

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>11D0879716</p>	<p>(X3) Date Survey Completed</p> <p>11/05/2019</p>
<p>Name of Provider or Supplier</p> <p>Northside Hospital - Alpharetta</p>	<p>Street Address, City, State</p> <p>3400 C Old Milton Parkway Suite 100, Alpharetta, GA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on November 05, 2019. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:</p>
<p>D5293</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on quality assurance (QA) document review and laboratory consultant interview, the laboratory failed to document all general laboratory systems QA activities as required. Findings include: 1. QA documents review revealed there was no QA documentation available at the time of survey for 2018 and 2019. 2. An interview with the laboratory consultants in a conference room on 11/5/2019 at approximately 12:20 p.m. confirmed there was no QA documentation available for the aforementioned period, 2018 and 2019.</p>
<p>D5417</p>	<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 the laboratory tour, inspection of the flammable cabinet and an interview with the general supervisor, it was determined that the laboratory failed to check its testing supply inventory properly for expiration dates before use. Findings include: 1. Laboratory tour revealed: 5% apple cider vinegar expired 12/1/2016, Xylene expired 10/2018, Eosin-Y expired 04/2019 and Hematoxylin 7211 expired 12/2018. 2. An interview with the general supervisor at approximately 12:23 pm on 11/5/2019 during the tour confirmed the reagents were expired.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's maintenance and Quality Assurance(QA) records and an interview with the general supervisor, the laboratory director failed to ensure that Monthly (QA) reports and maintenance logs in 2018 and 2019 were reviewed and signed. Findings include: 1. Monthly maintenance and Quality Assurance(QA) logs were not reviewed and signed in 2018 and 2019 by the Technical Supervisor(TS), who also serves as the laboratory director. 2. An interview with the general supervisor on 11/5/ 2019 at approximately 12:35 pm, in the conference room confirmed that maintenance logs and QA logs were not reviewed and signed by the (TS), who is also the laboratory director in 2018 and 2019.