

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0257390	(X3) Date Survey Completed 07/02/2025
Name of Provider or Supplier Wellstar Sylvan Grove Hospital	Street Address, City, State 1050 McDonough Road, Attn Laboratory, Jackson, GA	
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	A proficiency testing desk review was completed on July 2, 2025. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following condition deficiencies were cited: D2016 - 42 CFR 493.803 Condition: Successful participation [proficiency testing] D6076 - 42 CFR 493.1445 Condition: High Complex Laboratory Director
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 review of the Centers for Medicare and Medicaid Services (CMS) CASPER</p>

	<p>155 report and review of the laboratory 's American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory participation in PT in the specialty of Immunohematology for Compatibility testing for 3 out of 5 events for event 3 of 2023, event 2 of 2024, and event 1 of 2025. Refer to D 2173</p>
D2173	<p>COMPATIBILITY TESTING CFR(s): 493.863(a)</p> <p>(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS CASPER 155 report and review of the laboratory 's API proficiency testing (PT) reports, the laboratory failed to maintain satisfactory participation in PT in 3 out of 5 events in the specialty of Immunohematology for Compatibility Testing . Findings include: 1. Desk review of the CMS CASPER 155 report revealed the laboratory failed Compatibility Testing on: 2023 Event 3 score: 80% 2024 Event 2 score: 40% 2025 Event 1 score: 40% 2. Desk review of the laboratory's proficiency testing reports from API confirms the laboratory failed Compatibility testing on the aforementioned events resulting in the non-initial unsuccessful performance.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CMS CASPER 155 report and review of the laboratory 's API PT reports, the laboratory director failed to provide overall management and direction for proficiency testing to ensure successful participation in PT for the specialty of Immunohematology for Compatibility Testing. Refer to D6089 and D6092.</p>
D6089	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 review of the CMS CASPER Report 155 and the API 2023 event 3, 2024 event 2, and 2025 event 1 PT evaluation reports, the laboratory director failed to ensure successful proficiency testing performance in Compatibility Testing in three of five testing events, resulting in the non-initial unsuccessful participation for Compatibility Testing. Refer to D 2173</p>
D6092	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1445(e)(4)(iv)

(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

This STANDARD is not met as evidenced by:

Based on surveyor proficiency testing (PT) desk review of the CMS CASPER 155 report and the laboratory's API proficiency testing records on 12/16/24, the laboratory director failed to ensure an approved corrective action plan was followed to ensure successful participation in PT. Refer to D 2173