Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0869030	08/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Atlantic General Hospital	9733 Healthway Drive, Berlin, 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 chemistry proficiency testing (PT) records and interview with the laboratory supervisor, the laboratory did not ensure that each step in the testing of the PT samples were maintained for the required 2 years. Findings: 1. The chemistry PT records from the third event of 2016 through the second event of 2018 (6 events) were reviewed. The laboratory's record system did not include the original instrument printouts with the PT records. 2. According to the laboratory supervisor the chemistry PT results are stored in the analyzers since they do not have a patient identification number and are not transferred to the laboratory information system (LIS). When the laboratory staff went to retrieve the PT results from the chemistry analyzers they were informed that the results are only stored on the analyzers for 30 days. The original PT values that were reported to the PT agency were no longer retrievable from the analyzers. 3. During the survey on 08/23/2018 at 3:00 PM the laboratory supervisor confirmed that the laboratory's record system did not ensure that the each step in the testing, original records of the chemistry PT results, were maintained for the required 2 years.

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 interview with the laboratory (lab) technical consultant/supervisor, the lab did not establish policies to have the lab director assess this employee for the technical consultant/supervisor duties that they perform. The lab did not have records for this competency check and this was confirmed during interview with the technical consultant/supervisor in the afternoon of August 23, 2018.
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: A. Based on review of the laboratory's general procedure manual and interview with the testing person/pathologist, the laboratory did not have written policies and procedures for specific activities performed by the Histology department. Findings: 1. When the surveyor asked to review the written protocol for the Histology department the testing person stated that there were no written policies and procedures. The pathologists follow the laboratory's general policies and procedures but there are no specific written instructions for the Histology department. Policies and procedures must include but are not limited to the applicable instructions listed in 493.1251(b)(1-14). 2. During the survey on 08/22/17 at 11:00 AM the testing person confirmed that there were no written policies and procedures with specific Histology policies and procedures. B. Based on review of the laboratory's general procedure manual and interview with the laboratory supervisor, the laboratory did not update the duties and responsibilities of the "Work Stations" for the Chemistry department. Findings: 1. The general laboratory policies and procedures lists the duties and responsibilities for each department in the laboratory under the title "Work Station." Review of the Chemistry

	"Work Station" showed that the "Pathology pending logs" were the responsibility of the Chemistry department. 2. According to the laboratory supervisor the Chemistry department was no longer responsible for this task and that the information technology (IT) department is now responsible for the "Pathology pending logs." 3. During the survey on 08/23/17 at 3:00 PM the laboratory supervisor confirmed that the general laboratory procedure manual had not been updated to delete the review of "Pathology pending logs" from the Chemistry department and add the review to the IT department.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the staining station in the histology department and interview with the testing personnel, the laboratory did not label the staining dishes with identity and concentration of the contents. Findings: 1. Observation of the staining system showed that the containers for the stains did not have labels identifying the contents. The laboratory staff confirmed that the containers were not labeled identifying the contents of each container. 2. During the survey on 08/23/2018 at 3:00 PM the testing personnel confirmed that the containers used for staining in the histology department did not have labels identifying the contents of each solution used in the staining process.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: A. Based on record review and interview with laboratory (lab) staff, the lab did not ensure reagents were not used past expiration. Findings: 1. The bacteriology lab uses the P disk (differentiation disk). The quality control results for the disk are recorded on the quality control log, but this record does not include the manufacturer name, lot number and expiration date of the P disk in use; 2. The bacteriology lab did not record the manufacturer name, lot number and expiration date of Gram stain reagents used to stain patient slides for microscopic examination for bacteria; and 3. These findings were confirmed during interview with lab staff between 1 and 3 pm on 8/22/18. 07149 B. Based on review of the validation records for both Vista chemistry analyzers and interview with the laboratory supervisor, the laboratory did not ensure that reagents and standards used for the validations were not used after their expiration date. Findings: 1. The summary reports for the validations of each Vista analyzers did not include the expiration dates of the reagents and the lot numbers and expiration dates of the standards used to perform the validation on both analyzers. 2. During the survey

	on 08/23/2018 at 3:00 PM the laboratory supervisor confirmed that the validation records that were available did not include the expiration dates of the reagents and the lot numbers and expiration dates of the standards used to perform the validation.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the microbiology lab did not document the observed quality control reactions for the rapid latex identification of streptococci antigen (Streptex). Findings: 1. The lab performs a rapid latex identification test for streptococci antigen; 2. The lab performs external (liquid) positive and negative quality control checks for each box, lot number and shipment of test kits received and placed in use; 3. The lab reports the quality control reactions as "OK" on the quality control report, but does not document each positive and negative reaction observed as a result of the quality control testing including any internal quality control checks that were performed; and 4. These findings were confirmed during interview with lab staff between 1 and 3 pm on 8/22/18.
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 on review of the normal patient ranges listed on the Vista (chemistry analyzer) instrument printout, the ranges listed on the validation records and interview with the laboratory supervisor, the laboratory director did not ensure that the normal patient ranges that were listed in the analyzer were the same values listed in the validation records. Findings: 1. The validation records and instrument printouts were reviewed to verify that the normal patient ranges verified during the validation process matched the values entered into each Vista analyzer. Seven different analytes were randomly reviewed to verify accuracy. Three of the seven did not match. The findings are listed below. 2. Review of the instrument data in the 2 Vista analyzers showed that the normal patient value for vitamin B-12 was 254 - 1,320 and the validation records

	showed the normal patient range as 193 - 986. 3. Review of the instrument data in the 2 Vista analyzers showed that the normal patient value for carbamazepine was 8 - 12 in Vista 1, 4 - 12 in Vista 2 and the validation records showed the normal patient range as 4 - 12. 4. Review of the instrument data in the 2 Vista analyzers showed that the normal patient value for thyroid stimulating hormone (TSH) was 0.350 - 3.70 and the validation records showed the normal patient range as 0.358 - 3.740. 5. During the survey on 08/23/18 at 3:00 PM the laboratory supervisor confirmed that the normal patient values listed in the validation records did not always match the values entered into the 2 Vista analyzers.