Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0982695	04/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Women's Medical Center, The	515 Westbank Expressway, Gretna, LA	

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
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: A Follow-up survey was performed at Newco Women's Medical Center, CLIA # 19D0982695, on April 25, 2023. Based on review of the laboratory's policy and procedure manual and quality control records, as well as interview with laboratory personnel, the laboratory failed to establish a complete policy for the establishment of chemistry quality control ranges. Findings: 1. Review of the laboratory's policy for establishing quality control ranges revealed the laboratory did not have clear and detailed instructions for determining the laboratory's individual mean and standard deviation. The policy stated: - The QC ranges from each manufacturer are calculated

	to a +/- 3 SD range, using the mean and standard deviation provided within the package insert. - QC material is run 5-10 consecutive times to make sure that each result falls within range. - If the results do not fall within range, the control will be repeated. If the results fail a third time, the mean and standard deviation must be calculated to be most accurate to represent the data the instrument is producing. 2. Further review of the laboratory's policy revealed the laboratory did not include clinical references to support the use of +/- three (3) standard deviations for calculating quality control limits. 3. In interview on April 25, 2023 at 12:01 p.m., Testing Personnel 1 stated the laboratory chose three standard deviations because of failed quality control runs using two standard deviations. She stated the laboratory contacted the instrument's manufacturer and was told by the manufacturer that three standard deviations was acceptable due to the age of the instrument. 4. Review of the laboratory's quality control records revealed acceptable ranges of "3SD" were utilized for BioRad Liquichek Immunoassay Plus Control Lot 85310 beginning August 26, 2022 for the following analytes: Prolactin, Estradiol, FSH, Free T4, TSH, HCG (quantitative), LH, and Progesterone. 5. In interview on April 25, 2023 at 12:01 p.m., Testing Personnel 1 stated the laboratory chose three standard deviations because of failed quality control runs using two standard deviations. She stated the laboratory contacted the instrument's manufacturer and was told by the manufacturer that three standard deviations was acceptable due to the age of the instrument
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: A Follow-up survey was performed at Newco Women's Medical Center, CLIA # 19D0982695, on April 25, 2023. Based on observation, review of package insert and the laboratory's policy and procedure manual, as well as interview with laboratory personnel, the laboratory failed to document the expiration date required by the manufacturer upon opening quality control material for hematology testing. Findings: 1. Observation by surveyors during the laboratory tour on April 25, 2023 at 9:35 a.m. revealed three hematology quality control vials in a cup with only the original manufacturer's expiration date and no open or updated expiration date documented on them. -L1 XN-L Check, Lot 30421401, expiration date May 23, 2023 -L2 XN-L Check, Lot 30421402, expiration date May 23, 2023 -L3 XN-L Check, Lot 30421403, expiration date May 23, 2023 2. Review of the package insert for "XN-L Check" revealed "Opened vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2-8 degrees C after being re-capped." 3. In interview on April 25, 2023 at 9:52 a.m., Testing Personnel 2 stated the vials in the cup were the in use Sysmex quality controls. She stated the controls are used for two weeks and then discarded. She confirmed the updated expiration date was not documented on the vials.