

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0303094	(X3) Date Survey Completed 04/12/2018
Name of Provider or Supplier Field Pediatrics Pc	Street Address, City, State 1106 Gleneagles Drive, Huntsville, 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 the laboratory's optional IQCP (Individualized Quality Control Plan) for the Bacteriology media, patient results logs and an interview with the Laboratory Director, the surveyor determined the laboratory failed to document each lot number/expiration of Uricult media, and failed to check and document each lot number for the ability to support growth in 2017 and 2018 (in the absence of an alternative provision in the IQCP). The findings include: 1. During the initial tour of the laboratory on 4/12/2018 at 9:15 AM, the laboratory included Urine Colony Count on Uricult media as an on-site testing procedure. 2. A review of the laboratory's optional IQCP (Individualized Quality Control Plan) for the Bacteriology media (implemented in 10/18/16) revealed a QC Plan that specified each lot number of media would be visually inspected. However, the plan did not specify the Laboratory Director would accept the manufacturer's quality control procedures (proving the media's ability to support growth), replacing the requirement for the laboratory to perform this test on each lot number of media on site. 3. A review of the patient results logs revealed the testing personnel performed and documented visual inspections of the media each time a culture was set up, however there was no documentation of the lot number and expiration of the Uricult media used for the patient testing in 2017 and 2018. This information should have been recorded on the</p>

back of the patient log sheets where space was provided for the Uricult media's "date opened, lot number, and expiration". The laboratory further failed to specify the date the media's ability to support growth was checked (in the absence of an alternative provision in the IQCP). 4. During an interview on 4/12/2018 at 11:45 AM, the Laboratory Director was asked if staff documented the appearance and quality of each lot number of Uricult media. The Director reviewed the records with the surveyor and stated the testing personnel documented the media quality every time a culture was plated on the agar. When asked what lot number was in use, the Director reviewed the back of the sheet and confirmed the staff had failed to record the in-use date, lot number and expiration of the Uricult media. He then consulted the staff setting up the cultures who confirmed they had forgotten to record this information in 2017-2018. The surveyor then asked if staff checked the Uricult media's ability to support growth, and the Director stated that was done when the media was used for a culture. When asked if staff are documenting this date, the Director confirmed they were not. Thus the above noted findings were confirmed. SURVEY:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor