

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1064292	(X3) Date Survey Completed 10/07/2025
Name of Provider or Supplier Select Laboratories- Sc Llc	Street Address, City, State 1051 Bill Buyck Blvd, Manning, 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
D0000	An offsite Proficiency Testing Desk Review survey was conducted at Select Laboratories on October 7, 2025. The facility was found to be out of compliance with the conditions of 42 CFR Part 493 CLIA Laboratory Requirements. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a desk review of proficiency testing (PT) records from the Certification and

	Survey Provider Enhanced Reporting (CASPER) 0155 report and AAB-Medical Laboratory Evaluation (AAB-MLE) proficiency testing records, the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty of Routine Chemistry for the analyte Aspartate Aminotransferase {AST (SGOT)}, and Prolactin. Refer 2096
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CASPER 0155 report and AAB-Medical Laboratory Evaluation (AAB-MLE) 2024 and 2025 proficiency testing records, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two of three consecutive testing events in the subspecialty of Chemistry for the analyte Aspartate Aminotransferase (AST), and Prolactin. Findings included: 1. Review of the CAPSER 0155 report revealed the following results: Routine Chemistry 2024 2nd Event: The laboratory received an unsatisfactory score of 0% for Aspartate Aminotransferase (AST). Routine Chemistry 2025 1st Event: The laboratory received an unsatisfactory score of 60% for Aspartate Aminotransferase (AST), Routine Chemistry 2025 1st Event: The laboratory received an unsatisfactory score of 40% for Prolactin. Routine Chemistry 2025 2nd Event: The laboratory received an unsatisfactory score of 40% for Prolactin. 2. A review of the AAB-Medical Laboratory Evaluation 2024 and 2025 proficiency testing records (Chemistry AAB-MLE M2 2024, M3 2024, M1 2025) confirmed the laboratory received the above results.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of CASPER 055 report and AAB-Medical Laboratory Evaluation 2024 and 2025 records, the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure proficiency testing samples were tested as required. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a proficiency testing desk review of CASPER 0155 report and AAB-Medical Laboratory Evaluation 2024 and 2025 records, the laboratory director failed to ensure proficiency testing samples were as required. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2096