Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D1067110	02/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Monument Health Rapid City Clinic, 5th Street	2805 5th Street, Rapid City, 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 2/22/18. The Regional Health Medical Clinic laboratory was found not in compliance with these requirement(s): D5217 and D5471.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review, policy review, and interview with the technical consultant, the laboratory (lab) failed to ensure twice a year accuracy checks had been done as required for one of two test methods, potassium hydroxide (KOH) preparations, not included in CLIA proficiency testing programs for nonwaived testing. Findings include: 1. Review of the lab's 2017 KOH Comparison forms revealed KOH accuracy checks had been done on 12/15/17. No other accuracy check documentation had been available. Review of the lab's Quality Assurance policy revealed accuracy checks between the the laboratory and Rapid City Regional Hospital should have been done twice a year. Interview on 2/22/18 at 10:50 a.m. with the laboratory personnel A indicated she had been unaware the KOH accuracy had only been done once during 2017.
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 KOH patient log, and interview with the technical consultant, the laboratory failed to check each lot number or shipment of the KOH reagent for its positive reaction and document the lot number for 24 of 24 months reviewed (1/1/16 to 12/31/17). Findings include: 1. Review of available records revealed no documentation of quality control (QC) having been done on KOH reagents in the year 2016 or 2017. In addition, lot numbers had not been documented in 2016 or 2017. Review of the KOH patient log revealed KOH testing had been performed on twenty seven patient specimens during 2016 and twenty five patient specimens during 2017. Observation of the KOH bottle at 10:50 a.m. on 2/22/18 revealed no documentation of when the bottle had been received. That bottle appeared to be unopened. Interview at the above time with lab personnel A revealed she thought QC upon opening a new bottle or shipment was a recommendation only.