| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 52D2087422 | 02/20/2018 |
| **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 |
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| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of proficiency testing (PT) records and interview with the general supervisor, the laboratory does not have records showing the director attested to the routine integration of the samples into the patient workload using the laboratory's routine methods for two of three PT events in 2017. Findings include: 1. Review of toxicology PT records from 2017 show the laboratory director did not sign the attestation statement for the second event in 2017. The attestation statement for event three is not available. 2. Interview with the general supervisor on February 20, 2018 at 10:45 AM confirmed the laboratory director did not attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. |
| **D2010** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(2)<br><br>The laboratory must test samples the same number of times that it routinely tests patient samples.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of proficiency testing (PT) records and interview with the general supervisor, the samples for event one in 2017 were tested two times while |

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| | patient samples are routinely tested once. Findings include: 1. Review of PT records for event one of 2017 show two set of laboratory test results for each sample. The test results do not indicate a reason for the repeated analysis. No test records are available for events two and three. 2. Interview with the general supervisor on February 20, 2018 at 10:45 AM confirmed patient samples are routinely tested once and the PT samples were not tested the same number of times as patient samples. |
| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of proficiency testing (PT) records and interview with the executive director, the laboratory did not maintain copies of all PT records for two of three events in 2017. Findings include: 1. Review of PT records for 2017 showed records for the second and third events in toxicology are limited to screen prints of results from the PT provider's website for each event and an attestation statement for event two signed by the analyst. 2. Interview with the executive director, staff A, on February 20, 2018 at 3:00 PM revealed the screen prints of the PT records for event two and three had been printed earlier that day when the records for the events were not found in the laboratory, and confirmed the records were not retained for two years. |
| **D3007** | FACILITIES<br>CFR(s): 493.1101(b)<br><br>The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory records and test reports, and interview with the general supervisor, testing was limited or discontinued due to insufficient reagents in July, August, and October 2017, and from November 16, 2017 - January 16, 2018. Findings include: 1. Review of calibration records and patient test reports showed no indication testing was performed from November 16, 2017 through January 16, 2018. Test reports from January 17, 2018 show only Ethyl Alcohol and Cannabinoid test results were reported. Review of corrective action logs for October 5, 2017 through October 31, 2017 showed the following reagents were not available for the seven days testing was performed: 10/5/17: Cocaine, Ethanol, and Opiate 10/13/17: Cocaine and Opiate 10/17/17: Cocaine and Opiate 10/19/17: Cocaine and Opiate 10/24/17: Cocaine and Opiate 10/26/17: Opiate 10/31/17: Amphetamine, Benzodiazepine and Opiate 2. Interview with the general supervisor on February 20, 2018 at 1:00 PM |

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| | revealed the laboratory routinely performs six tests on all samples received for testing. The supervisor confirmed the laboratory did not have sufficient reagents to perform all testing ordered during the time periods shown in finding one. Further interview revealed the laboratory also did not perform Amphetamine or Benzodiazepine testing in July and performed no testing in August 2017 due to insufficient reagents or supplies. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory reagent records and interview with the general supervisor, the laboratory has not retained reagent lot number and expiration date records along with dates of use to show expired reagents were not used for testing. Findings include: 1. Review of laboratory records showed no records of lot numbers and expiration dates of reagents used other than the reagents currently in use. 2. Interview with the general supervisor on February 20, 2018 at 1:00 PM confirmed the laboratory did not retain records of reagents used other than current reagent information and cannot show that expired reagents were not used for testing. |
| **D5022** | TOXICOLOGY<br>CFR(s): 493.1213<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on surveyor review of manufacturer instructions, procedures, laboratory records, and patient test reports, and interviews with the general supervisor and the executive director (staff A), the laboratory has not met the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. Findings include: 1. The laboratory has not defined specimen storage requirements and stability characteristics to ensure optimal integrity of the sample through the testing process. See D5203. 2. Procedures do not specify the control and calibration procedures used in the laboratory. See D5403. 3. The laboratory has not performed routine maintenance on the Mindray BS-200 as required. See D5429. 4. Patient test results were reported when control results were not acceptable. See D5481. 5. The laboratory's analytic quality assessment procedures are not adequate to identify and correct problems in the analytic system. See D5791. |
| **D5203** | SPECIMEN IDENTIFICATION AND INTEGRITY<br>CFR(s): 493.1232<br><br>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 |

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| | results.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of patient test reports, procedures and manufacturer's instructions, and interview with the executive director, the laboratory has not identified specimen storage requirements and stability specifications to ensure optimum integrity of samples through the testing process. Findings include: 1. Review of patient test reports from testing performed on January 17, 2018 show approximately 30 patient samples were tested and reported for alcohol and cannabinoid testing. The reports show the specimens tested were collected on December 12, 14, 19 and 20, 2017. Additional samples collected in December were tested later in January. 2. The manufacturer's instructions for Ethyl Alcohol and Cannabinoid assays state "Testing fresh urine specimens is suggested". No specific instructions for storage or stability are identified in the laboratory procedures. 3. Interview with the executive director, staff A, on February 20, 2018 at 3:30 PM confirmed the laboratory had not established written policies and procedures for specimen handling and storage to ensure the integrity of samples prior to testing. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of procedures and interview with the executive director, the procedures do not define the control and calibration procedures used for testing on the Mindray BS-200 analyzer. Findings include: 1. Review of the laboratory procedure for Amphetamine testing showed no identification of the type of control, the levels to test or how to evaluate the results. The procedure states "It is recommended that two levels of control material be assayed daily. The Amphetamine procedures includes two methods of calibration, one method requiring six calibrators and a second method requiring the use of only Calibrator 1. The procedure does not specify which method is in use in the laboratory. Review of other test procedures performed in the laboratory showed similar language. The general "Quality Control Guidelines" section of the procedure manual shows acceptable quantitative ranges for controls (Drug of Abuse |

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| | Test) DOAT-4 and DOAT-5 that were developed during the initial validation of the analyzer. The lot number used to determine the provided ranges is not identified, but states: "When new Lot #s are provided to the laboratory of The Power of Change, Inc., the mean value and ranges must be developed for both negative and positive controls". 2. Interview with the executive director, staff A, on February 20, 2018 at 3: 00 PM confirmed the procedures do not provide instructions for calibration or control procedures. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Maintenance Log Checklist and interview with the general supervisor, the laboratory has not performed maintenance on the Mindray BS-200 as required. Findings include: 1. Review of the Maintenance Log Checklist from July 7, 2017 through November 16, 2017 shows: a. No maintenance was documented from August 1 through August 24, 2017, and monthly maintenance was not performed in August 2017. b. During the six weeks between Sunday, August 27 and Sunday, October 8, 2017, weekly maintenance was only performed twice, on September 8 and September 28. c. Maintenance required every six months (clean dust screens and replace water filter assembly) was not documented. 2. Interview with the general supervisor on February 20, 2018 at 11:30 AM revealed the water filter assembly was last replaced in February 2016, and confirmed maintenance had not been performed as required through 2017. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory records and patient test reports, and interview with the executive director, patient test results were reported when control results did not meet the laboratory's criteria for acceptability. Findings include: 1. Review of the Quality Control (QC) Data Summary sheets for October 26, 2017 and the corrective action log from October 5 through 31, 2017 showed the following: Amphetamine Drug of abuse testing (DOAT) control DOAT5, was tested twice because initial result was flagged as out of range; the second DOAT5 result, 794 ng/mL (nanograms per milliliter), remained outside the acceptable control range on the analyzer (504 - 792 ng /mL) and was flagged but was accepted. The corrective action log shows errors were noted (flags were present) for Amphetamine controls three of the previous five days of testing. Benzodiazepine Control DOAT4 result 284.8 ng/mL, was flagged as out of range by the analyzer (201.6 - 272.8 ng/mL), but was accepted. The corrective action log shows errors were noted for Benzodiazepine controls five of the previous five days of testing. Cannabinoid Control DOAT4 result (54.9 ng/mL) was outside the |

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| | accepted range (35.0 - 49.0 ng/mL) but was accepted. Cocaine Controls, DOAT4 and DOAT5, were each tested three times to produce results in the acceptable range. 2. Review of patient reports showed six patient test results were reported on October 26, 2017 including results for testing with unacceptable QC results. 3. Interview with the executive director, staff A, on February 20, 2018 at 3:30 PM confirms patient test results were reported when controls were not within acceptable ranges. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Room Temperature Log and interview with the general supervisor, four of twenty-four recorded temperatures from April through July 2017 were above the acceptable range as defined by the laboratory. Findings include: 1. Review of the Room Temperature Log showed four of twenty-four recordings from April through July 2017 were outside the laboratory defined acceptable range of 15 to 30 degrees C (Celsius). The following unacceptable temperatures were recorded: Date / Temperature April 7 / 33 C June 2 / 31 C June 15 / 36 C July 7 / 32 C The record shows no evidence the unacceptable temperatures were recognized as out of range or that the log was reviewed. No corrective actions are recorded. 2. Interview with the general supervisor at 12:00 PM on February 20, 2018 confirmed the laboratory monitors room temperature and has set an acceptable range of 15 to 30 degrees C. Further interview confirmed temperatures were not within the acceptable range and corrective action was not documented and that the technical supervisor has not reviewed the log to ensure quality assessment activies are maintained to monitor, assess and correct problems. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on surveyor review of proficiency testing, maintenance and quality control records, and procedures, and interview with the general supervisor, the laboratory director has not provided overall management and direction in accordance with 493. 1445 of this subpart. Findings include: 1. Proficiency testing reports were not reviewed to evaluate the laboratory's performance and identify problems. See D6091. 2. A corrective action plan was not followed when unacceptable scores were received on proficiency testing reports. See D6092. 3. The quality control program was not maintained. See D6093. 4. Quality assessment programs were not maintained. See D6094. |
| **D6091** | LABORATORY DIRECTOR RESPONSIBILITIES |

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| | CFR(s): 493.1445(e)(4)(iii)<br><br>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of proficiency testing (PT) records and interview with the general supervisor, the laboratory director did not ensure PT reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings include: 1. Review of PT records from 2017 show no documented review of the second or third event. The third event included 50% scores for both the Ethyl Alcohol and Cannabinoid tests. 2. Interview with the general supervisor at 10:45 AM on February 20, 2018 confirmed the PT results from the second and third events in 2017 were not reviewed by appropriate staff to evaluate the laboratory's performance. |
| **D6092** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(iv)<br><br>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of proficiency testing (PT) records and interview with the general supervisor, the laboratory did not follow an approved corrective action plan when unacceptable scores were received for Ethyl Alcohol and Cannabinoids in 2017 on event three. Findings include: 1. Review of PT records shows 50% scores for Ethyl Alcohol and Cannabinoids on event three in 2017. No record of evaluation of the cause of the unacceptable results or a corrective action plan is evident. 2. Interview with the general supervisor on February 20, 2018 at 10:45 AM confirmed a corrective action plan had not been developed in response to the unacceptable scores on event three in 2017. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory records including quality control (QC) records and procedures, and interview with the general supervisor, the laboratory director has not ensured the QC programs were maintained to assure the quality of services provided and identify failures in quality as the occurred. Findings include: 1. Review of the Quality Control Guidelines from the laboratory procedure manual show: a. "Levey-Jennings graph must be produced once every three months to analyze the trends being produced by the BS200." b. "Linearity testing must be done at least once per year." c. "Quality Controls must be run, and in control to begin testing the |

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| | daily patient samples." d. "When using a new lot # the technician must run 10 replicates to establish a new mean to determine an acceptable range." 2. Review of laboratory records showed: a. No evidence of Levey-Jennings graphs for quality control review. b. No evidence of linearity testing in 2017. c. Review of QC Data Summary sheets from the BS-200 show controls were accepted and patient results reported when flags were present and controls were outside the ranges identified on the analyzer. See D5481. d. The acceptable ranges identified in the procedure manual do not show the lot number of controls used to develop the ranges. The procedure manual range for Cannabinoid for Drug of Abuse Testing (DOAT) Control DOAT4 (25 - 38 (nanograms per milliliter) ng/mL) does not match the range on the analyzer (35 - 49 ng/mL). The acceptable ranges identified in the procedure show the laboratory uses controls DOAT4 and DOAT5 for Ethyl Alcohol testing. Review of control results shows the laboratory uses 50 mg/dL (milligram per deciliter) and 300 mg/dL controls for the Ethyl Alcohol assay. 3. Interview with the general supervisor on February 20, 2018 at 1:30 PM: a. Confirms Levey-Jennings charts have not been printed since July 2017. b. Confirms linearity testing has not been performed as required. c. Confirms patient results were reported when controls were not within the acceptable ranges identified for the test. d. Revealed a new lot number of DOAT5 control was started without obtaining or evaluating the manufacturer's assayed acceptable ranges for the testing performed. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Maintenance Log Checklist and interview with the general supervisor, the laboratory director has not maintained a quality assessment program that identifies failures in quality as they occur. Findings include: 1. Review of the Maintenance Log Checklist from July 7, 2017 through November 16, 2017 shows: a. Maintenance on the Mindray BS-200 was not performed as required. See D5429. b. The checklist was filled on October 13, 2017. However, the general supervisor added entries for six additional dates in the margins. c. There is no evidence of review by the technical supervisor who is also the laboratory director. 2. Interview with the general supervisor on February 20, 2018 at 11:30 AM confirmed the laboratory director did not identify the failures in the performance of analyzer maintenance and has not maintained the quality assessment program. |
| **D6108** | LABORATORY TECHNICAL SUPERVISOR<br>CFR(s): 493.1447<br><br>The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on surveyor review of corrective action logs, laboratory and competency evaluation records and patient test reports, and interview with the general supervisor |

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| | and the executive director, the laboratory technical supervisor, who is also the laboratory director, did not provide technical supervision in accordance with 493.1451 of this subpart. Findings include: 1. The technical supervisor did not identify and resolve problems when control results were not acceptable. See D6118. 2. There is no evidence of review of quality control, maintenance, and proficiency testing records in the evaluation of competency of testing personnel. See D6123. This is a repeat deficiency previously cited on August 4, 2016. This is a repeat condition level deficiency previously cited on August 4, 2016. |
| **D6118** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(5)<br><br>The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of corrective action logs and interview with the general supervisor, controls were repeated multiple times for multiple assays on seven of seven days of testing in October 2017. The log shows no sign of review or involvement of the technical supervisor in the resolution of the technical problems. Findings include: 1. Review of the corrective action log from October 5 through October 31, 2017 shows out of range flags for Amphetamine (five of seven days), Benzodiazepine (seven of seven days), Cannabinoids (one of seven days), and Cocaine (one of seven days, reagent was not available five of seven days). The log shows no evidence of review or documented action taken by the technical supervisor. 2. Interview with the general supervisor on February 20, 2017 at 12:30 PM confirms the technical supervisor did not review or resolve technical problems. |
| **D6123** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(8)(iii)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory records from April through December 2017, competency evaluation forms from February 2018, and interview with the executive director, the quality control, proficiency testing and preventative maintenance records show no evidence of review as part of the competency evaluation. Findings include: 1. Review of maintenance records (July 2017 through November 2017) and temperature records (April 2017 through October 2017) show no evidence of review by the technical supervisor. These records include missing maintenance documentation and unacceptable temperatures. See D 5429 and D5791. Records for the second and third proficiency testing event in 2017 were not available and evidence of review or corrective action was not present. The third event included unacceptable results that were not evaluated. See D6092. Random review of quality control records from July through December 2017 showed no evidence of review by the technical supervisor. Quality control records include examples of acceptance of results outside the acceptable range. See D 5481. 2. Competency evaluation forms for the general |

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| | supervisor, who is also the only testing personnel, signed by the laboratory director on February 14, 2018, showed no indication the issues identified in finding one were considered in the evaluation of competency. 3. Interview with the executive director, staff A, on February 20, 2018 at 3:00 PM confirmed the competency evaluation of the general supervisor and testing personnel by the technical supervisor, who is also the laboratory director, did not reflect the problems identified in the laboratory records. This is a repeat deficiency previously cited on August 4, 2016. |