

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1016855	(X3) Date Survey Completed 10/08/2019
Name of Provider or Supplier Covance	Street Address, City, State 100 Mettlers Road Po Box 2360, East Millstone, 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: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to evaluate coded results obtained in the Total Bile Acid (TBA) events in 2018 and 2019 performed with the College of American Pathologists (CAP). The findings include: 1. The laboratory did not evaluate Code 26 (educational challenge) obtained for: a. TBA in TBLA-A - 2018 event. Samples TBLA-01 thru 03. b. TBA in TBLA-B - 2018 event. Samples TBLA-04 thru 06. c. TBA in TBLA-A - 2019 event. Samples TBLA-01 thru 03. 2. The GS confirmed on 10/8/19 at 10:30 pm that the laboratory failed to evaluate coded results for PT events.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials</p>

having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on surveyor review of Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to perform and document QC verification for Diazyme QC used for Total Bile Acids (TBA) on the Advia 1800 analyzer from 11/14/17 to the date of survey. The GS confirmed on 10/8/2019 at 12:00 pm that QC verification was not properly documented before use.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(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.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual and interview with the General Supervisor (GS), the laboratory failed to establish a written procedure to verify new Quality Control (QC) material before use for Total Bile Acid tests performed on the Advia 1800 analyzer from 11/14/17 to the date of survey. The GS confirmed on 10/8/19 at 1:00 pm that the laboratory did not have a procedure to verify new QC.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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 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 a lack of a Quality Assurance (QA) plan and interview with the General Supervisor (GS), the Laboratory Director failed to establish a QA plan from 11/14/17 to the date of the survey. The GS confirmed 10/8/19 at 12:00 pm that a QA plan had not been established.

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 Personnel Files and interview with the General Supervisor (GS), the Laboratory Director failed to have education documented for one out of six Testing Personnel from 11/14/17 to the date of the survey. The GS confirmed on 10/8/19 at 10:40 am that all education records were not available.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual and interview with the General Supervisor (GS), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements for Total Bile Acids tests from 11/14/17 to the date of the survey. The GS confirmed on 10/8/19 at 10:30 am that a CA procedure was not established.