Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0220811	06/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hagerstown Reproductive Health Svcs	160 West Washington Street, Hagerstown, MD	

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: Based on record review and interview with lab staff, the lab did not have a written procedure for performing quality control testing for the non waived urine pregnancy test. Findings: 1. the labs written procedure did not state the frequency in which positive and negative external (liquid) quality control samples are tested; and 2. staff stated that the lab tests external quality control samples (positive and nagative) each day of patient testing.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the written procedure and interview with lab staff on the day of survey, the labs written procedure for performing the Rh (D) test does not agree with the manufacturers instructions. The labs written procedure states that the lab will dispense two drops of anti-D Rh antisera and 2 drops of albumin control into each test tube as instructed, but the manufacturer states that the tests are performed by dispensing one drop of anti-D and one drop of albumin control into appropriate tubes.
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 interview with lab staff on the day of survey, the lab did not have written procedures to periodically verify the performance of quality control reagents used for Rh (D) testing. Findings: 1. The laboratory will select an Rh (D) positive and negative patient sample during daily routine testing, and use those samples to check the positive and negative reactivity of the Anti- D reagent used to perform the Rh (D) test. These samples are used for several days and then replaced by a second set of patient samples having the same reactivity; and 2. The lab did not periodically confirm or check the control system by either split sampling of their controls with another lab or testing reagents with known reactivity against control samples. These checks need to be conducted with the frequency determined by the lab director.