Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0862498	01/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
West Rock Pediatrics And Adolescent Care	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The Laboratory of Sydney Z. Spiesel, Ph.D., M.D., was surveyed pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) on January 30, 2018.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to check each new lot number and shipment of bacitracin discs for positive and negative reactivity in the subspecialty of bacteriology. Findings include: 1. Surveyor observation on 1/30/18 at 11:15 AM revealed the laboratory is using Taxo-A discs with lot number 6356539 expiring on 7/31/18. 2. Record review of the laboratory's quality control (QC) log for Taxo-A discs on 1/30/18 revealed documentation for positive and negative QC analysis for the above lot of bacitracin discs was not available. 3. Staff interview with the laboratory director on 1/30/18 at 11:15 AM conformed the above findings. 4. The laboratory performs 443 throat cultures annually in the subspecialty of bacteriology.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)

	(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. This STANDARD is not met as evidenced by: Based on record review and laboratory director (LD) 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 quality control records for Healthlink Strep Select Agar (SSA) on 1/30/18 revealed the laboratory failed to document the ability of the media to support growth, select or inhibit specific organisms for each lot number and shipments received in 2016 and 2017. This is a repeat deficiency. 2. Review of the quality control records for Orion Diagnostica Uricult media on 1/30/18 revealed the laboratory failed to document the ability of the media to support growth, select or inhibit specific organisms for each lot number and shipments received in 2016 and 2017. 3. Staff interview with the LD on 1/30/18 at 11:00 AM confirmed the laboratory did not check each new lot number or shipment of SSA or Uricult media for their ability to support growth and, as appropriate, select or inhibit specific organisms. The LD stated the laboratory relied on the manufacturer's testing and only documented the physical condition of the media when received. The LD confirmed the laboratory is not following the individualized quality control plan (IQCP) submitted with the last onsite survey in 2016. 4. The laboratory performs 547 cultures annually in the specialty of microbiology.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director (LD) failed to assess and evaluate the competency of all testing personnel (TP) to ensure performance all testing operations are conducted reliably and accurately. Findings include: 1. Record review of CMS-209 form (Laboratory Personnel Report) on 1/30 /18 revealed the laboratory employed 2 TP to perform moderate complexity tests. 2. Record review of TP competency records on 1/30/18 revealed the laboratory failed to provide evidence of documentation of 2 of 2 TP annual competency evaluations to assess their knowledge and skills. 3. Staff interview with the LD on 1/30/18 at 10:15 AM confirmed: a. Annual competency evaluation of 2 of 2 TP was not performed or documented in 2016 and 2017. b. 2 of 2 TP performed testing in 2016 and 2017. 4. The laboratory performs 547 tests annually in the specialty of microbiology.