

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0955750	<b>(X3) Date Survey Completed</b> 10/28/2019
<b>Name of Provider or Supplier</b> Brownsville Childrens Clinic	<b>Street Address, City, State</b> 4430 E 14th St Ste A, Brownsville, 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 at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS 2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> 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 the laboratory's verification records for the Medonic M Series hematology analyzer, and staff interview, it was revealed the laboratory failed to have documentation of complete verification studies prior to performing patient testing. The findings were: 1. A review of the laboratory's verification studies for the Medonic M Series hematology analyzer (serial number: 28793) performed in May 2017</p>

revealed the laboratory failed to have documentation of evaluating newborn patient normal ranges. 2. An interview with Testing Personnel #2 (as listed on Form CMS-209) on 10/28/2019 at 15:34 hours in the conference room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS-209, review of laboratory personnel records, and confirmed in interview of facility personnel, the technical consultant failed to perform testing personnel competency assessments at least twice the first year of patient testing 2 of 5 testing persons listed on Form CMS-209. The findings were: 1. Review of the laboratory's submitted Form CMS-209, signed by the laboratory director on October 28, 2019, revealed the laboratory designated 5 testing persons for moderate complexity testing in hematology. 2. Review of personnel records for Testing Personnel 3 (as listed on Form CMS-209) revealed the testing person had a start date of March 1, 2017. 1st Competency Assessment: 11-05-2017 2nd Competency Assessment: 06-02-2018 (3 months, 1 day later) 3. Review of personnel records for Testing Personnel #4 (as listed on Form CMS-209) revealed the testing person had a start date of November 6, 2017. 1st Competency Assessment: 05-10-2018 2nd Competency Assessment: 12-10-2018 (1 month, 4 days later) 4. The technical consultant failed to perform testing personnel competency evaluations at least twice the first year of patient testing for Testing Personnel 3 and Testing Personnel 4 (as listed on Form CMS-209). 5. An interview with the technical consultant on October 28, 2019 at 14:00 hours in the conference room confirmed the findings. She revealed she thought competency assessments were annually. Key: CMS - Centers for Medicare and Medicaid Services