Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0671810	11/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Uf Health Pediatrics - Millhopper	5528 Nw 43rd Street, Gainesville, 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	At the time of the announced, on-site recertification survey, Nancy M. Worthington, M.D., was found NOT in compliance with the CLIA laboratory requirements of 42 CFR 493. .
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed proficiency testing for the analytes of Hematocrit (HCT) and Red Blood Cell Count (RBC) in the specialty of Hematology for the first event of 2018, failed proficiency testing for the analyte of Platelets for the third event of 2018, and failed proficiency testing for the analytes granulocytes, lymphocytes, and monocytes for the first event of 2019. The findings include: The 11/13/19 record review of the One World Accuracy/Accutest proficiency scores for Event 1 of 2018 showed the facility scored a 60% for the analyte Hematocrit and 60% for the analyte RBC. The review of the 3rd event of 2018 showed the facility scored a 60% for the analyte Platelets. The review of the 1st event of 2019 showed a score of 0% for the analytes of granulocytes, lymphocytes, and monocytes. The interview with the Laboratory Director on 11/13/19 at 12:45 pm confirmed the proficiency failure and determined the failure of the 1st event of 2019 was due to a transcription error. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification

	procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to document calibration verification procedures at least once every six (6) months. The findings include: Review of the CellDyne Emerald calibration records showed the most recent CellDyne calibration to be in September 2019. The previous documented calibration record showed a date of October 2018. There was no documentation showing calibration prior to October 2018 or 6 months after October 2018. Interview with the testing person at 1:50pm on 11/13/19 indicated that calibration had been performed because the instrument requires it, but was unable to locate the missing documentation.