Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2014717	02/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Star Laboratory Corporation	125 Fleming Street, Piscataway, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories and the laboratory accession log from 8/2 /24 to 2/6/24, the laboratory failed to maintain licensure for Prothrombin Time (PT), International Normalized Ratio (INR) and Partial Thromboplastin Time (PTT) as part of their NJCLL since 8/1/23 and performed PT, INR and PTT on 40 patients since 8/2 /24. The Program Manager for the Clinical Laboratory Improvement Services (CLIS) confirmed on 2/5/24, prior to the recertification survey, that the laboratory had PT, INR and PTT removed from their NJCLL license on 8/1/23 due to deficiencies found during a NJCLL survey on that date. The General Supervisor #1 and Technical Supervisor #2 as provided on the CMS-209 stated on 2/6/24 at 12:30 pm that the laboratory was not aware that PT, INR and PTT had been removed from their NJCLL.
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: A) Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisors (GS) the laboratory failed to review coded and unacceptable results for Therapeutic Drug Testing, General chemistry and Diagnostic

	Immunology performed with the College of American Pathologists (CAP) in calendar years 2022 and 2023. The findings include: 1. The laboratory received Unacceptable results for event C-B 2023 General Chemistry/Therapeutic Drugs. a) Phenobarbital samples CHM-06,07,08,09,10 were graded unacceptable. 2. The laboratory received "see not [11]" results for event C-B 2022 General Chemistry/Therapeutic Drugs. a) LDL measured samples CHM-06,07,08,09,10 where graded "see not [11]" unable to analyze (documentation to be provided by laboratory) 3. The laboratory received "see not [11]" results for event S-B 2023 Diagnostic Immunology a) Rubella Ab, quant-IU /m samples RUN-06,07,08,09,10 where graded "see not [11]" unable to analyze (documentation to be provided by laboratory). 4. There was no documented evidence that aforementioned coded and unacceptable results were reviewed. 5. The GS#2 listed on CMS form 209 confirmed on 2/6/24 at 11:14 am that the laboratory did not review coded and unacceptable PT results. 48354 B) Based on surveyor review of the PT records and interview with the GS, the laboratory failed to review coded and unacceptable results for Hepatitis Viral Load (HVL) events performed with CAP in calendar years 2022. The findings include: 1. Specimen HCV2-01 for PT Event HVL-A-22 had coded message "see note 11." 2. There was no documented evidence for evaluation or corrective action taken. 3. The GS #2 as listed on the CMS-209 form confirmed there was no evaluation or corrective action for the above mentioned specimen.
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: A) Based on surveyor review of the Procedure Manual (PM), and interview with the General Supervisor (GS) the laboratory failed to have a procedure for verifying the Laboratory Information System (LIS) Estimated Glomerular Filtration Rate (eGFR) calculations from 2018 to the date of survey. The GS confirmed on 2/7/24 at 10:30 am that the laboratory failed to have a procedure for verifying eGFR LIS calculations. 48354 B) Based on surveyor review of the Procedure Manual (PM), and interview with the General Supervisor #2, the laboratory failed to follow the procedure for " lot to lot probe comparisons for the Human Pappilloma Virus (HPV) assay performed on the Hologic Panther analyzer " from 5/7/23 to 2/6/24. The findings include: 1. The PM states "Since lots of probes change over time, the probe quality will be assessed at the introduction of a new lot number." "Record lot to lot results and file in the HPV quality control binder." 2. There was no documented evidence the procedure was performed. 3. The GS #2 as listed on the CMS-209 form confirmed on 2/6/24 at 12:00 pm, the laboratory failed to follow the PM.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic

	examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the "Quality and Safety (General) Policies Standard Operation Procedure Manual" (QSPM), "Hematology Procedure Manual" (HPM) and "Beckman Coulter Unicel DxH 600 Instructions for Use" (IFU) and interview with the General Supervisor #1 (GS #1) on the CMS-209 form, the laboratory failed to have all applicable procedures for chemistry, endocrinology, general immunology, urinalysis, complete blood cell (CBC), automated differential and manual differential testing in the QSPM and HPM from 8/27/18 to the date of the survey. The findings include. 1. The laboratory failed to provide established reportable ranges for CBC and instructions on how to report patient results beyond those ranges either through the Beckman Coulter Unicel DxH 600, the laboratory information system (LIS) and/or through written documentation near the instrument as chosen by the laboratory in the HPM. 2. The laboratory failed to provide quality control (QC) procedures for assayed and non-assayed QC material and instructions as to whether each new lot has acceptable QC ranges verified or established in the QSPM. 3. The laboratory failed to provide a written procedure for reporting, chemistry, endocrinology, general immunology, urinalysis, CBC, automated differential and manual differential patient results in their new LIS which went into use in December 2023. 4. The laboratory failed to provide a written procedure instructing how the laboratory verifies calculations performed by instruments and/or the LIS and the frequency of verification. 5. The laboratory failed to include changing the normal patient mean (NPM) and International Sensitivity Index (ISI) in either the LIS or Sysmex CA 600, wherever the International Normalized Ratio (INR) is calculated, used for coagulation testing and changing the reference ranges on the final reports for the Prothrombin Time (PT) and INR as part of the written procedure for changing lots of thromboplastin in the QSPM. 6. The GS #1 confirmed on 2/6/24 at 10:45 am that the laboratory did not provide the aforementioned written procedures.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by:

	A) Based on surveyor review of patient work records, review of the Liquichek Immunoassay Plus Control Instructions for Use (IFU) and interview with the General Supervisor (GS), the laboratory failed to follow the IFU for the Endocrinology testing performed on the Vitros analyzer from 8/27/18 to the date of survey. The findings include: 1. Liquichek Immunoassay Plus Control IFU stated "once thawed, do not refreeze this product. Discard the remaining material." 2. The laboratory thawed aliquoted and refroze the Quality Control (QC) material 3. Approximately 15 patients were run and reported each month. 4. The GS#2 on CMS-209 form confirmed on 2/7 /24 at 2:00 pm that the laboratory failed to follow the IFU. 48354 B) Based on surveyor observation of calibration material, surveyor review of the Manufacturers package insert (MPI), maintenance records and interview with the General Supervisor (GS) #2, the laboratory failed to follow the MPI for performing Specific Gravity (SG) calibration used in Urinalysis testing performed on the Arkray Aution Max analyzer from 10/13/23 to 2/2/24. The findings include: 1. The MPI for the SG Calibrator states "Transfer the entire solution from each bottle into the measurement container, and use in accordance with operating manual for the analyzer.Do not reuse." 2. The SG calibrator lot 3D90 had an opened date of 10/13/23 and was labeled as in use. 3. The GS #2 stated "the SG calibrator bottle can be used up to four times." 4. The maintenance records in the instrument showed it was last calibrated on 2/2/24. 5. The last patient performed on the analyzer was on 11/14/23 and was within the 30 days of the calibration. No other patient tests were observed to be performed after 11/14/23. 6. The GS#2 as listed on the CMS-209 form confirmed on 2/7/24 at 11:20 am that the laboratory failed to follow the MPI.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Beckman Coulter AU 5800, Beckman Coulter ISE High and Low Serum Standards, Ortho Vitros 3600, Beckman Coulter Unicel DxH 600, Accu-Scope Microscope, Sysmex CA600, Siemens Hematek Stainer, Diesse Minicube, Hologic Panther Fusion, Diasorin Liaison XL, Arkray Aution Max AX-4030 Instructions for Use (IFU's), the room temperature and humidity logs and interview with the General Supervisor #1 (GS #1) on the CMS-209 form, the laboratory failed to provide accurate acceptable ranges for room temperature and humidity consistent with the manufacturer's requirements in the Chemistry, Vitros, Hematology and Microbiology/Urinalysis/Molecular rooms from 8/27/18 to the date of the survey. The findings include: 1. The room temperature and humidity logs used in the Chemistry room stated the acceptable ranges were 64-84F for room temperature and 16-70% for humidity but the strictest requirements based on the Beckman Coulter AU 5800 and ISE High and Low Serum Standards IFU's requires 64-77F and 20-80%. 2. The room temperature log used in the Vitros room stated the acceptable range was 58-85F for room temperature but the strictest requirement based on the Ortho Vitros 3600 IFU requires 59-86F. 3. The room temperature and humidity logs used in the

	Hematology room stated the acceptable ranges were 60-90F for room temperature and 16-70% for humidity but the strictest requirements based on the Beckman Coulter Unicel DxH 600, Accu-Scope Microscope, Sysmex CA600, Siemens Hematek Stainer and Diesse Minicube IFU's requires 64-80F and 30-80%. 4. The humidity log used in the Microbiology/Urinalysis/Molecular room stated the acceptable range was 16-70% for humidity but the strictest requirement based on the Hologic Panther Fusion, Diasorin Liaison XL and Arkray Aution Max AX-4030 IFU's requires 20-80%. 5. The GS #1 confirmed on 2/6/24 at 2:30 pm that the laboratory failed to provide accurate acceptable ranges for room temperature and humidity consistent with the manufacturer's requirements found in the IFU's on all aforrementioned room temperature and humidity logs.
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: Based on surveyor observation of Aution Sticks 9EB, surveyor review of the Procedure Manual (PM) and interview with the General Supervisor #2 (GS), the laboratory failed to put updated expiration dates on the Aution Sticks 9EB container for urinalysis tests from 12/29/23 to 2/7/24. The findings include: 1. The PM states "Open product stability is 31 days in the bottle and 3 days on the analyzer." 2. One Aution Sticks 9EB bottle was only labeled with an open date of 12/29/23. 4. The analyzer had not performed patient testing since 11/14/23. 5. The GS #2 as listed on the CMS-209 form confirmed on 2/7/24 at 11:45 am, the laboratory failed to put updated expiration dates on the Aution sticks 9EB.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 a review of the Bio-Rad Liquichek Unassayed Multiqual Quality Control (QC) records Manufacturers Package Insert (MPI) and interview with the General Supervisor (GS), the laboratory use expired QC from 1/31/24 to the date of survey. Findings Include: 1. The MPI stated "Thawed Opened: Once thawed, opened and stored tightly capped at 2 to 8 C this product will be stables as follows - all analytes 14 days Except AST/SGOT Bilirubin (Neonatal and Bilirubin (total): 9 days - Bilirubin (direct), Cholesterol (HDL), Cholinesterase, Creatine Kinase (CK) phosphorus and triglycerides: 7 days, - LAP Arylamidase: 3 days". 2. Opened date on the QC material was 1/24/24. 3. Approximately 15 patients where run and reported with expired QC. 4. The GS#2 on CMS-209 form confirmed on 2/7/24 at 2pm the laboratory used expired QC.

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: Based on the lack of Performance Specification (PS) records and calculation verification records and interview with the General Supervisor #1 (GS #1) on the CMS-209 form, the laboratory failed to provide PS for complete blood cell (CBC) and automated differential testing performed on the Beckman Coulter Unicel DxH 600 and calculation verification records from 8/27/18 to the date of survey. The findings include: 1. There was no evidence that the laboratory performed PS including but not limited to accuracy, precision, linearity to establish their own reportable ranges or verified manufacturer's reference intervals on the Beckman Coulter Unicel DxH 600. 2. The was no evidence that the laboratory performed calculation verifications for all calculations performed by instruments and/or the laboratory information system (LIS). 3. The GS #1 confirmed on 2/6/24 at 11:00 am that the laboratory could not locate the PS records for the Beckman Coulter Unicel DxH 600 used for CBC and automated differential testing and did not verify calculations.
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: Based on the lack of Quality Control Verification (QCV) records and interview with the General Supervisor (GS), the laboratory failed to verify Liquichek Immunoassay Plus Control before use for Endocrinology tests from 8/2718 to the date of survey. The GS#2 on the CMS-209 form confirmed 2/7/24 at 2:15 pm that QC material was not verified before putting in 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: A) Based on surveyor review of the "Policy for the Verification and Confirmation of Hematology Results" and "Verification and Confirmation for Automated Results" written procedures (WP's), 10 patient specimens raw data print-outs and final reports, the laboratory failed to follow their own WP's for complete blood cell (CBC) with automated differential testing from 8/27/18 to the date of the survey. The findings include: 1. The laboratory failed to follow their WP's which state that for an "R flag", the "results must be confirmed by reviewing a manual differential slide" on 1 out of 10 CBC with automated differentials patient results reviewed from 11/2/23 to 1/30/24. 2. Specimen ID B240300012B tested on 1/30/24 had an R flag on the Platelet (PLT) result but there was no documentation of manual differential review and the PLT result was reported. 3. This deficiency was found after the survey and is confirmed by the surveyor based on review of the aforementioned WP's and patient raw data print-out and final report. 48354 B) Based on a lack of Quality Control Verification (QCV) records, surveyor review of the Procedure Manual (PM) and interview with the General Supervisor #2 (GS), the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 2/7/22 to 2/7/24. The findings include: 1. The laboratory failed to follow the QCV procedure that stated how to verify new lots of controls before they were put in use for the following tests and systems : a) Rapid Plasma Reagin (RPR) b) Human Pappilloma Virus (HPV), HPV GT, Chlamydia and Gonorrhea (CT/GC) combo, Trichomonas, Human Immunodeficiency Virus (HIV) VL and Hepatitis C Virus (HCV) VL tests performed on the Hologic Panther. c) C. difficile, Enteric Bacteria Panel, Extended Enteric Bacteria Panel, Enteric Viral and Enteric Parasite Panel performed on the BD Max. 2. The GS #2 as listed on the CMS-209 form confirmed on 2/7/24 at 11:40 am that the laboratory failed to follow the QCV procedure for the aforementioned tests and systems.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 General Supervisor (GS), the Laboratory Director (LD) failed to ensure that PS were adequate to perform Chemistry tests performed on the Beckman Coulter Cobas AU5800 and Vitros 3600 analyzers from 2017 to the date of survey. The findings include: 1. The laboratory failed to perform a normal patient range study. 2. The GS#2 on CMS form 209 confirmed on 2/6/24 at 11:15 am that not all PS were adequate.

D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on surveyors review of the Procedure Manual (PM), Performance Specifications (PS), Instrument and Test Records and interview with the General Supervisor (GS), the LD failed to ensure that Testing Personnel (TP) are performing the test methods as required for accurate results for Chemistry testing. The findings include: 1. TP was unable to provide the linearity values for all analytes entered and run on the Beckman coulter Cobas AU5800. 3. The GS#2 on CMS form 209 confirmed on 2/7/24 at 1:45 PM that that LD did not ensure that TP are performing test accurately and reliably.