

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0662461	<b>(X3) Date Survey Completed</b>  11/14/2019
<b>Name of Provider or Supplier</b>  Bh Pediatric Clinic	<b>Street Address, City, State</b>  1500 Dodson Ave, Suite 260, Fort Smith, AR	
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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Through observation, lack of documentation and interview it was determined the laboratory failed to monitor room temperature in one of two rooms in which supplies with storage temperature requirement were stored. Findings follow: A) During a tour of the laboratory on 11/14/19 at approximately 09:30 AM, two boxes of Coulter AcT Diff Reagent kit lot # 8547135 with an expiration date of 2020-05-06 with a storage temperature requirement of 2 degrees C. to 25 degrees C. were observed stored in a radiology area separate from the laboratory . B) Upon request, the laboratory was unable to provide records of room temperature in the radiology area. C) In an interview on 11/14/19 at approximately 09:30 AM, the laboratory staff member, identified as number three on the CMS 209 form, stated that the laboratory did not monitor the room temperature in the radiology area identified above.</p>