

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2155894	(X3) Date Survey Completed 01/17/2023
Name of Provider or Supplier Bvp Ascension Seton Williamson Path	Street Address, City, State 1st Floor Laboratory 201 Seton Pkwy, Round Rock, TX	
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
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 review of the laboratory's policies and procedures, test reports / quality control (QC) records, and interview, the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Immunohistochemical (IHC) stains and Special stains for the interpretation of dermatopathological specimens for one of four reports reviewed. Finding follow. A. Review of the laboratory's policy and procedure titled Quality Program, 03/01/2019, under Quality Assessment of the Sample Preparation and Slides stated, "The pathologist reviewing the case will review the sample preparation quality by reviewing the following: processing quality, embedding quality, microtomy quality, and staining quality. Any quality issues will be documented on the Daily Slide Quality Monitor Form, along with the resolution of the defect..." The policy did not address the documentation of controls for IHC and Special stains. The laboratory's practice was to document controls for the IHC and Special stains in the test report. B. Review of 1 of 4 test reports/cases from 01/08/21 - 12/14/22 did not include QC for the intended reactivity</p>

to ensure predictable staining characteristics for the following IHC and Special stains:
Surgical Path # Date Reported IHC/Special Stain 1. MS21-1588 05/14/2021 GMS
stain C. Interview with the Director of Operations on January 11, 2023, at 1155 hours
confirmed the performance of the QC for the Special stain was not recorded on the
test report.