Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2104579	03/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Aspirus Keweenaw Hospital	205 Osceola Street, Laurium, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Regional Laboratory Director, the laboratory failed to operate as a separate laboratory to comply with 493. 43 for 2 (March 2022 to March 2024) of 2 years reviewed. Findings include: 1. The surveyor observed the laboratory testing area was located at the same address as two other laboratories, 23D0038123 Aspirus Keweenaw Hospital Laboratory and 23D03821310 Aspirus Laurium Clinic. 2. A review of the laboratory's Form CMS-116 revealed the laboratory operates Monday-Friday 7:00 am to 3:00 pm. 3. An interview on 3/12/24 at 11:35 am with the Regional Laboratory Director revealed the laboratory follows the same policies as the 23D0038123 Aspirus Keweenaw Hospital Laboratory, that this laboratory operates 24 hours a day, 7 days a week, confirming the laboratories are testing concurrently, and they use the same staff. .
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with Testing Personnel #2, the laboratory failed to follow its specimen labeling policy for three patient histopathology slides observed. Findings include: 1. The surveyor observed three patient histopathology slides labeled with "32", "81A", and "136C" on 3/12/24 at 9:24 am. 2. A review of the laboratory's "Tissue Sectioning Procedure" revealed a section titled "Labeling Slides" stating, "Label the slides with the same identifier as the block (i.e. S10-001 A, S10-001 B, etc.). If more than one slide per block label each slide: 1, 2, 3, etc. in the upper right hand corner indicating the number of the secession per block." 3. An interview on 3/12/24 at 9:24 am with Testing Personnel #2 confirmed the slides did not include the same identifiers as the blocks.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Manager, the laboratory failed to establish test procedures to include the microscopic examiniation and detection of inadequately prepared slides for its histopathology and cytology testing for 2 (March 2022 to March 2024) of 2 years reviewed. Findings include: 1. A review of the laboratory's stain quality assessments revealed stain quality was not assessed and documented for 3 of 5 patient testing dates reviewed: a. Patient #1 had urine cytology testing performed on 9/1/22. b. Patient #2 had a thyroid fine needle aspirate performed on 12/27/23. c. Patient # 5 had H. pylori staining performed on a colon tissue specimen on 4/5/23. 2. The surveyor requested the laboratory's test procedures for the histopathology and cytology microscopic examinations on 3/12/24 at 2:55 pm and documentation was not made available. 3. An interview on 3/12/24 at 4:02 pm with the Laboratory Manager confirmed the laboratory had not established test procedures to include microscopic examiniation and detection of inadequately prepared slides for its histopathology and cytology testing.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation and interview with Testing Personnel #2, the laboratory failed to label a coplin jar containing xylene with the storage requirements and expiration date for 1 coplin jar observed. Findings include: 1. The surveyor observed a clear glass coplin jar on the counter of the laboratory with "xylene" written on it on 3/12/24 at 9:22 am. 2. A review of the laboratory's "Chemical Hazards and Labeling Procedure" revealed a section stating, "The name of the chemical and its concentration should be included on the label. The date the reagent was prepared or opened, and the expiration date must also be present." 3. An interview on 3/12/24 at 9: 22 am with Testing Personnel #2 confirmed the coplin jar with xylene was not labeled according to laboratory policy.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Manager, the laboratory failed to assess and document staining materials for intended reactivity for 3 (Patients 1, 2, and 5) of 5 patient testing dates reviewed. Findings include: 1. A review of the laboratory's stain quality assessments revealed stain quality was not assessed and documented for 3 of 5 patient testing dates reviewed: a. Patient #1 had urine cytology testing performed on 9/1/22. b. Patient #2 had a thyroid fine needle aspirate performed on 12/27/23. c. Patient # 5 had H. pylori staining performed on a colon tissue specimen on 4/5/23. 2. An interview on 3/12/24 at 1:29 pm with the Laboratory Manager confirmed intended reactivity for staining materials had not been assessed for the patient testing date listed above.
D6081	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(d) Each individual may direct no more than five laboratories. This STANDARD is not met as evidenced by: . Based on record review and interview with the Regional Laboratory Director, the Laboratory Director simultaneously directed six nonwaived laboratories (23D0382352, 23D0382367, 23D0381976, 23D0382444, 23D0038123, and 23D2104579). Findings include: 1. The surveyor reviewed the CMS database on 3/12 /24 at 10:07 am to help the laboratory enter the Laboratory Director's other

	laboratories on Form CMS-116 and found the Laboratory Director was listed as the Laboratory Director for the following nonwaived laboratories: a. 23D0382352 Portage Hospital, LLC, Certificate of Accreditation. b. 23D0382367 Aspirus Houghton Clinic Laboratory, Certificate of Provider-Performed Microscopy Procedures. c. 23D0381976 Marshfield Medical Center- Dickinson, Certificate of Accreditation. d. 23D0382444 Aspirus Ontonagon Hospital Laboratory, Certificate of Accreditation. e. 23D0038123 Aspirus Keweenaw Hospital Laboratory, Certificate of Accreditation. f. 23D2104579 Aspirus Keweenaw Hospital Pathology, Certificate of Accreditation. 2. An interview on 3/12/24 at 4:02 pm with the Regional Laboratory Director and the Laboratory Manager confirmed the Laboratory Director had been directing six nonwaived laboratories.