Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2056631	04/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Treasure Coast Pathology Lab Llc	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	A recertification survey was conducted on April 19, 2023. Treasure Coast Pathology Lab LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of competency records and procedure manual, and interview, the laboratory failed to document the competency assessment for one of one testing personnel who is also the general supervisor for 2021 and 2022. Findings: Review of the Laboratory Personnel Report signed and dated on 04/19/2023 by the Laboratory Director showed there were only two people listed on the report. The same person was the laboratory director, clinical consultant, and technical supervisor, and another person was the general supervisor and testing personnel. Review of competency evaluations for 2021 and 2022 showed the evaluations on the Testing Personnel was not signed by the Laboratory Director. Review of competency evaluations for 2021 and 2022 also showed the evaluations did not include all the job duties performed by the testing personnel and general supervisor. Review of the procedure manual revealed a form titled "Competency Evaluation of Technical Staff." The competency evaluation for the technical staff was not filled out on the testing personnel. On 04/19 /2023 at 12:52 PM, General Supervisor stated that the competency evaluations were not signed by the Laboratory Director and that she did not know whose signature was on them. On 04/19/2023 at 1:00 PM, General Supervisor agreed the competency evaluations filled out did not apply to her job duties.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview, the laboratory failed to have a step-by-step procedure for the grossing of pathology specimens on 04/19/2023. Findings: Review of the procedure manuals showed there was no procedure on grossing. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 4/19 /2023, the laboratory had an estimated annual test volume of 3,000 histopathology tests. On 04/19/2023 at 12:11 PM, the General Supervisor stated she did not know what happened to the grossing policy.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the reagent log and interview, the laboratory failed to record the open dates for all reagents used in their Hematoxylin & Eosin (H & E), Alcain Blue /Periodic Acid-Schiff (AB/PAS), and Giemsa stains from 03/30/2021 to 04/19/2023. Findings: The laboratory used the following reagents: 100% Reagent Alcohol, Alcain Blue 2.5, Bluing Reagent, Clarifier 2, Cytoseal XYL, Eosin Y, Giemsa, Hematoxylin, Isopropyl Alcohol, Periodic Acid, and Schiff Reagent. Review of the laboratory's reagent log showed there were no open dates listed. On 04/19/2023 at 11:31 AM, General Supervisor acknowledged the open dates were not recorded.