

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D1000815	(X3) Date Survey Completed 03/15/2018
Name of Provider or Supplier Sanford Dermatology Clinic	Street Address, City, State 1310 W 22nd Street, Sioux Falls, SD	
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 for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 3/15/18. The Sanford Dermatology Clinic laboratory was found not in compliance with this requirement: D5471.
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the potassium hydroxide (KOH) reagent, review of the Fungal (KOH) Prep for Dermatophytoses procedure, annual test volume form, and interview with the laboratory director, the laboratory failed to check each lot number or shipment of the KOH reagent for its positive reaction prior to patient testing for 24 of 24 months reviewed (2/1/16 to 3/1/18). Findings include: 1. Review of available records revealed no documentation of quality control (QC) having been done on the KOH reagent in 2016, 2017 or 2018. In addition lot numbers, received and opened dates had not been documented in 2016, 2017, or 2018. Observation of the KOH reagent (lot # 123312, expiration date 2/2/19) at 9:30 a.m. on 3/15/18 revealed no documentation of when the reagent had been received. Review of the Fungal (KOH) Prep for Dermatophytoses procedure (approved 12/30/15) revealed the only required QC was ensuring "the microscope had maintenance performed in the last 12</p>

months." During 2017, 386 KOH patient procedures had been performed. Interview at the above time with the laboratory director revealed he was unaware QC was required upon receipt of a new lot number or shipment.