

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0672002	(X3) Date Survey Completed 02/06/2024
Name of Provider or Supplier Brett Coldiron Md	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3003	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and an interview with the Office Manager, the laboratory failed to be arranged and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies was minimized. This deficient practice had the potential to affect 2,924 out of 2,924 specimens tested in the subspecialty of Histopathology from 05/31/2022 through 02/05/2024. Findings Include: 1. The Inspector directly observed the laboratory on 02/05/2024 at 1:15 PM and found the laboratory was cluttered with a large amount of surgical equipment on three towels located across the entryway counter, an uncapped Isopropyl Alcohol bottle located near the sink, random items on and near the tissue embedder, and two uncapped inking bottles under the counter. 2. Direct observation of the grossing area, on the date of the inspection at 1:15 PM, revealed a stained white plastic cutting board with no disinfecting materials or changeable surface covers found. Two small caps of ink with no covers were located near the cutting board. Also, two small wooden sticks used for tissue inking were sitting next to each cap of ink, but no new sticks for tissue inking were found. 3. Further observation found two out of two Hematoxylin reservoirs on the autostainer were crusty with crystallized reagent coating each container. 4. The Office Manager confirmed the laboratory was cluttered and needed cleaned. The interview occurred on 02/05/2024 at 1:40 PM. Note: photos of the laboratory were taken for reference.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p>

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

ITEM 1 Based on document review and an interview with the Office Manager, the laboratory failed to establish and follow a written procedure for the transport conditions of specimens to be tested at an off-site laboratory. This deficient practice had the potential to affect 735 out of 735 Histopathology specimens transported and processed at an off-site laboratory from 05/31/2022 through 02/05/2024. Findings Include: 1. Review of the laboratory's policy and procedure titled, "Histopathology", unsigned and not dated by the Laboratory Director, provided on the date of inspection, did not find any mention of specimen handling and transport conditions for specimens sent off-site. 2. Review of the untitled policy and procedure manual, provided on the date of inspection, did not find any mention of specimen handling and transport conditions for specimens sent off-site. 3. The Inspector requested a policy and procedure for the specimens transported from the laboratory to an off-site location which included specimen handling and transport conditions from the Office Manager. The Office Manager confirmed there was no policy and procedure which included the specimen handling and transport conditions, and was unable to provide the requested information. The interview occurred on 02/05/2024 at 11:30 AM. ITEM 2 Based on document review and an interview with the Office Manager, the laboratory failed to establish and follow a written policy and procedure for the specimen acceptability and rejection of Mohs tissue specimens. This deficient practice had the potential to affect 2,924 out of 2,924 patients tested in the subspecialty of Histopathology from 05/31/2022 through 02/05/2024. Findings Include: 1. Review of the laboratory's policy and procedure titled, "Histopathology", unsigned and not dated by the Laboratory Director, provided on the date of inspection, did not find any mention of Mohs tissue specimen acceptability and rejection procedures. 2. Review of the untitled policy and procedure manual, provided on the date of inspection, did not find any mention of Mohs tissue specimen acceptability and rejection procedures. 3. The Inspector requested a policy and procedure for the Mohs tissue specimen acceptance and rejection including documentation from the Office Manager. The Office Manager confirmed the laboratory did not establish a policy and procedure for specimen rejection. The interview occurred on 02/05/2024 at 11:00 AM.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on direct observation and an interview with the sole Processing Personnel, the laboratory failed to ensure that the laboratory's reagents were not used when they had exceeded their expiration dates. This deficient practice had the potential to affect

2,924 out of 2,924 patients tested in the subspecialty of Histopathology from 05/31/2022 through 02/05/2024. Findings Include: 1. Review of the laboratory's "Histopathology" policy and procedure, provided on the date of the inspection, found the following statement: "Do not use reagent after expiration date." 2. Direct observation of the laboratory and reagent storage areas on the date of inspection, at 1:10 PM, revealed the following expired reagents: Quantity - Reagent 1 - Eosin; lot 2115902; expiration 6/10/23 1 - Pro-Par Clearant; lot 7128; expiration 12/13/23 1 - 10% Formalin; lot MER44991GL; expiration 2/5/23 3. The sole Processing Personnel confirmed the above listed reagents were expired and utilized for patient testing procedures. The interview occurred on 02/05/2024 at 2:00 PM. %; percent

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(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, the laboratory failed to follow written policies and procedures and document all 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 2,924 out of 2,924 patients tested in the subspecialty of Histopathology from 05/31/2022 through 02/05/2024. Findings Include: 1. Review of the laboratory's policy and procedure titled "Quality Assurance Manual" 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. The Inspector requested documentation for the monitoring of test requisitions from the Office Manager. The Office Manager confirmed the laboratory did not monitor test requisitions for appropriateness to the patient's age, sex, and diagnosis, and was unable to provide the requested documents. The interview occurred on 02/05/2024 at 12:45 PM.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy and procedure manual and an interview with the Office Manager, the Laboratory Director failed to ensure approved policies and procedures were available to all personnel responsible for any aspect of the testing process. This deficient practice had the potential to affect 2,924 out of 2,924 tested under the subspecialty of Histopathology from 05/31/2022 through 02/05/2024. Findings Include: 1. Review of the laboratory's untitled policy and procedure manual, contained in a black 3-ring binder, failed to find the Laboratory Director's approval

via signature and date. 2. Review of two out of two policies and procedures contained in file folders failed to find the Laboratory Director's approval via signature and date. 3. The inspector requested policies and procedures approved by the Laboratory Director from the Office Manager. The Office Manager confirmed the policies and procedures were not approved and signed by the Laboratory Director. The interview occurred on 02/05/2024 at 12:00 PM.