

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D0475217	<b>(X3) Date Survey Completed</b> 10/17/2023
<b>Name of Provider or Supplier</b> Okmulgee Pediatrics & Family Care	<b>Street Address, City, State</b> 916 E 8th St, Okmulgee, OK	
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>	The recertification survey was performed on 10/17/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and testing person #1 at the conclusion of the survey.
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with testing person #1, the laboratory failed to ensure waived test kits were stored as required by the manufacturer, in a room denoted as the store room. Findings include: (1) Observation of the store room and interview with testing person #1 on 10/17/2023 at 09:30 am, identified the following: (a) Six boxes of Quidel QuikVue Strep A, lot # 708663, storage temperature of 15-30 degrees Celsius; (b) Two boxes of BD Veritor Sars-Co-V-2 , lot # 3251389, storage temperature of 2-30 degrees Celsius; (c) Seven boxes of BD Veritor Sars-CoV-2 &amp; Flu A+B lot # 3185306, storage temperature of 2-30 degrees Celsius. (2) Interview with testing person # 1 on 10/17/2023 at 09:30 am confirmed the laboratory was not monitoring the temperature of the store room.</p>
<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>

This STANDARD is not met as evidenced by:

Based on observation and interview with testing person #1, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the laboratory on 10/17/2023 at 09:00 am, identified the following expired collection swabs that appeared to be available for use: (a) Diagnostic Hybrids 3ml UTM Swabs - lot # 212015 with an expiration date of 07/31/2023. (b) Diagnostic Hybrids 3ml VCM Swabs - lot # 214375 with an expiration date of 07/31/2023. (2) Interview with testing person #1 10/17/2023 at 09:00 am confirmed the Diagnostic Hybrid swabs were available for use.