Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0657443	10/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Amz Laboratory	105 North Delaware Avenue, Minersville, PA	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview with the testing personnel (TP), the laboratory failed to examine and test AAB PT routine chemistry and hematology samples in the same manner as patient specimens from 2018 to the date of survey. Findings Include: 1. On the day of survey, 10/31/2019, the surveyor asked if AAB routine chemistry and hematology PT samples are run the same as patient specimen? The TP stated "No, they calibrate the instrument before PT samples are analyzed and PT samples are run in duplicate. 2. The TP confirmed patient specimens are not run in duplicate and calibration is performed by manufactures procedures on 10/31/2019 around 9:33 am.
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 on review of laboratory procedure manuals and interview with testing personnel (TP), the laboratory failed to establish a competency assessment (CA) procedure to assess the competency of 1 of 1 TP performing Microscopic urinalysis examinations, complete blood count testing (CBC) and clinical chemistry testing in 2018 and 2019. Findings Include: 1. On the day of survey, 10/31/2019, the laboratory failed to provide a written CA procedure to assess the competency of 1 of 1 testing personnel (TP) performing microscopic urinalysis examinations, CBC's tests on the Sysmex XP 300 analyzer and clinical chemistry testing performed on the Cobas Integra 400 analyzer in 2018 and 2019. 2. The TP confirmed the findings above on 10 /31/2019 around 10:00 am.
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 on review of the laboratory procedure manuals and interview with the testing personnel (TP), the laboratory failed to establish a written quality assessment (QA) policy and procedure for ongoing mechanisms to monitor, assess, and, when indicated, correct problems identified for the laboratory from 2018 to the day of survey. Findings Include: 1. On the day of survey, 10/31/2019, review of the laboratory's manuals revealed that the laboratory did not to have a written policy for how to assess the quality of its laboratory systems. 2. The TP confirmed the laboratory does not a have quality assessment procedure on 10/31/2019 around 10:10 am.
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 on the review of the microscopic urinalysis procedure and interview with testing personnel (TP), the laboratory failed to include, requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, referral, criteria for specimen acceptability and rejection, reportable ranges, reference intervals, panic or alert values and pertinent literature references in the microscopic urinalysis examination procedure from 2018 to the date of survey. Findings Include: 1. On the date of survey, 10/31/2019, review of the microscopic urinalysis examination procedure revealed the following areas were not included in the procedure: - Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection. - The reportable range for test results for the test system. - Reference intervals (normal values). - Panic or alert values. - Pertinent literature references. 2. The TP confirmed the finding above on 10/31/2019 around 9: 45 am.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation of the laboratory microscopes and thermometers and interview with the testing personnel (TP), the laboratory failed to document maintenance for 1 of 1 AO Series 20 microscope and 3 of 3 thermometers (room temperature, freezer temperature and refrigerator temperature) from 2018 to the time of survey. Findings Include: 1. On the day of survey, 10/31/2019, the laboratory could not provide microscope maintenance for 1 of 1 AO Series 20 microscope used for microscopic urinalysis examinations from 2018 to October 2019. 2. The TP could not provide documentation of maintenance for 3 of 3 thermometers located in the laboratory for room temperature, freezer temperature and refrigerator temperature from 2018 to October 2019. 3. 481 Microscopic Urinalysis examination were analyzed in 2018. 4. 489 Microscopic Urinalysis examination were analyzed in 2019 (01/01/2019 to 10/31 /2019). 5. The TP confirmed the findings above on 10/31/2019 around 10:05 am.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the microscopic urinalysis procedure, review of quality control records, and interview with the testing personnel (TP), the laboratory failed to perform quality control (QC) each day of patient testing for Microscopic Urinalysis examinations performed from 2018 to the date of survey. Findings Include: 1. The Microscopic Urinalysis Procedures states, "The QC chart and QC results will be reviewed before any tests are performed and will be documented in the patient notes, each day of testing." 2. On the date of survey, 10/31/2019, the laboratory could not provide QC documentation for Microscopic Urinalysis examinations performed each day of patient testing from January 2018 to October 2019. 3. 481 microscopic urinalysis examination were analyzed in 2018. 4. 489 microscopic urinalysis examination were analyzed in 2019 (01/01/2019 to 10/31/2019). 5. The TP confirmed the finding above on 10/31/2019 around 10:30 am.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the review of American Association of Bioanalysts (AAB) 2018 and 2019 proficiency testing (PT) scores and interview with the testing personnel (TP), the laboratory director failed to identify problems that required a corrective action for routine chemistry PT samples in 2018 and 2019 Findings Include: 1. On the day of survey, 10/31/2019, review of PT records revealed, the laboratory did not document corrective actions for the following AAB routine chemistry PT scores that were less than 100% in 2018 and 2019: - AAB 2018, Event #1, Total protein 80% - AAB 2018, Event #1, Blood urine nitrogen (BUN) 80% - AAB 2018, Event #1, Triiodothyronine 80% - AAB 2018, Event #1, TY 80% - AAB 2018, Event #2, Total Bilirubin 80% - AAB 2018, Event #2, Cholesterol, HDL 80% - AAB 2018, Event #2, Total Bilirubin 80% - AAB 2018, Event #3, Potassium (K) 80% - AAB 2019, Event #1, Chloride (CL) 80% - AAB 2019, Event #1, Thyroid stimulating hormone (TSH) 80% 2. The laboratory director acknowledged the scores of 80% with their signature, but no assessment was made on 3 out of 3 events in 2018 and 2 of 3 events in 2019. 3. The TP confirmed the findings above at 10/31/2019 around 9:35 am.