Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D2123371	01/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Avera Medical Group - Pierre Mohs Laboratory	The Helmsley Center, Pierre, 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 1/9/19. The Avera Medical Group - Pierre MOHS laboratory was found not in compliance with the following requirement: D5471.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (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. This STANDARD is not met as evidenced by: Based on interview with testing personnel A and review of annual statistics form and available quality control (QC) forms, the laboratory failed to check each lot number or shipment of the potassium hydroxide (KOH) reagent for its reactivity prior to patient testing for fungal elements for approximately 2.5 of 2.5 months (mid-October 2018 through January 9, 2019.) Findings include: 1. Review of QC records revealed no documentation of QC for the KOH reagent used when reading patient slides for presence or absence of fungal elements. Review of the annual testing volume form indicated an estimated 100 KOH patient tests would have been done within a full twelve months from mid-October 2018 through mid-October 2019. Interview during the morning of 1/9/19 with testing personnel A revealed she had been unaware KOH exams were currently being performed by one of the dermatologists. Her discussion with the dermatologist revealed QC had not been performed on the reagent when a shipment of the existing or new lot number had been received.