

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D1075648	(X3) Date Survey Completed 11/29/2018
Name of Provider or Supplier Memphis Childrens Clinic	Street Address, City, State 9860 East Old Goodman Road, Olive Branch, MS	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the AcT Diff 2 analyzer records from 1/20/17 through 11/29/18 and confirmation with staff at 10:30am, the laboratory failed to retain the quality control (QC) assay sheets for the AcT Diff 2 controls for at least 2 years.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of calibration records for the AcT Diff 2 hematology analyzer since the last survey on 1/19/17, and lack of documentation of calibration, the laboratory</p>

failed to document, as performed, calibration on the AcT Diff 2 analyzer every 6 months. Findings include: Review of calibration records for the AcT Diff 2 hematology analyzer revealed the analyzer had not been calibrated since 12/4/17. This time period exceeds the laboratory policy and the manufacturer's calibration requirement of every 6 months.