Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0698986	02/20/2020
Name of Provider or Supplier	**Street Address, City, State**	
Emw Womens Surgical Center	136 W Market St, Louisville, KY	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on staff interview and record review of proficiency testing results from the American Proficiency Institute (API) proficiency testing agency, on 02/20/2020, the laboratory failed to ensure proficiency testing samples were tested by all testing personnel who routinely perform patient testing for Complete Blood Count (CBC) analysis. The findings include: 1. There was no evidence of Testing Personnel #2, Testing Personnel #3, and Testing Personnel #4 listed on the CMS Form 209 testing proficiency samples for three (3) testing events in 2018 and three (3) testing events in 2019. 2. Testing personnel acknowledged in an interview at 10:08 AM, on 02/20 /2020, the laboratory failed to have a system to ensure proficiency testing samples were rotated among all testing personnel responsible for patient testing.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on staff interview and record review on 02/20/2020, the Laboratory Director failed to perform and document annual competency using the six (6) mandated

	competency assessment requirements for testing personal. Competency assessment was not performed using six (6) methods of assessment for four (4) out of four (4) employees from 03/07/2018 through 02/19/2020. Findings include: 1. Record review on 02/20/2020, revealed there was no documented competency assessments for Complete Blood Count (CBC) testing and Rhesus (Rh) typing from 03/07/18 through 02/19/2020, for four (4) employees that included the following: competency assessments failed to include direct observation of routine patient test performance, direct observation of performance of instrument maintenance function checks and calibration, monitoring the recording and reporting of test results. In addition, there was not documented evidence the facility reviewed of worksheets, reviewed of quality control records, reviewed proficiency test results, reviewed maintenance records, the assessment of testing external proficiency testing samples and problem solving skills. An interview with the testing staff on 02/20/2020 at 9:30 AM revealed the facility failed to have a system in place between 03/07/18 through 02/19/2020 to ensure competency was performed using all six (6) mandated competency assessment requirements.
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 staff interview and record review of facility policy and procedure review on 02/20/2020, the laboratory failed to include requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing. In Addition, referral and criteria for specimen acceptability and rejection. Control procedures. Reference intervals (normal values). Imminently life-threatening test results, or panic or alert values. The findings include: 1. Policy review conducted on 02/20/2020, revealed the laboratory did not have all the necessary procedural requirements for the procedure Rhesus (Rh) typing. 2. Interview with the laboratory staff, at 10:35 AM, on 02/20/2020, confirmed the laboratory did not have a system in place to ensure all the policies and procedures contained all the information needed to perform and report the test.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on staff interview and record review on 02/20/2020, the laboratory failed to monitor and document the humidity and room temperature in the laboratory from 03 /10/18 through 02/19/2020. The findings include: 1. The Manufacturer's operations manual for the Act Diff analyzer lists an operating range for humidity for the analyzer between twenty percent (20%) to eighty percent (80%), and room temperature between sixteen (16) and thirty-five (35) degrees Celsius. 2. Review of Maintenance logs revealed the temperature and humidity was not monitored and documented from 03/10/18 and 02/19/2020. 3. Testing personnel acknowledged in an interview at 10:32 AM on 02/20/2020, the laboratory failed to have a system in place to ensure the temperature and humidity was monitored and documented daily, using the manufacturer's recommended range.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on staff interview and record review on 02/20/2020, the laboratory failed to include a positive and negative control material for the Rhesus (Rh) antigen typing for five (5) of five (5) days of patient testing. The findings include: Record review of quality control logs, on 02/12/19, 3/14/19, 7/30/19, 5/21/19, and 08/15/19, revealed there was only one (1) level of control run each day of testing. An interview with the testing personnel, at 10:35 AM on 02/20/2020, revealed the laboratory failed to have a system in place to ensure positive and negative control material were run and documented on all days of patient testing.