

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0691343	(X3) Date Survey Completed 04/30/2019
Name of Provider or Supplier Bergen Clinical Labs Inc	Street Address, City, State 40 Engle St, Englewood, 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
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 within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Immucor Blood Grouping Reagent Package Insert (RPI) and interview with the Technical Supervisor (TS), the laboratory failed to follow RPI instructions for Anti-D (Series 4) tests from 2/24/17 to the date of survey. The findings include: 1. The RPI stated "Using a transfer pipette, add 1 drop of 2-5% suspension of Red Blood Cells (RBC)" but the laboratory did not ensure the suspension added was 2-5% RBC. 2. Approximately 15 patients are run each day. 4. The TS confirmed on 4/30/19 at 2:10 pm that the RPI was not followed.</p>
D5803	<p>TEST REPORT CFR(s): 493.1291(b)</p> <p>Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Patients Charts (PC), Test Results (TR) and interview with the Technical Supervisor (TS), the laboratory failed to have all tests performed on the PC from 2/24/17 to the date of the survey. The findings include: 1.</p>

	<p>The laboratory performed Rubella and Human Immunodeficiency Virus (HIV) tests for an insurance client but did not report the TR in the PC. 2. The TS confirmed on 4/30/19 at 2:10 pm that the TR was not in the PC.</p>
<p>D5891</p>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Supervisor (TS), the laboratory failed to establish a procedure for verifying manually entered results from 2/24/17 to the date of survey. The TS confirmed on 4/30/19 at 2:00 pm that the laboratory did not have the procedure mentioned above.</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(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;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, Competency Assessment (CA) records and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to establish a CA procedure with all the required elements to ensure Testing Personnel are competent to perform tests from 2/24/17 to the date of the survey. The findings include: 1. The CA did not include: a. Monitoring the recording and reporting of results. b. Review of worksheets, quality control records, and preventative maintenance records. c. Direct observation of performance of instrument maintenance and function checks. d. Assessment of test performance through Proficiency Testing or internal blind samples. e. Assessment of problem solving skills. 2. The TS confirmed on 4/30/19 at 2:30 pm that a CA procedure was not adequately established.</p>
<p>D6074</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with the Technical Supervisor (TS), the Testing Personnel failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Sysmex XP-300 and the BioMrieux Mini Vidas analyzer from 2/24 /17 to the date of the survey. The TS confirmed on 4/30/19 at 1:45 pm that trends and shifts were not reviewed.