

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0898463	(X3) Date Survey Completed 06/17/2021
Name of Provider or Supplier North Hudson Ivf Center For	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5211	<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:</p> <p>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 & Motility event A and B in 2020. The finding includes: 1. The laboratory did not evaluate Code 26 (Educational Challenge) response from CAP for Sperm Morphology & Motility Non WHO %, Forward Progression No in events A and B 2020. 2. The LD confirmed on 6/17/21 at 10:00 am that the laboratory failed to evaluate coded results for Sperm Morphology & 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 Ligand-General for events A, B and C in 2019. The finding includes: 1. The laboratory did not evaluate Code 20 (No appropriate target/response could not be graded) response from CAP for Thyroid Stimulating Hormone for events C and B 2019. 1. The laboratory did not evaluate Code 20 (No appropriate target/response could not be graded) response from CAP for Human Chorionic Gonadotropin (hCG) in event B 2019. 2. The LD confirmed on 6/17/21 at 10:00 am that the laboratory failed to evaluate coded results for Sperm Morphology & Motility. Note: This was previously cited on 9/24/18, and 4/6/17</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results</p>

within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Operators Manual (OM), Quality Control Records (QCR) and interview with Laboratory Director (LD), the laboratory failed to follow the OM for the Tosoh AIA-360 analyzer used for Endocrinology testing in March 2021. The findings include: 1) The OM states the Calibration Void (CV) flag is as follows "Calibration Void. Cause: 1. Valid calibration periods of 30 or 60 days expired 2. This flag will appear for 60 days after the curve has expired, Resolution: Recalibrate, accept curve, and then recalculate results in result review" 2) Follicle-stimulating hormone (FSH), and Prolactin (PRL) had CV flags on 3/1/21, 3/8/21, 3/15/21 and 3/29/21. 3) No documented evidence to show FSH and PRL were recalibrated before running patient samples. 4) The LD confirmed on 6/17/21 at 12:00 pm that the laboratory failed to follow the OM.

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 surveyor review of the Performance Specification (PS) records and interview with the Laboratory Director (LD), the laboratory failed to ensure that all PS procedures were performed for endocrinology testing on the Tosoh AIA-360 analyzer from October 2020 to the date of survey. The finding includes: 1. The laboratory did not verify Patient Normal Range. 2. The LD confirmed on 6/17/21 at 11:15 am that not all PS were performed.

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

	<p>Based on surveyor review of Calibration Records (CR), Quality Control Records (QCR) and interview with the Laboratory Director (LD), the laboratory failed to perform and document Calibration procedures for Endocrinology Tests performed on the Tosoh AIA-360 analyzer from 3/1/21 to 3/29/21. The finding includes: 1) QCR revealed that Follicle-stimulating hormone (FSH), and Prolactin (PRL) were not calibrated in March of 2021 2) The LD confirmed on 6/17/2021 at 11:30 am that the Calibration was not performed on the above analytes in March of 2021.</p>
<p>D5447</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Laboratory Director (LD), the laboratory failed to perform and document two levels of external controls on each day of patient testing for Endocrinology test performed on the Tosoh AIA-360 analyzer from 1/6/21 to 1/30/21. The findings include: 1. The laboratory reported Follicle-stimulating hormone (FSH), Thyroid Stimulating Hormone (TSH), Prolactin (PRL), Luteinising Hormone (LH), Estradiol (E2) and Human Chorionic Gonadotropin (hCG) results but there was no documented evidence that QC was performed every day of patient testing. 2. The laboratory ran and reported 36 patients. 3. The LD confirmed on 6/17/21 at 11:20 am that two levels of QC were not run each of patient testing.</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Laboratory Director (LD), the LD failed to ensure that PS procedures performed on the Tosoh AIA-3670 analyzer were adequate from October 2020 to the date of survey. The findings include: 1. The LD did not review and sign the PS results. 2. The LD did not verify Patient Normal Range. 6. The LD confirmed on 6/17/2021 at 10:20 am that PS records were not adequate.</p>