| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 42D2180272 | 06/11/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Csl Plasma, Inc | 7800 Rivers Ave, North Charleston, SC | |

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 |
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| **D0000** | An announced onsite CLIA recertification survey was conducted on June 11, 2026, at the laboratory of CSL Plasma - North Charleston by the South Carolina Department of Public Health (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with Medicare condition 42 CFR Part 493, CLIA requirements for laboratories. The following is a list of deficiencies cited as a result of the June 11, 2026 recertification survey: |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on records review, lack of documentation, and staff interview, the laboratory failed to provide documentation of a written personnel competency evaluation procedure. Findings included: 1. Records review of testing personnel listed on the CMS 209 form reveals 21 out of 23 TP had personnel competency documentation. 2. Review of the policy and procedure manual reveals a lack documentation for a policy and procedure for personnel competency evaluation. 3. In an interview on June 11, 2026 at 12:30pm in the laboratory conference room with the Assistant Manager of Quality and the Center Manager, the findings were confirmed. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>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 general laboratory systems requirements specified at 493.1231 |

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| | through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on records review, lack of documenmtation, and staff interview, the laboratory failed to provide documentation of a Quality Assurance (QA)Policy and Procedure. Findings Included: 1. During the June 11, 2026 survey, the surveyor requested documentation of the laboratory's written QA policy and procedure. None was provided. 2. Records review of laboratory documentation reveals QA activities were being performed. 3. In an interview on June 11, 2026 at 12:30pm in the laboratory conference room with the Assistant Manager of Quality and the Center Manager, the findings were confirmed. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on CLIA standard 493.1256, the procedure manual must include the following when applicable to the test procedure: quality control (QC)procedures as to the number and frequency of testing controls. Findings included: 1. During the June 11, 2026 survey, the surveyor was informed that all of the laboratory's policies and procedures electronically stored. 2. The surveyor asked for a copy of the QC policy and procedure be printed from the laboratory's Laptop personal computer. None was provided. 3. The laboratory provided evidence of QC performance on 04/02/2026 for analyte total protein to the surveyor. 4. In an interview on June 11, 2026 at 12:30pm in the laboratory conference room with the Assistant Manager of Quality and the Center Manager, the findings were confirmed. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The |

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| | laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on procedure manual review and staff interview, the laboratory failed to have documentation of established quality control (QC)procedures to monitor the accuracy and precision of the complete analytic process. Findings included: 1. During the recertification survey, the surveyor requested documentation of the laboratory's established control procedures. None was provided. 2. During the survey, the surveyor was provided an example of QC for total protein performed on the Kova Refractometer. 3. In an interview on June 11, 2026 at 12:30pm in the laboratory conference room with the Assistant Manager of Quality and the Center Manager, the findings were confirmed. |