

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0302324	(X3) Date Survey Completed 03/15/2023
Name of Provider or Supplier Decatur Diagnostic Laboratory Inc	Street Address, City, State 2828 Highway 31 South, Decatur, AL	
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 review of Microbiology quality control records, and interviews with Testing Personnel #1 and the Technical Consultant, the laboratory failed to: (1) document the physical inspection of culture media on four shipments received in 2022; (2) implement a mechanism to document the sterility of each lot number of media since the previous survey on 4/7/2021 to the date of the current survey on 3/15/2021; and (3) implement a mechanism to check each lot number of media for its ability to support growth and, as appropriate, select or inhibit the growth of specific organisms since the previous survey on 4/7/2021 to the date of the current survey on 3/15/2021. The findings include: 1. A review of Microbiology records revealed no documentation of culture media quality control (QC) records. During an interview at 2:00 PM the surveyor requested these records from Testing Personnel #1, who provided the Remel shipment invoices. 2. A review of the Remel shipment invoices revealed the testing personnel usually completed the "INSPECTED BY" and "DATE" fields on the invoices, however there was no documentation of inspection on four 2022 shipments, as follows: 5/26/2022, 9/7/2022, 11/22/2022, and 12/8/2022. There was no other documentation of Media QC procedures. 3. During an interview on 3/15/2022 3:20 PM, the surveyor asked the Technical Consultant if the laboratory had procedures that specified: (A) the appropriate physical characteristics of the media the testing</p>

personnel "inspected"; (B) how the laboratory determined and documented the "sterility" of the culture media; and (C) how the laboratory determined and documented the ability of each lot number of culture media (Chocolate agar, MacConkey agar and Columbia Naladixic Acid [CNA]) to support growth and, as appropriate, select or inhibit the growth of specific organisms. The Technical Consultant confirmed the laboratory did not have the above procedures, and had not performed media QC because they had not realized it was required. SURVEYOR ID# 32558 Licensure and Certification Surveyor