

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0968213	(X3) Date Survey Completed 03/25/2025
Name of Provider or Supplier Associated Specialists Inc	Street Address, City, State 527 Medical Park Drive, Suite 204, Bridgeport, WV	
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 (PT) desk review was conducted for Associated Specialists Inc., on March 25, 2025, by the West Virginia Office of Laboratory Services. The laboratory PT evaluations were reviewed for successful participation and compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. The identified unsuccessful participation is an initial occurrence and explained below.
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 CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from American Proficiency Institute (API), and phone interview with</p>

testing personnel (TP1), the laboratory failed to achieve satisfactory performance for the specialty #0525 Endocrinology in two consecutive testing events in 2024 and 2025, resulting in an initial occurrence of unsuccessful participation. Refer to D2108.

D2108

ENDOCRINOLOGY
CFR(s): 493.843(g)

(g) Failure to achieve an overall testing event score of satisfactory performance for 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 review of CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from American Proficiency Institute (API), and phone interview with testing personnel (TP1), the laboratory failed to achieve satisfactory performance for the specialty of #0525 Endocrinology in two consecutive testing events in 2024 and 2025, resulting in an initial occurrence of unsuccessful participation in PT. Findings:
1. Review of CASPER 155D PT report identified the following unsuccessful participation for the #0525 Endocrinology specialty: 30% event 3 2024 65% event 1 2025
2. Review of API PT evaluations confirmed the unsatisfactory performance for the #0525 Endocrinology specialty in two consecutive testing events with the following unsatisfactory analyte scores: 2024 Event 3 #0545 Free TY 0% #0585 TSH 60% 2025 Event 1 #0541 Folate, Serum 40% #0600 Vitamin B12 20%
3. A phone interview with TP1, 3/25/25 at 8:45 AM, verified the occurrence of unsuccessful participation in PT for specialty #0525 Endocrinology.