

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2024211	(X3) Date Survey Completed 07/21/2021
Name of Provider or Supplier Society Hill Reproductive Medicine	Street Address, City, State 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview with the General Supervisor (GS) and consultant, the laboratory failed to have attestation statements provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples for endocrinology were tested in the same manner as patient specimens in 2019 and 2020. Findings Include: 1. On the day of survey, 07/21/2021, the following AAB PT attestation statements for endocrinology were not signed by the analyst and the laboratory director in 2019 and 2020: - 2019 Event # 1, 2 and 3. - 2020 Event #2. 2. The AAB PT attestation statements for the 2020 events #1, #3 and 2021 event #1, were signed by 2 of 2 testing personnel not delegated as a designee. 3. The GS confirmed the findings above on 07/21/2021 around 10:35 am.</p>
D5205	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p>

The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

This STANDARD is not met as evidenced by:

Based on review of laboratory procedures and interview with the general supervisor (GS) and consultant, the laboratory failed to establish a complaint policy and document problems reported to the laboratory from 2019 to the day of survey. Findings include: 1. On the day of survey, 07/21/2021, the laboratory could not provide a complaint policy in place that describes how complaints and problems reported to the laboratory are handled from 07/21/2019 to 07/21/2021. 2. The GS confirmed the finding above on 07/21/201 around 10:25 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 laboratory procedures and interview with the general supervisor (GS) and consultant, the laboratory failed to establish a complete competency assessment procedure to assess the competency of 3 of 3 testing personnel (TP) performing endocrinology testing and semen analysis examinations and 1 of 1 general supervisor (GS) for their supervisory responsibilities in 2019 and 2020. Findings include: 1. The Individual Performance Improvement Policy states, "All employees will be evaluated annually by direct observation by the laboratory director". 2. On the day of survey, 07/21/2021, the laboratory could not provide a complete competency assessment procedure to assess the competency of 3 of 3 TP performing endocrinology testing, semen analysis examinations and 1 of 1 GS for their supervisory responsibilities from 07/21/2019 to 07/21/2021. 3. Review of TP records revealed, TP #2 and #3 were not assessed for competency in 2019 and 2020. 4. Review of 2021 competency assessment records revealed, the 6 point of competency were not assessed for each test system performed by each TP. 5. The GS confirmed the findings above on 07/21/201 around 9:35 am.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with general supervisor (GS) and

consultant, the laboratory director failed to specify in writing the responsibilities and duties for 3 of 3 testing personnel (TP) and 1 of 1 GS prior to reporting patient test results from 2019 to the day of survey. Findings Include: 1. On the day of survey, 07/21/2021, the laboratory could not provide in writing the responsibilities and duties for 3 of 3 TP performing endocrinology and semen analysis testing and for 1 of 1 GS their duties performed from 07/21/2019 to 07/21/2021. 2. The GS confirmed the finding above on 07/21/2021 around 10:25 am.