

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2289086	<b>(X3) Date Survey Completed</b>  06/04/2025
<b>Name of Provider or Supplier</b>  Denville Pediatrics	<b>Street Address, City, State</b>  299 Cherry Hill Road, Parsippany, NJ	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) 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), and interview with the Nurse Manager (NM), the laboratory failed to have a procedure for verification of performance specifications for tests performed by the laboratory from May 2024 to 6/4/25. The NM confirmed on 6/4/25 at 10:35 am, the laboratory did not have the above mentioned procedure.</p>
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Reports (FR) and interview with the Nurse</p>

Manager (NM), the laboratory failed to ensure the FR had all the required information from May 2024 to 6/4/25. The finding includes: 1. The laboratory failed to have the correct address on the FR. a) The laboratory is located at 299 Cherry hill road, Suite 203 Parsippany, NJ, 07054 b) The laboratory had an address of 141 East Main Street Denville, NJ, 07834 on the FR. 2. The NM confirmed on 6/4/25 at 11:10 PM that the laboratory failed to have the correct address on the FR

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:  
Based on the lack of Performance Specification (PS) records and interview with the Nurse Manager (NM), the Laboratory Director (LD) failed to ensure that PS was performed on Urine Cultures from May 2024 to 6/4/25. The NM confirmed on 6/4/25 at 10:35 am that PS was not performed.