

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2114693	(X3) Date Survey Completed 09/26/2022
Name of Provider or Supplier Radiant Dermatology And Aesthetics Pllc	Street Address, City, State 22659 Highway 59 N Suite 140, Kingwood, 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	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observations in the laboratory and staff interviews, it was determined the laboratory failed to ensure 13 of 13 Hematoxylin and Eosin (H&E) stain reagent secondary containers were labeled with the required information. Findings included: 1. Surveyor's observations on 09/26/2022 at 0950 hours in the laboratory revealed an automated stainer storing 13 open containers with H&E stain reagents in use. None of the reagent containers were labeled in any manner indicative of their content. 2. In an interview on 09/25/2022 at 0950 hours in the laboratory, the</p>

facility's Histotechnologist stated that there was a legend of container content, but confirmed that the containers were not labeled/numbered to correspond with the legend. The legend was not displayed for reference. 3. In an interview on 09/25/2022 at 0955 hours in the laboratory, the facility's Practice Manager, after own observations, confirmed the findings.

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 surveyor's observations in the laboratory and staff interview, it was determined the laboratory failed to ensure Toluene reagents, used in Histopathology as tissue fixative, were not used beyond expiration date for 2 of 2 in use containers observed. Findings included: 1. Surveyor's observations on 09/26/2022 at 0950 hours in the laboratory revealed 2 opened containers of Toluene reagent: Mercedes Scientific OPTICMOUNT 1 Toluene 500mL (milliliter) bottle. Lot: 85927 Expiration date: 06/21 Mercedes Scientific OPTICMOUNT 1 Toluene 4oz (ounce) bottle. Lot: 75218 Expiration date: 10/20 2. In an interview on 09/26/2022 at 0950 hours in the laboratory, the facility's Histotechnologist, when asked about the two bottles of Toluene in use, stated that the Toluene reagent was transferred as needed from the larger (500mL) bottle to the smaller (4oz) bottle as needed, but confirmed that the lot number and expiration dates were not amended on the smaller bottle to reflect the lot in use. She was not aware the reagents expired. This confirmed the findings.