

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2008696	(X3) Date Survey Completed 05/16/2019
Name of Provider or Supplier Dermatopathology Lab Of Central States	Street Address, City, State 7450 Hospital Drive, Suite 370, Dublin, 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 Consultant, the laboratory failed to document all control procedures for immunohistochemical (IHC) stains and special stains in 15 out of 91 documents reviewed for the year 2018. Findings Include: 1. Review of the procedure manual found a policy for IHC and special stain quality control, documented each time of use, which complied with the regulation. 2. Review of 91 IHC and special stain quality control documents, found 15 documents that failed to record the reactions and observations of the positive and negative IHC and special stain controls each time of use. 3. An interview with the Laboratory Consultant, on 5/16/19 at 3:11 pm, confirmed that the laboratory failed to record record the reactions and observations of the positive and negative IHC and special stain controls each time of use.</p>