

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2242017	(X3) Date Survey Completed 08/29/2022
Name of Provider or Supplier Capital Oral Pathology	Street Address, City, State 3535 Fishinger Rd, Ste 262, Hilliard, OH	
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
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director (LD), the laboratory failed to document all quality control procedures performed at this location, to include the reactions and observations of the control slides for the professional component of histopathology at this location. This deficient practice had the potential to affect 16 patients tested at this laboratory from 04/27/2022 to 08/29/2022. Findings Include: 1. Review of the procedure manual found a quality control policy for the professional component of histopathology: "Troubleshooting Protocols 1. All immunohistochemical stains and special procedures are accompanied by a control. 2. Check for presence of control. 3. Check for validity/accuracy of control stain..." 2. Record review failed to find documentation of quality control each day of patient testing for the professional component of histopathology. 3. An interview with the LD, on 08/29/2022 at 2:17 PM, confirmed the laboratory failed to document quality control each day of patient testing.</p>