

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1106522	(X3) Date Survey Completed 05/05/2021
Name of Provider or Supplier Naples Center For Dermatology And Cosmetic Surgery	Street Address, City, State 950 N Collier Blvd Ste 303, Marco Island, 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 recertification survey was conducted on 5/5/21 at Naples Center for Dermatology and Cosmetic Surgery, a clinical laboratory in Marco Island, Florida. Naples Center for Dermatology and Cosmetic Surgery is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the noncompliance.
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 observations, record review, and interview with the Laboratory Supervisor the laboratory failed to document the lot number and expiration of the reagents being used for Hematoxylin and Eosin (H & E) staining since 04/2019. The findings included: Observations taken during the tour of the laboratory on 5/5/21 at 10:00 a.m., revealed the current reagents being used for H&E staining are 100% Alcohol (Lot# 2036512 expiration 7/8/23), Hematoxylin (Lot# 1915730 expiration 6/12/21), Eosin (Lot#2021707 expiration 8/18/22), Xylene Substitute (Lot#2019706 expiration 7/16 /24), and Scotts Tap Water (Lot#2020628 expiration 7/30/21). Review of the reagent logs revealed that the current lots were not documented when they were put into use. The last date each was updated: 100% Alcohol (Lot# 1920301 no expiration) in May 2020, Hematoxylin (Lot#1915730 no expiration date) in March 2020, Eosin (Lot#1931113 no expiration date) in January 2020, Xylene Substitute (Lot#1833226</p>

no expiration) on November 2019, and Scotts Tap Water (Lot#1903519 no expiration) on April 2019. Interview on 5/5/21 at 12:30 p.m., the Laboratory Supervisor confirmed that the current Lot numbers and expirations were not being captured on the reagent log.