Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0691033	06/13/2019
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . I. Based on review of American Proficiency Institute (API) proficiency testing (PT) documentation for 2017, 2018 and 2019, confirmed by staff interview, the laboratory director failed to attest to the routine integration of samples into the patient workload using the laboratory's routine methods. Findings: a. Review of API PT documentation for testing in hematology revealed the laboratory director failed to sign the attestation statements for the 3rd testing event of 2017 and the first testing event of 2018. b. In an interview at the site on 06-13-2019, testing person 1 (CMS form 209) confirmed that the forms were unsigned. She stated she had become involved in proficiency testing in late 2018 when the previous principal testing person had retired. II. Based on review of American Proficiency Institute (API) proficiency testing (PT) documentation for 2017, 2018 and 2019, confirmed by staff interview, the testing person failed to attest to the routine integration of samples into the patient workload using the laboratory's routine methods. a. Review of API PT documentation for testing in hematology revealed the person performing the testing failed to sign the attestation statement for the first testing event of 2018. b. In an interview at the site on 06-13-2019, testing person 1 confirmed that the form was unsigned. Refer to I b above. .
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

	This STANDARD is not met as evidenced by: . Based on review of American Proficiency Institute (API) proficiency testing (PT) documentation for 2017, 2018 and 2019, confirmed by staff interview, the laboratory failed to attain a satisfactory score for hematology analyte White Blood Cell differential count (WBC diff) in the third testing event of 2018. Findings: 1. Review of API PT documentation for hematology testing revealed the following scores: Hematology 3rd event 2018 Granulocytes (%) Sample Reported Expected Score HEM-11 69.7 70.1-73.7 Unacceptable HEM-12 81.2 80.3-85.6 Acceptable HEM-13 84.3 82.5-85.8 Unacceptable HEM-14 63.8 68.6-73.1 Acceptable HEM-15 45.0 41.8-49.4 Acceptable Analyte score: 60% Lymphocytes (%) Sample Reported Expected Score HEM-11 26.5 21.4-26.2 Unacceptable HEM-12 13.5 10.1-13.6 Acceptable HEM-13 12.7 11.1-14.0 Acceptable HEM-14 32.0 22.4-27.5 Unacceptable HEM-15 51.6 44.9-55.0 Acceptable Analyte score: 60% The unacceptable scores for Granulocytes (%) and Lymphocytes (%) combined to yield a score for analyte WBC diff of 73%. 2. In an interview at the site on 06-13-2019, testing person 1 confirmed the unacceptable scores. .
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: . Based on review of API PT documentation for 2017,2018 and 2019, confirmed by staff interview, the laboratory failed to take appropriate action to correct problems associated with unsatisfactory performance in hematology. Findings: 1. Review of API PT documentation revealed unsatisfactory performance for analyte WBC diff in the third testing event of 2018. Refer to D2121. 2. Review of API PT documentation revealed unsatisfactory performance for analyte Granulocytes (%) in the third testing event of 2018. Refer to D2121. 3. Review of API PT documentation revealed unsatisfactory performance for analyte Lymphocytes (%) in the second and third testing events of 2018. Refer to D2130. 4. Available laboratory documentation included no evidence of investigation or corrective action regarding the above PT failures. 5. In an interview at the site on 06-13-2019, testing person 1 confirmed the unsatisfactory scores but could offer no evidence of investigation or corrective action. She further stated she had been hired in November 2018 and had not participated in the testing events in question. .
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

	This STANDARD is not met as evidenced by: . Based on review of American Proficiency Institute (API) proficiency testing (PT) documentation for 2017, 2018 and 2019, confirmed by staff interview, the laboratory failed to attain successful performance in hematology testing for the analyte Lymphocytes (%). Findings: 1. Review of API PT documentation for hematology testing revealed the following scores: Hematology 2nd event 2018 Lymphocytes (%) Sample Reported Expected Score HEM-06 15.6 11.6-14.4 Unacceptable HEM-07 26.6 24.3-28.7 Acceptable HEM-08 52.2 45.6-53.6 Acceptable HEM-09 14.3 10.6-13.9 Unacceptable HEM-10 26.5 23.9-27.1 Acceptable Analyte score: 60% Hematology 3rd event 2018 Lymphocytes (%) Sample Reported Expected Score HEM-11 26.5 21.4-26.2 Unacceptable HEM-12 13.5 10.1-13.6 Acceptable HEM-13 12.7 11.1-14.0 Acceptable HEM-14 32.0 22.4-27.5 Unacceptable HEM-15 51.6 44.9-55.0 Acceptable Analyte score: 60% Unacceptable scores in two consecutive testing events resulted in unsuccessful performance for the analyte Lymphocytes (%). 2. In an interview at the site on 06-13-2019, testing person 1 confirmed the unacceptable scores. .
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: . Based on review of quality assessment documentation for 2017, 2018 and 2019 and staff interview, the laboratory failed to discuss quality assessment procedures with appropriate staff and to document general laboratory systems quality assessment activities. Findings: 1. Quality assessment documentation was reviewed. A binder in the laboratory area included a section for Quality, which contained forms such as: Problem Identification and Resolution Worksheet Quarterly Chart Review Quality Control Action Log Specimen Rejection Log Critical Values Log 2. The most recent entry in any of the above logs was in the Quality Control Action Log; 04-28-2017. The most recent indication of director review was 05-01-2017. No other evidence of quality assurance documentation, review or discussion was found or could be offered during the survey. 3. In an interview at the site on 06-13-2019, testing person 1, when shown the section containing the logsheets and associated policy, stated she had "seen it but didn't know what it was." .
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

	This STANDARD is not met as evidenced by: . Based on review of API PT documentation for hematology testing in2017, 2018 and 2019, confirmed by staff interview, the laboratory director failed to ensure that all proficiency testing reports were reviewed by the appropriate staff to evaluate performance and identify problems requiring corrective action. Refer to D2128. .
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: . Based on review of API PT documentation for hematology testing in2017, 2018 and 2019, confirmed by staff interview, the laboratory director failed to ensure that corrective action was taken when PT results were found to be unacceptable or unsatisfactory. Refer to D2128. .
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on review of laboratory personnel documentation and staff inteview, the laboratory failed to show evidence of appropriate education for testing person 1. Findings: 1. In the course of the survey, education and training documentation for testing person 1 was requested. No high school diploma or equivalent was found or could be offered. 2. In an interview at the site on 06-13-2019, testing person 1 stated that she had graduated from high school, but her documentation was at home. .
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to

	analyzing patient specimens. This STANDARD is not met as evidenced by: . Based on review of laboratory personnel documentation and staff inteview, the laboratory failed to show evidence of appropriate training for testing person 1. Findings: 1. In the course of the survey, education and training documentation for testing person 1 was requested. No documentation of training specific to the operation of the Cell-Dyne Emerald hematology analyzer was found or could be offered. 2. In an interview at the site on 06-13-2019, testing person 1 was asked if she had a checklist or other evidence of training in the use of the instrument. She said, "Not that I know of." She further stated that she had been trained on the operation of the hematology analyzer by the previous user. .