Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0239127	03/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Eagle Central Laboratory	301 East Wendover Avenue, Suite 300, Greensboro, 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
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 2018, 2019, and 2020 hematology records and interview with TP (testing personnel) 3/5/20, the laboratory failed to retain documentation of daily background checks performed on the DXH-800 for at least two years. Review of 2018, 2019, and 2020 DXH-800 hematology records revealed there were no background records available for review. During interview at approximately 3:40 p. m., TP #4 and the TC stated that they thought backgrounds were stored in the analyzer. An attempt to print a random background from March 2018 revealed the background reports were not available for March 2018. Additional attempts to print background reports revealed reports from 8/15/18 to 3/5/20 were available in the analyzer, but the reports indicated a pass/fail result only and did not include the actual values obtained.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test

	results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2018, 2019, and 2020 temperature and humidity logs, and interview with TC (Technical Consultant) 3/5/20, the laboratory failed to take and document corrective action for humidity readings outside the acceptable limits. The laboratory's "Central Laboratory Instrument Operation Temperature and Humidity Verification Procedure" reads, "... verify that the relative humidity of the lab for the chemistry analyzer should be between 20-80%, and the hematology analyzer 20-85%." The "Temperature / Humidity / End of Day Log" reads the lab humidity readings should be between 20-80%. Review of 2018, 2019, and 2020 temperature and humidity logs revealed recorded humidity readings below acceptable limits on the following days with no corrective action documented: a. January 2018: 19% humidity documented on 1/2-5, 1/8, 1/15-16, 1/19 and 1/24; b. February 2018: 18% humidity documented on 2/1; c. March 2018: 19% humidity documented on 3/5-6 and 3/14; 18% humidity documented on 3/15-16, 3/22-23 and 3/26; d. November 2018: 18% humidity documented on 11/12 and 11/27-29; e. December 2018: 18% humidity documented 12/5-7, 12/11-14, 12/18-19 and 12/26-27; f. January 2019: 18% humidity documented on 1/10-11, 1/14-17, 1/21-23, 1/25 and 1/28-31; g. February 2019: 18% humidity documented on 2/1, 2/4, 2/11, 2/14-15, 2/19-20 and 2/25-27; h. March 2019: 18% humidity documented on 3/5-8,3/12-13, 3/18-22 and 3/27-29; i. April 2019: 18% humidity documented on 4/1-4; 19% humidity documented on 4/29; j. November 2019: 19% humidity documented on 11/13; 18% humidity documented on 11/14, 11/18, 11/21, and 11/25-26; 17% humidity documented on 11/15; k. December 2019: 18% humidity documented on 12/3-6, 12/9, 12/13, 12/18-20 and 12/26; 19% humidity documented on 12/12; l. January 2020: 18% humidity documented on 1/6-10, 1/17, 1/20-24 and 1/27-31. During interview at approximately 2:00 p.m., the TC verified the low humidity readings and the absence of an acknowledgement or corrective action.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with the TC (technical consultant) 3/5/20, the TC failed to perform and document annual competency evaluations for 5 of 5 TP (testing personnel) during 2018. The laboratory's 'PERSONNEL ASSESSMENT" policy states "... Technical competency is assessed by use of Minimum Competency Evaluation Forms. The forms are reviewed in detail with the employee by the Administrative Lab Director annually to ensure technical competency in all areas of the laboratory on an annual basis. ..." Review of personnel records for 5 of 5 TP revealed competency evaluations performed in June 2019, but there were no 2018 competency evaluations available for review. During interview at approximately 10:00 a.m., the TC confirmed there were no 2018 competency evaluations performed.

D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records 3/5/20 and the deficiency cited at D6065, the laboratory failed to verify that 1 of 5 testing personnel (TP # 5) met the minimum education requirements for performing moderate complexity testing.
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 personnel records and interview with TP (testing personnel) 3/5 /20, the laboratory failed to ensure that 1 of 5 testing personnel (TP #5) met the minimum education requirements for performing moderate complexity testing. Review of personnel records for TP #5 revealed a translation to English of the information from a high school transcript obtained outside the United States and certification as a phlebotomy technician. The personnel records did not include a credential evaluation by a nationally recognized organization to determine equivalency of the education to education obtained in the United States. During interview at approximately 9:45 a.m., TP #5 stated she had not had a credential evaluation performed. She stated she was unaware it was required.