Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407520	(X3) Date Survey Completed 02/11/2019
Name of Provider or Supplier Hrmc Physicians Clinic	**Street Address, City, State** 534 Oregon 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 2/11/19. The Tschetter & Hohm Clinic PC laboratory was found not in compliance with the following requirements: D5447 and D5471.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the creatinine kinase MB (CKMB), myoglobin and troponin (nonwaived test method) quality control (QC) records and interview with the laboratory manager, the laboratory failed to perform two levels of controls or establish an equivalent quality control method to verify the accuracy of CKMB, myoglobin, and troponin test results for 13 of 14 dates (11/13/18, 11/16/18, 11/19/18, 11/23/18, 11/26/18, 11/30/18, 12/10/18, 12/11/18, 12/14/18, 12/15/18, 12/17/18, 12/19/18, and 12/21/18) of patient testing reviewed. Findings include: 1. Review of the CKMB, myoglobin, and troponin QC records revealed QC results had not been documented on the 13 days identified above. Patient test results had been reported to the provider on those days. Interview on 2/11/19 at 0910 with the laboratory manager revealed: *The laboratory runs QC once per month or upon receipt of a new shipment of reagents per the manufacturers requirements in the package insert. *She did not know that CLIA required QC to be performed on each day of patient testing.
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 verify each lot number or shipment of the KOH reagent for its positive reactivity prior to testing 67 of 67 patient specimens tested during 2018. Findings include: 1. Observation on 2/11/2019 at 9:30 a.m. revealed a bottle of KOH reagent (lot # 1824011, expiration date 8/28/19) was available for use on 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 sixty-seven KOH patient tests had been performed during 2018. 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. They had not perfomed QC on the KOH reagent as long as she had worked there.