

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2150941	<b>(X3) Date Survey Completed</b>  02/14/2022
<b>Name of Provider or Supplier</b>  Wake Diagnostics Inc	<b>Street Address, City, State</b>  5129 Nc Highway 55, Suites 103-104, Durham, NC	
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>D5423</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of patient test reports and interview with General Supervisor (GS)2/14/22, the laboratory failed to establish performance specifications for the stability of SARS-CoV-2 specimens not processed within the laboratory's established stability criteria. Findings: Review of laboratory procedure "Collection, Storage, and Shipping of Nasopharyngeal (NP) and Anterior Nasal (AN) Specimens" revealed "4. Storage...Store specimens at 2-8 degrees celcius (C) for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at negative (-) 20 degrees C or below.". Review of random patient test reports revealed specimens for SAR-CoV-2 testing were tested greater than 72 hours after collection. For example: 1. Specimen #362752 was collected on 12/28/21, test results were reported 1/2/22 approximately 120 hours after collection. 2. Specimen #362748 was collected on 12/28/21, test results were reported 1/3/22 approximately 144 hours after collection. 3. Specimen #362463 was collected on 12/28/21, test results were reported 1/2/22 approximately 120 hours after collection. 4. Specimen #362460 was collected on 12/28/21, test results were reported 1/3/22, approximately 144 hours after</p>

collection. Interview with GS at approximately 1:00 p.m. confirmed specimens were tested greater than 72 hours after collection. The GS also confirmed specimens greater than 72 hours after collection were not stored at -20 degrees C or below. He stated from 12/25/21 through 1/7/21 the facility was completely overwhelmed with the volume of testing during this time period.