Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0906863	02/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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
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 document review and interview with laboratory personnel, the laboratory failed to evaluate unacceptable proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 02/02/18 at 9:00 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) proficiency provider. 3. The laboratory received unacceptable PT results from API for the events and analytes listed below. Event/Analyte ID Lab API 2016 3rd event PLT* HEM-03 54 55-92 2017 2nd event MCV* HEM-06 83.9 84.6-91.5 HEM-07 87.1 87.4-94.0 HEM-08 91.6 91.9-99.0 HEM-09 87.3 87.9-94.8 4. PT records indicated a calibration verification would be performed to evaluate the unacceptable PT result from 2016. Calibration verification records from 2016 were not found. The laboratory was unable to provide calibration verification records from 2016 upon request. 5. An evaluation of the unacceptable PT results from 2017 was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 6. In an interview on 02/02/18 at 10:30 a.m., TP1 confirmed the above finding. * Note PLT - Platelets MCV - Mean Corpuscular Volume
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 observation, document review and interview with laboratory personnel, the laboratory failed to ensure all required elements were included in the procedure manual. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 02/02/18 at 9:0 a.m. 2. A Cell-Dyn Emerald hematology analyzer was observed as present and available for use during the tour. 3. Reportable ranges for analytes tested on the hematology analyzer were not found in the untitled procedure manual found in the laboratory. 4. Reference ranges (normal values) for analytes tested on the hematology analyzer were not found in the untitled procedure manual found in the laboratory. 5. In an interview on 02/02/18 at 11:16 a.m., TP1 confirmed the above finding.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to perform and document required Hematology analyzer maintenance. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 02/02/18 at 9:00 a.m. 2. A Cell-Dyn Emerald hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Requirements for semi-annual piston lubrication were established in the Cell-Dyn Emerald Quick Reference Guide provided by the manufacturer. 4. Documentation of semi-annual piston lubrication was not found during review of laboratory records from January 2016 through January 2018. The laboratory was unable to provide this maintenance documentation upon request. 5. In an interview on 02/02/18 at 1:00 p.m., TP1 stated the Laboratory Director performed piston lubrication on 11/20/1,7 during the one calibration verification performed in the described timeframe, but the maintenance had not been documented.
D5435	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on observation and interview with laboratory personnel, the laboratory failed to perform and document function checks (calibration) for a Min/Max digital thermometer. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 02/02/18 at 9:00 a.m. 2. A digital Min/Max thermometer with serial number 150428488 was observed as in use in the laboratory refrigerator. Control materials and patient specimens were observed in the refrigerator. 3. A calibration due date of 06 /03/17 was indicated on the back of the digital Min/Max thermometer. The laboratory was unable to provide current calibration records upon request. 4. During on interview on 02/02/18 at 9:05 a.m., TP1 confirmed the Min/Max digital thermometer calibration was overdue.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to perform calibration verification on a hematology analyzer at least once every 6 months. Findings are as follows: 1. The laboratory performed

	Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 02/02/18 at 9:00 a.m. 2. A Cell-Dyn Emerald hematology analyzer was observed as present and available for use during the tour. 3. The laboratory performed calibration verification activities on one occasion, 11/20/17, during the time period reviewed, January 2016 through January 2018. The laboratory was unable to provide additional calibration verification records between January 2016 and January 2018 upon request. 4. In an interview on 02/02/18 at 10:10 a.m., TP1 confirmed the calibration verifications had not been performed with the frequency required. *This is a repeat finding from the 10/28/15 survey*
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on document review and an interview with laboratory personnel, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems when identified. Findings are as follows:: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 02/02/18 at 9:00 a.m. 2. The laboratory failed to establish a Quality Assurance program to monitor, assess, and when indicated, correct problems identified in the pre-analytic, analytic, and post-analytic systems such as, but not limited to, the following: a. The laboratory failed to evaluate unacceptable proficiency testing results. See D5211 b. The laboratory failed to ensure all required elements were included in the procedure manual. See D5403. c. The laboratory failed to document required Hematology analyzer maintenance. See D5429 d. The laboratory failed to perform and document function checks on a digital thermometer. See D5435 e. The laboratory failed to perform calibration verification on a hematology analyzer at least once every 6 months. See D5439 f. The laboratory failed to establish a written corrected reports procedure. See D5821 3. In an interview on 02/02/18 at 10:50 a.m., TP1 confirmed the above finding.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to establish and follow a written corrected reports procedure. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing

	Personnel 1 (TP1) during a tour of the laboratory on 02/02/18 at 9:00 a.m. 2. A corrected reports procedure was not found during review of laboratory policies and procedures. The laboratory was unable to provide a corrected reports procedure upon request. 3. In an interview on 02/02/18 at 10:55 a.m., TP1 confirmed the above finding.