Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0691343	09/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bergen Clinical Labs Inc	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
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) (c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to verifiy the accuracy at least twice annually for Hematology testing performed on the Sysmex XP-300 analyzer in the calendar years 2023 and 2024. The findings include: 1. The laboratory did not verify accuracy of the following analytes. a) Mean Corpuscular Volume (MCV) b) Mean Corpuscular Hemoglobin (MCH) c) Mean Corpuscular Hemoglobin Concentration (MCHC) d) Red Cell Distribution Width - Standard Deviation (RDW-SD) e) Red Cell Distribution Width -Coefficient of Variations (RDW-CV) f) Mean Platelet Volume (MPV) 2. The TS confirmed on 9/9/25 at 11:00 am, the laboratory did not verify accuracy for the above mentioned analytes at least twice annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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: A) Based on surveyor review of the Procedure Manual, and interview with the

	Technical Supervisor (TS), the laboratory failed to follow the "Periodic Procedures for Cartridges"from July 2020 to 9/9/25. 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 TS confirmed on 9/9/25 at 11:00 am, the laboratory did not follow the procedure stated above. Note: This was previously cited 3/23/21. B) Based on surveyor review of the PM and interview with the TS, the laboratory failed to follow their procedures "Laboratory Quality Management Program" and "Procedures and responsibilities" from 3/23/21 to 9/9/25. The findings include: 1. The PM stated "Monthly: The laboratory performs a quality system audit on a monthly basis", "The monthly audit begins with a discussion of any problems raised by the laboratory personnel. It continues with a review of all the following documentation". a) Laboratory environmental logs. b) Refrigerator and freezer temperature logs. c) Instrument maintenance logs. d) Remedial and alert logs. e) Levey-Jennings quality control plots. 2. There was no evidence that remedial and alert logs where maintained for all specialties. 3. There was no evidence that Levey-Jennings and quality control plots were maintained for all specialites. 4. There was no documented evidence that the above mentioned procedure was performed. 5. The TS confirmed on 9/9/25 at 11:00 am, the laboratory did not follow the procedure stated above. C) Based on surveyor review of the PM and interview with the TS, the laboratory failed to follow their procedure "internal Quality Control" from 3/23/21 to 9 /9/25. The findings includes: 1. The PM stated "QC data are reviewed regularly by the supervisors and printed monthly for review by the laboratory director (LD)" 2. There was no documented evidence the LD performed a monthly review of QC for any testing that the laboratory performed. 3. The TS confirmed on 9/9/25 at 11:00 am, the laboratory did not follow the procedure stated above. 48354 D) Based on surveyor review of the PM, Quality Control (QC) and interview with the TS, the laboratory failed to follow their procedure "Starting a New Lot of Controls" for Hematology tests performed on the Sysmex XP 300 analyzer from 4/6/23 to 9/9/25. The findings include: 1. The PM stated "Parallel test new lots of control by analyzing the three levels of control a minimum of twice a day for 5 days prior to expiration of the previous lot." 2. Surveyor review of QC reports revealed the laboratory did not parallel tests new lots of QC twice a day for five days. 3. The TS confirmed on 9/9/25 at 1:15pm, the laboratory did not follow the PM.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references.

	(b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A) Based on surveyor review of the Procedure Manual (PM), and interview with the Technical Supervisor (TS) the PM lacked a Quality Control (QC) procedure for Manual Urine Microscopic (MUM) tests from 9/16/24 to 9/9/25. The findings include: 1. There was no procedure for performing QC for MUM tests on each day of patient testing. 2. The TS confirmed on 9/9/25 at 1:25 pm, the PM lacked a QC procedure for MUM tests. B) Based on surveyor review of the PM and interview with the TS, the laboratory failed to have a written procedure for the criteria required for performing Urine Microscopy tests from 9/16/24 to 9/9/25. The findings include: 1. There was no written criteria to perform MUM tests 2. There was no source for the RI for MUM tests. 3. The TS confirmed on 9/9/25 at 12:00 pm the laboratory failed to have the criteria required for performing urine microscopy tests.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) reagents and interview with the Technical Supervisor (TS), the laboratory failed to document appropriate expiration dates on the Bio-Rad Lyphochek Immunoassay Plus Controls QC reagents in use on the Tosoh AIA-360 analyzer form 8/23/25 to 9/9/25. The findings include: 1. The Manufacturers Package Insert (MPI) stated "open vial stability is 7 days after opening and reconstituting." 2. The laboratory recorded an open and reconstitution date of 8/16/25 on the Bio-Rad Lyphochek Immunoassay Plus Controls QC. 3. Bio-Rad Lyphochek Immunoassay Plus Controls QC were then stable until 8/23/25, but the laboratory had a stability date of 8/31/25 recorded on the QC. 4. The TS confirmed on 9/9/25 at 11:10 am, the laboratory failed to document appropriate expiration dates on opened QC reagents.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) Records, Manufacturers Instructions for Use (MIU) and interview with the Technical Supevisor (TS), the

	laboratory used expired QC material for Endocrinology testing performed on the Tosoh AIA-360 analyzer from 8/23/25 to 9/9/25. The findings include: 1. The MIU for Bio-Rad Lyphochek Immunoassay Plus Control QC material stated, "After reconstituting and storing tightly capped at 2 to 8C this product will be stable as follows: All analytes: 7 days". 2. The laboratory reconstituted Bio-Rad Lyphochek Immunoassay Plus Control material on 8/16/25. 3. The QC expired on 8/23/25. 4. Approximately 24 patients were run and reported. 5. The TS confirmed on 9/9/25 at 12:00 pm, the laboratory used expired QC material.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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: Based on surveyor review of the Procedure Manual (PM), Sysmex Operators Manual, Calibration Verification Records (CVR) and interview with the Technical Supervisor (TS), the laboratory failed to perform calibration verificaton every six months for the Sysmex XP 300 analyzer from 3/15/25 to 9/9/25. The findings include: 1. Surveyor review of the CVR revealed the certificate of calibration verification expired on 3/15 /25. 2. Calibration verification was last performed on 9/16/24 for the Sysmex XP 300 analyzer. 3. The TS confirmed on 9/9/25 at 1:00 pm, the laboratory did not perfom calibration verificaton every six months.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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.

	This STANDARD is not met as evidenced by: A) Based on the lack of Quality Control (QC) records and interview with the Techincal Supevisor (TS), 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 9/9/25. The finding include: 1. There was no documented evidence that QC was verified before being put into use. 2. The TS confirmed on 9/9/25 at 10:15 am, 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 TS, 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 9/9/25. The finding includes: 1. There was no documented evidence that QC was verified before being put into use. 2. The TS confirmed on 9/9/25 at 10:15 am that the assayed values of QC material were not verified before putting in use. Note: This was previously cited 3/23/21.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Reports (TR) for Hematology and interview with the Technical Supervisor (TS) the laboratory failed to ensure TR included all the required information from 3/23/25 to 9/9/25. The findings include: 1. TR did not include the address of the laboratory where Hematology testing was performed. 2. The TS confirmed on 9/9/25 at 1:00 pm, the laboratory failed to ensure the TR included all the required information.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) 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. This STANDARD is not met as evidenced by: Based on the surveyor review of Patient Test Records (PTR), Procedure Manual (PM), and interview with the Technical Supervisor (TS), the laboratory failed to have accurate Reference Intervals (RI) for Hematology tests performed on the Sysmex XP 300 analyzer from 9/16/24 to 9/9/25. The findings include: 1. Surveyor review of PTR revealed the PM and PTR did not have matching RI for complete blood count tests. 2. The follwing analytes on the PTR did not have RI that matched in the PM: White

	Blood Cell, Red Blood Cell, Hemoglobin, Hematocrit, Mean Corpuscular Volume, Mean Corpuscular Hemoglobin Concentration, Mean Platelet Volume, Neutophil Percentage and Lymphocyte Percentage. 3. The TS confirmed on 9/9/25 at 12:20 pm, the laboratory did not have accurate RI on PTR.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on an interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 3/23/21 to 9/9/25. 1. The LD failed to ensure that PS procedures performed for testing performed on the Sysmex XP 300 analyzer were adequate: Cross refer D6086. 2. The LD failed failed to ensure the laboratory verified the accuracy of non regulated analytes for Hematology tests at least twice annually in the calendar years 2023 and 2024. Cross refer D6091. 3. The LD failed to ensure the Quality Assessment (QA) and Quality Control (QC) programs were maintained to assure the quality of laboratory services. Cross refer D6093.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure the PS for the Sysmex XP 300 analyzer were adequate before patient testing from 9/16/24 to 9/9/25 . The findings include: 1. Accuracy was not performed. 2. The normal patient reference ranges were not verified. 3. The LD did not sign or approve the PS before patient use. 4. The TS confirmed on 9/16/24 at 12:30 pm, the LD not ensure the PS records were not adequate.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiently Testing (PT) records and interview with

	the Techincal Supervisor (TS) the Laboratory Director (LD) failed to ensure that the laboratory verified the accuracy of Hematology testing at least twice annually in the calendar years 2023 and 2024. Cross Refer: D5219
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on survey review of the Procedure Manual (PM), Quality Control (QC) material and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure the Quality Assessment (QA) and Quality Control (QC) programs were maintained to assure the quality of laboratory services from 3/23/21 to 9/9/25. The finding includes: 1. The Laboratory failed to ensure that the laboratory verified the accuracy of Hematology testing at least twice annually. Cross refer D5219. 2. The laboratory failed to follow their procedure "Laboratory Quality Management Program". Cross refer D5401. 3. The laboratory used expired QC material. Cross refer D5417. 4. The laboratory did not perfom calibration verificaton every six months on the Sysmex XP 300 analyzer. Cross refer D5439. 5. QC material was not verified before use. Cross refer D5469 6. The TS confirmed on 9/9/25 at 1:10 pm, the QA and QC programs were not maintained.