

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0663229	(X3) Date Survey Completed 09/02/2020
Name of Provider or Supplier Big Horn Pediatrics Pc	Street Address, City, State 1308 West 4th Street, Gillette, WY	
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
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on Uricult media quality control records review, lack of documentation and interview with staff, the laboratory failed to check each new lot number of media for ability to grow bacteria and inhibition of bacteria unlikely to cause urinary tract infection for 6 of 6 shipments of media received from August 2018 to August 2020. The laboratory performed approximately 100 growth or no-growth urine cultures per year. Findings include: 1. Media quality control records review lacked documentation the laboratory checked each new lot number of Uricult media containing CLED + polymixin and MacConkey media for its ability to support bacterial growth and to inhibit Grams positive organisms for: Lot # Date in use Expiration Date 1832315 08 /17/2018 11/10/2018 1863636 12/18/2018 03/17/2019 1875027 03/18/2019 05/18 /2019 1888335 07/01/2019 07/01/2019 1890089 12/19/2019 03/22/2020 1893782 04 /15/2020 10/19/2020 2. In an interview conducted on 09/02/2020 at approximately 10: 40 A.M., staff confirmed they did not check the ability to support growth or inhibition of CLED plus polymixin and MacConkey Agar media with each new lot number or shipment of media received for urine cultures tested for growth or no growth.</p>