

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D0699364	<b>(X3) Date Survey Completed</b> 02/10/2021
<b>Name of Provider or Supplier</b> Hot Springs Pediatric Clinic Pa	<b>Street Address, City, State</b> 1920 Malvern Avenue, Hot Springs, 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>D0000</b>	. This is the recertification survey of the laboratory conducted on 2/10/2021. At the time of the recertification survey the laboratory was not in compliance with the following condition. 493.1421 Laboratory Testing Personnel
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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: . Through a review of Calibration documentation for the Coulter ACT Diff 2 Hematology analyzer and interviews with staff, it was determined the laboratory performed the Hematology Calibration on Calibration materials that had exceeded their expiration date. Survey findings follow: A. A review of the Calibration documentation for the Coulter ACT Diff 2 Hematology analyzer revealed the laboratory used expired calibration materials ( Coulter S-Cal Kit Lot# 4787 expiration date 6/30/2020) to perform the calibration on 6/27/2020. B. In an interview on 2/10/21 at 10:00 laboratory employee #2 (as listed on CMS 209) confirmed that she was aware the calibration material had exceeded the expiration date.</p>
<b>D6063</b>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p>

This CONDITION is not met as evidenced by:  
. Through a review of personnel files for eight of eight laboratory employees (listed on the form CMS-209), lack of documentation, and through interviews with staff, it was determined the laboratory testing personnel lacked documentation of appropriate education to qualify as a testing personnel. As cited at: D6065: testing personnel qualifications

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:  
. Through a review of personnel files for eight of eight laboratory employees (listed on the form CMS-209), through a lack of documentation, and through interviews with staff, it was determined that laboratory testing personnel #5 lacked documentation of appropriate education to qualify as moderate complexity testing personnel. As evidenced by: A. A review of eight of eight personnel records revealed documentation of appropriate education was not available for laboratory testing personnel #5 (as listed on the form CMS-209). B. In an interview at 11:45 on 02/10/2021, laboratory personnel #2 (as listed on the form CMS-209) confirmed the lack of documentation of appropriate education for testing personnel #5.