

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0283602	(X3) Date Survey Completed 05/10/2018
Name of Provider or Supplier Goodman Neil F Md Pa	Street Address, City, State 4675 Ponce De Leon Blvd Ste 204, Miami, FL	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to enroll in proficiency testing for serum human chorionic gonadotropin (hCG) for the 1st and 2nd event of 2018. Findings: Review of the laboratory's proficiency testing with American Association of Bioanalysts (AAB) showed that the laboratory failed to re-enroll in proficiency testing for serum hCG for the 1st and 2nd events in 2018. During an interview on 5/10/18 at 12:03 PM, Testing Personnel C acknowledged that the laboratory failed to re-enroll in proficiency testing for serum hCG.</p>
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</p>

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.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to retain the proficiency testing documents used to record the test results for serum human chorionic gonadotropin (hCG). Findings: Review of the laboratory's proficiency testing with American Association of Bioanalysts (AAB) showed that the laboratory failed to retain the test result records for hCG for the 2nd and 3rd events in 2016, and 1st, 2nd and 3rd events in 2017. During an interview on 5/10/18 at 10:36 AM, Testing Personnel C acknowledged that the laboratory recorded the hCG results but did not keep the paper the results were recorded on.

D5200

GENERAL LABORATORY SYSTEMS
CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
The laboratory's quality assessment program failed to correct identified problems in proficiency testing in 2016 and 2017, and failed to retain quality assessment review forms. Findings: Cross Reference D5211 and D5293. Based on record review and interview, the laboratory failed to document that the results of proficiency testing scores were reviewed (D5211), and the laboratory failed to retain documentation of quality assessment activity (D5293).

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to document that the results of proficiency testing scores were reviewed. Findings: Review of the laboratory's proficiency testing with American Association of Bioanalysts (AAB) showed that the laboratory director failed to sign proficiency testing performance evaluation forms for proficiency testing for Embryology, Andrology, and Fetal (semen count and semen morphology) for the 2nd event in 2016 and 1st and 2nd events in 2017 and for Chemistry (serum human chorionic gonadotropin - hCG) for 2nd and 3rd events in 2016, and 1st, 2nd and 3rd events in 2017. During an interview on 5/10/18 at 10:10 AM, Testing Personnel C acknowledged that the laboratory director had not signed the performance evaluation forms.

D5293

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to retain documentation of quality assessment activity. Findings: Review of the laboratory's quality assessment logs showed that the laboratory didn't have any "Quality Assurance Review" forms from 5/10/16 to 5/10/18 available for inspection. During an interview on 5/10/18 at 11:49 AM, Testing Personnel D acknowledged that their "Quality Assurance Review" forms were lost when they moved to their new location.

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 record review and interview, the laboratory's procedures on "Procedure for the use of Consult hCG combo for the purpose and identification of the presence of Beta hCG in serum (qualitative assessment)" and "Procedure manual for examination of Human Sperm Methodology for Analysis of the Morphological Characteristic of Spermatozoa" were incomplete. Findings: Review of the procedure "Procedure for the use of Consult hCG combo for the purpose and identification of the presence of Beta hCG in serum (qualitative assessment)" showed that the procedure didn't contain directions on labeling the patient samples. During an interview on 5/10/18 at 11:22 AM, Testing Personnel D acknowledged that the procedure didn't contain directions on labeling the patient samples. Review of the procedure "Procedure manual for examination of Human Sperm Methodology for Analysis of the Morphological Characteristic of Spermatozoa" showed that the procedure didn't contain directions on

labeling the patient sample slides. During an interview on 5/10/18 at 11:27 AM, Testing Personnel D acknowledged that the procedure didn't contain directions on labeling the patient sample slides.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on record review and interview with staff, the laboratory's quality assessment program failed to monitor the accuracy of test results that are manually entered into the laboratory's electronic medical record system. Findings: Record review of the laboratory's "Quality Assurance Review" showed that there was no mention of comparison of test results for semen analysis handwritten results and transcribed semen analysis test results in their electronic medical record system E Clinical's. During an interview on 5/10/18 at 11:35 AM, Testing Personnel D stated that they don't do any verification of the semen analysis results that are entered into the computer.

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 record review and interview, the laboratory director failed to provide overall management and direction to ensure the laboratory was enrolled in proficiency testing for serum human chorionic gonadotropin (hCG) for the 1st and 2nd event of 2018, and failed to ensure that all proficiency testing reports were reviewed. Findings: Cross reference D6015 and D6018. Based on record review and interview, the laboratory director failed to provide overall management and direction to ensure the laboratory was enrolled in proficiency testing for serum human chorionic gonadotropin (hCG) for the 1st and 2nd event of 2018 (D6015), and failed to ensure that all proficiency testing reports were reviewed (D6018).

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory director failed to provide overall management and direction to ensure the laboratory was enrolled in proficiency testing for serum human chorionic gonadotropin (hCG) for the 1st and 2nd event of 2018. Findings: Review of the laboratory's proficiency testing with American Association of Bioanalysts (AAB) showed that the laboratory failed to re-enroll in proficiency testing for serum hCG for the 1st and 2nd events in 2018. During an interview on 5/10/18 at 12:03 PM, Testing Personnel C acknowledged that the laboratory failed to re-enroll in proficiency testing for serum hCG.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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;

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory director failed to ensure that all proficiency testing reports were reviewed. Findings: Review of the laboratory's proficiency testing with American Association of Bioanalysts (AAB) showed that the laboratory director failed to sign proficiency testing performance evaluation forms for proficiency testing for Embryology, Andrology, and Fetal (semen count and semen morphology) for the 2nd event in 2016 and 1st and 2nd events in 2017 and for Chemistry (serum human chorionic gonadotropin - hCG) for 2nd and 3rd events in 2016, and 1st, 2nd and 3rd events in 2017. During an interview on 5/10/18 at 10:10 AM, Testing Personnel C acknowledged that the laboratory director had not signed the performance evaluation forms.