Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0921039	06/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Arthur L Autz, Md Pc	1610 Old Country Road, Westbury, NY	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor's review of the manufacturer's packet insert for OSOM Ultra Influenza A&B, Pro Advantage Rapid Strep, Pro Advantage uhCG and interview with the technical consultant, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls with each new kit of Influenza A&B, kit of Rapid Strep, and new kit of uhCG opened. FINDINGS: 1. The laboratory is using the OSOM Ultra Influenza, the Pro Advantage Rapid Strep, and the Pro Advantage uhCG kits. 2. On June 6, 2019 at approximately 2:30 PM the technical consultant confirmed surveyor's findings that documentation for the required external control testing was not available for Influenza A&B and for uhCG for calendar year 2018 and up to survey date. 3. The technical consultant confirmed surveyor's findings that the only available documentation for the required external control testing for Rapid Strep was for March and July 2018. 4. Approximately 100 patient specimens were tested and reported for Rapid Strep, Influenza A&B, and uhCG testing during the above time frames.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on the surveyor's review of American Proficiency Institute (API) Proficiency Testing (PT) reports and an interview with the technical consultant, the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes: 2017 second event: Monocytes = 40% Cell ID = 80% Red Blood Cells (RBC) = 80% Hemoglobin (HGB) = 80% 2017 third event: Cell ID = 80%
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a surveyor's review of hematology calibration records and interview with the technical consultant, calibration of the hematology analyzer was not performed at the frequencies required by the laboratory's calibration protocol and by the manufacturer of the analyzer. FINDINGS: 1. The laboratory is using the Coulter AcT Diff analyzer. The laboratory's calibration policy and the manufacturer of the hematology analyzer require analyzer calibration every six months. 2. The documentation of the Coulter AcT Diff analyzer calibration available for review was for calibration performed on 3/15/17, 3/15/18, 9/10/18 and 1/18/19. The hematology analyzer was therefore out of calibration from 10/9/17 through 3/14/18 3. The records indicated that the laboratory's attempt of calibration failed on 8/23/17. 4. Approximately 70 patient specimens were tested and reported for hematology during the above time period when analyzer was out of calibration. THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON JUNE 30, 2017.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Quality Control (QC) procedure for hematology and confirmed in a interview with the technical consultant, the laboratory failed to follow the laboratory's required QC policy/QC procedure and perform a lot to lot verification of the hematology controls used for the Coulter AcT Diff analyzer prior to use in calendar year 2018 and up to survey date. THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON JUNE 30, 2017.
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 surveyor's findings and an interview with the technical consultant, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the surveys conducted on 9/24/15 and 6/30/2017; 2. Maintained the laboratory's QC program for hematology. Refer to D6020; and, 3. Maintained the laboratory's established QA program for all phases of laboratory testing. Refer to D6021. THIS IS A REPEATED DEFICIENCY FROM THE SURVEYS CONDUCTED ON SEPTEMBER 24, 2015 AND JUNE 30, 2017.
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 a review of quality control records, and an interview with the technical consultant, the laboratory director failed to ensure that the QC program for hematology was maintained to assure quality laboratory services. Refer to: D1001, D5469
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 surveyor review of Quality Assessment (QA) procedures, reviews and an interview with the technical consultant, the director failed to ensure that the laboratory's QA program for hematology was maintained for all phases of laboratory testing. Refer to: D5211, D5437 THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON JUNE 30, 2017.