

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0991906	<b>(X3) Date Survey Completed</b> 11/28/2018
<b>Name of Provider or Supplier</b> Filosa Childrens Clinic	<b>Street Address, City, State</b> 1240 Business 83 Suite B, Mission, 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>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for Siemens 10SG Multistix. The findings were: 1. Surveyor observation on November 28, 2018 09:45 hours in the laboratory revealed the following expired Siemens 10SG Multistix: Lot 704047 Expiration Date: 10-31-18 2. The manufacturer's instructions for the Siemens 10SG Multistix under, "Storage" stated, "Do not use the strps after their expiratio date." 3. The laboratory performed 11 patient tests from November 1, 2018 to November 28, 2018 when the test strips were expired. 4. An interview with the technical consultant on 11/28/2018 at 09:50 hours in the break room confirmed the findings.</p>
<b>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and confirmed in interview of facility personnel, the laboratory failed to ensure expired items were not available for use in patient testing.</p>

The findings were: 1. Surveyor observation in the laboratory on 11/28/2018 at 09:45 hours during the initial tour of the laboratory revealed the following expired items: Universal Transport Medium (UTM) Lot 170307 Expiration Date: 09-07-2018 Quantity: 13 Purple Top Tubes (K2 EDTA) Lot 6124782 Expiration Date: 09-2017 Quantity: 38 Tiger Top (Serum Separator Tubes) Lot 6274792 Expiration Date: 09-30-2017 Quantity: 97 2. Interview with the technical consultant on 11/28/2018 at 09:50 hours in the break room confirmed the findings.