

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D1002756	(X3) Date Survey Completed 06/07/2018
Name of Provider or Supplier Oxford Pediatric Group Plc	Street Address, City, State 101 Farm View Drive, Oxford, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of Beckman Coulter AcT Diff Coulter ES Cell QC (quality control), control assay sheets and confirmation with testing personnel #1 at 12:00 pm, the laboratory failed to follow the manufacturer's instructions for the opened vial stability for the hematology QC material from 3/28/18 through 5/9/18. Findings include: The Beckman Coulter AcT Diff control 4C ES Cell manufacturer's instructions state the hematology controls (low normal, high) should only be used for 35 days or a maximum of 20 entries after opened. The following AcT Diff hematology controls were in use past the open vial stability expiration date: Beckman Coulter 4C ES Cell Control - Opened and used on 3/28/8 through 5/9/18: Low Control lot number 069300 exp date 6/18/18 Normal lot number 079300 exp date 6/18/18 High lot number 089300 exp date 6/18/18 According to staff the control vials were used until empty which exceeded the opened vial expiration dates required by the manufacturer. Approximately 150 patient samples were run during this time period from 3/28/18 through 5/9/18.</p>