Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0915078	01/22/2026
Name of Provider or Supplier	**Street Address, City, State**	
Huron Medical Center Pc	1221 Pine Grove Ave, 2nd Floor, Port Huron, MI	

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 survey was performed on January 22, 2026 by the State of Michigan Department of Licensing and Regulatory Affairs. The laboratory was found out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following Condition: 493.803 Condition: Successful participation.
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 review of the CMS database, American Proficiency Institute (API) proficiency testing reports, and interview with the technical consultant, the laboratory failed to participate in proficiency testing for the hematology analyte, erythrocyte

	count, for one (2025 Event 3) of three testing events reviewed (refer to D2123) and failed to achieve satisfactory performance for the hematology analyte, erythrocyte count, for two (2025 Event 1 and Event 3) of three consecutive events (refer to D2130).
D2123	HEMATOLOGY CFR(s): 493.851(c) (c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: . Based on record review of the CMS database, American Proficiency Institute (API) proficiency testing reports, and interview with the technical consultant, the laboratory failed to participate in proficiency testing for the hematology analyte, erythrocyte count, for one (2025 Event 3) of three testing events reviewed. Findings include: 1. A record review of the American Proficiency Institute (API) proficiency testing records revealed final reports were not submitted to API for the third event of 2025 for hematology. 2. A record review of the CMS database revealed the laboratory failed to participate for one out of three consecutive PT events for the analyte: erythrocyte count. Erythrocyte Count PT Event Score 1st event 2025 60% 2nd event 2025 100% 3rd event 2025 0% 3. 2. A phone interview on 1/22/26 at 9:13 am with the technical consultant confirmed the above findings.
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 record review of the CMS database, American Proficiency Institute (API) proficiency testing reports, and interview with the technical consultant, the laboratory failed to achieve satisfactory performance for the hematology analyte, erythrocyte count, for two (2025 Event 1 and 2025 Event 3) of three testing events reviewed. Findings include: 1. A record review of the CMS database and API proficiency testing reports revealed the laboratory failed to acheive satisfactory performance for two out of three consecutive PT events: Erythrocyte Count PT Event Score 1st event 2025 60% 2nd event 2025 100% 3rd event 2025 0% 2. A phone interview on 1/22/26 at 9: 13 am with the technical consultant confirmed the above findings.