

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0705309	(X3) Date Survey Completed 06/23/2021
Name of Provider or Supplier Rushmore Ob/Gyn	Street Address, City, State 3006 Tower Road, 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	An initial survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 6/23/21. The Rushmore OB/GYN laboratory was found not in compliance with the following 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, record review, and interview, the laboratory failed to verify each lot number or shipment of the potassium hydroxide (KOH) reagent for its positive reactivity to ensure accurate results prior to testing patient specimens for nineteen of nineteen months (12/15/19 through 6/23/21). Findings include: 1. Observation on 6/23/21 at 10:00 a.m. revealed a bottle of KOH reagent (lot number 026-00, expiration date 10/31/21) was available for use on patient specimens. The bottle of KOH reagent was almost empty. There was no documentation as to whether or not the missing reagent had been used on patient specimens or discarded. Review of available records revealed KOH quality control (QC) had not been documented in 2019, 2020 or to date in 2021 for any lot number or different shipments of the same lot number. Review of the reported laboratory test volumes indicated approximately eighty-three KOH patient tests had been performed during the last twelve month period without reagent QC to ensure accurate patient test results. Review of the Clinical Laboratory Improvement Act (CLIA) database revealed the laboratory had</p>

previously held a provider performed microscopy CLIA certificate. Interview on 6/23/21 at 10:15 a.m. with laboratory staff A revealed she: *Confirmed only the providers performed KOH testing. *Confirmed she had not performed KOH QC on the current lot of reagent. *Was not aware of any documentation of KOH QC. Interview on 6/23/21 at 10:30 a.m. with the office manager B revealed the providers had been performing KOH testing since the clinic had opened approximately six years ago. The laboratory director was unavailable for interview at the time of the survey.

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 record review and interview, the laboratory failed to verify one of one microbiology culture media (Lim broth) for its optimum ability to support growth along with inhibitory characteristics. Quality control (QC) had not been performed on this media for 6 months (November 2020 through June 23, 2021). Findings include: 1. Review of the QC logs revealed there was no documentation indicating the laboratory had checked the Lim broth media (lot number 0337980, expiration date 9/3/21) for its ability to support and inhibit growth. Inability of this culture media to support and inhibit specific microorganisms could affect the accuracy of patient results. Review of the reported laboratory test volumes revealed one hundred seventy-five Group B Streptococcus tests had been performed using the Lim broth. Interview with testing personnel A on 6/23/21 at 10:15 a.m. revealed she confirmed Lim broth QC for growth and inhibitory characteristics had not been performed.