

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0862498	<b>(X3) Date Survey Completed</b>  07/15/2021
<b>Name of Provider or Supplier</b>  West Rock Pediatrics And Adolescent Care	<b>Street Address, City, State</b>  8 Lunar Drive, Woodbridge, CT	
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 record review and staff interview, the laboratory failed to check each lot number and shipment of media for its ability to support growth and, as appropriate, select or inhibit specific organisms in the specialty of microbiology. Findings include: 1. Review of the laboratory's quality control (QC) procedure for Uricult media on 7/15/21 revealed the following. "On receipt examine 1 paddle for freedom from contamination and for smooth, moist surface (similarly, examine each paddle before use), then dip paddle into a mixture of E. Coli WR 1802 and Streptococcus pyogenes ATCC 19615 suspended together in sterile diluent and incubate unit at 35 degrees for 24 hours. Colonies typical for E. Coli must grow on both the Levine EMB and the CLED culture medium in the Uricult medium. The Strep. pyogenes must not grow on either side of the paddle." 2. Review of the QC records for Aidian Uricult media (Lot # 1900513 with an expiration of 11/15/21) on 7/15/21 revealed the laboratory failed to document the ability of the media to support growth, select or inhibit specific organisms for each lot number. 3. Staff interview with the laboratory director (LD) on 7/15/21 at 11:15 AM confirmed the above findings. The LD stated he/she did not recall the Individual Quality Control Plan (IQCP) setup in the past and reverted back to testing for growth. The LD further stated the laboratory is only reporting colony counts and only documented the physical condition of the Uricult media when</p>

received. 4. The laboratory performs 60 Uricult cultures annually in the specialty of Microbiology. 5. This is a repeat deficiency.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to evaluate the competency of testing personnel (TP) to perform moderate complexity testing annually. Findings include: 1. Record review of the laboratory's TP competency records on 7/15/21 revealed 2 of 3 TP performing moderate complexity testing were not evaluated to assess their competency in all six required competency assessment criteria. TP#1 was hired on 8/1/19 and TP# 2 was hired on 9/2/20. 2. Staff interview with laboratory director (LD) on 7/15/21 at 11:30 AM confirmed 2 of 3 TP were not evaluated in all six required competency assessment criteria to perform moderate complexity testing. The LD further stated all three TP are performing moderate complexity testing in the specialty of Microbiology. 3. The laboratory performs 146 tests in the specialty of Microbiology annually. 4. This is a repeat deficiency.