Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0477059	**(X3) Date Survey Completed** 04/11/2023
Name of Provider or Supplier Clinical Pediatric Assoc Of North Texas	**Street Address, City, State** 2020 W State Hwy 114 Suite 300, Grapevine, TX	
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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy, patient test reports, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for flags on the Cell-Dyn Emerald hematology analyzer for 1 of 19 patients reviewed in January 2023. Findings included: 1. Review of Cell-Dyn Emerald Operator's Manual page 3-13 revealed: "WBC Measurand Flags An asterisk (*) for count invalidation or (s) suspect measureand [sic] flags are displayed with the corresponding results. These flags are generated after the instrument evaluates the measured data for a particular measurand or group of measurands. The result may be suspect due to interfering substances or the inability of the instrument to measure a particular measurand due to a sample abnormality. The name of each flag, how it is displayed, the cause of the flag, and the action to be taken are given in the following explanations. NOTE: Count Invalidation (*) flags will supersede Suspect Measureand [sic] (s) flags if generated at the same time." Page 13-4 revealed Table 3.4 WBC Flags ... Measurand: Differential Result Flag: s Text in Flags Box: L2 (white text) Result Displayed: XXXXX Cause: May indicate the presence of myelocytes, lymphoblasts, or basophils. Action: Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required. 2. Review of the laboratory's

	"CBC Flag Protocol" policy revealed: "WBC Flags for CELL-DYN Emerald Flags indicate a problem with the testing. An asterisk invalidates the result. An (s) indicates a suspect result. Any flagged result should not be recorded in the patient's chart. All flagged results will be blacked out by testing personnel so that providers will not see or use these results. Compliance will be monitored on quarterly audit. Any flagged or suspect result should be brought to the ordering provider's attention for instruction whether to redraw, redraw and send to a reference lab or cancel the test depending on the clinical situation. Refer to June 2010 section of the operator's manual attached for possible causes of the flagging. All redraws will be at the discretion of the ordering provider." 3. Review of patient Cell-Dyn Emerald hematology analyzer test reports revealed patient test results with flags were reported in January 2023. The following flagged results were reported: 01/26/2023 Patient ID: 61362 Parameter: LYM; Result: 5.9 10*3 u/L; Flag: s Parameter: MID; Result: 2.0 10*3 u/L; Flag: s Parameter: GRA; Result: 7.0 10*3 u/L; Flag: s Parameter: LYM%; Result: 39.7%; Flag: s Parameter: MID%; Result: 13.6%; Flag: s Parameter: GRA%; Result: 46.7%; Flag: s 4. During an interview on 04/11/2023 at 12:10 pm, Testing Person-1 after review of records, confirmed the above findings.