

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D0672002	<b>(X3) Date Survey Completed</b>  02/17/2026
<b>Name of Provider or Supplier</b>  Brett Coldiron Md	<b>Street Address, City, State</b>  3024 Burnet Avenue, Cincinnati, OH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Office Manager (OM), the laboratory failed to establish and follow written policies and procedures and document all quality assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the general laboratory systems. This deficient practice had the potential to affect one out of one patient Histopathology test result from 12/16 /2024 through 12/16/2024. Findings Include: 1. Review of the laboratory's policy and procedure titled "Quality Assurance Manual" approved via signature and date by the Laboratory Director on 01/14/2026, and provided on the date of inspection, found the following statement: "The Laboratory Director will review the Corrective Action to ensure that appropriate action is taken and proper procedures are followed. A Corrective Action Request Form (see Section IV- page 25) will be filled out whenever a problem arises in calibration, an out-of-control situation occurs which is not resolved by a simple repeat analysis, or a failure of proficiency testing occurs." 2. Review of the "Specimen Rejection Log" revealed one entry dated 12/13/2024, with no accession number, the patient's full name, and the following information: "UC said no tissue in jar. Re-biopsy@MOHS 1/8/25" 3. Review of the "Diag. Path Book" showed an entry dated 12/16/24 for the same patient listed in the "Specimen Rejection Log", indicating a biopsy procedure was performed. 4. During an interview on 02/17 /2026 at 12:55 PM, the OM confirmed the date in the Specimen Rejection Log was incorrect for the lost specimen entry, a Corrective Action Request Form was not completed as required by the laboratory's Quality Assurance Manual, and the</p>

laboratory did not document assessment activities related to monitoring, assessing, and correcting problems within the general laboratory systems.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1299(a)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Office Manager (OM), the laboratory failed to follow written policies and procedures and document all quality assessment activities of an ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. This deficient practice had the potential to affect 3,812 out of 3,812 patients tested in the subspecialty of Histopathology from 02/07/2024 through 02/17/2026. Findings Include: 1. Review of the laboratory's policy and procedure titled "Quality Assurance Manual" approved via signature and date by the Laboratory Director on 01/14/2026, and provided on the date of inspection, found the following statement: "Relationship of Patient Information to Test Results The Laboratory Director will ensure the appropriate laboratory personnel monitor test requisitions for appropriateness to the patient's age, sex, and diagnosis." 2. Record reviews did not find any documentation for monitoring test requisitions, or an ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. 3. An interview on 02/17/2026 at 12:30 PM with the OM confirmed the laboratory did not document the assessment activities to monitor test requisitions for appropriateness to the patient's age, sex, and diagnosis, and was unable to provide the requested documents.