procedure revealed a section titled "Specimens" stating, "Use only the specimen described in the individual test instructions. Be sure that the specimen has been properly collected, stored, and labeled with patient's first and last name as well as the date of collection." 3. An interview on 9/30/20 at 10:22 am with TP1 confirmed the laboratory did not label specimen aliquot tubes with patient identification.
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 record review and interview with the Technical Consultant (TC), the laboratory failed to verify the accuracy of its toxicology testing at least twice annually for 1 (July 2019 to July 2020) of 1 year reviewed. Findings include: 1. An interview on 9/30/20 at 9:27 am with the TC revealed the laboratory started patient testing on 7 /27/19. 2. A review of the laboratory's test menu revealed it is currently testing the following analytes: a. Amphetamines b. Cocaine c. Methadone d. Opiates e. Oxycodone f. Benzodiazapine 3. A review of the laboratory's proficiency testing documentation revealed a lack of data for 2019. 4. A review of the laboratory's established "Proficiency Testing" procedure revealed a section titled "Split Samples" stating, "If proficiency testing is not provided for an analyte, then split samples will be run twice per year. Two samples will be run and each samples difference must be within 25%. A score of less than 80% will be considered failing and corrective action must be taken and documented." 5. An interview on 9/30/20 at 9:51 am with the TC confirmed the laboratory did not perform verification of accuracy testing in toxicology for 2019.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . The laboratory failed to meet applicable preanalytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to have a test request for patients receiving toxicology testing. Refer to D5301. 2. The laboratory failed to include the patients' date of birth on test requests. Refer to D5305. 3. The laboratory failed to establish specimen rejection policies. Refer to D5311 A. 4. The laboratory failed to follow written policies for specimen acceptability. Refer to D5311 B.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to have a test request for patients receiving toxicology testing for 4 (Patients 1, 4, 6, and 8) 8 patient testing records reviewed. Findings include: 1. A review of patient testing records revealed the following patients had toxicology testing performed: a. Patient 1 testing performed on 9/5/20. b. Patient 4 testing performed on 2 /22/20. c. Patient 6 testing performed on 10/26/19. d. Patient 8 testing performed on 8 /9/19. 2. The surveyor requested the test requests for the patients listed above on 9/30 /20 at 10:47 am and they were not made available. 3. An interview on 9/30/20 at 11: 30 am with the TC confirmed the laboratory did not have test requests for the patients listed above.

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: . A. Based on observation and interview with the Technical Consultant (TC), the laboratory failed to include patients date of birth on test requests for 1 (Patient 10) of 18 patient specimens with test requests observed. Findings include: 1. An observation of patient specimens in laboratory on 9/30/20 at 10:43 am revealed Patient 10's requisition for toxicology testing had a lack of date of birth. 2. An interview on 9/30 /20 at 11:30 am with the TC confirmed the laboratory did not include the date of birth on the test request.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: . A. Based on record review, observation, and interviews, the laboratory failed to establish specimen rejection policies for 14 (July 2019 to September 2020) of 14 months reviewed. Findings include: 1. An observation on 9/30/20 at 10:45 am revealed a bag of urine specimen cups with urine leaking from the cups. 2. An interview with Testing Personnel #1 on 9/30/20 at 10:45 am confirmed the urine specimen cups had been leaking. 3. The surveyor requested a specimen rejection policy on 9/30/20 at 10:45 am and it was not made available. 4. An interview on 9/30 /20 at 10:45 am with the Technical Consultant confirmed the laboratory did not establish a specimen rejection policy. B. Based on observation, record review, and interviews, the laboratory failed to follow written policies for specimen acceptability for 4 (Patients 1, 4, 5, 9) of 9 patient testing records reviewed. Findings include: 1. An observation made by the surveyor on 9/30/20 at 10:28 am revealed 18 specimens stored in the refrigerator with the following collection dates indicated on the specimen cups: a. 12 specimens were collected on 9/14/20 b. 5 specimens were collected on 9/17

	/20 c. 1 specimen was collected on 9/11/20 2. An interview on 9/30/20 at 10:28 am with Testing Personnel #1 revealed the laboratory does not test refrigerated urine specimens greater than two weeks old. 3. A review of the laboratory's "LZI Oxycodone Enzyme Immunoassay" manufacturer package insert revealed a section titled, "Specimen Collection and Handling" stating, "If the sample cannot be analyzed immediately, it may be refrigerated at 2-8 degrees Celsius for up to seven days." 4. A review of patient testing records revealed the following patients with test report dates greater than 7 days after collection date: a. Patient 1 collected on 8/27/20, tested on 9/5 /20 b. Patient 4 collected on 2/7/20, tested on 2/22/20 c. Patient 5 collected on 12/18 /19, tested on 12/27/19 d. Patient 9 collected on 9/14/20, tested on 9/30/20 5. An interview on 9/30/20 at 11:30 am with the Technical Consultant confirmed the laboratory did not ensure specimens met acceptability criteria prior to patient testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to verify the criteria for acceptability of control materials in toxicology testing for 14 (July 2019 to September 2020) of 14 months the laboratory has been established. Findings include: 1. A review of the laboratory's established "New Lot Control" procedure revealed a section stating, "Whenever you receive a new lot number of control, you must run that control 5 runs or days with the old lot number to verify the new controls package insert values before putting them into use." 2. The surveyor requested the documentation of verification of controls on 9/30/20 at 9:30 am and it was not made available. 3. An interview on 9/30/20 at 9:35 am with the TC confirmed the laboratory did not verify the new lots of controls prior to putting them into use.