Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D1041003	05/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Massachusetts Eye Research & Surgery	1440 Main Street, Waltham, MA	

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
D0000	A CLIA recertification survey was conducted for the Massachusetts Eye Research & Surgery Institution laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493.
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 record review of the laboratory procedure manual and patient test logs, observation of testing personnel (TP) and interview with the regulatory consultant (RC, TP#1 and TP#2, the laboratory failed to follow the procedure manual as written in the specialty of Hematology. Findings include: 1. Surveyor observation of the laboratory on 5/24/2023 at 11:50 AM revealed, ten EDTA lavender top tubes containing blood in a specimen rack. Each tube only had a hand written 4 digit number on the tube as an identifier. 2. Surveyor observation of TP#1 performing phlebotomy on 5/24/2023 at 11:55 AM revealed, TP#1 drew an EDTA lavender top tube from the patient and only wrote a 6 digit number on the tube as an identifier. 3. Record review on 5/24/2023 of the 5/24/2023 patient log revealed: a. A column titled 'Lab ID' b. Each patient had a 6 digit number written in the 'Lab ID' column by their name on the log. 4. Record review on 5/24/2023 of the laboratory's 'Venipuncture Procedure' revealed, "Label the tube with the patient's name immediately. Correct labeling is critical. Included with the patient's name on the tube should be the date drawn, chart number, initials of technician drawing the specimen and tests requested." 5. Staff interview with the RC, TP#1, and TP#2 on 5/24/2023 at 12:00 PM confirmed:

	a. The 10 EDTA tubes indicated in #1 above only had a 4 digit number on the tube as an identifier and does not follow the procedure as written in the 'Venipuncture Procedure' indicated in #4 above. b. The EDTA tube drawn by TP#1 and observed by the surveyor was labeled with only a 6 digit number as an identifier and does not follow the procedure as written in the 'Venipuncture Procedure' indicated in #4 above. c. The 4 digit numbers on EDTA purple top tubes indicated in #1 above are the last 4 digits of the 6 digit number on the patient log. d. The 6 digit number on the patient log corresponds to the 6 digit number written on the patient specimen indicated in #2 above. 6. The laboratory performs 27,000 Complete Blood Counts annually in the specialty of Hematology.
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 record review and staff interview, the laboratory failed to include the reference ranges for complete blood counts in the procedure manual in the specialty of Hematology. Findings include: 1. Record review on 5/24/2023 of the laboratory's 'Procedure Manual' compared to a final patient test report, revealed: The procedure manual did not contain the reference ranges for White Blood Cell Count (WBC), Red Blood Cell Count, Hemoglobin, Hematocrit, Red Cell Distribution Width, Mean Corpuscular Volume, Mean Corpuscular Hemoglobin, Mean Corpuscular Hemoglobin Concentration, Platelet Count, Mean Platelet Volume, and Automated WBC Differential. 2. Staff interview with the Regulatory Consultant on 5/24/2023 at 12:30 PM confirmed the above findings. 3. The laboratory performs 27,000 Complete Blood Counts annually in the specialty of Hematology.
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, record review and staff interview, the laboratory failed to label reagents with the open and expiration dates in the specialty of Hematology. Findings include: 1. Surveyor observation on 5/24/2023 at 11:45 AM of the laboratory refrigerator, revealed the following Hematology controls open and in use without an open date and expiration date indicated on the tube: a. Cell-Dyn 18 Plus Control, lot number L3065. b. Cell-Dyn 18 Plus Control, lot number N3065. c. Cell-Dyn 18 Plus Control, lot number H3065. 2. Record review on 5/24/2023 of the laboratory's 'Labeling Policy' revealed, "All reagents, solutions, culture media, control & calibration materials, & other supplies must be labeled. Labels must indicate: identity, strength or concentration, recommended storage requirements, preparation & expiration dates." 3. Record review on 5/24/2023 of the laboratory's 'MERSI Lab Regulatory Test List' revealed, "CBC, Abbott Emerald, Controls 3 levels, low, medium, high, store @ 2-8 degrees C, Good for 7 days once opened." 4. Record review on 5/24/2023 of the laboratory's 'Daily Emerald Checklist' revealed, "Controls are good for 7 days in the refrigerator." 5. Record review on 5/24/2023 of the Cell-Dyn 18 Plus Control package insert revealed, "Once opened, containers can only be used for the number of days stated on the assay sheet." 6. Record review on 5/24/2023 of the Cell-Dyn 18 Plus Control Assay Sheet for the control lot numbers indicated in #1 above, revealed, "8 consecutive-day open-tube stability." 7. Staff interview on 5/24 /2023 at 11:45 AM with the Regulatory Consultant confirmed the Abbott Emerald Cell-Dyn controls listed in #1 above were open and in use and did not have an open date or expiration date indicated on the tubes. 8. Staff interview on 5/24/2023 at 11:50 AM with Testing Personnel #1 (TP#1) confirmed the Abbott Emerald Cell-Dyn controls listed in #1 above were open and in use and did not have an open date or expiration date indicated on the tubes. TP#1 stated, "We open new vials every week." 9. The laboratory performs 27,000 Complete Blood Counts annually in the specialty of Hematology.