Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0707975	09/08/2025
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
D5030	ORAL PATHOLOGY CFR(s): 493.1220 If the laboratory provides services in the subspecialty of Oral pathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interview with the Laboratory Coordinator (LC), the laboratory failed to establish policies and procedures for assessing competency of laboratory personnel (refer to D5209), failed to include control procedures for Periodic Acid-Schiff (PAS) stain in the laboratory procedure manual (refer to D5403), and failed to ensure document negative reactivity for Periodic Acid-Schiff (PAS) staining (refer to D5473).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Coordinator (LC), the laboratory failed to establish policies and procedures for assessing laboratory personnel competency for 2 (September 2023 to September 2025) of 2 years. Findings include: 1. A review of staff personnel records revealed that competency assessments were not performed for the following laboratory personnel: a. Testing Personnel: TP1,

	TP2, TP3, TP4 b. Clinical Consultants: CC1, CC2, CC3, CC4 c. Technical Consult: TS1 d. General Supervisor: GS1 2. A request was made to the LC on 9/8/2025 at 11: 56 am for the missing competency assessments and documentation was not provided. 3. A request was made to the LC on 9/8/2025 at 11:56 am for the competency assessment policy and documentation was not provided. 4. An interview was conducted with the LC on 9/8/2025 at 11:57 am which confirmed that the competency assessments had not been performed for the above laboratory personnel. ***Repeat Deficiency from June 10, 2015 and September 19, 2019 Surveys***
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 (LC), the laboratory failed to include control procedures for Periodic Acid-Schiff (PAS) stain in the laboratory procedure manual for 2 (September 2023 to September 2025) of 2 years. Findings include: 1. Review of the laboratory procedure manual revealed that control procedures for PAS stain were not included. 2. A request was made on 9/08 /2025 at 3:15 pm to the TP5 for control procedures for PAS stain and was not provided. 3. An interview conducted with the LC on 9/08/2025 at 5:30 pm confirmed that the control procedures for the PAS stain were not included in the laboratory's procedure manual.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel (TP5), the laboratory

	failed to document negative reactivity for Periodic Acid-Schiff (PAS) staining for 2 (September 2023 to September 2025) of 2 years. Findings include: 1. An interview conducted on 9/08/2025 at 3:15 pm with TP5 revealed that the laboratory performs Periodic Acid-Schiff (PAS) staining on oral pathology specimens if indicated. 2. On 9 /08/2025 at 3:15 pm, the surveyor requested documentation of PAS staining control results demonstrating both positive and negative reactivity for each date of use. The laboratory was unable to provide documentation of negative reactivity. 3. An interview conducted on 9/08/2025 at 3:15 pm with TP5 confirmed that the laboratory does not document negative reactivity for PAS stains. *This is a repeat deficiency from August 1, 2023*
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 record review and interview with the laboratory coordinator, the laboratory director failed to ensure notification to the state agency of the change in laboratory director (refer to D6079), failed to ensure control procedures for Periodic Acid-Schiff (PAS) stain were included in the laboratory procedure manual (refer to D6093A), failed to ensure negative reactivity Periodic Acid-Schiff (PAS) stains was documented (refer to D6093B), failed to ensure a quality assessment program identified failures in quality was established (refer to D6093C), and failed to ensure competency assessments policies and procedures were established (refer to D6103).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory coordinator (LC), the laboratory director failed to ensure the state agency was notified of a change in laboratory director (LD) within the required timeframe. Findings include: 1. Record review of the CMS-116 and CMS-209 forms completed for the survey revealed a different individual listed as laboratory director compared to the laboratory director listed in the CMS database. 2. An interview with the LC conducted on 09/08/2025 at 3: 15 pm, confirmed that a new LD began serving on May 1, 2025. 3. On 09/08/2025 at 3:15 pm, the surveyor requested documentation of notification to the state agency

	regarding the change in LD. The laboratory was unable to provide documentation and the LC confirmed that they failed to notify the State Agency. 42 CFR 493.51 - Notification requirements: (a) Laboratories issued a certificate of compliance must meet the following conditions: (1) Notify HHS or its designee within 30 days of any change in: (i) Ownership; (ii) Name; (iii) Location; (iv) Director; or (v) Technical supervisor (for laboratories performing high complexity testing only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: . A. Based on record review and interview with the laboratory coordinator, the laboratory director failed to ensure control procedures for Periodic Acid-Schiff (PAS) stain were included in the laboratory procedure manual. Refer to D5403. B. Based on record review and interview with laboratory coordinator, the laboratory director failed to ensure negative reactivity for Periodic Acid-Schiff (PAS) stains was documented. Refer to D5473. C. Based on record review and interview with the laboratory coordinator (LC), the laboratory director failed to ensure a quality assessment program that identified failures in quality was established for 2 (September 2023-September 2025) of 2 years. 1. A record review of the procedure manual revealed the laboratory did not have a quality assessment policy established. 2. On 09/08/2025 at 3: 15 pm, a request was made for the laboratory's quality assessment policy and it was not provided. 3. On 09/08/2025 at 3:15 pm, an interview with the LC confirmed the lab did not have a quality assessment policy and that when a discrepancy in test results occurs, the faculty consult with each other but it is not documented.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory coordinator, the laboratory director failed to ensure a competency assessment policy was established for 2 (September 2023-September 2025) of 2 years. Refer to D5209.