

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0866065	(X3) Date Survey Completed 07/18/2024
Name of Provider or Supplier Base Dermatology	Street Address, City, State 26400 W 12 Mile Road Suite 180, Southfield, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP1) and the Laboratory Director (LD), the laboratory failed to perform maintenance for 93 of 122 days (June 27, 2024, October 2022, September 2022 and August 2022) for Cryostat. Findings include: 1. Record review of the laboratory equipment records revealed that maintenance was not performed on Cryostat for 8 of 8 cases on June 27, 2024. Further review revealed that records were missing for 3 months in 2022 (October 2022, September 2022, and August 2022). 2. Record review of the laboratory procedure "Materials, Reagents, and Equipment," Number 5, "Equipment" states in letter A, "All equipment is maintained per manufacturer's instructions located in the service manuals." 3. Interview with TP1 and LD on July 18, 2024, at 1:05 pm confirmed that maintenance was not performed as indicated above.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on observation, record review and interview with Testing Personnel (TP1), the laboratory failed to ensure 3 bottles of reagent were not used after their expiration date. Findings include: 1. The surveyor observed 3 bottles of Tissue Tek OCT Compound used for microscopic tissue examination on 07/18/2024 at 9:45 am with expiration dates of 1/2023 (1 bottle), and 6/2023 (2 bottles) in the laboratory available for use. 2. An interview with TP1 on 7/18/24 at 9:45 am confirmed the reagents were expired. 3. Record review of the laboratory's procedure, "Materials, Reagent, and Equipment," section 3b, states: "The expiration dates of all reagents and stains are checked periodically to ensure they will not be used after they expire as this could hinder the test result."

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(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.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel (TP1) and Laboratory Director (LD), the laboratory failed to perform stain quality control for microscopic tissue evaluation on June 27, 2024, and 4 of 21 months of testing (November 2022, October 2022, September 2022 and August 2022). Findings include: 1. The surveyor reviewed the laboratory's stain quality control records and noted that stain quality was not assessed for the following: a. Record review for stain quality assessment was not conducted on June 27, 2024, for 8 of 8 cases. b. The surveyor determined that documentation for stain quality assessment was not available for 4 months in 2022. 2. Interview with TP1 and LD on July 18, 2024, at 1:05 pm confirmed documentation of the assessment of stain quality on June 27, 2024 was not performed and Quality Control (QC) for (November 2022, October 2022, September 2022 and August 2022) were not available. 3. Record review of the laboratory's quality control procedure, "Quality Control Log Procedure...Section A...Every MOHs must be reviewed by the physician for quality control. A MOHs Quality Control Log book is kept indicating the date and accession number for each MOHs. If there are multiple partes to the case, these are recorded separately. The physician will rate the sectioning and staining based on the scale below: Excellent = Exceeds quality control standards Good = Meets quality control standards but improve Poor = Does not meet quality control standards"