Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0981375	06/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
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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 upon the review of confidential patient medical records, 1 of 4 patient records lacked the required documentation of testing and test results. Findings: 1. 1 of 4 randomly selected patient records was unable to be retrieved from the patient's electronic chart. The manual test result form documents the results of the laboratory testing performed by the testing personnel.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based upon a review of laboratory personnel files, review of laboratory written policies and procedures, and interview with Testing Personnel 1 (TP1), the laboratory failed to establish a written policy to assess employee competency. Findings: 1. No written policy to establish the criteria of when and how employee competency is assessed, and who administers the employee competency, could be located. 2. There is a laboratory form to document employee competency. The competencies for current employees were assessed and signed by testing personnel. 3. Interview with TP1, on 6

	/6/19 at approximately 230 PM, confirmed that there is no written policy for employee competency and that employee competency was evaluated by testing personnel.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based upon a review of the laboratory's policies and procedures and an interview with Testing Personnel (TP1), the laboratory failed to establish a written policy/procedure for Quality Assessment (QA) of the general laboratory systems. Findings: 1. No written policy or procedure for QA of the general laboratory systems could be located. This includes the monitoring and assessment of confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing evaluation. 2. The laboratory is performing QA monitoring of general laboratory systems documented on monthly QA forms. These QA forms are not being signed by the laboratory director. 3. An interview with TP1, on 6/6/19 at approximately 210 PM, confirmed there is no written policy or procedure for QA of the general laboratory systems.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based upon a review of written policies and procedures, and an interview with Testing Personnel 1 (TP1), the laboratory failed to establish written policies and procedures for (4) specimen storage and preservation and (7) specimen acceptability and rejection. Findings: 1. No written policy or procedure for specimen storage and preservation or specimen acceptability and rejection criteria could be located. 2. An interview with TP1, on 6/6/19 at approximately 240 PM, confirmed that there are no written policies or procedures to address specimen storage and preservation, specimen acceptability and rejection criteria.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

	This STANDARD is not met as evidenced by: Based upon a review of the laboratory's policies and procedures and an interview with Testing Personnel (TP1), the laboratory failed to establish a written policy/procedure for Quality Assessment (QA) of preanalytic systems. Findings: 1. No written policy or procedure could be located for QA of the preanalytic system, which includes the following: test request and specimen submission, handling, and referral. 2. The laboratory is performing QA monitoring of all preanalytic systems, documented on monthly QA forms. These QA forms are not being signed by the laboratory director. 3. An interview with TP1, on 6/6/19 at approximately 210 PM, confirmed there is no written policy or procedure for QA of the preanalytic system.
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: Based upon a review of written policies and procedures, and an interview with Testing Personnel 1 (TP1), the laboratory failed to establish written policies and procedures for (1)specimen storage and preservation, specimen acceptability and rejection, or (14) course of action to take if system becomes inoperable. Findings: 1. No written policy or procedure for specimen storage and preservation, and specimen acceptability and rejection could be located. 2. No written policy or procedure for course of action to take if test system becomes inoperable could be located. 3. An interview with TP1, on 6/6/19 at approximately 240 PM, confirmed that there are no written policies or procedures to address specimen storage and preservation, specimen acceptability and rejection, and an inoperable test system.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based upon a review of all written policies and procedures (AFFIRM VPIII COLLECTION/PROCESSING/TREATMENT, URINE DIP, URINE 10 DIP) the laboratory director had not signed and dated all procedures and policies. Findings: 1. Examination of the laboratory written policies and procedures found them not signed and dated by the current laboratory director. 2. The laboratory utilizes the manufacturer's instrument user manual for the BD AFFIRM VPIII as the test procedure manual. It was not signed and dated by the laboratory director.
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 upon a review of the laboratory's policies and procedures and an interview with Testing Personnel (TP1), the laboratory failed to establish a written policy/procedure for Quality Assessment (QA) of analytic systems. Findings: 1. No written policy or procedure could be located for QA of the analytic system, which includes the following: procedure manual, test systems/equipment/supplies, establishment and verification of performance specifications, maintenance and function checks, calibration and calibration verification procedures, control procedures, comparison of test results, corrective actions, and test records. 2. The laboratory is performing QA monitoring of pre-analytic, analytic, and post-analytic functions documented on monthly QA forms. These QA forms are not being signed by the laboratory director. 3. An interview with TP1, on 6/6/19 at approximately 210 PM, confirmed there is no written policy or procedure for QA of analytic systems.
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 upon a review of the laboratory's policies and procedures and an interview with Testing Personnel (TP1), the laboratory failed to establish a written policy/procedure for Quality Assessment (QA) for postanalytic systems. Findings: 1. No written policy or procedure could be located for QA of the postanalytic system, which includes test reports. 2. The laboratory is performing QA monitoring of postanalytic functions documented on monthly QA forms. These QA forms are not being signed by the laboratory director. 3. An interview with TP1, on 6/6/19 at approximately 210 PM, confirmed there is no written policy or procedure for QA of postanalytic systems.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based upon review of personnel records, quality control logs, quality assessment (QA) documents, written laboratory policies and procedures, the laboratory director (LD) has not met the responsibilities required, including the employment of competent and qualified personnel and assuring compliance with applicable regulations. Findings: 1. Upon review of current testing personnel, 3 of 3 testing personnel were found to have an expired West Virginia laboratory license, as required by WV 64 CSR 57, Clinical Laboratory Technician and Scientist Licensure and Certification Rule. 2. The current employee competencies were conducted and signed by testing personnel. No written employee competency policy or procedure can be located. 3. The monthly QA documents were not signed or dated by the LD. No written QA policy or procedure could be located. 4. Laboratory policies and procedures reviewed did not have a current LD signature and date, including: AFFIRM VPIII COLLECTION/PROCESSING/TREATMENT, URINE DIP FOR PROTEIN/GLUCOSE, URINE 10 DIP, and the manufacturer instruction manual for the BD AFFIRM VPIII. 5. No written policy or procedure could be located for specimen storage and preservation, specimen acceptability and rejection criteria, or how to handle an inoperable testing system.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based upon review of personnel records, quality control logs, quality assessment (QA) documents, and written policies and procedures, the laboratory director (LD) has not met the responsibilities required, including the employment of competent and qualified personnel and assuring compliance with applicable regulations. Findings: 1. 3 of 3 testing personnel were found to have an expired West Virginia laboratory license. An expiration date of 3-1-19 was found for 3 of 3 testing personnel in the West Virginia licensure database. 2. The current employee competencies were conducted and signed by testing personnel. No written policy or procedure to assess and monitor employee competency could be located. 3. No written policy or procedure could be located to establish or monitor quality assessment. Laboratory monthly QA documents were not signed by current LD. 4. Laboratory policies and procedures did not have a current LD signature or date. These written policies were AFFIRM VPIII COLLECTION/PROCESSING/TREATMENT, URINE DIP FOR PROTEIN/GLUCOSE, URINE 10 DIP, and the manufacturer instruction manual for

	the BD AFFIRM VPIII. 5. No written policy or procedure for employee competency assessment, specimen storage and preservation, specimen acceptability and rejection, inoperable test system, or quality assurance could be located.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based upon review of written laboratory policies and procedures, the laboratory failed to have a written Quality Assessment (QA) policy or procedure. Findings: 1. No written Quality Assessment policy or procedure for the laboratory could be located. 2. The laboratory is performing Quality Assessment of preanalytic, analytic, postanalytic, and general laboratory systems and documenting on a monthly QA form. This form is not signed and dated by the laboratory director.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based upon review of personnel records and written laboratory policies and procedures, the laboratory has no written policy or procedure to monitor and assess testing personnel competency. Findings: 1. No written policy or procedure to monitor and assess employee competency could be located. 2. The current employee competencies were signed by testing personnel.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all

	personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based upon review of all the written laboratory procedures and policies, there are not approved written procedures for all aspects of the testing process. Findings: 1. 4 of the 4 written laboratory policies and procedures are not signed and dated by the laboratory director. 2. No written policy or procedure for employee competency, Quality Assurance, specimen storage and preservation, specimen acceptability and rejection criteria, and how to handle testing with an inoperable test system could be located.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based upon a review of laboratory personnel files, review of laboratory written policies and procedures, and interview with Testing Personnel 1 (TP1), the technical consultant is not evaluating the competency of testing personnel. Findings: 1. No written policy to establish the criteria of when and how employee competency is assessed, and who is to administer the employee competency could be located. 2. There is a laboratory form to document employee competency. The competencies for current employees were assessed and signed by testing personnel, not the technical consultant. 3. Interview with TP1, on 6/6/19 at approximately 230 PM, confirmed that testing personnel were performing the competencies.
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based upon review of personnel files, West Virginia licensure verification, and interviews with testing personnel, there are no individuals performing moderate complexity testing that possess a current West Virginia laboratory license, as required by the state rule WV 64 CSR 57 Clinical Laboratory Technician and Scientist Licensure and Certification Rule. Findings: 1. All 3 of 3 testing personnel were found to have expired West Virginia laboratory license. 2. Interviews with all 3 testing personnel, on 6/6/19 at approximately 110 PM, confirmed they had no current West Virginia laboratory license.