

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0857452	<b>(X3) Date Survey Completed</b>  07/25/2024
<b>Name of Provider or Supplier</b>  Alabama Pediatrics	<b>Street Address, City, State</b>  2815 Independence Drive, Birmingham, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5477</b>	<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 the USP (Urine Split Plate) QC (Quality Control) log, the USP patient log, and an interview with Testing Personnel #1, the laboratory failed to document media lot numbers and expiration dates for every lot number prior to use for patient testing. This was noted for 58 days of 16 months reviewed in 2023 through 2024. The findings include: 1. A review of the USP QC log revealed no documentation of media from when the last lot expired to when the new lot was put into use for the following: a) Lot# 517460 was put into use 1/4/23 and expired 2/12/23; 24 days later, b) Lot# 521291 was put into use 3/8/23 and expired 4/24/23; 9 days later, c) Lot# 524542 was put into use 5/3/23 and expired 6/14/23; 25 days later, d) Lot# 621077 was put into use 2/3/24 and expired 4/30/24. 2. A review of the patient log revealed 36 patient urine cultures were performed on the 58 days of no media documentation. 3. During an interview on 7/25/2024 at 2:41 PM, TP #1 confirmed media documentation was missed.</p>