

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1030051	(X3) Date Survey Completed 11/12/2025
Name of Provider or Supplier East Lake Pediatrics	Street Address, City, State 4156 Woodlands Pkwy Ste B, Palm Harbor, FL	
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
D0000	An announced CLIA recertification survey was conducted at East Lake Pediatrics on 11/12/2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. A Standard deficiency was cited as follows:
D6005	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c)</p> <p>(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to establish a policy to be onsite once every six months and failed to document any onsite visits from 1/1/2025 to 11/12/2025. Findings included: 1. The Laboratory Policy and Procedure policy signed by the Laboratory Director on 5/02/2022, failed to contain a policy to be onsite once every six months and to document any onsite visits. 2. Testing Personnel B and E, who were staff onsite during the recertification survey, on 11/12/2025 at 11:40 a.m., stated the Laboratory Director came onsite to the laboratory frequently but there was no documentation of the visits and what was performed during the visits.</p>