Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2237783	08/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
For Her Health S C	33 W Higgins Rd - Ste 800, S Barrington, IL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to enroll in an approved proficiency testing (PT) program for bacteriology (Gardnerella vaginalis) in 2022 and 2023. Findings include: 1. Review of laboratory records revealed the laboratory began testing for Gardnerella vaginalis utilizing the BD Affirm VPIII Microbial Identification testing system in the month of November 2022. 2. Review of laboratory records revealed no documented evidence of PT for Gardnerella vaginalis / bacteriology testing in 2022 and 2023. 3. On 08/28/2023 at 12:00 p.m., an interview with the LD revealed the laboratory failed to enroll in PT for bacteriology analyte Gardnerella vaginalis in 2022 and 2023.
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 laboratory records, lack of documentation, and interview with the laboratory director (LD) on 08/28/2023 at 12:00 p.m., the laboratory failed to meet the requirements of the general laboratory systems. Findings Include: 1. The laboratory failed to establish and follow written policies and procedures to assess the competency of four of four testing personnel (TP 1, TP 2, TP 3, and TP 4) listed on the Laboratory Personnel Report CLIA Form CMS - 209 (see D5209). 2. The laboratory failed to evaluate and document the biannual method accuracy for moderate complexity hematology Fern testing (see D5217).
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 review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to establish and follow written policies and procedures to assess the competency of four of four testing personnel (TP 1, TP 2, TP 3, and TP 4) listed on the Laboratory Personnel Report (CLIA Form CMS - 209) for moderate complexity microbiology testing for parasitology (Trichomonas), bacteriology (Gardnerella vaginalis), mycology (Yeast, candida only) and hematology Fern testing in 2022 and 2023. Affecting a total of 202 patient tests performed. Findings include: 1. Review of laboratory records and lack of documentation revealed the laboratory failed to establish and follow written policies and procedures to assess the competency of four of four testing personnel (TP 1, TP 2, TP 3, and TP 4) for moderate complexity Trichomonas, Gardnerella, Candida, and Fern testing in 2022 and 2023. Affecting 202 patient tests. a. Trichomonas (parasitology) = 54 tests performed b. Gardnerella vaginalis (bacteriology) = 54 tests performed c. Yeast, candida only (mycology) = 54 tests performed d. Fern testing (hematology) = 40 tests performed 2. On 08/28/2023 at 12:00 p.m., the LD confirmed the above finding.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to evaluate the biannual method accuracy for moderate complexity hematology Fern testing at least twice a year in 2022 and 2023. Findings include: 1. Review of laboratory records and lack of documentation revealed that the laboratory failed to evaluate and document the

	biannual method accuracy for moderate complexity hematology Fern testing in 2022 and 2023. Affecting 40 fern tests. a. 2022 and 2023: 40 Fern tests. 2. On 08/29/2023, at 12:00 p.m., the LD confirmed Finding 1.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interviews with the laboratory director (LD) and testing personnel (TP) revealed the laboratory failed to monitor and evaluate the overall quality of the analytic systems for this condition. Findings Include: 1. The laboratory failed to demonstrate performance specifications comparable to the manufacturer characteristics for accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals before reporting BD Affirm VPIII Microbial Identification patient test results. (See D5421). 2. The laboratory failed to provide laboratory personnel a written procedures manual for the moderate complexity hematology Fern testing system (see D5401). 3. The laboratory failed to outline all components of the moderate complexity testing procedures for one of one microbiology testing system; the BD Affirm VPIII Microbial Identification Test for parasitology (Trichomonas), bacteriology (Gardnerella vaginalis) and mycology (Yeast, candida only; see D5403).
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 review of laboratory records, lack of documentation and interview with testing personnel (TP), the laboratory failed to make available a written procedures manual for Fern testing in 2022 and 2023. Findings Include: 1. Surveyor review of laboratory records and lack of documentation revealed the laboratory failed to provide laboratory personnel a written procedures manual for the moderate complexity hematology Fern testing system in 2022 and 2023. 2. On 08/28/2023 at 10:55 a.m., TP 3 confirmed the above findings.
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 review of laboratory records, lack of documentation and interview with testing personnel (TP), the laboratory failed to outline all components of the testing procedures for the BD Affirm VPIII Microbial Identification Test for parasitology (Trichomonas), bacteriology (Gardnerella vaginalis) and mycology (Yeast, candida only) in 2022 and 2023. Findings include: 1. Review of the "BD Affirm VPIII Microbial Identification Test" manufacturer's instructions for use revealed the lack of documentation to meet the procedure manual requirements for parasitology (Trichomonas), bacteriology (Gardnerella vaginalis) and mycology (Yeast, candida only) in 2022 and 2023. The instructions failed to include the following elements: a. Requirements for patient labeling, and the criteria for specimen acceptability and rejection. b. Calibration and calibration verification procedures. c. Imminently life-threatening test results, or panic or alert values. d. 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. e. Description of the course of action to take if a test system becomes inoperable. 2. On 08/28/2023 at 10:55 a.m., TP 3 confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP), the laboratory failed to demonstrate performance specifications comparable to the manufacturer characteristics for accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals before reporting moderate complexity BD Affirm VPIII Microbial

	Identification patient test results for parasitology (Trichomonas), bacteriology (Gardnerella vaginalis) and mycology (Yeast, candida only) in 2022 and 2023. Affecting a total of 162 patients. Findings include: 1. Review of the "Affirm VPIII Method Validation Worksheet" and lack of documentation revealed the laboratory failed to demonstrate performance specifications comparable to the manufacturer characteristics for accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals before reporting moderate complexity BD Affirm VPIII Microbial Identification patient test results for parasitology (Trichomonas), bacteriology (Gardnerella vaginalis) and mycology (Yeast, Candida only) in 2022 and 2023. Affecting a total of 162 patients. a. Trichomonas = 54 tests performed b. Gardnerella vaginalis = 54 tests performed c. Yeast, Candida only = 54 tests performed 2. On 08/28/2023 at 10:35 a.m., an interview with TP 3 confirmed the above finding.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with testing personnel (TP), the laboratory director failed to ensure approved procedure manuals were available to all personnel responsible for two of two test systems (BD Affirm VPIII Microbial Identification and Fern testing) in 2022 and 2023. Findings include: 1. Review of the "BD Affirm VPIII Microbial Identification Test" manufacturer's instructions for use revealed the lack of documentation to meet the procedure manual requirements for moderate complexity Trichomonas, Gardnerella vaginalis, and Yeast testing in 2022 and 2023. (Refer to D5403). 2. The laboratory failed to provide laboratory personnel a written procedures manual for Fern testing in 2022 and 2023. (Refer to D5401).
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the technical consultant (TC) failed to evaluate four of four testing personnel (TP 1, TP 2, TP 3, and TP 4) listed on the Laboratory Personnel Report (CLIA Form CMS - 209) for competency at least semiannually during the first year of moderate complexity microbiology and hematology patient testing in 2022 and 2023. Affecting a total of 202 patient tests performed. Findings include: 1. Review of laboratory records and lack of documentation revealed the laboratory failed

	to document and maintain at least semiannually the competency records of TP 1, TP 2, TP 3, and TP 4 for Trichomonas, Gardnerella, Candida, and Fern testing in 2022 and 2023. Affecting 202 patient tests. a. Trichomonas (parasitology) = 54 tests performed b. Gardnerella vaginalis (bacteriology) = 54 tests performed c. Yeast, candida only (mycology) = 54 tests performed d. Fern testing (hematology) = 40 tests performed 2. On 08/28/2023 at 12:00 p.m., the LD confirmed the above finding.