

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0930930	(X3) Date Survey Completed 10/24/2019
Name of Provider or Supplier University Of Miami Chds Pediatrics	Street Address, City, State 8932 Sw 97 Ave Ste D, Miami, 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	A recertification survey was conducted on October 24, 2019. University of Miami CHDS Pediatrics clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>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 run proficiency testing samples the same number of times, as it routinely tests patient samples for 2018 (3rd event) and 2019 (1st, 2nd and 3rd event) for the specialty of Hematology. Findings: Review of the laboratory's proficiency testing with American Proficiency Institute (API) for 2018 3rd event and 2019 1st, 2nd and 3rd events showed that the laboratory re-ran proficiency sample more than once by different testing personnel. Review of the hematology analyzer's instrument printout for the 1st and 2nd events in 2019 showed two sets of results from the same date with the names of the testing personnel written on it. During an interview on 10/24/19 at 1:50 PM, Laboratory Director stated that they rotated whose proficiency testing results were submitted, but that all testing personnel present when the proficiency testing samples arrived ran the proficiency samples.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When</p>

control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to perform quality control lot to lot comparisons from 7/18 to 10/24/19 for hematology controls. Findings: Review of the quality control logs showed that there were no lot to lot comparisons of the hematology controls for the Cell Dyn 3200 hematology analyzer. The "Cell Dyn 3200 System Operators Manual" states "New lots of controls should be analyzed in parallel with the current lots prior to their expiration. During an interview on 10/24/19 at 3:57 PM, Laboratory Director acknowledged that the laboratory did not perform control lot to lot comparisons of the hematology controls.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory's patient reports failed to list the reference ranges used to interpret the hematology test results for 2 (A, C) out of 3 (A, B, C) patients. Findings: Review of the laboratory test results showed the reference ranges used to interpret test results for 2 (A,C) out of 3 (A, B, C) patients were missing. During an interview on 10/24/19 at 3:57 PM, the Testing Personnel A acknowledged that the patient reports did not have the reference ranges listed.