Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2024211	06/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Society Hill Reproductive Medicine	822 Pine Street, Unit 4b, Philadelphia, PA	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on the review of personnel records and interview with the General Supervisor (GS), the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor who met the qualifications specified in the Pennsylvania (PA) Clinical Lab Act from 07/06/2022 to 06/22/2023. Findings include: 1. The PA regulations (5.23 (a)(3)) states: "No person shall be a supervisor in a clinical laboratory unless he conforms with the following requirements: He shall hold a B.S. or A.B. degree from an accredited institution with a major in medical technology or one of the biological, physical or chemical sciences and shall have had at least 6 years' experience acceptable to the Department in one or more of the applicable categories in the clinical laboratory." 2. On the day of survey, 06/22/2023 at 10:39 am, review of personnel credentials revealed that 1 of 1 GS has a Bachelor of Science degree in Biology (awarded on May 09, 2020). 3. The laboratory was unable to provide the acceptable experience needed for 1 of 1 GS in order to perform the duties of a supervisor in the state of Pennsylvania. 4. The GS confirmed the findings above on 06/22/2023 around 10:50 am.
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 the laboratory procedures, competency assessment records and interview with the general supervisor (GS), the laboratory failed to establish written policies and procedures to assess the competency of 1 of 3 testing personnel (TP) performing endocrinology testing and semen analysis examinations and 1 of 1 general supervisor (GS) for their supervisory responsibilities in 2022 and 2023. Findings include: 1. On the day of the survey, 06/22/2023 at 10:59 am, the laboratory could not provide a written procedure to assess the 6-month competency during the first year of employment for 1 of 3 TP (CMS 209, personnel # 2) who started working in the laboratory on July 6, 2022. 2. The laboratory could not provide competency assessment records for 1 of 1 GS for their supervisory responsibilities in 2022 and 2023. 3. The GS confirmed the findings above on 06/22/2023 around 12:30 pm. * Repeat deficiency.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the validation records, the manufacturer's package inserts (PI), database search and interview with the General Supervisor (GS), the laboratory failed to establish--before reporting patient test results-complete performance specifications for Sperm DNA Fragmentation testing using the Halosperm HT-HS10 kit (manufacturer: Halotech) from October 2022 to June 2023. Findings include: 1. On the day of survey, 06/22/2023 at 11:47 am, review of the validation records, the manufacturer's package inserts (PI), and observation of laboratory kits revealed that the laboratory was performing a diagnostic test using the Halosperm HT-HS10 kit which is not an FDA-approved test system. 2. Before patient samples were analyzed, the laboratory did not establish performance specifications of accuracy, precision, analytical sensitivity, analytical specificity, reportable range and reference intervals (normal values). 3. The GS confirmed the findings above on 06/22/2023 at 01:40 pm.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the General Supervisor (GS), the laboratory failed to include the required disclaimer on patient reports stating that the test developed for the Sperm DNA Fragmentation testing was not approved or cleared by the U.S Food and Drug Administration (FDA) from November 2022 to the date of survey. Findings include: 1. On the day of survey, 06/22/2023 at 12:49 pm, a review of 2 of 2 test reports revealed the test reports did not include the required disclaimer stating that the test developed for the Sperm DNA Fragmentation testing (Halotech) was not approved or cleared by the FDA from November 2022 to June 2023. 2. The GS confirmed the finding above on 06/22/2023 at 01:40 pm.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the Beckman Coulter Access 2 analyzer validation records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to ensure that the performance specification procedures used to determine the accuracy, precision, linearity, and comparison studies for Anti-Mullerian Hormone (AMH) testing performed on the Beckman Coulter Access 2 analyzer were adequate before reporting patient test results from April 2023 to May 2023. Findings include: 1. On the day of survey, 06/22/2023 at 11:24 am, review of the validation records revealed that the validation performed on February 2023 did not include the laboratory's acceptable criteria for performance specifications for precision, accuracy, reportable ranges, and comparison studies for Anti-Mullerian Hormone (AMH). 2. Record review revealed that the LD did not review and approve the validation for the Beckman Coulter Access 2 analyzer performed in February 2023. 3. The GS confirmed the finding above on 06/22/2023 at 01:40 pm.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the quality control (QC) records, lack of documentation, and interview with the General Supervisor (GS), the laboratory director (LD) failed to

	ensure that a QC program was established and maintained to ensure the quality of services provided for 1 of 2 hematology tests performed from November 2022 to the date of survey. Findings include: 1. On the day of the survey, 06/22/2023 at 12:30 pm, the laboratory could not provide documentation of the negative QC performed for the following 1 of 2 hematology tests performed from November 2022 to 06/22/2023: - Sperm DNA fragmentation via sperm chromatin dispersion 2. The GS confirmed the finding above on 06/22/2023 at 01:40 pm.