

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0963925	(X3) Date Survey Completed 07/30/2019
Name of Provider or Supplier Forefront Dermatology, Sc DbA Skin Center,	Street Address, City, State 6550 N Federal Hwy Ste 320, Fort Lauderdale, 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 July 30, 2019. Roger H Stewart MD PA was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have a negative control slides for recording the negative reactivity and failed to record the positive and negative reactivity for each for Immunohistochemical (IHC) stains from 7/30/17 to 7/30/19. Findings: Only the microscopic examination of the IHC slides is performed at the laboratory. Review of patient slides showed that there was no negative control slides for 1 (#2) out of 5 (#1, 2, 3, 4, 5) patient slides reviewed. The laboratory was unable to provide a log showing the evaluation of the positive and negative reactive IHC control slides. The laboratory evaluates the following IHC stains: CK 903 ((34betaE12, High Molecular Weight Cytokeratin Squamous Epithelium Carcinoma IHC stain), Melan-A (Melanocytic IHC stain), S100 (Neural Tissue/Lesion and Melanoma IHC stain), and Sox-10 (Melanoma IHC stain). During an interview on 7/30/19 at 11:23 AM, the Testing Personnel C confirmed they don't have separate negative control slides for IHC stained slides and that there was no log for recording the reactivity of positive and negative IHC control slides.</p>
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 record review and interview, the laboratory failed to document and maintain a record of the open dates for reagents used in their Hematoxylin & Eosin (H&E), Periodic Acid Schiff (PAS) and Acid- Fast Bacilli (AFB) stains. Findings: Record review of the laboratory's logs titled "Laboratory Reagent Log" and "Laboratory Reagent Log Sheet" showed that the laboratory failed to record when the reagents were opened from 7/30/17 to 7/30/19. During an interview on 7/30/19 at 10:05 AM, the Testing Personnel C confirmed they didn't record the open date for their reagents on the logs.