Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D1045438	01/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Aspirus Plover Clinic Laboratory Vern Holmes Dr	5409 Vern Holmes Dr, Stevens Point, 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	A CLIA validation survey was completed on 01/23/2025, the laboratory was found out of compliance with the CLIA regulations. The conditions not met: D2016 - 42 C.F.R. 493.803 Condition: Successful Participation D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high 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 surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER 0155D) proficiency testing (PT) and American Proficiency Institute (API) proficiency testing (PT) records and interview with the general supervisor, the laboratory failed to successfully obtain an overall 100% satisfactory

	testing event score in PT for compatibility testing in the specialty of immunohematology for two out of two consecutive events for 2022-3 and 2023-1, resulting in unsuccessful PT performance. See D2181
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) (e) Failure to achieve an overall testing event score of satisfactory 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 surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER 0155D) proficiency testing (PT) and American Proficiency Institute (API) proficiency testing (PT) records and interview with the general supervisor, the laboratory failed to successfully obtain an overall 100% satisfactory testing event score in PT for compatibility testing in the specialty of immunohematology for two out of two consecutive events for 2022-3 and 2023-1, resulting in unsuccessful PT performance. Findings include: 1. Review of PT records in the federal CASPER reporting system on January 3, 2025, showed the laboratory had an unsuccessful performance for compatibility testing for PT events 2022-3 and 2023-1. Event 2022-3, score 60% Event 2023-1, score 80% 2. Review of API PT evaluation reports showed the laboratory had an unsuccessful performance for compatibility testing in the specialty of immunohematology for two consecutive events. Event 2022-3, score 60%, sample numbers: SER-12 and SER-14. Event 2023-1, score 80%, sample numbers: SER-03. 3. Interview with the general supervisor on January 23, 2024, at 8:50 AM confirmed the laboratory failed to successfully obtain satisfactory PT event scores for two consecutive events for compatibility testing resulting in unsuccessful PT performance.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the technical consultant, the laboratory failed to document corrective action for four of four analytes with an 80% score on 2023-Chemistry-Core-Event 2. Findings include: 1. Review of PT records for the second chemistry event in 2023 showed the laboratory received a score of 80% for pCO2, pH, pO2, and thyroid stimulating hormone (TSH) analytes. Further review of the PT records showed no documentation of corrective action for the four analytes. 3. Interview with on January 23, 2025, at 10:45 AM confirmed the laboratory failed to perform and document corrective action when scores were not 100%.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i)

	Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview the technical consultant, the laboratory did not perform calibration verification every six months for one of one required coagulation analytes on the Stago Satellite coagulation analyzer. Finding include: 1. Review of Stago Satellite D-Dimer calibration verification records showed calibration verification was performed August 21, 2022, July 7, 2023, August 5, 2023, March 24, 2024 and August 31, 2024. Further review showed no additional calibration verification when due on February 21, 2023 and February 5, 2024. 2. Interview with the technical consultant on January 23, 2025, at 10:50 AM confirmed the laboratory did not perform calibration verification every six months for all required analytes on the Stago Satellite coagulation analyzer.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by: Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER 0155D) proficiency testing (PT) and American Proficiency Institute (API) proficiency testing (PT) records and interview with a technical consultant, staff A, the laboratory director failed to ensure the laboratory achieved successful performance for compatibility testing in the specialty of immunohematology for two out of two consecutive events for 2022-3 and 2023-1, resulting in unsuccessful PT performance. See D6092
D6092	LABORATORY DIRECTOR RESPONSIBILITIES 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 review of the federal Certification and Survey Provider Enhanced Reports (CASPER 0155D) proficiency testing (PT) and American Proficiency Institute (API) proficiency testing (PT) records and interview with a technical consultant, staff A, the laboratory director failed to ensure the laboratory achieved successful performance for compatibility testing in the specialty of immunohematology for two out of two consecutive events for 2022-3 and 2023-1, resulting in unsuccessful PT performance. Findings include: 1. Review of PT records in the federal CASPER reporting system on January 3, 2025, showed the laboratory had an unsuccessful performance for compatibility testing for PT events 2022-3 and 2023-1. Event 2022-3, score 60% Event 2023-1, score 80% 2. Review of API PT evaluation reports showed the laboratory had an unsuccessful performance for compatibility testing in the specialty of immunohematology for two consecutive events. Event 2022-3, score 60%, sample numbers: SER-12 and SER-14. Event 2023-1, score 80%, sample numbers: SER-03 3. Interview with the general supervisor on January 23, 2025, at 8:50 AM confirmed the laboratory director did not ensure the laboratory did not fail two consecutive PT events when the laboratory failed to successfully obtain an overall 100% satisfactory testing event score in PT for compatibility testing in the specialty of immunohematology for two out of two consecutive events for 2022-3 and 2023-1, resulting in unsuccessful PT performance.