Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0092869	03/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Manchester Memorial Hospital	71 Haynes Street, Manchester, CT	

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:
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 and staff interview laboratory failed to follow written policies and procedures in the specialty of Hematology. Findings include: 1. Record review on 3/11/2020 of the laboratory's policy and procedure (page -14) for running quality control (QC) for complete blood count (CBC) tests revealed, "XN CHECK (all 3

	control vials) will be run twice per day before patient testing." 2. Record review on 3 /11/2020 of the QC peer evaluation Insight reports (for analyzers with serial number # 17784 and #17778) from Sysmex for CBC, revealed the laboratory personnel did not run QC materials twice on the following days when patient samples were tested and reported. 6/21/19- No second shift QC performed. 6/22/19- No QC performed all day. 8/4/19- No second shift QC performed. 8/6/19- No first shift QC performed. 10/10/19- No second shift QC performed. 1/27/20- No second shift QC performed. 2/21/20- No second shift QC performed. 3. Record review on 3/11/2020 of the Insight report referenced in #2 above revealed the lack of corrective actions for not following the laboratory's policy referenced in #1 above. 4. Staff interview the technical supervisor on 3/11/2020 at 2:30 PM confirmed the above findings. 5. The laboratory performs 95,352 CBC tests annually.
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 surveyor observation, record review and staff interview, the laboratory failed to provide a complete embedding procedure to reflect the actual procedure and equipment in place in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 3/12/2020 at 10:55 AM of the histology embedding center revealed the embedding equipment included a paraffin tapper. 2. Record review on 3 /12/2020 of the 'Procedure for Embedding' and the 'Procedure for the Prevention of Cross Contamination during Histogic Preparation' revealed the laboratory did not document the use of tappers in the step by step procedures and include the proper handling/cleaning of tappers to prevent cross-contamination. 3. Staff interview with histology technician #1 on 3/12/2020 at 10:55 AM confirmed the use of tappers and he /she cleans with gauze between cases. 4. The laboratory processes 52,000 histology blocks in the subspecialty of histopathology annually.
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 appropriate expiration dates in the specialty of Hematology. Findings include: 1. Surveyor observation on 3/11/2020 at 2:45 PM of the Sysmex XN CHECK quality control (QC) materials for complete blood count (CBC) revealed the following QC's in use with no open and/or updated expiration date marked on the vials: a. Level 1 QC with lot # 00061101 and a manufacturer expiration date 3/29/2020. b. Level 2 QC with lot # 00061102 and a manufacturer expiration date 3/29/2020. c. Level 3 QC with lot # 00061103 and a manufacturer expiration date 3/29 /2020. 2. Record review of the Sysmex XN CHECK - QC package insert (document # 350597-6) on 3/11/2020 revealed, "Open vials and vials which have been sampled by cap piercing will retain stability for 7 days if stored at 2-8 C after being re-capped." 3. Surveyor observation on 3/11/2020 at 2:45 PM of the Sysmex XN CHECK-BF quality control (QC) materials for body fluid count (BF) revealed the following QC's in use with no open and/or updated expiration date marked on the vials: a. Level 1 BF-QC with lot # 00061301 and a manufacturer expiration date 3/29/2020. b. Level 2 BF-QC with lot # 00061302 and a manufacturer expiration date 3/29/2020. 4. Record review of the Sysmex XN CHECK - BF QC package insert (document # 350598-6) on 3/11/2020 revealed, "Open vials and vials which have been sampled by cap piercing will retain stability for 30 days if stored at 2-8 C after being re-capped." 5. Staff interview with the technical supervisor on 3/11/2020 at 3:00 PM confirmed the above findings. 6. The laboratory performs 95,352 CBC and 240 BF counts annually.
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 record review and staff interview, the laboratory failed to include two levels of quality control (QC) at different concentrations each day of testing patient samples in the specialty of Hematology. Findings include: 1. Record review of the QC peer evaluation Insight report from Sysmex for complete blood count (CBC) on 3/11/2020 revealed the laboratory personnel did not run two levels of QC materials on 6/22/19 before reporting patient samples. 2. Record review of the 'Lab Specimen Log' report on 3/11/19 revealed the laboratory performed 144 CBC tests on 6/22/19. 3. Staff interview with technical supervisor on 3/11/2020 at 2:30 PM confirmed the above findings.