Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0266322	11/19/2020
Name of Provider or Supplier	**Street Address, City, State**	
Shaw Center For Women's Health	918 South Broad Street, Thomasville, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on November 19, 2020. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the Quality Control for the Serum hCG Test, and the Affirm VPIII Test, the laboratory failed to perform QC for each new lot number, or every 30 days, which ever comes first, according to their written Individualized Quality Control Procedure. Reference: D5441
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental

	conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the Quality Control (QC) Procedure and Individual Quality Control Procedure (IQCP) and QC Logs for Serum hCG, and Affirm VP III , the laboratory failed to perform QC as described in their IQCP. Findings: 1. Review of the Affirm VPIII QC log, and the IQCP for the Affirm, indicated that not all lot numbers and expiration dates was being documented on the QC log. Without the documentation of the lot numbers and expiration, the laboratory did not document that the different kit lots were being tested every 30 days or with each new lot number, which ever came first. From 12/6/2018 to 11/29/2020 - there was 14 entries that did not have the kit expiration listed. there was 12 entries that did not have the QC expiration listed there was two date entries that did not have any QC results documented there was three dates that had gaps of two to three months that did not have documented QC 2. Review of the Serum hCG quality control log, and the IQCP for the Serum hCG, indicated that not all lot numbers and expiration dates was being documented on the QC log. There was gaps of greater than 30 days between documented lot numbers, and expiration dates. From 08/14/2018 to 10/2/2020 - there was only 11 entries for Serum hCG QC there was one entry that did not have the hCG kit lot and expiration dated there was gaps between the documented QC for the hCG from 1 month to up to 5 months with no documentation of QC being performed. 3. Interview with staff #2 (CMS 209 form), on November 19, 202 at approximately 1pm, in an office, confirmed that the aforementioned dates and gaps in the Affirm VPIII QC log, and the Serum hCG QC log was correct.