Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2138026	01/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Aspirus Dermatology Clinic	1901 Westwood Center Boulevard, Wausau, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records from 2020 and 2021 and interview with the laboratory director, the laboratory did not verify accuracy twice annually for frozen section diagnoses and immunohistochemical (IHC) stains. Findings include: 1. Review of laboratory records from 2020 and 2021 showed frozen section diagnoses were made in 2020 and 2021. 21 frozen section diagnoses were reported in 2021. Review showed no record of evaluation of accuracy for frozen section diagnoses in 2020 or 2021. 2. Review of laboratory records for 2021 showed the laboratory performed 13 Cytokeratin 5 (CK5) IHC tests in 2021 with the first test performed on March 23, 2021. No evidence of twice annual accuracy verification is present for the CK5 IHC test. 3. Interview with the laboratory director on January 27, 2022 at 12:30 PM confirmed the laboratory had not verified accuracy twice annually in 2020 or 2021 for frozen section diagnoses or in 2021 for the CK5 IHC procedure.
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 surveyor review of the laboratory procedure for the Cytokeratin 5 (CK5) immunohistochemical (IHC) stain and interview with the laboratory director, the procedure did not specify the quality control reactions required for acceptable stain performance. Findings include: 1. Review of the IHC CK5 procedure showed no acceptable quality control parameters for the stain and did not identify how testing personnel would ensure positive and negative reactivity of the stain when evaluating patient slides. 2. Interview with the laboratory director on January 27, 2022 at 12:30 PM confirmed the procedure did not identify how testing personnel would evaluate stain quality each day of use to ensure acceptable positive and negative reactivity.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on surveyor review of manufacturer instructions and laboratory records and interview with the laboratory director, the laboratory did not document their evaluation of the Novodiax ihcDirect Cytokeratin 5 staining procedure. Findings include: 1. Review of the manufacturer instructions for the Novodiax ihcDirect Cytokeratin 5 (CK5) reagent showed the immunohistochemical (IHC) test procedure included variable timing steps for the pHRP (polymerized horseradish peroxidase) antibody (three to five minutes) and for the chromogen (one to three minutes). The instructions stated, "Users should determine the optimal incubation time for their particular chromogen or lab environment". 2. Review of laboratory records showed no documented evaluation of the test performance prior to use for patient testing on March 23, 2021. 3. Interview with the laboratory director on January 27, 2022 at 12: 30 PM confirmed the laboratory did not document the evaluation of the CK5 IHC reagent.