

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2056631	(X3) Date Survey Completed 06/17/2025
Name of Provider or Supplier Treasure Coast Pathology Lab Llc	Street Address, City, State 275 18th St Ste 101, Vero Beach, FL	
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	An announced CLIA recertification survey was conducted at Treasure Coast Pathology Lab LLC on June 17, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on interview, observation, review of quality control (QC) logs, reagent safety data sheets and equipment manuals, the laboratory failed to ensure protection from chemical hazards from 02/01/2023 to 06/17/2025. Findings: 1. Tour of the laboratory on 06/17/2025 at 1:15 PM, revealed there were two fume hoods, a Labconco Fume Absorbers Model 115V 3955200 Organic 30 inch and a Labconco Fume Absorbers Model 115 V 3955201 Formaldehyde 30 inch. The following reagents were used under the organic fume hood: Xylene, Hematoxylin, Eosin Y Solution, Vintage Bluing, A 100% Reagent Alcohol, and 95% Reagent Alcohol. The 10% Neutral Buffered Formalin was used under the Formaldehyde fume hood. 2. Review of the Fume Hood QC Logs: (#1 - Organic Filter / #2 - Formaldehyde Filter) showed the filters for the organic hood were replaced on 02/12/2024 and 3/12/2025, and the filters for the formaldehyde hood were replaced on 02/09/2023, 02/12/2024 and 3/12/2025. 3. Review of equipment manuals for the hoods provided instructions on how to calculate the carbon filters' life to determine how often the filters should be changed. 4. Review of the Safety Data Sheets showed the 10% Neutral Buffered Formalin and Xylene are GHS (Globally Harmonized System) Carcinogenicity classification Category 2 . According to Occupational Safety and Health Administration (OSHA)</p>

Hazardous Communication Standard 29 CFR 1910.1200 a GHS Carcinogenicity Category 2 is a substance that is suspected of causing cancer in humans. 5. Review of the Safety Data Sheets showed High Def and Hematoxylin may cause respiratory irritations. 6. During an interview on 06/07/2025 at 3:30 PM, Testing Personnel A stated they changed the filters once a year and she had never calculated the filter life.

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on review of quality control documents and interview, the laboratory failed to document the daily maintenance of the Hematoxylin and Eosin (H&E) stain from 03/12/2024 to 06/17/2025. Findings: Review of the the Daily Maintenance Chart for H&E Staining showed there was no documentation from 03/12/2024 to 03/31/2024, 04/12/2024 to 04/30/2024, and 06/01/2024 to 06/17/2025. During an interview on 06/17/2025 at 3:50 PM, Testing Personnel A said she stained slides every day and had not kept up with the recording of the maintenance of the H&E stain.