

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0492538	<b>(X3) Date Survey Completed</b>  12/29/2022
<b>Name of Provider or Supplier</b>  Ut Physicians Bay Area Pediatrics	<b>Street Address, City, State</b>  17150 El Camino Real, Houston, TX	
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>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the manufacturer's Operator's manual, the laboratory's policy, maintenance logs from January 2022 to November 2022, and confirmed in an interview found the laboratory failed to perform one of two semi-annual maintenance in 2022 for one of one Abbott Cell Dyn Emerald hematology analyzer. The findings were: 1. Review the manufacturer's operator's manual titled CELL-DYN Emerald Operator's Manual (9140853D-December 2009) under chapter 9 Service and Maintenance page 9-13 revealed Semi-Annual Maintenance, "Lubricating the Pistons: For optimal operation, the Syringe Pistons should be lubricated every six months as described below." 2. Review the laboratory's policy titled VI. Hematology A. Celldyn Emerald CBC machine under Limitations of Procedure revealed "3. Follow the recommended maintenance schedules and procedures as outlined in Section 9, Service and Maintenance of the Celldyn Emerald System Manual." 2. Review of the laboratory's maintenance logs from January 2022 to November 2022 revealed the laboratory failed to perform one of two semi-annual maintenance required by the manufacturer on one of one Abbott Cell Dyn Emerald hematology analyzer (SN: 034410-001540). 3. An interview with the laboratory director on 12/29/22 at 12:21 pm in a storage room confirmed the above findings.</p>