

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0391462	<b>(X3) Date Survey Completed</b>  06/29/2023
<b>Name of Provider or Supplier</b>  Tosa Pediatrics	<b>Street Address, City, State</b>  8651 W North Ave, Wauwatosa, WI	
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>D6000</b>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of laboratory records, procedures, and manufacturer instructions, and interview with the technical consultant and laboratory director, the director did not provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The laboratory cultured vaginal and rectal samples using a test system intended to culture and presumptively identify Group A Beta Hemolytic Streptococcus from throat samples without evaluating the test system accuracy for samples from non-throat sources. See D 6007.</p>
<b>D6007</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(1)</p> <p>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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of laboratory records, procedures, and manufacturer instructions, and interview with the technical consultant and laboratory director, the director did not ensure the laboratory evaluated the use of the Beta Hemolytic Group A Streptococcal Culture procedure performed on vaginal and rectal samples to ensure the test system provided quality laboratory results. Seven of nineteen samples the laboratory cultured for Group A Beta Hemolytic Streptococcus from April 29, 2022 through June 16, 2023 were from vaginal or rectal samples. Findings include: 1. Review of the 'Tosa Pediatric Culture Log' from April 29, 2022, through June 16, 2023, showed the laboratory documented cultures on the follow specimen types: Vaginal Strep, or VC: April 29, 2022, and February 16, 2023 Rectal Culture, RC, or Rectal Strep: June 10, August 5 and 18, 2022, and February 7 and 23, 2023. The log showed six additional cultures identified as "Strep" without identifying a source, and six "TC" (throat cultures). 2. Review of the procedure manual revealed a procedure, "Group A Beta Screen [Throat Culture]". The Specimen Collection portion of the procedure only addresses collection of throat specimens. No procedures were evident for collection or testing of rectal or vaginal specimens. 3. Review of the manufacturer's instructions, 'Bacitracin disc for identification' showed the intended use to be, "...the differentiation and presumptive identification of bacteria isolated in throat cultures". 4. Review of laboratory records showed no evaluation of the performance of Streptococcus Group A cultures on vaginal or rectal cultures to determine accuracy, precision, specificity, or sensitivity of the test system with vaginal or rectal samples. 5. Interview on June 29, 2023, at 10:00 AM with the laboratory director and the technical consultant confirmed the laboratory used the 'Group A Beta Screen [Throat Culture]' procedure for rectal and vaginal area skin specimens and confirmed the laboratory had not evaluated the test system for sources other than throat to ensure the procedure provided accurate results.