| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 34D2150204 | 10/13/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ottendorf Laboratories, Llc | 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 |
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| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of manufacturer's instructions, review of random patient test reports (#2006633, #20100700008, #20100700009), 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), Opiate, 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 #2006633 revealed the specimen was collected on 6/18/20 and received in the laboratory 6/25/20, approximately 7 days after collection. The specimen was not tested until 6/29/20, approximately 11 days after collection. b. Patient test report #20100700008 revealed the specimen was collected on 9/15/20 and received in the laboratory 10/7/20, approximately 22 days after collection. The specimen was not tested until 10/9/20, approximately 24 days after collection. c. Patient test report #20100700009 revealed the specimen was collected on 9/11/20 and received in the laboratory 10/7/20, approximately 26 days after collection. The specimen was not tested until 10/9/20, approximately 28 days after collection. During interview at |

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| | 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<br>CFR(s): 493.1253(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory QA (quality assessment) records, absence of validation records for the Dendi LIS (laboratory information system), and interview with the laboratory director 10/13/20, the laboratory failed to determine if the performance of the Dendi LIS was acceptable before performing patient testing. Findings: Review of laboratory QA records for July 2020 revealed the laboratory had installed the Dendi LIS on 7/28/20. Review of laboratory records revealed no documentation the laboratory had validated the performance of the Dendi LIS. Interview with the laboratory director at approximately 2:45 p.m. confirmed the laboratory had installed the Dendi LIS on 7/28/20 and also failed to validate the performance of the Dendi LIS before performing patient testing. |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the FDA website and manufacturer's package insert, review of the laboratory's validation procedure, review of the Synermed IR-500 validation records, and absence of documentation 10/13/20, the laboratory failed to establish performance specifications for analytical specificity to include interfering substances for Ethanol (ETOH) before performing patient testing. Findings: Review of the FDA website revealed the Lin-Zhi International, Inc Ethanol test reagent on the Synermed IR-500 has not been FDA-approved. The manufacturer's package insert states, "Performance characteristics presented in this package insert have been validated on the Hitachi 717. |

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| | If other instruments are used, performance will need to be validated by your laboratory." Review of the laboratory's validation procedure revealed for analytical specificity, "The laboratory will have documentation regarding interfering substances from product information, literature, or internal testing." Review of the Synermed IR-500 validation records revealed documentation that the laboratory validated the Synermed IR-500 for Ethanol (ETOH) on 2/18/19 for accuracy, precision, analytical sensitivity, and reportable range. There was no documentation available to indicate that the laboratory had established performance specifications for analytical specificity, including interfering substances. |
| **D6098** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(8)<br><br>The laboratory director must ensure that reports of test results include pertinent information required for interpretation.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of manufacturer's instructions, review of the laboratory's procedures, review of a random patient test report (#20100700009), 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 IR-500 laboratory 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 #20100700009 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<br>CFR(s): 493.1445(e)(12)<br><br>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>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. |