Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0041555	06/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Coteau Des Prairies Healthcare System	205 Orchard Drive, Sisseton, 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 6/12/18. The Coteau Des Prairies Healthcare System laboratory was found not in compliance with the following requirements: 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 the laboratory manager, the laboratory failed to: *Check each lot number or shipment of the KOH reagent for its positive reactivity prior to patient testing to ensure proper reactivity for eight of eight patients tested during 2017. Findings include:*Check each lot number or shipment of the Microscan gram positive and negative identification (ID) panels for their positive and negative reactivity prior to use for patient testing to ensure accurate identification of microorganisms for 590 of 590 patients tested during 2017. Findings include: 1. Observation of the KOH reagent (lot # 1233120, expiration date 2/2/19) at 12:40 p.m. on 6/12/18 revealed it had been received on 4/26//17. Review of available records revealed: *No documentation of quality control (QC) having been done on the KOH reagent lot number above since it had been received 4/26/17. *KOH QC had not been documented in 2016, 2017, or 2018 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 eight KOH patient tests had been performed duing 2017. Interview at the above time with the laboratory manager revealed she was unaware QC was required of a new lot number or shipment before use on patient samples. 2. Review of the bacteriology QC records revealed Microscan gram positive ID panel (lot #2019-03-09) did not have the positive reactivity checked in the novobiocin, -D-glucaronidase, and arabinase biochemical wells and the negative reactivity checked in the optochin and bacitracin biochemical wells. Review of the product insert revealed four additional organisms were required (S. saprophyticus ATCC 49907, S. xylosus ATCC 49148, S. pneumoniae ATCC 49136, and E. raffinosus ATCC 49464) besides the basic four organisms to monitor the positive and negative reactivity in the wells mentioned above. Review of the bacteriology QC records revealed Microscan gram negative ID panel (lot# 2019-01-09) did not have the positive reactivity checked in the urease, tartrate, and tobramycin biochemical wells and the negative reactivity checked in the nitrate reduction, kanamycin, oxidation/fermentation glucose, penicillin, and cephalothin biochemical wells. Review of the package insert revealed six additonal organisms were required (P. stuartii ATCC 49809, P. putida ATCC 49128, S. putrefaciens ATCC 49138, E. faecalis ATCC 29212, S. aureus ATCC 29213, and R. insidiosa ATCC 49129) besides the basic six organisms to monitor the positive and negative reactivity in the wells mentioned above. Review of the annual testing volume survey form indicated 590 patient microorganism ID panel tests had been performed in 2017. Interview on 6/12 /18 at 12:05 p.m. with the laboratory manager revealed they were unaware additional organisms were required to produce positive and negative reactions in each biochemical well on the Microscan ID panels.