Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0941021	04/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Oral Pathology Services	610 Professional Drive, Gaithersburg, MD	

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
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of patient final reports, records review, and interview with the laboratory director, the laboratory director failed to document the condition and disposition of patient specimens that did not meet the laboratory's criteria for acceptability (Refer to D5805). The cumulative effect of this systemic problem resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on review of "Specimen Requisition Log", "Log for Problem Finding and Remedial Action", "Universal Action Form", patient final reports, and interview with the laboratory director, (LD) the laboratory did not document the condition and disposition of patient specimens that did not meet the laboratory's criteria for acceptability on the final report. Findings: 1. The laboratory received two specimens, "A" and "B", that were recorded on the "Specimen Requisition Log" on 08/02/22. 2. Specimen "A" and "B" were then recorded on the "Log for Problem Finding and Remedial Action" log. Specimen "A" was recorded on 08/02/22. The "problem" was recorded as no patient information on label of vial containing specimen. Specimen "B" was recorded on 08/03/22. The "problem" was recorded as no patient information on specimen vial. The final solution for both specimens were that each of the doctor's offices were contacted and each patient's name was obtained and confirmed. 3. Specimen "A" and "B" each had a "Universal Action Form" completed. a) The "Event Information" had the following checked off on both forms: "UAF-02 Specimen Not Labeled with Patient ID*" and "UAF-04 Specimen Identity in Question*." b) The "Action Summary" had the following checked off on both forms: "Client Contacted", and "Demographics/Information Corrected." c) The "Resolution" had the following checked off on both forms: "Client Corrected Problem", and "Laboratory Director Follow-up." 4. The final reports for specimen "A" and "B" were reviewed. Under the "Gross:" section of the final report the following was written: "The specimen was received in one container in 10% formalin labeled with the patient's name "A" or "B." 5. The records show that the containers for patient "A" and "B" were not labeled when they were received. 6. During the survey on 04/20/23 at 1:00 PM, the LD confirmed that the final reports for patient's "A" and "B" failed to meet the laboratory's criteria for acceptability and failed to include the unlabeled status of the patient's vial when it was received. The LD stated that he was aware that the patient's final report had to include information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability but failed to include the information.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on the "Quality Assurance Program" procedure, review of proficiency testing (PT) results, and interview with the laboratory director (LD), the LD failed to ensure that the laboratory participated in PT and follow the written criteria in the laboratory's procedure for microscopic evaluation of oral pathology slides during 2022 and 2023. Findings: 1. The PT section within the laboratory's written "Quality Assurance Program" procedure stated: "All proficiency testing specimens are tested in the same manner as patient specimens in a double-blinded randomly selected fashion to assure the unbiased results." 2. The LD did not have PT documentation for 2022. The LD provided documentation for the PT performed in April 2023. The worksheet was labeled: "Oral Pathology Services Post-Reporting Verification (OPSPRV) Maryland Oral Diagnosis and Therapeutics, LLC 04/2023." The worksheet had six patients listed as case 1 through 6 along with the diagnosis for each case. 3. According to the LD, the six PT slides were taken to the other pathologist's office and were reviewed together as a consultation and not in the "double-blinded" fashion as required in the

	quality assurance procedure. 4. During the survey on 04/20/23 at 1:00 PM, the LD confirmed that the PT had not been performed in 2022 and that the PT performed in 2023 had not been performed in the "double-blinded" fashion as required in the quality assurance procedure.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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: Based on review of the "H & E [hematoxylin and eosin] Stain Rotation Log" and interview with the laboratory director (LD), the LD failed to ensure that the assistant that documented the rotation and changing of the stains on a monthly basis documented the correct date. Findings: 1. The laboratory is open Monday through Friday. The "H & E Stain Rotation Log" worksheets from July 2021 through April 2023 were reviewed. The assistant had documented that stains had been changed and rotated on the 15th of each month from July 2021 through April 2023. 2. Review of the calendar for those months showed that in January 2022, October 2022, and April 2023 the 15th was on a Saturday and for the months of May 2022, August 2022, and January 2023 the 15th was on a Sunday. 3. During the survey on 04/20/23 at 1:00 PM, the LD confirmed that the office was not open on Saturday and Sunday and that the assistant was not recording the actual date that the stains were being changed and rotated.
D6176	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(2) Each individual performing high complexity testing must maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens. This STANDARD is not met as evidenced by: Based on review of the "Quality Assurance Program" procedure, review of proficiency testing (PT) results, and interview with the laboratory director (LD), the LD acting as the testing personnel failed to ensure that the laboratory participated in PT and follow the written criteria in the laboratory's procedure for microscopic evaluation of oral pathology slides. Cross refer to D6089 for details.