

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0716803	(X3) Date Survey Completed 02/05/2025
Name of Provider or Supplier Irondequoit Pediatrics, PLLC	Street Address, City, State 809 East Ridge Road, Rochester, NY	
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
D3039	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)</p> <p>(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel training and competency records, laboratory policies and procedures manual, as well as interview with the Laboratory Director (LD), the laboratory failed to retain quality system assessment records for at least two years. FINDINGS: 1. There was no documentation of TP training and competency assessment performance for 2023 and 2024. 2. This is contrary to instructions indicated in the current, approved Quality Management Plan. 3. The LD confirmed the findings on February 5, 2025, at approximately 11:45 A.M.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel training and competency records, standard operating procedures (SOPs), as well as interview with the LD, the laboratory failed to comply with instructions indicated in the current, approved SOPs for employee and consultant competency assessment. FINDINGS: 1. There was no documentation of TP training and competency assessment performance for 2023 and 2024. 2. The TP training and competency assessment documentation for 2025 did not include the required six</p>

guideline criteria. 3. There was no documentation of training and competency assessment performance for the Clinical Consultant (CC) and Technical Consultant (TC). 4. These are contrary to instructions indicated in the current, approved SOPs. 5. The LD confirmed the findings on February 5, 2025, at approximately 12:00 P.M.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of waived and non-waived test manufacturer package insert specifications, Individualized Quality Control Plan (IQCP), lack of temperature and humidity records, as well as interview with the LD, the laboratory failed to monitor and document temperatures and humidity in the areas where waived and non-waived test kits were stored, patient specimens processed, and waived and non-waived testing performed. FINDINGS: 1. The Cepheid GeneXpert Assay IQCP specified acceptable temperature 20C - 28C and humidity 20% - 80%. 2. There was no documentation of room temperature and humidity in the areas where waived and non-waived test kits were stored, patient specimens were processed, and waived and non-waived testing were performed. 3. This is contrary to instructions indicated in the current, approved Quality Management Plan. 4. The LD confirmed the findings on February 5, 2025, at approximately 1:45 P.M.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of personnel training and competency records, SOPs, as well as interview with the LD, the LD failed to comply with instructions indicated in the current, approved SOPs for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency. Refer to D5209.