Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 31D0691343	**(X3) Date Survey Completed** 03/23/2021
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**
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to retain all records from Nonchemistry and Chemistry PT events performed with the American Association of Bioanalysts in the calendar year 2020. The findings include: 1. Graded results were missing for nonchemistry event Q3 2020. 2. The work records were not retained in the 2020 PT events Q1, Q2 and Q3. 3. The TC confirmed on 3/23/2020 at 9:30 am that PT records were not retained.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to review and evaluate results when they received an unacceptable score in Chemistry tests performed with the American Association of Bioanalysts in event Q2 for the calendar year 2020. The findings include: 1. The laboratory received an "out of grading range" for specimen 8 Glucose in - 2020 Q2. 2. There was no documented evidence that the laboratory investigated the failures. 3. The TC confirmed on 3/23/2021 at 10:00 am that the laboratory did not review and document an evaluation of unacceptable PT result.

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, and interview with the Technical Consultant (TC), the laboratory failed to follow the "Periodic Procedures for Cartridges" procedure. From July 2020 to the date of survey. The finding includes: 1. The PM stated "For acceptance of newly received cartridge lots, check the Temperature. If all windows are white or if only the A or B windows are blue or the 1 or 2 windows are red, then transit temperatures were satisfactory and the cartridges can be used" but there was no evidence the temperature was checked. 2. The TC confirmed on 3/23/2021 at 1:00 pm that the laboratory did not follow the procedure stated above.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: (a) Based on surveyor observation of the Quality Control (QC) reagents and interview with the Technical Consultant (TC), the laboratory failed to put a new expiration date on the Eightchek-3wp X-TRA QC reagents in use on the Sysmex XP-300c analyzer on the date of the survey. The findings include: 1. The Manufacturers Package Insert (MPI) stated "open vial stability is 14 days after opening." 2. The laboratory did not put new expiration dates on the Eightchek-3wp X-TRA QC after opening. 3. The TC confirmed on 3/23/2021 at 11:10 am the laboratory failed to put new expiration date on the QC reagents. (b) Based on surveyor observation of the QC reagents and interview with the TC, the laboratory failed to put a new expiration date on the Bio-Rad Lyphochek Immunoassay Plus Controls QC reagents in use on the Tosoh AIA-360 analyzer on the date of the survey. The findings include: 1. The Manufacturers Package Insert (MPI) stated "open vial stability is 7 days after opening." 2. The laboratory did not put new expiration dates on the Bio-Rad Lyphochek Immunoassay Plus Controls QC after opening. 3. The TC confirmed on 3/23/2021 at 11:10 am the laboratory failed to put new expiration date on the QC reagents.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Consultant (TS) the Laboratory Director (LD) failed to ensure that PS procedures performed on the Tosoh AIA-360 analyzer were adequate from July 2020 to the date of survey. The findings include: 1. The LD did not review and sign the PS results. 2. There was no documention evaluating accuracy, or reportable range study. 3. There were no work records to substantiate precision. 4. There was no raw data found for linearity, precision. 5. There was no documentation which showed what were acceptable results for linearity, accuracy and reportable range. 6. There was no documented evidence a reference range study was perofrmed. 7. The TC confirmed on 3/23/21 at 11:00 that PS records were not adequate. (b) Based on the lack of the PS records and interview with the TC the LD failed to ensure that any PS procedures were performed on Istat analyzers serial numbers 374151 and 374154 from Januaey 24, 2020 to the date of survey. The TC confirmed on 3/23/21 at 12:00 pm that PS were not performed on the aforementioned analyzers.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the 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: (a) Based on lack of Calibration Verification (CV) records and interview with the Technical Consultant (TC), the laboratory failed to perform and document CV procedures at least once every six months for Endocrinology Tests performed on the Tosoh AIA-360 analyzer from July 2020 to the date of the surveyor. The TC confirmed on 3/23/21 at 12:10 pm CV was not performed every six months. (b) Based on lack of CV records and interview with the TC, the laboratory failed to perform and

	document CV procedures at least once every six months for Chemistry Tests performed on the i-Stat analyzers from February 2020 to the date of the surveyor. The TC confirmed on 3/23/201 at 12:30 pm CV was not performed every six months.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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 having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: (a) Based on the lack of Quality Control (QC) records and interview with the Technical Consultant (TC), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Bio-Rad Lyphochek immunoassay plus control material performed on the Tosoh AIA-360 from July 2020 until the date of survey. The TC confirmed on 3/23/21 at 10:15 am that the assayed values of QC material were not verified before putting in use. (b) Based on the lack of QC records and interview with the TC, the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of I-Stat Tricontrols CHEM8+ Level one and two performed on the i-stat from February 2020 until the date of survey. The TC confirmed on 3/23/21 at 11:15 am that the assayed values of QC material were not verified before putting in use.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Records and interview with the Technical Consultant (TC), the laboratory failed to perform and document comparison studies for the two i-Stat analyzers twice per year from February 2020 to the date of the survey. The TC confirmed on 3/23/21 at 12:20 pm that the laboratory did not do comparison studies.
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 Technical Consultant (TC) the laboratory failed to have a procedure to verify new lots of controls before they were put in use from 4/30/19 to the date of the survey. The TC confirmed on 3/23/21 at 11:30 am that laboratory did not have the above procedure.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Consultant (TC) the Laboratory Director (LD) failed to ensure that verification procedures were performed for Human chorionic gonadotropin performed on the Tosoh AIA-3600 and Sodium, Potassium, Cholride and Glucose perfromed on the i-stat anlyzers from 1/24/20 to the date of survey. The TC confirmed on 3/23/2021 at 12:10 pm that verification studies were not performed.
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 Quality Control (QC) records and interview with the Technical Contultant (TC), the TC failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Tosoh AIA-360 and i-stat analyzers from 1/24/20 the date of survey. The TC confirmed on 3/23/21 at 12:45 pm that trends and shifts were not reviewed.