

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0310678	(X3) Date Survey Completed 04/22/2024
Name of Provider or Supplier Dermatology Associates, Pc	Street Address, City, State 2885 Boones Creek Road, Johnson City, TN	
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 observation of the laboratory and staff interview, the laboratory failed to ensure expired tissue marking dye was not used in micrographically oriented histographic surgery (Mohs) histopathology tissue processing for patient testing from 11.01.2023 through the survey date 04.22.2024. The findings include: 1. Observation of the Mohs laboratory in patient room number 1 on 04.22.2024 at 9:25 a.m. revealed one bottle of StatLab green tissue marking dye (lot number 132307) in use with an expiration date of 10.31.2023. 2. Interview on 04.22.2024 at 9:25 a.m. with the lead processing histotechnician confirmed the above survey findings.</p>
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 a review of the laboratory's Hematoxylin and Eosin (H&E) stain control slide log, laboratory policy, and staff interview, the laboratory failed to define the</p>

predicted characteristics of the H&E stain in 2023, though the survey date of 04.22.2024. The findings include: 1. A review of the laboratory's H&E stain control slide logs revealed the laboratory failed to document the predicted characteristics of the H&E stain quality for 2023 through the survey date of 04.22.2024. 2. A review of the laboratory's policy, "H&E Stain Approval Log," revealed the policy did not define the predictable characteristics of H&E stain quality. 3. An interview on 04.22.2024 at 11:45 a.m. with the lead processing histotechnician confirmed the above survey findings.