

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0408146	(X3) Date Survey Completed 04/04/2018
Name of Provider or Supplier Monument Health Spearfish Hospital	Street Address, City, State 1440 N Main, Spearfish, 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 4/4/18. The Regional Health Spearfish Hospital laboratory was found not in compliance with these requirements: D5471 and D5477.
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(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.</p> <p>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 testing personnel A, the laboratory failed to check each lot number or shipment of the KOH reagent for its positive reaction prior to patient testing for 23 of 23 months reviewed (5/1/16 to 4/4/18). Findings include: 1. Review of available records revealed no documentation of quality control (QC) having been done on the KOH reagent in 2016, 2017, or 2018. In addition lot numbers received and opened dates had not been documented in 2016, 2017, or 2018. Observation of the box of KOH ampules (lot # 7074640, expiration date 12/31/18) at 2:05 p.m. on 4/4/18 revealed it had been received on 5/5/17. The box of KOH reagent was approximately half full. During 2017, thirty one KOH patient procedures had been performed. Interview at the above time with testing personnel A revealed she was unaware QC was required upon receipt of a new lot number or shipment.</p>
D5477	CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of available QC records and interview, the laboratory failed to check three lot numbers of three types of media (BD Bactec aerobic, anaerobic, and pediatric blood culture bottles) for sterility and their optimum ability to support growth. Findings include: 1. Review of available QC records revealed the media identified above had not been checked to ensure the media performed as the manufacturer had stated for sterility or growth characteristics: a. BD Bactec Plus Aerobic/F bottles- lot # 8011748 b. BD Bactec lytic/10 Anaerobic/F bottles- lot # 7332625 c. BD Bactec Pediatrics Plus/F- lot # 8002689 Interview with testing personnel A on 4/4/18 at 2:05 p.m. revealed QC had not been performed on media before use or concurrent with patient specimens. She did not realize the requirement for documentation of physical characteristics of media, sterility, and ability to support growth of microorganisms upon receipt of a new lot number or shipment included blood culture bottles.