

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0649615	(X3) Date Survey Completed 07/10/2023
Name of Provider or Supplier Bethesda Dermatopathology Lab	Street Address, City, State 1730 Elton Road Suite 11, Silver Spring, MD	
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
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: Based on record review and interview with laboratory staff, the laboratory did not ensure that histology reagents, solutions, and other supplies are not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. Findings: 1. Record review showed that the "Slide Grid List" which lists the sequence numbers of prepared histology slides had a label on the top right of the page which documented the lot numbers of the hematoxylin and eosin (H&E) stains used for staining. The expiration dates were not documented on the label. 2. During an interview on 07/10/2023 at 12:40 PM, laboratory staff confirmed that the expiration dates for the H&E stains were not documented and stated that the laboratory did not record the lot numbers and expiration dates for the other histology reagents including "Penfix," 95% and 100% alcohol, xylene, and paraffin.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the</p>

reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on humidity log record review and interview with laboratory staff, the laboratory failed to document corrective action when laboratory humidity was out of range. Findings: 1. A review of the 2022 "Humidity and Room Temperature Quality Control Log" shows that the acceptable humidity range for the laboratory is "20% - 60%." 2. In January 2022 laboratory humidity was out of range 11 out of 21 days recorded; in February 2022 laboratory humidity was out of range five out of 20 days recorded; in March 2022 laboratory humidity was out of range three out of 23 days recorded; and in December 2022 laboratory humidity was out of range two out of 20 days recorded. 3. There were no corrective actions documented for these dates. 4. During an interview on 07/10/2023 at 1:15 PM, the laboratory staff confirmed that there were no corrective actions documented for the days that the laboratory humidity was out of range.