

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2293388	(X3) Date Survey Completed 09/27/2024
Name of Provider or Supplier Oralpath-Dentcare, Llc	Street Address, City, State 6865 Deerpath Rd, #302, Elkridge, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory procedure manual and proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory did not ensure that the PT procedure included information on how to evaluate and document histopathology PT results. Findings: 1. The PT procedure, "Alternate Proficiency Testing" states that the LD "will provide samples of slides for alternate proficiency testing, depending on the sample load, between 5% - 10% of the samples" and provides information on where the PT slides should be sent for evaluation by a second pathologist. The procedure does not say how the results of the alternate PT should be reviewed and evaluated for acceptability. 2. PT record review showed an undated letter, signed by the second pathologist which stated, "This is a sample of slides accessioned and reviewed in OralPath-DentCare, LLC, for review by [the second pathologist] to fulfill the proficiency testing requirement by CLIA." The letter listed five case numbers and the diagnosis given after the slides were interpreted by the second pathologist. 3. The letter did not include the original diagnosis given by the LD or documentation that the PT results had been evaluated for acceptability by the LD. 4. During an interview on 09/23/2024 at 12:30 PM, the LD confirmed that the PT procedure did not include information on how to evaluate and document histopathology PT results.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p>

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the histopathology quality control (QC) worksheets and interview with the laboratory director (LD), the laboratory did not document the acceptability of the control slide(s) with each batch of stained slides received from the processing laboratory. Findings: 1. The laboratory sends oral pathology specimens to an outside laboratory to perform the technical component of testing. Upon receipt, the pathologist is required to document the acceptability of the hematoxylin and eosin (H&E) stain on the "Histology/Non-Gyn Technical Evaluation" worksheet and the acceptability of any special stains on the "Specials (IHC/SS/Recuts/Other) Technical Evaluation" worksheet as "SAT" or "UNSAT". 2. A review of histopathology QC worksheets from January and February 2024 showed that H&E stain QC was not documented on the "Histology/Non-Gyn Technical Evaluation" worksheets prior to releasing the interpretation and final test results for 26 of 29 cases; and 3. Slide stain QC for special stains was not documented on the "Specials (IHC/SS/Recuts/Other) Technical Evaluation" worksheets prior to releasing the interpretation and final test results for three of six cases. 4. During an interview on 09/23/2024 at 12:30 PM, the LD confirmed that slide stain QC was not documented for each day of testing.