

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0874288	(X3) Date Survey Completed 01/14/2021
Name of Provider or Supplier New York Fertility Institute	Street Address, City, State 1016 Fifth Avenue, New York, NY	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's observation and confirmation by the clinical consultant/testing person and the laboratory director, at the time of this survey, the laboratory failed to discontinue the use of expired testing materials for patient testing. FINDINGS: The surveyor observed the following bottles of reagents, calibrators and audit calibrators in the laboratory refrigerator: 1. 1 bottle each of Audit Calibration/verification material for T3 Uptake #06523 expiration date 2/19/17; Beta-hcg lot# GYO3590 expiration date 10/31/17. 2. 1 bottle each of Calibration material for Beta-hcg lot# J633530 expiration date 5/31/20; T3 Uptake lot# A134427 expiration date 12/31/20; Estradiol lot# JZ32992 expiration date 11/30/20 and Progesterone lot# 1-6Y3C323 expiration date 10/31/19. 3. 1 bottle each of Diluents Beta-hcg lot# GY53519 expiration date 10/31/17 and 2 bottles of AIA Pack Diluents Concentrate lot# 1380076 expiration date 2/29/20 & Lot#1880065 expiration date 7/31/19. 4. TSH Reagent packs lot # JZ17297 expiration date 11/30/20 (Cup# 97) a. 8 patients samples were tested with the expired reagent cups from 12/4/20 through 1/4/21 5. Total of 3 reagent packs for T3 Uptake lot# JY12073 (Cup#73) expiration date 10/31/20 a. 2 patient samples were tested with the reagent cups from 12/4/20 through 1/4/21 b. 2 reagent packs for the same lot number and expiration date were not open</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the</p>

laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
 Based surveyor's review of the calibration verification records and an interview with the clinical consultant/testing person and the laboratory director, the laboratory failed to perform calibration verification at least once every six months for FSH and Beta-hcg endocrinology tests performed on the TOSOH AIA 360 from 1/14/2020 through 3/20/20 and again from 5/3/20 through survey date. FINDINGS: 1. At approximately 11:30 AM on January 14, 2021, the clinical consultant/testing person and the laboratory director confirmed that the laboratory had not performed calibration verification on the TOSOH AIA 360 from 1/14/2020 through 3/20/20 and again from 5/3/20 through survey date. a. FSH and Beta-hcg have a 2 point-calibrator and required calibration verification b. The laboratory closed from 3/20/20 through 5/13/20 due to Covid shutdown and reopened on 5/13/20. c. The last recorded calibration verification was 7/14/2019, it was due on 1/14/2020 d. TOSOH AIA 360 analyzer was therefore out of calibration from 1/14/2020 through 3/20/20 and again from 5/3/20 through survey date. 2. Approximately 120 patients were tested during this time period.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
 CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
 Based on surveyor's findings and an interview with the clinical consultant/testing person and laboratory director, the laboratory director failed to provide overall management of the laboratory. Refer to D6024

D6024

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on the surveyor's observation and review of calibration/verification records and confirmed in an interview with the clinical consultant/testing person and the laboratory director, the laboratory director failed to ensure that remedial action was taken and documented when problems were identified. Refer to D5417 and D5439