

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 43D0956802	<b>(X3) Date Survey Completed</b> 06/07/2019
<b>Name of Provider or Supplier</b> Advanced Dermatology Center Pc	<b>Street Address, City, State</b> 710 St Anne Street, Rapid City, SD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 6/7/19. The Advanced Dermatology Center PC laboratory was found not in compliance with the following requirement: D5471.
<b>D5471</b>	<p><b>CONTROL PROCEDURES</b> 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 annual test volume form, review of the procedure manual, and interview with the laboratory director, the laboratory failed to verify each lot number or shipment of the KOH reagent for its positive reactivity to ensure accurate results prior to testing patient specimens for 24 of 24 months (June 2017 through June 2019). Findings include: 1. Observation on 6/7/19 at 9:50 a.m. revealed a bottle of KOH reagent (lot K18731, expiration date 7/31/21) was available for use on patient specimens. The bottle of KOH reagent was approximately three-quarters full. There was no documentation as to whether or not the missing reagent had been discarded or used on patient specimens. Review of available records revealed KOH quality control (QC) had not been documented in 2017, 2018, or to date in 2019 for any lot number or different shipments of the same lot number. Review of the annual testing volume survey form indicated one-hundred KOH patient tests had been performed during 2018 without reagent QC to ensure accurate patient test results. Review of the</p>

procedure manual revealed the Potassium Hydroxide (KOH) Examination procedure had been written October 1993 and had last been reviewed by the laboratory director on 2/7/19. The procedure did not include any instructions for the performance and documentation of QC for the KOH reagent. Interview at the above time with the laboratory director revealed he was unaware QC was required of a new lot number or shipment before use on patient samples. They had not done QC on the KOH reagent as long as he had provided services at the office.