

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0268586	<b>(X3) Date Survey Completed</b>  04/15/2026
<b>Name of Provider or Supplier</b>  Pediatric Associates Inc	<b>Street Address, City, State</b>  1714 Main St, Jacksonville, FL	
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>D0000</b>	An announced CLIA recertification survey was conducted at Pediatric Associates on 4/15/2026. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D2010</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(2)</p> <p>(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure that proficiency testing (PT) samples were tested in the same manner as patient specimens for 10 of 10 samples reviewed (#HSY 06 through #HSY 15) during the 2025 second and third hematology events, when the laboratory tested each sample five separate times. Findings include: 1. A review of the American Proficiency Institute (API) hematology proficiency testing records on 4/15/2026 revealed that during the second testing event of 2025, the laboratory failed to run PT samples in the same manner as patient samples. Instrument printouts dated 7/16/2025 showed that samples HSY 06, HSY 07, HSY 08, HSY 09, and HSY 10 were each run five times at the following intervals: Sample HSY 06: 08:37:21, 14:28:02, 14:39:31, 14:41:28, and 14:53:33. Sample HSY 07: 08:40:25, 14:31:14, 14:55:18, 14:57:02, and 15:00:13. Sample HSY 08: 08:44:41, 14:33:23, 15:02:39, 15:04:24, and 15:05:42. Sample HSY 09: 08:48:20, 14:34:57, 15:08:16, 15:06:58, and 15:09:30. Sample HSY 10: 08:50:46, 14:36:17, 15:10:45, 15:17:43, and 15:19:05. 2. A review of the API hematology proficiency testing records on 4/15/2026 revealed that during the third testing event of 2025, the laboratory failed to test PT samples in the same manner as patient specimens. Instrument printouts dated 11/04/2025 showed that samples HSY 11, HSY 12, HSY 13, HSY 14, and HSY 15 were each run five times at the following intervals: Sample HSY 11: 12:10:41, 12:13:31, 12:15:15, 12:17:11, and 12:18:52. Sample HSY 12: 12:21:06, 12:22:46, 12:24:28,</p>

12:25:56, and 12:27:41. Sample HSY 13: 12:30:53, 12:32:07, 12:33:23, 12:36:13, and 12:37:53. Sample HSY 14: 12:45:16, 12:46:27, 12:48:43, 12:50:00, and 12:52:05. Sample HSY 15: 12:55:06, 13:02:42, 13:08:47, 13:14:46, and 13:16:28. 3. The laboratory's PT attestation statements for these events, signed by the testing personnel and the laboratory director, certified that "as closely as possible, these proficiency testing samples were tested in the same manner as patient specimens". 4. In an interview on 4/15/2026 at 11:20AM, the Laboratory Lead Supervisor confirmed that the laboratory routinely tests patient specimens twice if the results are abnormal. The staff member acknowledged that the repeated testing of the 2025 second and third event hematology PT samples was not consistent with the laboratory's routine patient testing procedures.