

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2013209	<b>(X3) Date Survey Completed</b>  11/29/2018
<b>Name of Provider or Supplier</b>  New Hope Fertility Center	<b>Street Address, City, State</b>  4 Columbus Circle, 4th Floor, New York, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the quality control (QC) records for the Horiba Pentra 60 C hematology analyzer and interview with the laboratory director and testing person, the laboratory failed to retain copies of the instrument maintenance records. Findings Include: It was confirmed by laboratory director and testing person on November 29, 2018 at approximately 1:30 pm, that the laboratory failed to retain the pass/fail maintenance records for the Horiba Pentra 60 C from the time of the last survey (June 1, 2017) through the date of this survey.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of personnel competency procedures, records and an interview with the laboratory director and testing person, the laboratory failed have complete policies and procedures to assess employees competency. Finding Include: At approximately 11:30 am on November 29, 2018, the laboratory failed to have procedures for direct observation of routine patient test performance (including patient</p>

preparation, if applicable, specimen handling, processing and testing); and the performance of instrument maintenance and function checks.

**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 a review of the laboratory procedure manual and an interview with the laboratory director and testing person, the laboratory failed to have a complete procedure manual. Findings Include: At approximately 12:30 pm on November 29, 2018, the laboratory failed to have procedures for 1) lot to lot verification for new lots of control material and 2) perform correlation between the two TOSOH 2000 AIA endocrinology analyzers used to perform patient testing.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of the quality assessment (QA) policy and confirmed in an interview with the laboratory director and testing person, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to D3031, D5209 and D5403.