

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0687945	(X3) Date Survey Completed 10/19/2022
Name of Provider or Supplier Jennifer Caudill Md Pllc	Street Address, City, State 5885 S Main St Suite 1, Clarkston, MI	
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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to ensure hematoxylin and eosin staining quality for biopsy microscopic tissue examinations each day of testing for 5 of 5 patients tested from January 2022 to October 2022. Findings include: 1. A review of the laboratory's "Pathology Log Sheet" for 2022 revealed the laboratory had performed biopsy microscopic tissue examinations with hematoxylin and eosin staining materials for 5 patients between January and October. 2. A review of the laboratory's "Guidelines for Slide Prep Only in Pathology Book" policy revealed a lack of process to perform and record hematoxylin and eosin staining quality. 3. The surveyor requested documentation of stain quality for the patient testing listed above on 10/19/22 at 12:15 pm and it was not made available. 4. An interview on 10/19/22 at 12:35 pm the Office Manager revealed the laboratory did not have documented stain quality for biopsies tested from January to October 2022.</p>