Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0931069	04/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Suncoast Pathology Inc D/B/A	1283 Jacaranda Blvd, Venice, 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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on twice annually peer review record review and interview with the Business Manager, the laboratory failed to have documentation for evaluation of histology peer review. Findings included: During twice annually peer review record review it was found that the laboratory had a log of samples that had been pulled for peer review but could not identity which samples were for histology frozen specimens and the logs did not include the evaluation of the peer review. During an interview on 04/30/2018 at 02:00 p.m., the Business Manager confirmed that the evaluation of the twice annual peer review had not been documented.
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 histology procedure manual review, hematoxylin and eosin (H & E) stain quality control logs for two out of two years (2016-2018) record review and interview with the Business Manager, the laboratory failed to include in the histology procedure manual the criteria to determine the acceptability of the H & E stain. Findings included: During H & E Quality Control logs record review for two out of two years (2016-2018), it was found that the Quality Control log did not include the criteria to determine the acceptability of the H & E stain. During the histology procedure manual review, it was observed that the procedure did not have criteria for determining acceptability of the H & E stain. During an interview on 04/30/2018 at 02:05 p.m., the Business Manager confirmed that the laboratory did not have the criteria for acceptability in the laboratory's manual.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the Quality Assurance procedure manual review and interview with the Business Manager, the Laboratory Director failed to ensure the Quality Management Assessment Plan was being maintained to assure the quality of laboratory services. Findings included: During the Quality Assurance procedure manual review, it was discovered that the Quality Assurance procedure manual contained a Quality Management Assessment Plan in the manual. The Plan states the Laboratory Director will be responsible for the advisement and oversight of all aspects of the Quality Management Plan and that there will be periodic monitoring which will be documented using the Quality Assessment Report Form which was not found on the day of survey. During an interview on 04/30/2018 at 02:10 p.m., the Business Manager confirmed that Quality Assessment periodic monitoring was not being documented.