

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1026975	(X3) Date Survey Completed 05/15/2018
Name of Provider or Supplier M T B Silverio Pediatrics Pa	Street Address, City, State 145 Uptown Ave, 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
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy,5 review of verification studies, review of personnel records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of training records for each testing person prior to patient testing when the laboratory implemented a new hematology analyzer in September 2016. The findings were: 1. Review of the laboratory's policy for new instrument implementation under, "Methods and Procedures" stated, "Before a new test or methodology is put to use, this facility will train laboratory staff responsible for the performance of the test. Documentation will be made in the Personnel section of this manual." 2. Review of the verification studies for the Medonic M-series hematology analyzer (serial number: 28235) revealed the laboratory implemented the analyzer on September 29, 2016. Under the training section, the following employees (as listed on the Form CMS-209) had signed the training document: Testing person 1 Testing person 3 Testing person 5 3. Review of the laboratory's personnel records revealed the following testing persons had no training documentation available for review for the Medonic M-series hematology analyzer: Testing person 2 Testing person 4 Testing person 6 4. An interview with testing person 1 (as listed on Form CMS-209) on 05/15/2018 at 1315 hours in the break room confirmed the findings.</p>

She confirmed that the testing persons had been trained but the training was not documented.