

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1026971	(X3) Date Survey Completed 05/15/2018
Name of Provider or Supplier Boys & Girls Pediatric Clinic Pa	Street Address, City, State 5850 Fm 802 Suite C-6-7, Brownsville, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's verification records, review of patient test results, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of completing verification studies prior to patient testing on the Medonic M-series hematology analyzer. 1. Review of laboratory policy, "Validation of a New Test System" (no approval date) stated, "Verification of manufacturer's normal values: This will be determined by demonstrating that 5 non-patient results are within the manufacturer's normal values." 2. Review of the laboratory's verification records for Medonic M-series hematology analyzer implemented in June 2017 revealed the laboratory verified the following patient ranges: 1 - 2 years 3 - 4 years 5 - 11 years 12 years Adult Female Adult Male 3. Further review of the verification records revealed the laboratory failed to provide documentation of verifying the following reference range: 2-6 months 4. Review of patient records revealed the following patients were tested using the unverified patient normal range: Testing Date: 10/14/2017 Date of Birth: 08/03/2017 Patient Age: 2 months, 11 days 5. An interview with the technical consultant on 05/18/2018 at 1030 hours in the office manager's office confirmed the findings.</p>