Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2101613	04/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Suncoast Pathology Rialto Laboratory	540 The Rialto, 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 record review of College of American Pathologists (CAP) proficiency testing records for the subspecialties for Histology(human epidermal growth factor receptor 2 (HER2), estrogen receptor (ER), and progesterone receptor (PGR) for two out of two years (1st and 2nd Events for 2016, and 1st and 2nd Events for 2017) the laboratory failed to verify the accuracy of Histology for proficiency testing that was not scored by the proficiency testing program. Findings included: During the record review of CAP proficiency testing records it was found that for two out of two years (1st and 2nd Events 2016 and 1st and 2nd Event 2017) HER2, and ER/PGR proficiency testing results that were not evaluated or scored by the proficiency testing had not been graded by the laboratory. The following were the ungraded results and the corresponding codes: HER2-A 2016 Event - Specimen # Core 08 HER2-41, Code 21 (Specimen problem), Specimen # Core 03 HER2-02 , Code 27 (Lack of participant or referee consensus), and Specimen # Core 07 HER2-02, Code 27 HER2-B 2016 Event - Specimen# Core 10 HER2--03, Code 27 HER2-A 2017 Event - Specimen# HER2-01, Code 27 PM2-A ER/PGR 2016 Event - Method/Specimen# Core ER Core 2 - % Staining PM2-01, Code 26 (Educational Challenge), Method /Specimen # ER Core 2 - Intensity PM2 - 01, Code 26, Code 26, Method/Specimen # ER Core 4 - Intensity PM2-01, Code 26, Method/Specimen # ER Core 6 - Intensity PM2-01, Code 26, Method/Specimen # ER Core 8 - Intensity PM2-01, Code 26, Method/Specimen # ER Core 9 - Intensity PM2-01, Code 26, Method/Specimen # ER Core 1-Intensity PM2-02, Code 26, Method/Specimen# ER Core 4 - Intensity PM2-02, Code 26, Method/Specimen# ER Core 5 - Intensity, Code 26, Method/Specimen #

ER Core 6 - Intensity, Code 26, Method/Specimen# ER Core 8 - Intensity PM2-02, Method/Specimen# ER Core 9 - Intensity, Code 26, Method/Specimen# ER Core 10 - Intensity, Code 26, Method/Specimen # PGR Core - 1% Staining - PM2-03, Code 27, Method/ Specimen # PGR Core 1 - Intensity, Code 26, Method/Specimen# PGR Core 2 - Intensity, Code 26, Method/Specimen# PGR Core 5 - Intensity, Code 26, Method /Specimen# PGR Core 7 - Intensity, Code 26, Method/Specimen# PGR Core 8 - Intensity, Code 26, Method/Specimen# PGR Core 9 - Intensity, Code 26, Method /Specimen# PGR Core 10 - Intensity, Code 26, Method/Specimen # PGR Core 1 - Intensity, Code 26, Method/Specimen# PGR Core 2 - Intensity, Code 26, Method /Specimen# PGR Core 3 - % Staining, Code 27, Method/Specimen # PGR Core 3 - Intensity, Code 26, Method/Specimen # PGR Core 4 - Intensity, Code 26, Method /Specimen# PGR Core 5 - Intensity, Code 26, Method/Specimen# PGR Core 7- Intensity, Code 26, Method/Specimen# PGR Core 8 - Intensity, Code 26, and Method /Specimen# PGR Core 10 - Intensity, Code 26. PM2-B 2016 ER/PGR Event Method /Specimen # ER Core 1 - Intensity, Code 26, Method/Specimen # ER Core 3 - Intensity PM2-05, Code 26, Method/Specimen # ER Core 4 - Intensity PM2-05, Code 26, Method/Specimen # ER Core 5 - Intensity PM2-05, Code 26, Method/Specimen# ER Core 7 - Intensity PM2-05, Code 26, Method/Specimen # ER Core 8 - Intensity PM2-05, Method/Specimen # ER Core 9- Intensity PM2-05, Code 26, Method /Specimen # ER Core 10 - Intensity -PM2-05, Code 26, Method/Specimen # ER Core 2 - Intensity PM2 -06, Method/Specimen # ER Core 3 - Intensity, Code 26, Method /Specimen # ER Core 4 - Intensity PM2-06, Code 26, Method/Specimen # ER Core 5 - Intensity PM2-06, Code 26, Method/Specimen # ER Core 7 PM2-06, Method /Specimen # ER Core 8 - Intensity PM2-06, Code 26, Method/Specimen # ER Core 9 - Intensity PM2-06, Code 26, Method/Specimen# ER Core 10 - Intensity PM2-06, Code 26, Method/Specimen # PGR Core 1 - Intensity PM2-07, Code 26, Method /Specimen # PGR Core 4 - Intensity PM2-07, Method/Specimen # PGR Core 5 - Intensity PM2-07, Method/Specimen # PGR Core 6 - Intensity PM2-07, Method /Specimen # PGR Core 8 - Intensity PM2-07, Method/Specimen # PGR Core 9 - Intensity PM2-07, Method/Specimen # PGR Core 10 - % Staining PM2-07, Code 21, Method/Specimen# PGR Core 2 - Intensity PM2-08, Code 26, Method/Specimen # PGR Core 3 - Intensity,PM2-08, Code 26, Method/Specimen # PGR Core 5 - Intensity, PM2-08, Code 26, Method/Specimen # PGR Core 6 - % Staining, PM2-08, Code 21, Method/Specimen # PGR Core 6-Intensity PM2-08, Code 26,, Method /Specimen # PGR Core 8 - Intensity PM2-08, Code 26, Method/Specimen # PGR Core 9 - Intensity PM2-08, Code 26, and Method/Specimen # PGR Core 10 - Intensity PM2-08, Code 26. PM2- A 2017 ER/PGR 2017 Event Method/Specimen # ER Core 1- % Staining PM2-01, Code 21, ER Core 2 Intensity PM2-01, Code 26, Method /Specimen# ER Core - 4 Intensity, Code 26, Method/Specimen# ER Core 7 - Intensity, PM2-01, Code 26, ER Core 8 - Intensity PM2-01, Code 26, ER Core -9 Intensity PM2-01, Code 26, Method/Specimen# ER Core 10 - Intensity, PM2-01, Code 26, Method/Specimen# ER Core 1 - Intensity PM2-02, Code 26, Method /Specimen# ER Core 2 - Intensity PM2-02, Code 26, Method/Specimen# ER Core 5 - Intensity PM2-02, Code 26, Method/Specimen# ER Core 6 - Intensity PM2-02, Code 26, Method/Specimen# ER Core 7 - Intensity PM2-02, Code 26, Method /Specimen#ER Core 8 - Intensity PM2-02, Code 26, Method/Specimen# ER Core 9 - Intensity PM2-02, Code 26, Method/Specimen# ER Core 10 - Intensity PM2-02, Code 26, Method/Specimen# PgR Core 3-% Staining PM2-03, Code 27, Method /Specimen# PgR Core 3 - Intensity PM2-03,Code 26, Method/Specimen# PgR Core 4 - Intensity PM2-03, Code 26, Method/Specimen# PgR Core 5 - Intensity PM2-03, Code 26, Method/Specimen# PgR Core 6 - Intensity PM2-03, Code 26, Method /Specimen# PgR Core 7 - Intensity PM2-03, Code 26, Method/Specimen# PgR Core 8 - Intensity PM2-03, Code 26, Method/Specimen# PgR Core 9 - Intensity PM2-03,

	Code 26, Method/Specimen# PgR Core 10 - Intensity PM2-03, Code 26, Method /Specimen# PgR Core 4 - Intensity PM2-04, Code 26, Method/Specimen# PgR Core 5 - Intensity PM2-04, Code 26, Method/Specimen# PgR Core 6 - Intensity PM2-04, Code 26, Method/Specimen# PgR Core 7 - Intensity PM2-04,Code 26, Method /Specimen# PgR Core 8 - Intensity PM2-04, Code 26, Method/Specimen# PgR Core 9 - % Staining PM2-04, Code 21, Method/Specimen# PgR Core 9 - Intensity PM2-04 Code 26, and Method/Specimen# PgR Core 10 - Intensity PM2-04, Code 26. PM2-B 2017 Event Method/Specimen# ER Core 1 - Intensity PM2-05, Code 26, Method /Specimen# ER Core 2 - % Staining PM2-05, Code 21, Method/Specimen# ER Core 4 - Intensity PM2-05, Code 26, Method/Specimen# ER Core 5 - Intensity PM2-05, Code 26, Method/Specimen# ER Core 6 - Intensity PM2-05, Code 26, Method /Specimen# ER Core 9 - Intensity PM2-05,Code 26, Method/Specimen# ER Core 10 - Intensity PM2-05, Code 26, Method/Specimen# ER Core 2 - Intensity PM2-06, Code 26, Method/Specimen# ER Core 3 - Intensity PM2-06, Code 26, Method/Specimen# ER Core 4 - Intensity PM2-05, Code 26, Method/Specimen# ER Core 5 - Intensity PM2 - 06, Code 26, Method/Specimen# ER Core 7 - Intensity PM2-065,Code 26, Method/Specimen# ER Core 8 - Intensity PM2-05, Code 26, Method/Specimen# ER Core 9 - Intensity PM2-06, Code 26, Method/Specimen# PgR Core 1 - Intensity PM2-07, Code 26, Method/Specimen# PgR Core 2 - Intensity PM2 - 07, Method /Specimen# PgR Core 3 - Intensity PM2 -07 Code 26, Method/Specimen#PgR Core 1 - % Staining PM2-08, Code 27, Method/Specimen# PgR Core 1 - Intensity PM2 - 08, Code 26, Method/Specimen# PgR Core 2 - Intensity PM2 - 08, Code 26, Method /Specimen# PgR Core 3 - Intensity PM2 - 08, Code 26, Method/Specimen# PgR Core 4 - Intensity PM2 - 08, Code 26, Method/Specimen# PgR Core 5 - % Staining PM2 - 08, Code 42, Method/Specimen# PgR Core 5 - Intensity PM2 - 08, Code 26, Method /Specimen# PgR Core 6 - Intensity PM2 - 08, Code 26, Method/Specimen# PgR Core7 - Intensity PM2 - 08, Code 26, and Method/Specimen# PgR Core 10 - Intensity PM2 -08, Code 26. During an interview on 04/30/2018 at 11:00, the Business Manager said the laboratory was checking results but not documenting the evaluation.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on College of American Pathologists (CAP) proficiency testing records for General Immunology and Histology two out of two years (2016 A and B Events and 2017 A and B Events) and interview with the Histotechnologist Supervisor and the Histology Technical Supervisor, the Laboratory failed to document corrective action for unsatisfactory scores. Findings included: During CAP proficiency testing record review it was discovered that the laboratory was self grading results and documenting why the result was unsatisfactory but did not provide corrective actions to ensure the incident would not recur. The items that needed corrective actions are the following: FL5 - A 2017 Event Method CD34 Specimen FL5-01 The laboratory result was positive and dim. Only 33% of participants agreed. Most participants called negative. The grade was code 26 (educational challenge). Method HLA - DR Specimen FL5-03 The Laboratory result was positive and normal. Only 13% of participants agreed. ost participants called negative. The grade was code 26. FL5 - B 2017 Event This event was submitted after the evaluation cut-off. Method CD34 Specimen FL5-04 The laboratory result was negative but was a transcription error. The result should have been test not performed. The grade was code 41 (Results for this kit were received

	past the evaluation cut-off date.. HER2 - B 2016 Method Core 02 Specimen HER2 - 04 The laboratory reported Insuff Core Tissue, and the grade was Code 21 (Specimen problem). Method Core 05 Specimen HER2 - 04 The laboratory did not provide a result. Grade was code 11 (Unable to analyze). HER2 - B 2017 Method Core 10 Specimen HER2 - 03 The laboratory reported Insuff Core Tissue and the grade was Code 21. ISH - B 2016 In Situ Hybridization Method ISH HER2 Core 3, ISH-HER2 Core 5, Specimen ISH2-03 The laboratory result was Indet/Unable to analyze and the grade was code 11. Method ISH HER2 Core 4 Specimen ISH2-04 The laboratory result was Indet/Unable to analyze and the grade was code 11. ISH - A 2017 In Situ Hybridization Method ISH HER2 Core 1, ISH HER2 Core 2, ISH HER2 Core 3, ISH HER2 Core 4, ISH HER2 Core 5 Specimen ISH2-01, Laboratory result was Indet /Unable to analyze and the grade was code 11. The laboratory notated that there was a staining failure from the technical laboratory. Method ISH HER2 Core 1 ISH HER2 Core 2, ISH HER2 Core 5, Specimen ISH - 02 The laboratory result was Indet/Unable to analyze and the grade was code 11. During an interview on 04/30/2018 at 11:50 a. m., the Histotechnologist supervisor confirmed that the laboratory did not document corrective actions for the General Immunology transcription error and confirmed that corrective action for other analytes. During an interview on 04/30/2018 at 12:05 p.m., the Histology Technical Supervisor stated the technical component of In Situ Hybridization was outsource and the other laboratory had an instrument the day of ISH - A 2017 proficiency testing. Also stated that the laboratory requested another CAP In Situ Hybridization proficiency testing but CAP would not send another set.
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 Histotechnologist Supervisor 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 12: 40 p.m., the Histotechnologist Supervisor confirmed that the laboratory did not have the criteria for acceptability in the laboratory's manual.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on cryostat instrument logs record review, and interview with the Histotechnologist Supervisor, the laboratory failed to document the humidity in the laboratory. Findings included: During review of the cryostat instrument logs, it was noticed that the laboratory was not documenting the humidity in the laboratory. During an interview on 04/30/2018 at 12:15 p.m., after requesting the cryostat instrument procedure manual, the Histotechnologist Supervisor read the on-line manual which stated the room humidity should not exceed 60%.
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 Histotechnologist Supervisor, 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 12:30 p.m., the Histotechnologist Supervisor confirmed that Quality Assessment periodic monitoring was not being documented.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of

	the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. 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 put in writing the responsibilities of each supervisor (3 out 3, Testing Personnel # 2, #4, and #5). Findings included: During the review of the Quality Assurance procedure manual, it was discovered that Quality Assurance procedure manual did not have the responsibilities in writing for the Technical Supervisor (Testing Personnel #2), and the 2 General Supervisors (Testing Personnel #4 and #5). During an interview on 04/30/2018 at 11:20 a.m., the Business Manager tried to find the written responsibilities but could not.
D6132	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(5) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2) must ensure that each individual examining gynecologic preparations participates in an HHS approved cytology proficiency testing program, as specified in 493.945 and achieves a passing score, as specified in 493.855. This STANDARD is not met as evidenced by: Based on College of American Pathologists (CAP) proficiency testing (PT) records for Cytology for two out of two years (2016 Polyadenylate polymerase (PAP) PT and 2017 PAP PT) the Cytology Technical Supervisors failed to document review of the Cytology proficiency testing. Findings included: During CAP Cytology proficiency testing record review, it was found that the Cytology Technical Supervisors were not documenting review of the 2016 Cytology PAP and 2017 Cytology PAP proficiency test results. During an interview on 04/30/2018 at 10:30 a.m., the Histotechnologist Supervisor confirmed that documentation was missing for the Cytology PAP proficiency test results.