

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0907757	(X3) Date Survey Completed 03/23/2021
Name of Provider or Supplier Brookhaven Tn Opco Llc	Street Address, City, State 2035 Stonebrook Place, Kingsport, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D1001	<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:</p> <p>===== Based on review of the manufacturers package insert for BinaxNOW COVID-19 Ag Card test and interviews with the Director of Nursing and Risk Manager determined that the laboratory failed to follow manufacture package insert for specimen collection for COVID-19 Ag Card test. The findings include: 1. Review of the manufacturers package insert for BianaxNOW COVID-19 Ag Card test states to use "nasal swab specimens." 2. Interviews with the Director of Nursing and Risk Manager on March 17, 2021 at 10:00 am confirmed that the laboratory failed to follow manufacturers package insert instructions for collecting nasal swab specimens. Director of Nursing and Risk Manager stated, "nasopharyngeal swab specimens" were used for BianaxNOW COVID-19 Ag Card testing. =====</p>