

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2110285	(X3) Date Survey Completed 08/01/2019
Name of Provider or Supplier Suncoast Skin Solutions Inc	Street Address, City, State 500 Vonderburg Dr Ste 302e, Brandon, 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 Suncoast Skin Solutions Inc. clinical laboratory on 07/31/19 to 08/01/19. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D5400 Analytic Systems 493.1250
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to establish performance specifications of the Ep-CAM(Ber-EP4) immunohistochemical (IHC) stain (a histologic stain used to aid in the diagnosis of basal cell carcinoma) which was performed on the Leica Bond - Max instrument. (See D5423).</p>
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as</p>

applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to establish performance specifications prior to reporting patient results for Ep-CAM (BerEP4) immunohistochemical (IHC) stain, a non FDA approved test, which was performed on the Leica-Bond Max automatic stainer from 12/19/18 to 07/31/19. The findings included: A review of the CMS-116 Application for Certification revealed a specialty of Histopathology with the following non-waived testing performed: hematoxylin and eosin (H&E), periodic acid Schiff's reagent, CD3, CD4, CD5, CD7, CD8, CD10, CD20, CD30, CD34, CD68, CK5/6, cytokeratin AE1/AE3, chromogranin, desmin, EMA, Factor 13A, K167, Melan A, S-100, SMA, tyrosinase, Ep-CAM(Ber-EP4), Sox 10, and synaptophysin. Record review of the "Antibody Validation Sign off" form that was signed 09/11/18 by the Lab Manager/Pathologist and Application Specialist showed "Validation In Progress" for the Ep-CAM(Ber-EP4) IHC stain. A review of the Final Pathology Reports revealed that the laboratory had prepared 41 Ep-CAM (Ber-EP4) patient slides (2 slide interpretations were done at the laboratory and 39 were sent to another laboratory for slide interpretation) since 12/19/18. Interview on 07/31/19 at 11:45 am with the Laboratory Manager revealed he was unsure why the laboratory had not established performance specifications for the Ep-CAM(Ber-EP4) IHC stain. On 08/01/19 at 12:00 pm. the Laboratory Director stated he was unaware that the Ep-CAM(Ber-EP4) performance specifications had not been established. Review of the Laboratory Policy and Procedure, effective 05/01/16, titled Instrument /Method/Product Validation Procedure revealed "It is the policy of Suncoast Skin Solution to validate new instruments/methods/products prior to reporting patient results. The validation method includes evaluation of accuracy and precision. Validation records are kept for as long as the instrumentation/method/product is in use, plus an additional 2 years..." The procedure documented that this policy applied to new staining (H&E, special stains, and immunohistochemistry) procedures.