Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2111115	05/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Excelsior Diagnostic Lab	12 Snow Hill St, Spotswood, NJ	

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 surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to maintain the attestation statement for Hematology PT provided by the Wisconsin State Laboratory of Hygiene (WSLH) for the first event of 2019. The TP confirmed on 5/1/19 at 11:05 am that attestation statement was not maintained.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to retain PT records performed with the

	Wisconsin State Laboratory of Hygiene for event 1 for 2019. The finding includes. 1) There were no graded results for " Module 1314, Chemistry endocrinology Therapeutic drugs". 2) The TP confirmed on 5/1/19 at 11:30 am that the laboratory failed to retain PT records.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate results when they received an unacceptable score in Hematology tests performed on the Sysmex XS 1000i analyzer with the Wisconsin State Laboratory of Hygiene (WSLH) in the 2019-HemReg1 event. The findings include: 1. The laboratory received "Fail" in 2019-HemReg1 on samples AF5-1 and AF5-2 for Mean Corpuscular Volume (MCV). 2. There was no documented evidence that the laboratory investigated the failures. 3. The TP confirmed on 5/1/19 at 10:42 am that the laboratory did not perform and document an evaluation of unacceptable PT results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow their "Quality Control Responsibilities" (QCR) procedure from August 2018 to the date of the survey. The finding include: 1 The QCR procedure stated "It is the responsibility of the person performing a particular procedure to initiate corrective action on out of range reports for each control that fails outside 2sd"" 2) There was no evidence documented evidence of corrective action on 2/6/19, 2/21/19, 3/1/19 and 3/8/19 for high Monocyte controls. 2. The TP on 5/1/19 at 11:20 am that the laboratory did not follow the QCR procedure.
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 surveyor observation of the Quality Control (QC) material and interview with the Testing Personnel (TP), the laboratory failed to put open and new expiration dates on Hematology e-CHECK controls from August 2018 to the date of survey. The TP confirmed on 5/1/19 at 10:30 am the laboratory failed to put open and new expiration dates on the control material.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to ensure two levels of QC were in range on each day of patient testing for Hematology tests performed on the Sysmex XS 1000i from 2/6/219 to the date of survey. The findings include: 1. A review of the QC records revealed that controls were out of range as follows: a. 2/6/19 - Monocytes high control. b. 2/21/19- Monocytes high control. c. 3/1/19 - Monocytes high control. d. 3/8/19 - Monocytes high control. 2. Approximately ten patients were run and reported each with one level of QC in range. 3. The TP confirmed on 5/1/19 at 10:50 am that laboratory failed to have to ensure two levels of QC was required in range on each day of patient testing.
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 review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify that the assayed QC materials were within the acceptable ranges before they were put into use for tests performed on the Olympus AU480 and Sysmex XS 1000i from August 2018 to the date of survey. The TP confirmed on 5/1/19 at 11:am pm that the laboratory did not verify QC materials.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR), Test Requisition (TR) and interview with the owner,the laboratory failed to ensure that the FR included the name of the laboratory where testing was performed and correct specimen collection time from August 2018 to the date of survey. The findings include; 1) The TR did not have the address of the reference laboratory where patient testing was performed. 2) The TP confirmed on 5/1/19 at 11:50 pm that FR did not have all the required and correct information.
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: a) Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to have a procedure to verify reference laboratory results that were manually entered into the laboratory information system from August 2018 to the date of the survey. The TP confirmed on 5/1/19 at 10:15 am that the laboratory did not have the procedure mentioned above. b) Based on surveyor review of the Final report (FR) and interview with the TP, the laboartory failed to identify problem on FR from August 2018 to the date of survey. The finding includes: 1. The collection time on the Test Requisition did not match the collection times on the FR 2. The TP confirmed on 5/1/19 at 10:30 am the the laboratory did not identify FR problem.