

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0180295	(X3) Date Survey Completed 09/15/2021
Name of Provider or Supplier Highlands Hospital	Street Address, City, State 401 E Murphy Ave Floor #1, Connellsville, PA	
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 review of Quality Control records, and personnel interview with the Laboratory Supervisor and the Lead Technician, the laboratory failed to perform end user quality control for each batch or shipment of media, before or concurrent with initial use . Findings: 1. Sterility of media and ability to support or inhibit growth was not documented for BD BACTEC Soybean-Casein Digest Broth, used on the Bactec FX40. 2. BD BACTEC Soybean-Casein Digest Broth, aerobic lot # 1061233 & anaerobic lot # 1039579 were used on the Bactec FX40, the date of the survey. 3. 894 incubate only specimens were run on the Bactec FX40 from 03/08/2021 to 09/14 /2021. 4. During the survey (approximately 15:00 09/14/2021), the Laboratory Supervisor confirmed the above findings.</p>