Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2078983	10/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bergand Group, The	1300 York Rd, C-100, Lutherville, MD	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on review of the toxicology proficiency testing (PT) records and interview with the testing person (TP), the laboratory failed to ensure that the PT attestation statements were being signed and dated by the laboratory director and testing person and the split sample results were being reviewed by the laboratory director. Findings: 1. The laboratory records show that the laboratory was enrolled in PT for Urine Drug Testing, Screening, Limited (UDS6), Urine Drug Adulterant/Integrity (DAI), and Ethanol Biomarkers (ETB). Each module has two annual events identified as A & B. A total of eight PT events from 2020 and 2021 were reviewed. 2. The following events from 2020 failed to include the signature and date of the laboratory director and testing person; UDS6-A, UDS6-B, DAI-B, and ETB-B. Events DAI-A, and ETB-A were missing. 3. The following events from 2021 failed to include the signature and date of the laboratory director and testing person; DAI-B, and ETB-B. Events UDS6-A, UDS6-B, DAI-A, and ETB-A were missing. 4. The TP explained that the PT modules were missing because the laboratory had not enrolled with the PT agency in a timely manner in 2020 and 2021. 5. In June of 2021 the laboratory discovered that

	they had not enrolled in an approved PT module for ETB and performed split samples with another facility. The split sample documentation did not include an evaluation and was not reviewed and dated by the laboratory director. 6. During the survey on 09 /21/2021 at 2:00 PM, the TP confirmed that the attestation statement and PT records were not being signed and dated as required; the split sample results were not reviewed by the laboratory director; and the laboratory was not enrolled in all the required modules for 2020 and 2021.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: I. Based on review of the proficiency testing (PT) records, procedure manual, and interview with the testing person (TP), the laboratory's procedure manual failed to include step-by-step instructions on how to perform and evaluate split samples in lieu of PT specimens. Findings: 1. In June of 2021 the laboratory discovered that they had not enrolled in an approved PT module for Ethanol Biomarkers (ETB). The laboratory performed split samples with another facility in lieu of PT. 2. The procedure manual did not have approved step-by-step instructions for performing and evaluating split samples in lieu of PT samples. 3. During the survey on 09/21/2021 at 1:00 PM, the TP confirmed that the procedure manual did not include approved step-by-step instructions for performing and evaluating split samples in lieu of PT samples. II. Based on review of the procedure manual, and interview with the TP, the laboratory's procedure manual failed to include step-by-step instructions for the collection and transportation of the urine specimens collected at the satellite office. Findings: 1. Review of the procedure manual showed that there were no step-by-step instructions for the collection and transportation of the urine specimens collected at the satellite office. 2. During the survey on 09/17/2021 at 2:00 PM, the TP confirmed that the procedure manual failed to include written instructions for the collection and transportation of the urine specimens collected at the satellite office. III. Based on review of the procedure manual, and interview with the TP, the laboratory's procedure manual failed to include step-by-step instructions for entering patent results into the electronic medical record (EMR) system. Findings: 1. Review of the procedure manual showed that there were no step-by-step instructions for entering patent results

	into the EMR system. 2. During the survey on 09/17/2021 at 2:00 PM, the TP confirmed that the procedure manual failed to include written instructions for entering patent results into the EMR system. VI. Based on review of the procedure manual, and interview with the TP, the laboratory's procedure manual failed to include the current forms used for documenting the acceptability of quality control (QC) test results. Findings: 1. Review of the procedure manual showed that the worksheet being used to record the acceptability of the QC test results was not included in the approved procedure manual. 2. During the survey on 09/17/2021 at 2:00 PM, the TP confirmed that the form for recording QC results had been changed several months ago and the procedure manual failed to include the current form used for documenting the acceptability of QC test results.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of instrument printouts, final reports and interview with the testing person (TP), the laboratory failed to maintain documentation of original patient reports when an error was detected in the results entered into the electronic medical record (EMR). Findings: 1. The TP explained that the toxicology analyzer was not interfaced with the EMR. The patient test results found on the instrument printouts are manually entered into the EMR. 2. When questioned about the discovery of erroneous test results being entered into the EMR, the TP stated that when an incorrect result was entered into the EMR, the office manager was notified to delete the report in the EMR so that the TP could generate a new report. The TP re-ordered the test and generated a new report, the results were entered and the report sent to the ordering physician. 3. The TP explained that the original test report was deleted and no longer available in the EMR and that there were no corrective actions documented to show that there was an error in entering the patient's test result. 4. During the survey on 09 /17/2021 at 2:00 PM, the TP confirmed that the original test report with the incorrect test result was deleted from the EMR and there was no documentation of the error and an analysis of the error.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview with the testing person (TP), the laboratory failed to establish policies and procedures for monitoring errors in patient test results that were manually entered into the electronic medical record (EMR). Findings: 1.

	The TP explained that the toxicology analyzer was not interfaced with the EMR. The results from the toxicology analyzer are manually entered into the EMR. 2. When questioned about the discovery of erroneous test results being entered into the EMR, the TP stated that the office manager was notified to delete the report in the EMR so that a new test report could be generated. 3. The TP stated that there were no records showing the results that were originally entered into the EMR, no documentation of an investigation of the error, and no corrective actions to help prevent reoccurrence of the error 4. During the survey on 09/17/2021 at 2:00 PM, the TP confirmed that the laboratory failed to establish policies and procedures for monitoring errors in patient test results that were incorrectly entered into the EMR and an analysis of the error. Cross refer to D5821.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records for toxicology and interview with the testing person (TP), the laboratory director failed to ensure that the laboratory was enrolled in all required PT modules for 2020 and 2021. Findings: 1. The laboratory records show that laboratory was enrolled in the following PT modules: Urine Drug Testing, Screening, Limited (UDS6), Urine Drug Adulterant/Integrity (DAI), and Ethanol Biomarkers (ETB). Each module has two annual events identified as A & B. 2. The laboratory records show that in 2020 the lab completed modules UDS6-A, UDS6-B, DAI-B and ETB-B. The PT records for modules DAI-A and ETB-A were missing. 3. The laboratory records show that in 2021 the lab completed modules DAI-A, DAI-B and ETB-B. The PT records for modules UDS6-A, UDS6-B and ETB-A were missing. 4. When interviewed about the missing modules the testing person stated that in 2020 the missing events were due to failure to enroll at the appropriate time so they only got one of the two modules. In 2021 the laboratory had also missed the enrollment date and did not contact the PT agency about late enrollment for UDS6. 5. During the survey on 09/17/2021 at 2:00 PM, the TP confirmed that the laboratory's system for PT enrollment did not ensure that the appropriate PT modules were ordered each year for testing as required by CLIA.