

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0687360	(X3) Date Survey Completed 05/17/2018
Name of Provider or Supplier Unity Health Newport	Street Address, City, State 1205 Mclain, Newport, AR	
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: Through a review of Media QC sheets for media received in 2017 and 2018, through lack of documentation, and through interviews with laboratory staff, it was determined the laboratory failed to check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response. Survey findings include: A. Media QC sheets for TSA (Trypticase Soy Agar) include media received on 3/28/2017, 5/12/2017, 6/13/2017, 7/18/2017, 9/9/2017, 9/14/2017, 10/11/2017, 11/3/2017, 11/27/2017, 1/4/2018, 1/11/2018, 2/2/2018, 2/22/2018, 3/8/2018, 3/29/2018, 4/20/2018, and 5/2/2018. The laboratory documented growth of E. coli and beta hemolysis by Strep pyogenes on lots received 6/13/2017 and 7/18/2017 (two of seventeen shipments of TSA). B. Media QC sheets for Maconkey Agar include media received on 2/9/2017, 3/28/2017, 5/12/2017, 6/20/2017, 8/23/2017, 9/1/2017, 10/11/2017, 10/20/2017, 11/6/2017, 11/27/2017, 1/4/2018, 1/18/2018, 2/2/2018, 3/8/2018, 4/11/2018, and 5/2/2018. The laboratory documented growth of E. coli, inhibition of Proteus mirabilis, and inhibition of Enterococcus faecalis on the lot received 5/12/2017 (one of sixteen shipments of Maconkey Agar). C. Media QC sheets for Chocolate Agar include media received on 2/9/2017, 3/28/2017, 5/19/2017, 7/24/2017, 9/13/2017, 11/6/2017, 1/4/2018, and 2/22/2018. The laboratory did not document growth of Neisseria</p>

gonorrhoeae or *Haemophilus influenzae* (zero of eight shipments of MacConkey Agar).
D. In an interview at 1:51 p.m. on 5/16/2018, laboratory employee #2 (as listed on the form CMS-209) confirmed the laboratory does not perform quality control cultures on each lot and shipment of media and further confirmed the laboratory did not have an Individualized Quality Control Plan for bacteriological media quality control.