Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2043076	05/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Fokus Family Services	2821 Vel R Phillips Ave Ste #123, Milwaukee, 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 maintenance records and interview with staff, the laboratory did not retain the maintenance log for the BS200 analyzer for September 2017. Findings include: 1. Review of maintenance records for the BS200 analyzer showed no record of maintenance performed in September 2017. 2. Interview with staff B on May 29, 2018 at 12:45 PM confirmed the maintenance log for September 2017 could not be located.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on surveyor comparison of laboratory procedures and interview with the executive director, the "Quality Control Guidelines" policy in the procedure manual does not include a date of initial use. Findings include: 1. Comparison of the "Quality Control Guidelines" policy in the procedure manual with the version provided with the plan of correction submitted in response to the September 26, 2016 survey show the two guidelines are not the same. 2. Further review of the policy in the procedure manual showed no evidence of a revision date or date of initial use. 3. Interview with

	the executive director, staff A, on May 29, 2018 at 11:15, confirmed procedures do not include a date of initial use.
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 procedures and calibration records, and interview with staff, the laboratory did not calibrate the BS200 analyzer at the frequency required by their procedures. Findings include: 1. Review of the cannabinoid and cocaine assay procedures from the laboratory's procedure manual showed routine calibration is required every two weeks. 2. Review of the calibration history record from the BS200 analyzer from August 22, 2016 through May 29, 2018 shows cannabinoid calibration was not performed every two weeks. The record shows cannabinoid calibrations on the following dates with no additional calibrations performed between the listed dates in each series: *March 18, April 5, and April 26, 2017 *May 26 and June 21, 2017 *August 17 and September 13, 2017 *October 14, November 18, and December 7, 2017 *December 13, 2017, January 21 and February 4, 2018 *February 20, March 20 and April 8, 2018 The report shows cannabinoid assay calibration has not been performed since April 8, 2018. Review of the calibration history record from the BS200 analyzer shows cocaine calibration was not performed every two weeks. The record shows cocaine calibrations on the following dates with no calibrations between the listed dates in each series: *December 15, 2016 and January 6, 2017 *August 17, 2017 and September 13, 2017 *October 28, 2017 and November 18, 2017 *December 13, 2017, January 7 and February 4, 2018 *February 18, March 31, and May 12, 2018 The report shows cocaine assay calibration has not been performed since May 12, 2018. Review of calibration reports for other analytes showed intervals greater than one month between calibrations: Opiates The calibration report showed no record of calibration between January 21 and February 27, 2018. The report shows no calibrations performed since April 17, 2018. Ethanol The calibration report showed only three calibrations since December 7, 2017. Calibration was performed on December 7, 2017, February 4, 2018, and May 15, 2018. Amphetamine The calibration report showed no record of calibration between May 26 and July 1, 2017. The calibration report showed no record of calibration between January 21 and March 11, 2018. Benzodiazepine The calibration report showed no record of calibration between December 7, 2017 and February 20, 2018. 3. Staff B confirmed during interview on May 29, 2017 at 11:45 AM that the calibration report showed calibrations were not completed as required. Staff B also stated calibration is required monthly and was not aware of the two week calibration requirements in the cocaine and cannabinoid procedures.

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 patient test reports and interview with the executive director, the test report does not indicate the current address of the laboratory. Findings include: 1. All reviewed patient test reports showed the laboratory is located in Suite 139 at 2821 N 4th Street. 2. The executive director, staff A, confirmed during interview on May 29, 2018 at 11:15 AM that the laboratory address on the test report had not been updated after the laboratory moved to Suite 123 in August 2017.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Item 1: Based on surveyor observation of quality control (QC) material available in the laboratory, review of laboratory records, and interview with staff, the laboratory director did not ensure records were retained to identify when a new lot number of quality control material was put into use. Findings include: 1. Observation of the quality control material available in the laboratory refrigerator on May 29, 2018 at 12: 40 PM showed a box of DOAT 5 (Drugs of Abuse Total Control Material level 5), lot number 19055 is opened, and no other lot number of DOAT 5 is available in the refrigerator. The box does not include an opened or in use date. 2. Review of laboratory records showed an untitled log with columns labeled Date, Item, Lot#, and Expiration. The log includes thirteen entries including control materials. The entries for DOAT- 4 and DOAT-5, include the lot numbers (19054 and 19055) and expiration dates but does not show the controls are in use. The eleven other entries on the log include dates ranging from July 1, 2017 through March 11, 2018. 3. Interview with the executive director on May 29, 2018 at 10:30 AM confirmed the controls in the refrigerator were in use and that records were not available to show when the current lot number of controls was started. Item 2: Based on surveyor review of laboratory procedures and records, comparison of quality control (QC) acceptable ranges on QC Data Summary Reports, and interview with staff, the laboratory director did not ensure the quality control ranges were evaluated. Findings include: 1. Review of the "Quality Control Guidelines" policy in the laboratory procedure manual showed "when new lots are received Testing Personnel must recalibrate and run five QC replicates to establish a new range and mean value." 2. Review of laboratory records showed no record of evaluation of means for the current lot number of control

	material. 3. Comparison of QC Data summary sheets printed from the analyzer on September 15, 2016, August 7, 2017, and May 22, 2018 show the same ranges in use on all three days. 4. Interview with staff B on May 29, 2018 at 12:45 PM confirmed there are no records available to show how the current ranges were derived or that the ranges were evaluated with each new lot of controls as required in the Quality Control Guidelines. Item 3: Based on surveyor review of laboratory records and procedures, and interview with staff, the laboratory director did not ensure the laboratory followed the requirements of the quality control program. 1. The "Quality Control Guidelines" policy in the laboratory procedure manual includes "Quality Controls must be run, and in control to begin testing the daily patient samples. If the control is "out" DO NOT run samples until determining what causes the control to be out, and solving the irregularity." 2. Review of QC Data Summary records show accepted control runs for THC (Tetrahydrocannabinol or Cannabinoid) and AMPH (Amphetamine) without evaluation of results that are out of range. No indication of review of the out of range result or repeat of the test is available. All results shown are ng/mL (nanograms / milliliter). Examples below are shown as: Control Level / Test / Result / Accepted Range. May 22, 2018 DOAT 5 / THC / 74.0 / 50.400 - 73.600 August 7, 2017 DOAT-4 / THC / 15.5 / 29.000 - 47.000 DOAT-4 / AMPH / 455.5 / 300.000 - 450.000 3. Interview with staff B on May 29, 2018 at 12:45 PM confirmed patient test results were reported when controls were out of range without further evaluation. This is a repeat deficiency previously cited September 26, 2016.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on surveyor review of maintenance logs for the BS200 analyzer and interview with staff, the technical supervisor, who is also the general supervisor, did not document review of the BS200 Maintenance logs from October 2017 through May 2018. Findings include: 1. Review of BS200 Maintenance logs show no documented review by the technical supervisor. The space on the log for documenting approval is filled with a typed notation, "See Master". 2. Interview with staff B on May 29, 2018 at 11:45 AM confirmed review of the maintenance logs is not documented.