Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0707975	08/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Um Oral Pathology Biopsy Service	1011 N University Avenue Room G018, Ann Arbor, 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
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 record review and interview with the Laboratory Coordinator, the laboratory failed to verify the accuracy of its oral pathology testing at least twice annually for 2 (August 2021 and August 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of verification of accuracy documentation for its oral pathology testing between August 2021 to August 2023. 2. The surveyor requested the laboratory's verification of accuracy documentation for its oral pathology testing between August 2021 to August 2023 on 8/1/23 at 10:30 am and it was not made available. 3. An interview on 8/1/23 at 12:37 pm with the Laboratory Coordinator confirmed verification of accuracy documentation for its oral pathology testing between August 2021 to August 2023 was not available.
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 Coordinator, the laboratory failed to include, as part of its oral pathology test procedures, the procedure for performing microscopic examination, including the detection of inadequately prepared slides for 2 (August 2021 to August 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's procedure manual revealed a lack of procedure for the performance of oral pathology microscopic examinations including the detection of inadequately prepared slides. 2. The surveyor requested the laboratory's procedure for the performance of oral pathology microscopic examinations including the detection of inadequately prepared slides on 8/1/23 at 12: 37 pm and they were not made available. 3. An interview on 8/1/23 at 12:37 pm with the Laboratory Coordinator revealed the laboratory had not established a procedure to include the performance of oral pathology microscopic examinations including the detection of inadequately prepared slides.
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 Coordinator, the laboratory failed to perform and document its Periodic Acid-Schiff (PAS) staining control procedures to include both positive and negative reactivity for 2 (August 2021 to August 2023) of 2 years. Findings include: 1. An interview on 8/1/23 at 11:36 am with Testing Personnel #6 revealed the laboratory performs Periodic Acid-Schiff (PAS) staining on some of its oral pathology specimens if indicated. 1. A review of the laboratory's procedure manual revealed the laboratory had a procedure for the performance of PAS staining on its oral pathology specimens. 2. The surveyor requested documentation of the PAS staining control procedures to include both positive and negative reactivity each date of use on 8/1/23 at 12:37 pm and it was not made available. 3. An interview on 8/1/23 at 12:37 pm with the Laboratory Coordinator revealed the laboratory had tested about 24 patients with PAS staining between August 2021 and August 2023 and had not performed and documented PAS staining control procedures to include both positive and negative reactivity each date of use.