

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0714644	(X3) Date Survey Completed 06/19/2018
Name of Provider or Supplier Patricia L Hughes Md	Street Address, City, State 140 Prospect Avenue, Hackensack, 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
D5020	<p>ENDOCRINOLOGY CFR(s): 493.1212</p> <p>If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that quality systems for the preanalytic and analytic phases of Endocrinology testing were monitored from June 2016 to the date of the survey. 1. The laboratory did not verify the accuracy of the Roche Cobas e411 analyzer before putting it into use. Cross Refer D 5421 2. The laboratory failed to establish written procedures to monitor and assess Quality Control (QC) for Endocrinology tests performed on the Roche Cobas e411 analyzer. Cross refer D 5791. 3. The laboratory failed to identify the source of the Reference Intervals (RI) used for endocrinology. Cross refer D 5807 4. The laboratory did not review and evaluate trends and/or shifts. Cross refer D 6074</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) results and interview with the Testing Personnel (TP), the laboratory failed to evaluate results when the laboratory received a grade of 50% for Andrology / Embryo Grading / Embryology / Fetal Fibronectin / Fetal Membrane Rupture test performed with the American Association</p>

	<p>of Bioanalysts (AAB) in 2017. The findings include: 1. The laboratory received a grade of 50% in the AAB 1st ship 2017 for Sperm Motility. 2. The laboratory received a grade of 50% in the AAB 1st ship 2017 for forward progression. 3. No evaluation was documented for any of the unacceptable analyte scores mentioned above. 5. The TP #1 listed on CMS form 209 confirmed on 6/19/18 at 2:00 pm that the laboratory did not perform and document corrective action of unacceptable PT results.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Patient Results (PR) and interview with the Testing personnel (TP), the laboratory failed to follow the procedure for data alarms for endocrinology tests performed on the Roche Cobas e411 analyzer from June 2016 to the date of the survey. The findings include: 1. The PM stated that PR flagged with "CarOvr" must be repeated but the laboratory did not rerun. 2. The TP was unaware of this procedure. 3. The TP #1 listed on CMS form 209 confirmed on 6/19/18 at 12:30 pm that the laboratory did not follow the PM.</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Performance Specifications (PS) records and interview with the Testing Personnel (TP), the laboratory failed to verify accuracy for Endocrinology tests performed on the Roche Cobas e411 analyzer before reporting patient test results from June 2016 to the date of survey. The finding includes; 1) There was no evidence that Accuracy was verified. 2) The TP #1 listed on CMS form 209 confirmed on 6/19/18 at 12:30 pm am that accuracy was not done.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

	<p>This STANDARD is not met as evidenced by:</p> <p>a) Based on the surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to establish written procedures QC lot verification for Endocrinology tests performed on the Roche Cobas e411 analyzer from June 2016 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 6/19/18 at 12:21 pm that the laboratory failed to establish written procedures for QC lot verification . b) Based on the surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to establish written procedures to monitor and assess Quality Control (QC) for Endocrinology tests performed on the Roche Cobas e411 analyzer from June 2016 to the date of the survey. The finding includes; 1. There was no control lot #, mean, standard deviation or Coefficient variation% entered for Luteinizing Hormone on the "Individual QC chart" between 4/2/18 and 5/4/18. 2. The TP #1 listed on CMS form 209 confirmed on 6/19/18 at 12:20 pm that the laboratory failed to establish written procedures to monitor and assess QC.</p>
<p>D5807</p>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report and interview with the Testing Personnel (TP), the laboratory failed to identify the source of the Reference Intervals (RI) used for endocrinology tests from June 2016 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 6/19/18 at 12:20 pm that the source of the RI was not known.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Laboratory Records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory. The findings include: 1. The LD failed to ensure that Quality Control programs were maintained. Cross refer to D 6020. 2. The LD failed to ensure that prior to testing patients' samples all testing personnel had the appropriate education. Cross refer to D 6029. 2. The LD failed to specify the duties and responsibilities of TP. Cross refer to D 6032</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

a) Based on surveyor review of the Quality Control QC records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure the QC Program for Endocrinology tests performed on the Roche Cobas e411 analyzer was accurately maintained from June 2016 to the date of survey. The findings include: a) The TP stated that the mean of each QC level analyte would be calculated from ten runs. 1) Bio-Rad Liquichek Immunoassay Plus Quality Control Lot # 40943 had "No Value" for four out of ten Human Chorionic Gonadotropin (HCG) results run for QC verification and was therefore calculated incorrectly. 2) Bio-Rad Liquichek Immunoassay Plus Quality Control Lot # 40943 had "No Value" for three out of ten Follicle-Stimulating Hormone results run for QC verification and was therefore calculated incorrectly. 3) The TP #1 listed on CMS for 209 confirmed on 6/19/18 at 1:00pm that the QC program was not maintained. b) Based on the QC data faxed for Bio-Rad Liquichek Immunoassay Plus Quality Control Lot#40960 the calculated mean of the laboratory did not match the actual calculated mean of the data. 1) The laboratory recorded the Estradiol QC level three mean was 628.1 pg/ml, the actual mean was 659.32 pg/ml. 2) The laboratory recorded the Estradiol QC level one mean was 44.20 pg/ml, the actual mean was 48.6 pg/ml. 3) The laboratory recorded the Estradiol QC level two mean was 255.9 pg/ml, the actual mean was 277.24 pg/ml. 4) The TP #1 listed on CMS for 209 confirmed on 6/19/18 at 1:05pm that the QC program was not maintained. c) Base on the "Individual QC charts" 1) Estradiol QC was out of range for two out of three levels on 5/11/18. 2) HCG QC was out of range three out of three levels on 5/11/18 3) Progesterone QC was out of range for two out of three levels on 5/15/18 and 5/18/18 4) Approximately 60 patients were run and reported. 5) The TP #1 listed on CMS for 209 confirmed on 6/19/18 at 1:31 pm that the QC program was not maintained.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Personnel Files and interview with the Testing Personnel (TP), the Laboratory Director failed to have education documented for two out of four TP from 5/18/16 to the date of the survey. The TP # 1 listed on the CMS form 209 confirmed on 6/16/18 at 1:30 pm that all TP did not have education records.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director (LD) did not specify in detail the duties and responsibilities of TP engaged in the performance of preanalytical, analytic and post analytic phases for Endocrinology tests from 5/18/16 to the date of survey. The TP # 1 listed on CMS form 209 confirmed on 6/19/18 at 11:15 am that the LD did not specify the duties and responsibilities of TP.

D6074

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(5)

Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Levy Jennings (LJ) records and interview with the Testing Personnel (TP), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for Endocrinology tests performed on the Roche Cobas e411 analyzer from June 2016 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 6/19/18 at 2:45 pm that trends and shifts were not reviewed.