

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0898463	<b>(X3) Date Survey Completed</b>  01/30/2024
<b>Name of Provider or Supplier</b>  North Hudson Ivf Center For	<b>Street Address, City, State</b>  385 Sylvan Avenue, Suite 12, Englewood Cliffs, NJ	
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>D2098</b>	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboraotry failed to attain a score of at least 80 percent for all Sex Hormones analytes performed on the Tosoh AIA for PT events provided by the College of American Pathologists (CAP) in calendar year 2023. The findings include: 1. The laboratory failed to achieve an 80 percent for the analyte Progesterone in PT event Y-B-2023. 2. The laboratory failed to achieve an 80 percent for the analyte Follicle Stimulating Hormone in PT event Y-A-2023. 3. The LD confirmed on 1/30/24 at 11:30am the laboratory failed to acheive an 80 percent for all analytes for Endocrinology testing.</p>
<b>D3037</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to retain copies of all PT records for testing performed with the College of American Pathologists (CAP) for Sex Hormones event Y-B-2022. The findings include: 1. The laboratory failed to retain work records and the attestation page for PT event Y-B-2022. 2. The LD confirmed on 1/30/24 at 11:30 am that PT records were not retained.</p>

<p><b>D5211</b></p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: A) Based on surveyor review of Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to evaluate coded results obtained from the College of American Pathologists (CAP) for Sperm Morphology &amp; Motility events A and B in 2022 and 2023. The finding includes: 1. The laboratory failed to evaluate Code 26 (Educational Challenge) response from CAP for Sperm Morphology &amp; Motility in events A and B of 2022 and 2023. 2. The LD confirmed on 1/30/24 at 11:00 am that the laboratory failed to evaluate coded results for Sperm Morphology &amp; Motility. B) Based on surveyor review of PT records and interview with the LD, the laboratory failed to evaluate coded results obtained from the CAP for Sex Hormones for event Y-A-2022 in calendar year 2022. The finding includes: 1. The laboratory failed to evaluate Code 22 (Result is outside the method/instrument reportable range) response from CAP for Estradiol for event Y-A-2022. 2. The LD confirmed on 1/30/24 at 11:00 am that the laboratory failed to evaluate coded results for Sperm Morphology &amp; Motility. Note: The laboratory was previously cited for this deficiency on previous surveys on 6/17/21, 9/24/18, and 4/6/17.</p>
<p><b>D5409</b></p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to record discontinuance dates for all applicable procedures for the Siemens Immulite analyzer from 6/17/21 to 1/30/24. The finding includes: 1. The LD stated the Siemens Immulite analyzer is no longer in use and the Tosoh AIA analyzer is currently in use for Endocrinology testing. 2. The LD confirmed on 1/30/24 at 11:45 am that discontinuance dates for all applicable procedures for the Siemens Immulite analyzer were not documented.</p>
<p><b>D5431</b></p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Maintenance Records (MR) and interview with the Laboratory Director (LD), the laboratory failed to document function checks for the pipettes used in Endocrinology and Hematology testing from 6/17/21 to 1/30/24. The</p>

	<p>finding includes: 1. The laboratory failed to have documented evidence for performing the procedure "accuracy checks for pipettors" on 3 out of 3 pipettors. 2. The LD confirmed on 1/30/24 at 11:45 am that the function checks on the pipettors were not performed.</p>
<p><b>D5805</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Test Reports (TR) and interview with the Laboratory Director (LD) the laboratory failed to ensure that the TR for Semen Analysis included all the required information from 9/24/18 to 1/30/24 . The finding include: 1. A review of ten TR revealed that a different physican was listed as the LD on the TR and not the current LD. 2. The LD confirmed on 1/30/24 at 10:45 am that the TR for semen analysis did not have the current LD listed as the LD of the laboratory.</p>
<p><b>D6018</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</p> <p>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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the LD failed to ensure that all PT results that were graded as unacceptable had corrective action performed for Endocrinology tests performed with the College of American Pathologists in the calendar year 2023. The findings include; 1. There was no documented evidence that corrective action was performed for failed analytes in PT events Y-A-2023 and Y-B-2023. Cross Refer D2098 2. The LD confirmed on 1/30/24 at 12:30 pm that the LD failed to ensure corrective action was performed on analytes graded as unacceptable.</p>
<p><b>D6021</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

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 surveyor review of the Quality Assessment (QA) plan, the Procedure Manual and interview with the Laboratory Director (LD), the LD failed to ensure the QA program was maintained to assure the quality of laboratory services provided from 6/17/21 to 1/30/24. The findings include: 1. There were no updated QA records available for review for calendar years 2022 and 2023. 2. The LD confirmed on 1/30/24 at 12:00 pm there were no QA records available for review for calendar years 2022 and 2023.

**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 surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the LD failed to ensure that all applicable procedures for Endocrinology and Hematology test were updated from 6/17/21 to 1/30/24. The findings include: 1. The LD failed to have step by step procedures in the PM for performing Endocrinology tests on the TOSOH AIA analyzer. 2. The LD failed to have procedures in the PM for resolving flagged results on the TOSOH AIA analyzer 3. The LD failed to have step by step procedures in the PM for performing Sperm and Motility tests on the CASA system analyzer. 4. The LD failed to update and discontinue procedures that referenced a Siemens Immulite analyzer that is no longer in use. 5. The LD confirmed on 1/30/24 at 11:30 am, the LD failed to have that an approved procedure manual that included all aspects of the testing process for Endocrinology and Hematology tests.