

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0860669	(X3) Date Survey Completed 08/25/2025
Name of Provider or Supplier Mackey Family Practice Pa	Street Address, City, State 1025 W Meeting St, Lancaster, 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 Mackey Family Practice, PA on August 25, 2025. The laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, at 42 CFR Part 493. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016-Successful Participation CFR(S): 493.803(a)(b)(c) D6000-Moderate Complexity Laboratory Director CFR(S): 493.1403
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of Certification and Survey Provider Enhanced Reporting (CASPER) 0155D report and American Proficiency Institute</p>

	<p>Testing (API) 2025 (Events 1, and 2) records, the laboratory had not successfully participated 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 Chemistry for analytes Albumin, Aspartate Aminotransferase (AST). Refer to 2096.</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CASPER 0155D report and API Proficiency Testing 2025 Chem records (Events 1 and 2), revealed that the laboratory failed to achieve a satisfactory performance for the same analytes or test in two consecutive testing events or two out of three consecutive testing is unsuccessful performance in the specialty and subspecialty of Chemistry, Albumin and AST. Findings included: 1. A review of the laboratory's API PT evaluation for the 1st and 2nd event of 2025 revealed that the laboratory failed to achieve satisfactory scores in two consecutive testing events: Chemistry 2025-1st Event the laboratory received an unsatisfactory score of 20% for Albumin. Chemistry 2025-1st Event the laboratory received an unsatisfactory score of 40% for Aspartate Aminotransferase (AST). Chemistry 2025-2nd Event the laboratory received an unsatisfactory score of 40% for Albumin. Chemistry 2025-2nd Event the laboratory received an unsatisfactory score of 40% for Aspartate Aminotransferase (AST). 2. A review of the CASPER 0155D report confirmed the laboratory received the above results. 2025-Chemistry-1st and 2nd Event</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing desk review of CASPER 0155D report and API Proficiency Testing 2025 records, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing desk review of CASPER 0155D report and API</p>

Proficiency Testing 2025 records, the laboratory director failed to ensure that the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to 2096.