Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2056631	02/12/2019
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
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 record review and interview, the laboratory procedure manual did not include instructions for making the 95%, 50%, and 70% alcohol solutions from 2/12 /17 to 1/12/19. Findings: Review of the laboratory's procedure manual showed that the procedure titled, "Hematoxylin and Eosin Stain" failed to have instructions for making the 95% and 50% alcohol solution. Review of the laboratory's procedure manual showed that the procedure titled, "Destaining Slide Protocol" failed to have instructions for making the 70% alcohol solution. On 2/12/19 at 11:32 AM, Histology Technician stated that he made the 95%, 50% and 70% alcohol solutions and that the

	procedures did not contain instructions for making the 95%, 50% and 70% alcohol solutions.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the Laboratory Director's approval, signature and date on the procedure manual. Findings: Review of the "Lab Director Routine Visit" log showed that the laboratory had a new director in November 2017. Review of the manuals titled, Procedure Manual, Safety Manual, Client Services Manual, and HIPAA Policy Manual showed that the current laboratory director had not signed the manuals. The manuals were last signed by the former laboratory director on 1/9/17. During an interview on 2/12/19 at 11:57 AM, Histology Technician stated that he could not find anything that showed that the current Laboratory Director approved, signed, and dated the manuals.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the test reports did not identify the name and location where the technical component was performed for 1 of 5 patients, (#1). Findings: A review of patient test reports from 7/6/17 to 1/28/19 was preformed. The "Pathology Report" for patient #1 dated 1/28/19 failed to list the name and location of where the technical component was performed. During an interview on 2/12/19 at 11: 50 AM, Histology Technician acknowledged that the name and location where the technical component was performed was not listed on the pathology report for patient #1. The Histology Technician also stated that the technical component had not appeared on the pathology reports since the laboratory performing the reading of the slides changed their forms.