Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2132876	08/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Wellbeing Institute	3615 N Prince Village Place, Ste 121, Tucson, AZ	

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 lack of manufacturer's package inserts presented for review for testing performed on the Indiko Plus analyzer and interview with the Laboratory Director (LD), the laboratory failed to retain the manufacturer's package insert for at least 2 years for each lot of Quality Control (QC) and test reagent material used on the analyzer. Findings include: 1. During the survey conducted on August 25, 2023, no evidence was presented for review to indicate the laboratory retained the manufacturer's assay information sheets for at least 2 years for each lot of QC and test reagent material used on the Indiko Plus toxicology analyzer. 2. The LD interviewed on August 25, 2023 at 10:50 AM confirmed the laboratory failed to retain the manufacturer's assay information sheets for at least 2 years for each lot of QC and test reagent material used on the analyzer indicated above. 3. The laboratory reports approximately 18,000 urine drug screen tests annually, which are performed on the Indiko Plus analyzer.
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 lack of accuracy verification documentation for review for urine drug screen testing and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy of urine drug screen testing at least twice annually during 2021 and 2022. Findings include: 1. No documentation was presented for review during the survey conducted on August 25, 2023 to indicate the laboratory verified the accuracy of urine drug screen testing at least twice annually during 2021 and 2022. 2. The LD interviewed on August 25, 2023 at 11:45 AM confirmed the laboratory failed to verify the accuracy of urine drug screen testing at least twice annually during 2021 and 2022. 3. The laboratory performs urine drug screen testing on the Indiko Plus analyzer, with an annual test volume of 18,000. The urine drug screen test includes the following analytes: Amphetamine, Benzodiazepine, Cocaine, Opiate, Oxycodone, Buprenorphine II and Creatinine.
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 lack of test requisition documentation for review and interview with the Laboratory Director (LD), the laboratory failed to have a written or electronic request for patient testing for two out of two patient records reviewed during the survey. Findings include: 1. No written or electronic request for urine drug screen testing was presented for review for two out of two patient records reviewed during the survey, accession# 0100020566 tested on 8/03/23 and accession# 0100016182 tested on 8/03 /22. 2. The LD interviewed on August 25, 2023 at 10:30 AM confirmed the laboratory failed to have an electronic or written test requisition for testing that was performed on the patients indicated above. 3. The laboratory reports approximately 18,000 urine drug screen tests annually.
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 review of the laboratory's quality control (QC) records and policies, lack of QC lot correlation documentation and interview with the Laboratory Director (LD), the laboratory failed to verify the criteria for acceptability of quality control materials.

	Findings include: 1. The laboratory performs a semi-quantitative urine drug screen test on the Indiko Plus analyzer, with a reported annual test volume of 18,000. 2. No documentation was presented for review to indicate the laboratory verified the criteria for acceptability of each lot of control material used on the analyzer indicated above from January 2021 through the date of the survey on August 25, 2023. 3. The laboratory's established QA policy states, "New lot check in of reagents is done in order to validate the lot to lot variability. When the use new control lot is started, record the new lot # on the run control sheet. Make sure the control lot runs according to the Package Insert. QC should be acceptable for new lots in which there has been no loss of integrity to the sample or analyte." 4. The LD interviewed on August 25, 2023 at 11:35 AM confirmed the laboratory failed to follow the established policy indicated above to verify and document the criteria for acceptability of control lots used on the Indiko Plus analyzer. 5. The number of QC lots used on the analyzer from January 2021 through the date of the survey could not be determined at the time of the survey.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of relative humidity logs, lack of corrective action presented for review and interview with the Laboratory Director (LD), the laboratory failed to document corrective action taken for humidity measurements that were outside the laboratory's established range. Findings include: 1. The laboratory performs patient testing on the Indiko Plus toxicology analyzer, with a reported annual test volume of 18,000. The laboratory's established humidity range for the room where patient testing occurs is 40-80%. 2. Review of the monthly 'Laboratory Room Relative Humidity Log' from January 2022 through the date of the survey on August 25, 2023 revealed the documented humidity was not within the laboratory's established humidity range on 13 out of 144 testing dates. 3. The laboratory failed to document corrective action taken for the humidity measurements that were outside the laboratory's established humidity range on the 13 testing dates indicated above. 4. The LD interviewed on August 25, 2023 at 11:55 AM confirmed the laboratory failed to document any corrective action for the humidity measurements that were outside the laboratory's established humidity range for the 13 testing dates indicated above.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of

	specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of urine drug screen test records generated from the Indiko Plus analyzer, review of the CMS-209, Laboratory Personnel Form and interview with the testing personnel (TP-1), the laboratory's test records failed to include the correct identify of each testing personnel who performs testing on the Indiko Plus analyzer. Findings include: 1. The CMS-209, Laboratory Personnel form presented for review during the survey indicated two testing personnel, TP-1 and TP-2, who perform urine drug screen testing on the Indiko Plus analyzer. 2. Two out of two test reports reviewed during the survey, accession# 0100020566 and #0100016182, indicated the testing was performed by TP-2. 3. The TP-1 interviewed on August 25, 2023 at 10:40 AM stated that TP-1 performed the testing for each patient indicated above, not TP-2. During the interview it was revealed that each testing personnel must log into the analyzer using individual login credentials and TP-2 was still logged in when TP-1 performed the patient testing indicated above. 4. The laboratory reports approximately 18,000 urine drug screen tests annually.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) policies and procedures, review of Quality Control (QC) results, and interview with the Laboratory Director (LD), the laboratory failed to follow established QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems. Findings include: 1. The laboratory performs 18,000 urine drug screen tests annually on the Indiko Plus toxicology analyzer. 2. The laboratory's established QA policy and procedure reviewed during the survey states, "When the use new control lot is started, record the new lot # on the run control sheet." 3. No evidence was presented for review during the survey to indicate the laboratory recorded the lot number and expiration date of each QC material used on the Indiko Plus analyzer from January 2021 through the date of the survey on August 25, 2023. 4. Review of QC printouts from the analyzer from 12/13/21, 8/03/22 and 8/03/23 revealed the following QC materials were used: DOAT 4, DOAT 5, Buprenorphine II Low, Buprenorphine II High, Creatinine 1.3 and Creatinine 23. The QC printout contains an area under the name of each QC material used for testing to input the Lot# and Expiration Date, however the QC printouts reviewed for the dates indicated above listed "N/A" for the lot # and expiration date of each control material. 5. The LD interviewed on August 25, 2023 at 11:10 AM confirmed the laboratory failed to follow established QA policies and procedures to monitor, assess and correct problems identified with the analytic systems, specifically the laboratory's failure to record lot numbers and corresponding expiration dates for each lot of QC material used on the Indiko Plus analyzer.

D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the Laboratory Director (LD), the laboratory failed to have a system in place to ensure the accuracy of test results that are manually entered into the patients' Electronic Medical Record (EMR). Findings include: 1. The laboratory performs urine drug screen testing on the Indiko Plus analyzer under the subspecialty of Toxicology, with a reported annual test volume of 18,000. 2. The test results generated from the analyzer are manually entered by testing personnel into the patients' EMR. 3. No documentation was presented for review to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are manually entered from the Indiko Plus analyzer to the patients' EMR. 4. The LD interviewed on August 25, 2023 at 11:20 AM confirmed that the laboratory failed to have a system in place to verify the accuracy of the patient test results that are manually entered from the analyzer to the EMR.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of initial training documentation for one out of two testing personnel (TP #2) and interview with the Laboratory Director (LD), the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of services offered. Findings include: 1. No initial training documentation was presented for review for one out of two testing personnel (TP-2) who began patient testing in August 2022. 2. The LD interviewed on August 25, 2023 at 10:16 AM confirmed the laboratory failed to provide documentation of initial training for TP-2 as indicated above. 3. The laboratory reports approximately 18,000 urine drug screen tests annually, which are performed on the Indiko Plus analyzer.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation and interview with the Laboratory Director (LD), the technical consultant failed to evaluate and document the performance of one testing personnel, at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for one out of one testing personnel (TP-2) who began patient testing in August 2022. 2. The LD interviewed on August 25, 2023 at 10:16 AM confirmed that the technical consultant failed to perform and document a semiannual competency evaluation for the testing personnel indicated above. 3. The laboratory reports approximately 18,000 urine drug screen tests annually, which are performed on the Indiko Plus analyzer..
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on lack of competency evaluation documentation for review and interview with the Laboratory Director (LD), the technical consultant failed to evaluate and document the performance of one individual responsible for moderate complexity testing at least annually. Findings include: 1. No annual competency evaluation documentation from 2023 was presented for review for one out of one testing personnel (TP-2)who began patient testing on the Indiko Plus analyzer in August 2022. 2. The LD interviewed on August 25, 2023 at 10:16 AM confirmed the technical consultant failed to evaluate and document the performance of TP-2 at least annually, who is responsible for moderate complexity testing.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the Laboratory Director, the laboratory failed to have academic credentials required to qualify one of one testing personnel for the speciality of chemistry for moderate complexity testing (Refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS

	CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the Laboratory Director, the laboratory failed to have documentation of academic credentials to qualify one of two testing personnel (TP-2) for moderate complexity testing. Findings include: 1. Review of the personnel records for one of two testing personnel for the speciality of chemistry revealed the laboratory failed to have academic credentials to qualify TP-2. 2. Interview with the Laboratory Director on August 25, 2023 at 10:15 AM confirmed the laboratory failed to have the required documentation to qualify TP-2 for moderate complexity testing. 3. The laboratory reports approximately 18,000 urine drug screen tests annually.