Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2087422	02/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Power Of Change Inc	2821 N Vel R Phillips Ave, Suite 131, 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
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 surveyor review of laboratory procedures and interview with the technical supervisor, the laboratory does not have a written step-by-step procedure to ensure positive identification through the testing process. Findings include: 1. Review of "Processing Patient Samples" revealed the procedure does not include instructions to assign numerical identification and label patient samples through the testing phase. 2. Interview with the technical supervisor on February 17, 2020 at 12:18 PM revealed testing personnel assign each sample a number as part of the daily run. Testing personnel also number the specimen and test requisition for the run to correlate with the sample identification on the Mindray BS 200 analyzer. Further interview revealed the procedure had no written step-by-step instructions for this process and testing personnel were not consistently following the process. This is a repeat deficiency from February 20, 2018.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

	This STANDARD is not met as evidenced by: Based on surveyor review of patient test requisitions, Mindray BS 200 analyzer reports, and interview with the technical supervisor, the laboratory did not enter the date of birth accurately for three of eight patients on January 14, 2020. Findings include: 1. Review of patient test requisitions showed: Patient 1 date of birth: November 30, 1990 Patient 2 date of birth: July 21, 1991 Patient 3 date of birth: May 31, 1965 2. Review of MindRay BS 200 analyzer reports showed: Patient 1 date of birth: January 30, 1990 Patient 2 date of birth: July 12, 1991 Patient 3 date of birth: March 12, 1955 3. Interview with the technical supervisor on February 17, 2020 at 11: 57 AM confirmed the laboratory did not enter the date of birth accurately in the Mindray BS 200 for three of eight patients on January 14, 2020.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on surveyor review of patient test requisitions, analyzer reports and laboratory procedures, observation of patient urine samples and interview with the technical supervisor, the laboratory did not have a mechanism to monitor, assess and correct problems identified in the preanalytic system. Findings include: 1. Review of patient test requisitions and analyzer reports revealed the laboratory did not correct problems identified with inaccurate date of birth on three of eight patients on January 14, 2020. See D5309. 2. Review of "Collection of Patient Sample" procedure showed specimen labels must contain patient's name, date of birth, date of collection and initials of collector. Observation of previously tested patient urine samples on February 17, 2020 at 11:54 AM in the bottom refrigerator showed no collector initials on the specimen label. See D6175. 3. Interview with the technical supervisor on February 17, 2020 at 12:18 PM confirmed the laboratory does not have a mechanism in place to monitor, assess and correct problems identified in the preanalytic processing of patient testing. Further interview confirmed the technical supervisor was aware of inaccurate dates of birth on analyzer reports but had not evaluated or taken steps to resolve the issue.
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 surveyor review of laboratory procedures and interview with the technical supervisor, the laboratory did not define acceptable quality control (QC) ranges for the Mindray BS 200 analyzer in their procedures. Findings include: 1. Review of "Quality Control Guidelines" procedure revealed no defined criteria for establishing QC ranges for the Mindray BS 200 analyzer. 2. Review of the Amphetamine procedure revealed no defined criteria for establishing QC ranges for the Mindray BS 200 analyzer. 3. Interview with the technical supervisor on February 17, 2020 at 11:10 AM revealed the acceptable quality control ranges on the Mindray BS 200 analyzer are +/- (plus or minus) twenty percent of the mean for most analytes other than opiates, which is +/- fifteen percent of the mean. Further interview confirmed the laboratory does not have the acceptable QC ranges defined in the procedure. This is a repeat deficiency previously cited on February 20, 2018.
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: Item 1 Based on surveyor review of temperature logs and laboratory procedures, observation of the specimen refrigerator and interview with the technical supervisor, the laboratory did not document temperatures on each day of operation from April 2019 through September 2019. Findings include: 1. Review of three separate temperature logs from April through September 2019 revealed: a. "Top Fridge": The laboratory did not document the temperature on three of one hundred seventeen days. The records show no temperatures recorded from July 23 through July 25, 2019. b. "Bottom Fridge": The laboratory did not document the temperatures on seventy-two of one hundred seventeen days. The records show no temperatures recorded on April 1, 2019 through July 20, 2019, July 22, August 3, and August 20, 2019. c. "Room Temperatures": The laboratory did not document the temperature on ten of one hundred seventeen days. The records show no temperatures recorded on April 1-2, May 22-23, June 24, July 13, August 3, August 5-6, and September 6, 2019. Further review revealed the laboratory director reviewed the logs and did not address the missing temperature recordings. 2. Interview with the technical supervisor on February 17, 2020 at 10:20 AM confirmed the laboratory did not document eighty-five temperatures from April 2019 through September 2019. Item 2 Based on surveyor observation of the specimen refrigerator, review of laboratory procedures, and interview with the technical supervisor, the laboratory did not have a mechanism

	to ensure accurate reading of temperatures in the bottom refrigerator. Findings include: 1. Observation of the bottom refrigerator on February 17, 2020 at 10:15 AM revealed a thermometer with graduations at zero, five and ten degrees C (Celsius) to monitor temperature. 2. Review of the Amphetamine procedure revealed specimens held for reference laboratory testing are to be stored at 2-8 C. 3. Interview with the technical supervisor on February 17, 2020 at 10:20 AM confirmed the laboratory did not have a thermometer in the bottom refrigerator that could ensure accurate readings through the required 2-8 C range defined by the laboratory. Further interview confirmed the laboratory holds specimens in this refrigerator for referral to the reference laboratory for confirmation testing.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on surveyor review of temperature logs and interview with the technical supervisor, the laboratory did not document corrective action for thirty of thirty-three temperatures outside of the acceptable range from April 2019 through September 2019. Findings include: 1. Review of temperature logs from April 1 through September 30, 2019 revealed: a. "Top Fridge": The laboratory did not document corrective action for eleven of thirteen temperatures outside the acceptable range. b. "Bottom Fridge": The laboratory did not document corrective action for eight of nine temperatures outside the acceptable range. c. "Room Temperature": The laboratory did not document corrective action for eleven of eleven temperatures outside the acceptable range. Further review revealed the laboratory director had reviewed the logs but did not recognize the lack of documented corrective action. 2. Interview with the technical supervisor on February 17, 2020 at 10:20 AM confirmed there was no documentation of corrective action available for thirty of thirty-three temperatures outside the acceptable range from April 2019 through September 2019.
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: Based on surveyor review of laboratory procedures and quality control (QC) records and interview with the technical supervisor, the laboratory director had not ensured the QC programs were established and maintained. Findings include: 1. Review of the "Quality Control Guidelines" from the laboratory procedure manual showed testing personnel must recalibrate and run five QC replicates to establish a new range and mean value on receipt of a new lot of controls. 2. Review of the Amphetamine, Cannabinoid and Cocaine procedures showed testing personnel must run a minimum of ten QC replicates to establish a new range and mean value on receipt of a new lot of controls. 3. Review of quality control records showed receipt of a new lot of Drugs

	of Abuse Testing (DOAT) QC on November 10, 2019. Further review showed no documentation of replicate QC testing prior to use to establish a new range and mean value. 4. Interview with the technical supervisor on February 17, 2020 at 11:00 AM confirmed the individual analyte procedures and "Quality Control Guidelines" provided inconsistent information on quality control requirements for new lots. Further interview confirmed the laboratory did not perform QC replicates and establish new mean and ranges with the new lot of DOAT QC in November 2019. This is a repeat deficiency previously cited on February 20, 2018.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures, observation of completed patient urine specimens and interview with the technical supervisor, the laboratory did not follow the procedures for specimen handling and processing while performing patient testing on the Mindray BS 200 toxicology analyzer. Findings include: 1. Review of the "Collection of Patient Sample" procedure revealed the collector must label all samples with the patient's name, date of birth, date of collection and initials of collector. The procedure also stated "Patient Specimen should not be run if missing any of the above data". 2. Observation of patient urine samples in the refrigerators on February 17, 2020 at 11:54 AM revealed the collector(s) did not initial five of five randomly observed samples. 3. Interview with the technical supervisor on February 17, 2020 at 11:55 AM confirmed the laboratory performed patient testing on samples that were missing collector's initials.