

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0124054	(X3) Date Survey Completed 08/20/2025
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
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. In addition, retain the following:</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 1/3/24 to 8/20/25. 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. COA for lots 1925761 and 1926104 were not retained. 3. The LM confirmed on 8/20/25 at 11:00 am, the COA for all Uricult media were not retained. Note: This deficiency was previously cited on the survey performed on 1/2/24.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Manager (LM), the laboratory failed to review all unsatisfactory scores and document corrective action taken for PT results obtained from the College of American Pathologists (CAP) for Bacteriology tests from 4/28/25 to 8/20/25. The findings include: 1. The laboratory received unacceptable results for Throat Culture</p>

sample TC-01 for event MC4-A 2024. 2. There was no documented corrective action taken by the laboratory. 3. The LM confirmed on 8/20/25 at 12:15 pm, the laboratory did not review all unsatisfactory scores and document any corrective action taken.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Manager (LM), the laboratory failed to establish corrective action procedures for Proficiency Testing (PT) from 1/3/24 to 8/20/25. The finding includes: 1. The laboratory did not establish a procedure that stated what corrective actions to take for unsatisfactory PT scores. 2. The LM confirmed on 8/20/25 at 11:35 am, the laboratory did not establish corrective action procedures for PT.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM), and interview with the Laboratory Manager (LM), the laboratory lacked a written Quality Control (QC) procedure for performing QC on Uricult media for Bacteriology tests from 1/3/24 to 8/20/25. The findings include: 1. The laboratory did perform QC on Uricult media but there was no written procedure in the PM for performing QC for Uricult media on each new lot and/or shipment. 2. The LM confirmed on 8/20/25 at 11:25 am, the PM lacked a written QC procedure for Uricult media.

D5787

TEST RECORDS

CFR(s): 493.1283(a)

(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on surveyor review of Test Records (TR) and interview with the Laboratory Manager (LM), the laboratory failed to maintain an accurate record system for Bacteriology tests from 8/1/25 to 8/20/25. The findings include: 1. Surveyor review of ten TR for Throat cultures and Urine Colony Count revealed the TR did not have a culture read date or time. 2. The LM confirmed at 11:45 am on 8/20/25, the laboratory did not maintain accurate record system.