Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2132876	10/19/2018
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
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: Based on review of patient test requisitions and interview with the laboratory director, the laboratory's test requisition failed to include the required information. Findings include: 1. The laboratory began patient testing in December 2017 under the sub-specialties of Routine Chemistry and Toxicology, with an approximate annual test volume of 17,400. 2. It is the practice of the laboratory to perform a urine drug screen test on each patient's specimen. The testing is performed on the Indiko Plus Analyzer and includes the following analytes/assays: Creatinine, Amphetamine, Cocaine, Opiate, Oxycodone, and Buprenorphine. 3. The laboratory's test requisition presented for review during the survey failed to include the patient's sex and age or date of the birth of the patient. 4. The laboratory's test requisition presented for review during the survey failed to include the time of specimen collection. 5. The laboratory's test requisition presented for review during the survey failed to include the test(s) to be

	performed, specific to the analytes tested. 6. The laboratory director confirmed that the test requisitions reviewed during the survey failed to include the information listed above.
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: Based on lack of documentation for review and interview with the facility personnel, the laboratory failed to monitor and document the room temperature, refrigerator temperature, freezer temperature and humidity of the laboratory where reagents and specimens are stored and patient testing is performed. Findings include: 1. The laboratory began patient testing in December 2017 under the sub-specialties of Routine Chemistry and Toxicology, with an approximate annual test volume of 17,400. 2. The laboratory performs patient testing on the Indiko Plus Chemistry analyzer which has a humidity requirement of 40% - 80%, as stated in the manufacturer's operating manual. 3. The laboratory utilizes a refrigerator and freezer to store test reagents and patient specimens, if needed. 4. No documentation was presented for review during the survey to indicate the laboratory monitored and documented the room temperature and humidity of the laboratory where patient testing was performed, as well as the refrigerator and freezer temperatures. 5. The facility personnel confirmed that the laboratory was not monitoring the temperatures and humidity levels as stated above.
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 facility personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are manually transcribed into the patients' Electronic Medical Record (EMR). Findings include: 1. The laboratory performs approximately 17,400 patient tests annually under the sub-specialty of Routine Chemistry and Toxicology. 2. The laboratory performs testing on the Indiko Plus analyzer, and the test results are

	transmitted from the analyzer to a secure email connection. The test results are then manually transcribed into the patients' EMR. 3. No documentation was presented for review during the survey to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are manually transcribed from the Indiko Plus analyzer to the patients' EMR.. 4. The facility personnel confirmed that the laboratory did not have a system in place to verify the accuracy of the patient test results that are generated from the analyzer and transcribed into the EMR.