

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D1086599	<b>(X3) Date Survey Completed</b>  12/29/2022
<b>Name of Provider or Supplier</b>  Childrens Medicine Pc	<b>Street Address, City, State</b>  1500 Peachtree Industrial Boulevard Suite 250, Suwanee, GA	
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>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on December 29, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D5807</b>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on patient final lab reports review in 2021, 2022 and interviews with the office manager and laboratory's Technical Consultant(TC), the laboratory failed to provide the units of measure and reference ranges for CBC results from the Cell-Dyn Emerald Hematology analyzer. Findings: 1. Review of patient final reports in 2021 and 2022 revealed reports did not have the units of measure and reference ranges for each analyte and differential of the Complete Blood Count (CBC) from the Cell-Dyn Emerald Hematology Analyzer. 2. Interviews with the office manager, (TS), and (TPs #3 and #6 CMS 209) on 12/29/2022, at approximately 12:00 PM, in the break room, confirmed that the units of measure and the reference ranges for each analyte and differential were not on the final reports that were randomly selected for review in 2021 and 2022 from the Cell-Dyn Emerald Hematology Analyzer.</p>