

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0124054	(X3) Date Survey Completed 01/02/2024
Name of Provider or Supplier Tiefenbrunn & Fortin Pediatrics	Street Address, City, State 503 Cranbury Road, East Brunswick, NJ	
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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to maintain a NJCLL for calendar year 2023 or any prior years. The Laboratory manager confirmed on 1/2/24 at 11:30 am that the laboratory did not maintain a NJCLL for 2023 or any prior years.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Manufacturers Package Insert (MPI) and interview with the Laboratory Manager (LM) the laboratory failed to retain Certificates of Analysis (COA) for Uricult media used for Bacteriology tests from 2/10/22 to the date of the survey. The findings include: 1. The MPI for Uricult media states "remove certificates of analysis from package insert for each new lot and attach to QC records." 2. The LM confirmed on 1/2/24 at 11:00 am that the COA for Uricult media were not retained.</p>

<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Uricult Manufacturers Specifications (MS) and interview with the Laboratory Manager (LM) the laboratory failed to have written procedures for resulting urine cultures using Uricult media from 1/2/24 to the date of survey. The LM confirmed on 1/2/24 at 12:00 pm, the laboratory failed to have written procedures for resulting urine cultures using Uricult media.</p>
<p>D5477</p>	<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 surveyor review of the Quality Control (QC) records, the Procedure Manual and interview with the Laboratory Manager (LM), the laboratory failed to check each new lot number and shipment of Selective Strep Agar (SSA) media for its ability to inhibit specific organisms from 2/10/22 to the date of the survey. The findings include: 1. The laboratory failed to use at least one organism to confirm the inhibitory characteristic of SSA media. 2. The LM confirmed on 1/2/24 at 11:30 am the laboratory did not perform the above mentioned QC on SSA media.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of a Quality Assessment (QA) plan, review of the Procedure Manual and interview with the Laboratory Manager (LM), the Laboratory Director (LD) failed</p>

to establish a QA program to assure the quality of laboratory services provided from 2/10/22 to the date of the survey. The LM confirmed on 1/2/24 at 11:00 am that the LD failed to establish a QA program.