

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0521144	(X3) Date Survey Completed 06/23/2021
Name of Provider or Supplier St Mary's Health	Street Address, City, State 701 Lewiston St, Cottonwood, ID	
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 a record review and an interview with the laboratory manager on 6/23/2021, the laboratory failed to check each lot of prepared plated and liquid medium for its ability to support growth and/or inhibit growth before performing patient testing. The findings include: 1. A review of microbiology quality control (QC) records identified that the laboratory failed to perform and QC to show the ability of the prepared plated and liquid medium to support growth on MacConkey II Agar lot number 1131748 (BD BBL), Blood Agar, 5% Sheep Blood lot number 305635 (Remel), Fluid Thioglycol media lot number 1056319 (BD BBL), Lim Broth lot number 1078394 (BD BBL) and Enterococcosel Agar lot number 1091934 (BD BBL). 2. A review of microbiology QC records identified that the laboratory failed to perform and document QC to show the ability of the media to inhibit growth on selective media, MacConkey II Agar lot number 1131748 (BD BBL) and Enterococcosel Agar lot number 1091934 (BD BBL). 3. An interview with the laboratory manager on 6/23 /2021 at 8:50 am confirmed that the laboratory failed to perform and document QC on prepared plated and liquid medium. 4. The laboratory reports performing 2523 microbiology tests annually.</p>