

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D1032166	<b>(X3) Date Survey Completed</b>  02/02/2023
<b>Name of Provider or Supplier</b>  Healthykids Of Gardendale	<b>Street Address, City, State</b>  1127 Pecan Avenue, Gardendale, AL	
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>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: Based on a review of the Hematology calibration and Quality Control (QC) records, and an interview with Testing Personnel #1, the laboratory used expired QC and expired calibration material on the Beckman Coulter AcT Diff Hematology analyzer. The surveyor noted the laboratory utilized an expired kit for one of three calibrations in 2022, and expired QC for one day of patient testing in January 2023. The findings include: 1. A review of the Hematology Calibration and QC records revealed the following: a) The Hematology AcT Diff analyzer was calibrated on 11/17/2022; the calibrator used expired on 11/12/2022. b) QC was performed on 1/17/2023; all three levels of QC expired on 1/16/2023. A review of the patient log revealed one patient CBC (Complete Blood Count) was performed on 1/17/2023. 2. During an interview on 2/2/2023, at 11:55 AM, Testing Personnel #1 confirmed the above findings.</p>
<b>D6054</b>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with Testing Personnel</p>

#1, the technical consultant failed to ensure all testing personnel had documentation of annual competency assessments. The surveyor noted no documentation of the 2021 annual competency assessment for one of six testing personnel listed on the CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of the personnel records revealed Testing Personnel #2's annual competency evaluations were performed in September 2020 (reviewed during the previous survey) and in July 2022. There was no documentation of a 2021 annual competency assessment. 2. During an interview on February 2nd, 2023, at 11:50 AM, Testing Personnel #1 confirmed the above findings.