

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0926810	(X3) Date Survey Completed 03/27/2019
Name of Provider or Supplier Dakota Dermatology Ltd	Street Address, City, State 4950 South Minnesota Ave, 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 3/27/19. The Dakota Dermatology LTD laboratory was found not in compliance with the following 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 KOH reagent log, and interview with the laboratory manager, the laboratory failed to verify the lot number of the KOH reagent for its positive reactivity to ensure accurate results prior to testing patient specimens for 15 of 15 months (1/1/18 to 3/27/19). Findings include: 1. Observation on 3/27/19 at 4:14 p.m. revealed a bottle of KOH reagent (lot K175F1, expiration date 5/31/20) was on the counter by the microscope in the laboratory. It had been available for use on patient specimens. The bottle of KOH reagent was approximately three quarters full. Review of the KOH reagent log revealed the bottle had been received in November 2017. No quality control (QC) had been documented as being done and acceptable from then until 3/27/19. Interview during the survey with the laboratory manager revealed: *They had not done QC on the KOH reagent prior to use on patient specimens. *There had been 240 patient specimens tested with that lot number of KOH reagent from 1/1/18 through 3/27/19.</p>