Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2177811	10/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Westwood Medical, Pc	839 Majestic Court, Suite 3, Gastonia, NC	

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
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 review of 2019 and 2020 CAP (College of American Pathologists) and AAB (American Association of Bioanalysts) proficiency testing records and interview with the laboratory director 10/13/20, the laboratory failed to enroll in proficiency testing or establish a system to verify the accuracy of its urine toxicology testing at least twice a year. Review of 2019 and 2020 CAP and AAB proficiency testing records revealed the records were not for this laboratory but were for a sister laboratory in the same location. There were no records available to indicate that this laboratory had enrolled in proficiency testing or established a system to verify the accuracy of the urine drug screens performed on the Synermed IR-500 analyzer and the urine drug confirmations performed on the Shimadzu 8040 LCMS (liquid chromatography-mass spectrometry) analyzer. During interview at approximately 11:05 a.m., the laboratory director confirmed that the laboratory was not enrolled in proficiency testing and had not performed any activity to verify the accuracy of the urine drug screens performed on the IR-500 and the urine drug confirmations performed on the Shimadzu 8040. He stated they just started patient testing in August 2020 and they were "working on it".
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of random patient test reports (#200100900026, #200100900025), and interview with testing personnel (TP #1) 10 /13/20, the laboratory failed to follow manufacturer's instructions for specimen storage and stability requirements for toxicology testing performed on the Synermed IR-500 analyzer. Findings: The laboratory uses Lin-Zhi toxicology reagents for Amphetamine, Cannabinoid (THC), Opioid, Ethanol, and Cocaine drug screen testing on the Synermed IR-500 analyzer. Review of manufacturer's instructions for all Lin-Zhi toxicology reagents revealed "If a sample cannot be analyzed immediately, it may be refrigerated at 2-8 degrees Celsius for up to three days. For longer storage, keep sample frozen at -20 degrees Celsius and then thaw before use." Review of random patient test reports revealed the laboratory failed to test refrigerated specimens within 3 days as required by manufacturer's instructions. Examples: a. Patient test report #200100900026 revealed the specimen was collected on 10/8/20 and was not tested until 10/12/20, approximately 4 days after collection. b. Patient test report #200100900025 revealed the specimen was collected on 10/8/20 and was not tested until 10/12/20, approximately 4 days after collection. During interview at approximately 3:30 p.m., TP #1 stated specimens were sometimes held in the refrigerator until the next testing day if there were not enough specimens for a test run. He stated that the laboratory does not freeze specimens at -20 degrees Celsius as required by the manufacturer for long term storage .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the absence of records, review of laboratory validation records and interview with the laboratory director 10/13/20, the laboratory failed to validate the performance of the Dendi LIS (laboratory information system) and failed to verify performance specifications for Amphetamine, Cocaine, Cannibinoid (THC), and Opiate urine drug screen testing on the Synermed IR-500 analyzer before performing patient testing. Findings: 1. The laboratory failed to determine if the performance of the Dendi LIS was acceptable prior to the initiation of patient testing in August 2020. There was no documentation the laboratory validated the performance of the Dendi LIS. Interview with the laboratory director at approximately 2:45 p.m. confirmed the laboratory failed to validate the performance of the Dendi LIS before performing patient testing. 2. The laboratory failed to verify performance performance specifications for Amphetamine, Cocaine, Cannabinoid (THC), and Opiate urine drug screen testing performed on the Synermed IR-500 analyzer. Four laboratories share the Synermed IR-500 analyzer, performing patient testing on different days and/or at different times. Review of laboratory validation records revealed the urine drug screen assays were validated for one of the sister laboratories on 2/18/19. Review of records

	revealed no documentation this laboratory validated the performance of the Amphetamine, Cocaine, Cannabinoid (THC), and Opiate assays on the Synermed IR-500 before the start of patient testing in August 2020.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on the absence of records, review of laboratory validation records and interview with the laboratory director 10/13/20, the laboratory failed to validate all performance specifications for urine toxicology testing on the Shimadzu 8040 LCMS (liquid chromatography-mass spectrometry) analyzer #2 and Ethanol (ETOH) testing performed on the Synermed IR-500 analyzer before performing patient testing. Findings: 1. The laboratory failed to validate all performance specifications for all testing performed on the Shimadzu 8040 LCMS analyzer #2 before performing patient testing. Three laboratories share the Shimadzu 8040 LCMS analyzer #2, performing patient testing on different days and/or at different times. The laboratory began patient testing in August 2020. Review of validation records for the Shimadzu 8040 LCMS analyzer #2 revealed the validation was completed 5/18/19 by a sister laboratory. There was no documentation this laboratory had validated all performance specifications before beginning patient testing in August of 2020. Interview with the laboratory director at approximately 11:00 a.m. confirmed the sister laboratory had performed the validation of the Shimadzu 8040 LCMS analyzer #2. He stated he was not aware that each laboratory using the analyzer would need to validate all performance specifications and he assumed they would be able to sign off on the validation performed by the other laboratory. 2. The laboratory failed to validate all performance specifications for Ethanol on the Synermed IR-500 analyzer before performing patient testing. Four laboratories share the Synermed IR-500 analyzer, performing patient testing on different days and/or at different times. The laboratory began patient testing in August 2020. Review of Synermed IR-500 validation records revealed the assay was validated by a sister laboratory 2/18/19. Review of records revealed no documentation this laboratory validated all performance specifications for Ethanol on the Synermed IR-500 before beginning patient testing in August 2020.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

	This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of laboratory procedures, review of a random patient test report (#20100900012), and interview with the laboratory director 10/13/20, the laboratory director failed to ensure that patient test reports included pertinent information required for interpretation. Findings: Review of the manufacturer's instructions for Amphetamine, Cocaine, Cannabinoid (THC), and Opiate drug screen testing revealed the assays are intended for qualitative and semi-quantitative determination, or presence or absence of the analytes. For example: The product insert for Lin-Zhi International, Inc Cannabinoids (cTHC) Enzyme Immunoassay states, "Intended Use...The assay provides a rapid screening procedure for determining the presence of cannabinoids in urine. The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or Liquid Chromatography /Mass Spectrometry are the preferred confirmatory methods...Results Qualitative A sample with a change in absorbance equal to, or greater than, that obtained with the cutoff calibrator is considered positive. A sample with a change in absorbance lower than that obtained with the cutoff calibrator is considered negative....Semi-Quantitative The semi-quantitative mode is for the purposes of (1) enabling laboratories to determine an appropriate dilution of the specimen for verification by a confirmatory method such as GC/MS, LC/MS or (2) permitting laboratories to establish quality control procedure." The laboratory's IR-500 procedure for each drug analyte states, "Limitations of the Procedure ...The test is not intended for quantifying these single analytes in samples...Positive results should be confirmed by other affirmative, analytical chemistry methods (e.g. chromatography), preferably GC/MS or LC/MS." Review of a random patient test report #20100900012 revealed a numerical (quantitative) value in units of ng/mL (nanogram/milliliter) in the "result" column of the test report instead of a positive or negative result. During interview at approximately 1:30 p.m., the laboratory director confirmed that urine drug screen results were being reported with a numerical value which was an error with the new Laboratory Information System.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 review of personnel records and interview with the laboratory director 10/13 /20, the laboratory director failed to ensure that 1 of 1 testing personnel (TP #1) received appropriate training for the services offered and had demonstrated that he could perform all testing operations reliably prior to testing patient specimens. Review of personnel records revealed there was no training documentation available to demonstrate that TP #1 was trained on the Synermed IR-500 analyzer and the Shimadzu 8040 LCMS (liquid chromatography-mass spectrometry) analyzer. During interview at approximately 1:15 p.m., the laboratory director stated that he trained TP #1 on both analyzers but he did not document the training.