Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0246868	08/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Atrium Health Wake Forest Baptist Internal	1771 Tate Boulevard Se, Suite 103, Hickory, 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
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 laboratory's policies and procedures, review of 2016, 2017, and 2018 API (American Proficiency Institute) proficiency testing records, and interview with TP (testing personnel) 8/8/18, the laboratory failed to test proficiency samples in the same manner that proficiency samples were tested. Findings: 1. The laboratory's "Proficiency Testing" policy states "... PROCEDURE: 1. Proficiency testing will be rotated among the techs so that everyone working in a lab discipline participates in the testing throughout the year. ..." Review of 2016, 2017, and 2018 API proficiency testing records revealed that TP #1 signed the attestation statement as the testing personnel for the 2016 2nd and 3rd hematology test events, the 2017 1st, 2nd, and 3rd hematology test events, and the 2018 1st and 2nd hematology test events. During interview at approximately 12:10 p.m., TP #1 confirmed that she tested all the proficiency samples and TP #2 did not participate in proficiency testing. She verified that TP #2 performs testing on patient specimens. 2. The laboratory's "Proficiency Testing" policy states "... PROCEDURE: ... 4. Proficiency test samples will be tested in exactly the same manner as patient samples are tested. ... b. Samples will only be repeated (e.g. with panic values) if a patient sample would have been repeated under the same circumstances. ..." The laboratory's list of critical values states "1. Repeat all

	critical values before reporting. ..." Review of 216, 2017, and 2018 API proficiency testing records revealed the laboratory failed to repeat critical values obtained on the following proficiency samples: a. 2016 3rd hematology test event - critical values on sample #12 for WBC (white blood cell count), hemoglobin, and hematocrit; b. 2017 2nd hematology test event - critical values on sample #6 for WBC, hemoglobin, and hematocrit; c. 2017 3rd hematology test event - critical values on sample #15 for WBC, hemoglobin, and hematocrit; d. 2018 1st hematology test event - critical values on sample #1 for WBC, hemoglobin, and hematocrit; e. 2018 2nd hematology test event - critical values on sample #8 for hemoglobin and hematocrit. During interview at approximately 12:10 p.m., TP #1 confirmed that they do not repeat critical values obtained on proficiency samples.
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 on review of 2017 and 2018 laboratory records and interview with TP (testing personnel) 8/8/18, the laboratory failed to retain all quality control records for at least two years. Findings: Review of 2017 and 2018 Coulter AcT diff 2 hematology quality control records revealed the laboratory failed to maintain the assay sheets for the following lot numbers of Coulter 4C-ES control material: abnormal low 069000, normal 079000, and abnormal high 089000, expiration date 5/7/18. During interview at approximately 3:00 p.m., TP #1 confirmed that the assay sheets were not available for review.
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 review of the laboratory's policies and procedures and interview with TP (testing personnel) 8/8/18, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The procedure manual did not include collection instructions for vaginal, skin, hair, and nail specimens for the wet prep and KOH (potassium hydroxide) tests. 2. The procedure manual contained a "SLIDES FOR REVIEW BY DIRECTOR" procedure dated 9/96 which described the criteria for pathologist review of peripheral blood smears. During interview at approximately 11:15 a.m., TP #1 confirmed that they do not make or review peripheral blood smears on-site. 3. The procedure manual contained multiple quality control policies, and it was unclear which ones were current. Examples: a. The 'HEMATOLOGY ACT DIFF II" policy states "... Quality Control Requirements: Quality Control Material: 4C Frequency of running: 3 levels of control, Low, Normal, and High are run each day of testing Remedial actions: 1. Repeat the control 2. Check expiration dates 3. Get out new bottle of control and re-run 4. Call technical service 5. Re-Calibrate if necessary - then re-run controls ..." b. The "CBC Quality Control & Calibration Procedures" policy states "1. Everyday the test is performed coulter 4C Plus Controls ES Low, Normal, & High must be tested. Once a month the results are sent to Beckman coulter for evaluation. ... 2. If controls are not within limits ..refer to the Quality Control manual or call Beckman Coulter ..." c. The "Quality Control Policy and Guidelines" procedure states "... POLICY: A minimum of 2 levels of quality control (QC) will be tested every day of patient testing for all non-waived tests. ... PROCEDURE: ... Refer to laboratory-specific information for each analyzer to determine the specific controls used for that analyzer. ..." TP #1 stated during interview at approximately 3:00 p.m. that they use Coulter 4C ES control material and she stated that they do not send results to Beckman Coulter for evaluation. 4. The "GENERAL LABORATORY CONDITIONS" policy states "Each day of operation the temperature will be read and recorded for all refrigerators/freezers. ..." a. The policy lists the acceptable refrigerator temperature range as "2 degrees C to degrees C." The policy does not include the maximum acceptable reading for refrigerator temperature. b. The policy does not list the acceptable range for room temperature.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions and review of the laboratory's 2016, 2017, and 2018 daily temperature logs 8/8/18, the laboratory failed to define an acceptable range for humidity that was consistent with manufacturer's instructions for operation of the Dimension Xpand chemistry analyzer. The Dimension Xpand/Xpand Plus Operator's Guide states on page 1-32 "... Room Temperature Rquirements ... Relative humidity must be maintained at greater than or equal to 20% and less than or equal to 80%. ..." Although review of daily temperature logs revealed documented

	humidity readings were not outside the acceptable limits during 2016, 2017, and 2018, the logs listed the acceptable range for humidity as 20%-85% which was inconsistent with manufacturer's instructions.
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: Based on review of the laboratory's policies and procedures and review of 2017 and 2018 hematology quality control records 8/8/18, the laboratory failed to discard control materials that had exceeded their expiration date. The laboratory's "Quality Control Policy and Guidelines" procedure states "... GENERAL GUIDELINES: ... 9. QC material will not be used beyond the expiration date defined by the control manufacturer." Review of 2017 and 2018 hematology quality control records revealed: 1. the laboratory used quality control material on 12/4/17 (lot numbers 067800, 077800, 087800) that expired 12/1/17. 2. the laboratory changed the lot number of abnormal high quality control material in the analyzer on 3/1/18, but failed to change the expiration date. The laboratory used the quality control material (lot number 089000) with the expiration date listed as 3/19/18 from 3/1/18 - 5/7/18. The laboratory changed the lot number of abnormal low quality control material in the analyzer on 3/2/18, but failed to change the expiration date. The laboratory used the quality control material (lot number 069000) with the expiration date listed as 3/19/18 from 3/2/18 - 5/7/18.
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 on review of 2016, 2017, and 2018 laboratory records 8/8/18, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure the establishment and maintenance of an effective quality control program (see D6020). 2. The laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program (see D6021).
D6020	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 the quality control program is established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2017 and 2018 quality control and quality assessment records, and interview with TP (testing personnel) 8/8/18, the laboratory director failed to ensure the establishment and maintenance of a quality control program to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to retain hematology quality control records for at least two years (see D3031 and D8103). 2. The laboratory's quality control procedure was not complete and current (see D5403). 3. The laboratory used expired hematology quality control material (see D5417). 4. The laboratory failed to have a system in place to evaluate shifts and trends in hematology quality control. The "INVESTIGATION OF QUALITY CONTROL PROBLEMS & QC REVIEW" procedure states "... 6. Check QC records for trends, shifts, etc. ... Also any trends or shifts in QC data must be noted, and if warranted, steps taken to rectify the problem. ..." Review of 2017 and 2018 hematology quality control records revealed there were no quality control summaries available for review. Review of 2017 and 2018 quality assessment records revealed the following regarding quality control: a. On 3/31/17: "... We are still working with the 'Wake Beaker' team on the interface. ..." b. On 5/30 /17: "... It dept. is working on interfacing QC..." c. On 12/22/17: "... Continue to work on QC program and interface with Epic. ..." d. On 4/27/18: "... Working with Winston Campus IT dept. to interface QC..." e. On 5/30/18: "... will be working with IT dept. on QC interface. ..." f. On 8/2/18: "Still working with IT dept on interface for QC..." During interview at approximately 3:00 p.m., TP #1 confirmed that they don't have a mechanism for evaluating shifts and trends. She stated that they review daily quality control results, but they do not print summaries for each month or lot number. She stated that they used a free program downloaded from the internet for a short time, but they are no longer using it.
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 laboratory's quality assessment plan and review of 2016, 2017, and 2018 quality assessment records 8/8/18, the laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program designed to identify and correct problems and prevent their recurrence. The laboratory's quality assessment plan states "... RESPONSIBILITY The lab service is under the jurisdiction of the Lab Director and lab manager. It is the responsibility of the lab manager to implement the plan. The lab director and lab manager will be responsible either directly or by delegation for the following: ... 2. Review QA monthly with Lab director and lab manager 3. Implementing action to improve service 4. Follow up reviews to show proof of improved service 5. Implementing of policies and procedures and evaluation of their effectiveness 6. Assuring the prompt, accurate,

	and reliable reporting of test results. ... 8. Maintaining required enrollment in Proficiency testing programs, with appropriate review and actions. 9. Overseeing quality control program ..." Review of 2016, 2017, and 2018 quality assessment records revealed the laboratory documented monthly activity including a "LAB DIRECTOR STAFF MEETING" between the laboratory director and TP #1. The meeting documentation included reviews of quality control, quality assessment, maintenance, proficiency testing, personnel, and management, and a section for "DISCUSSION". There were no problems noted. The laboratory's quality assessment program failed to identify problems identified during the survey in the following areas: 1. proficiency testing (see D2006); 2. quality control (see D3031, D5417, D6020, D8103); 3. procedures (see D5403); 4. test systems (see D5413).
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of 2016, 2017, and 2018 quality assessment records, review of 2017 and 2018 quality control records, and interview with TP (testing personnel) 8/8/17, the laboratory failed to provide all records needed by the surveyors to determine compliance with the quality control requirements of part 493. Review of 2016, 2017, and 2018 quality assessment records revealed the following notation "As of July 5, 2016, Our labdaq system was hit by lighting and we no longer has access to any patient information or qc information. We will be sending all labs to our Winston campus for processing until further notice. We will only be performing off line test that can be manually entered into the epic system directly into patient's charts." The notation was dated 7/10/16 and was signed by TP #1, but was not signed by the laboratory director. During interview at approximately 3:00 p.m., TP #1 stated that the laboratory did not have quality control records prior to 3/14/17 available for review.