

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2042281	(X3) Date Survey Completed 08/07/2025
Name of Provider or Supplier Morrell Dermatology, Pa	Street Address, City, State 3560 Delaware Suite 901, Beaumont, TX	
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
D0000	The laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a recertification survey completed on August 7, 2025.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of laboratory supplies, laboratory annual test volumes, and interview, the laboratory failed to remove from use 23 of 23 expired materials available for use in tissue grossing and staining of patient slides for diagnostic interpretation. The findings included: 1. Review of the laboratory policy titled "Quality Control Manual", section "Test Methods, Equipment, Reagents, Materials, and Supplies", included the following statement: "Reagents, solutions, culture media, control materials, calibration materials and other supplies are not used when they have exceeded their expiration dates, have deteriorated or are substandard quality." 2. Review of the laboratory supplies included the following 23 expired materials utilized in patient tissue marking for grossing orientation, and staining of slides for diagnostic interpretation: The following seven Cancer Diagnostics Inc (CDI) Tissue Marking Dyes were on the counter and in use for tissue grossing orientation: Violet; in use. No lot or expiration date on bottle. Orange; in use. No lot or expiration date on bottle. Yellow; in use. No lot or expiration date on bottle. Red; in use: Lot 16266, Exp 2018/04 Green; in use. No lot or expiration date on bottle. Blue; Lot 18274, exp 2020/04 Black; Lot 16256, exp 2018/03 The following 14 CDI inks were found to be unopened in a drawer, directly under the in-use stains, and available for use in patient tissue inking: Green, Lot 20049, Exp 2022-02-28 Black, Lot 20062, Exp 2022-03-31 Orange, Lot 20086, Exp 2022-03-31 Yellow, Lot 20058, Exp 2022-02-28</p>

Red, Lot 20017, Exp 2022-01-31 Blue, Lot 20015, Exp 2022-01-31 Blue, Lot 18274, Exp 2020/04 (5 bottles) Blue, Lot 18250, Exp 2020/04 (3 bottles) The following two Eosin Y stains were available for use in the H&E staining of patient slides for diagnostic interpretation: Eosin Y 1% Alcoholic, Lot 2207, EXP 2024-07-26 (opened 7/21/2023) Eosin Y 1% Alcoholic, Lot 2263, EXP 2024-09-20 Surveyor asked if the laboratory had any CDI marking dye or Eosin Y that were not expired, and none could be provided. 3. Review of the laboratory provided test counts included an annual test volume of 500 patients. 4. In an interview on 8/7/2025 at 10:50 hours, in the laboratory, the practice administrator confirmed expired CDI inks and Eosin Y were available for use and had been used in patient inking and staining.