

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0395521	(X3) Date Survey Completed 06/03/2026
Name of Provider or Supplier Aspirus Kronenwetter Clinic	Street Address, City, State 1881 Cty Hwy Xx, Mosinee, WI	
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	The following deficiencies are a result of a desk review of proficiency testing (PT) scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of the Clinical Laboratory Improvement Amendments (CLIA) program. 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 American Proficiency Institute (API) PT reports, and interview with the Laboratory Director, the laboratory failed to successfully participate in a PT program approved by Centers for Medicare and Medicaid Services (CMS), for each analyte or test in which the laboratory is certified under Clinical Laboratory Improvement Amendments (CLIA). The laboratory failed to successfully participate in the speciality of hematology for the white blood cell (WBC) differential test. Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a PT desk review of CASPER 0155 report and API PT 2025 Event 2 and 2026 Event 1 records, and interview with the Laboratory Director, the laboratory failed to achieve satisfactory performance (80% or better) for the WBC differential test in the speciality of hematology in two out of three consecutive testing events resulting in unsuccessful performance. Findings include: 1. Review of the CASPER 0155 report revealed the following results: Hematology 2025-Event 2: the laboratory received an unsatisfactory score of 20% for WBC differential. Hematology 2026-Event 1: the laboratory received an unsatisfactory score of 0% for WBC differential. 2. Review of the API Hematology/Coagulation Performance Summary report for 2025 - 2nd Event and 2026 -1st Event confirmed the laboratory received the above results. 3. A phone interview with the Laboratory Director on June 3, 2026, at 2:10 PM confirmed the laboratory's unsuccessful PT performance in the WBC differential test and confirmed understanding that this is a mandatory PT deficiency.
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 surveyor review of records from the Certification and Survey Provider Enhanced Reporting (CASPER) reports and American Proficiency Institute (API) proficiency testing (PT) reports, and interview with the Laboratory Director, the Laboratory Director failed to provide overall management and direction of the laboratory services. The Laboratory Director failed to ensure the laboratory tested and reported PT samples 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 PT desk review of CASPER 0155 report and API 2025 and 2026 records, the Laboratory Director failed to ensure PT samples were tested as required. The Laboratory Director failed to ensure successful participation for the WBC differential test in a Centers for Medicare and Medicaid (CMS) approved PT program. Refer to D2130.