

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0688523	(X3) Date Survey Completed 02/09/2022
Name of Provider or Supplier Montgomery Pediatric Associates	Street Address, City, State 420 Cotton Gin Road, Montgomery, 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
D5479	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the Bacteriology Quality Control (QC), the Blood Agar Instructions for Use, and an interview with Testing Personnel #1, the laboratory failed to follow the manufacturer's specifications, and document visual inspections when using the Blood Agar for Throat Cultures. This was noted from the previous survey (08/21/2019) to the current survey (02/09/2022). The findings include: 1. A review of the Bacteriology QC revealed the laboratory did not document visual inspections of the Blood Agar Media to check for signs of contamination and deterioration, upon receipt. 2. A review of the Blood Agar Instructions for Use revealed, under User Quality Control, "...Hardy Diagnostics recommends end users check for signs of contamination and deterioration..." 3. During an interview on 02/09/2022 at 10:50 AM, Testing Personnel #1 stated the Testing Personnel performed visual inspections, however they failed to document the checks since the laboratory changed from HealthLink (when a label was provided) to Hardy Diagnostic media at the end of 2019.</p>