Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D2026672	02/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
New Life Family Medicine	118 3rd Street Southeast, 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 2/13/19. The New Life Family Medicine 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, and interview with laboratory staff A, the laboratory failed to check each lot number or shipment of the KOH reagent for its positive reactivity prior to patient testing for 14 of 14 patients tested during 2018. Findings include: 1. Observation on 2/12/19 at 9:05 a.m. revealed a bottle of KOH reagent (lot # 7438-00, expiration date 8/19) was available for use for patient specimens. The bottle of KOH reagent was approximately three quarters full. Review of available records revealed KOH QC had not been documented in 2017, 2018, or 2019 for any lot number, different shipments of the same lot number, or when a different lot number had been received. Review of the annual testing volume survey form indicated fourteen KOH patient tests had been performed duing 2018. Interview at the above time with laboratory staff A revealed she was unaware QC was required of a new lot number or shipment before use on patient samples. The laboratory had not perfomed QC on the KOH reagent in the approximately five years she had worked there.