Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0407513	08/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Huron Regional Medical Center	172 Fourth Street Se, Huron, 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 8/9/21 through 8/10/21. The Huron Regional Medical Center 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 observation of the potassium hydroxide (KOH) reagent, review of the annual test volume form, quality control (QC) records, and interview with testing personnel A, the laboratory failed to check each lot number or shipment of the KOH reagent for its positive reaction for 32 of 32 months reviewed (1/1/19 to 8/10/21). Findings include: 1. Review of available records revealed no documentation of quality control (QC) had been completed on KOH reagents during 2019, 2020 or to date in 2021. There was no documentation indicating QC had been performed on the current lot number in use before being used on patient specimens. Review of the annual test volume form revealed KOH testing had been performed on three patient specimens during 2020 without reagent QC to ensure accurate patient test results. Observation of open bottle of KOH reagent at 12:30 p.m. on 8/10/21 revealed the reagent was available for use on patient specimens. Interview at 12:10 p.m. on 8/10/21 with testing personnel A revealed: *She confirmed QC had not been verified before the KOH

	reagent had been placed into use for testing patient samples. *They had not performed QC verification on KOH reagent as long as she had worked there. She had worked there approximately 4 years.