

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2107298	<b>(X3) Date Survey Completed</b>  01/15/2025
<b>Name of Provider or Supplier</b>  Humboldt Family Walk-In Clinic	<b>Street Address, City, State</b>  1600 Coleman Drive, Humboldt, TN	
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>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>493.15(e) 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 of the laboratory, review of the manufacturer's package insert, the United States (U.S.) Food and Drug Administration (FDA) database, laboratory patient activity logs, and staff interviews, the laboratory did not follow the manufacturer's instructions for the CorDx COVID-19 Ag Test kit when it performed approximately 265 COVID-19 Ag tests on patients under the age of two since testing began on 09/17/2024. The findings include 1. Observation of the laboratory on 01/15/2025 at 9:15 a.m. revealed the CorDx COVID-19 Ag Test kit used for patient testing. During the observation, the technical consultant state that the laboratory performed COVID-19 testing on all patient age groups with the CorDx COVID-19 Ag Test kit. Testing person three stated that the laboratory began using the test kit in September 2024. 2. A review of the CorDx COVID-19 Ag Test kit manufacturer package insert in the section "WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION" revealed, "Do not use on anyone under 2 years of age." 3. A review of the FDA database revealed the CorDx COVID-19 Ag Test kit was classified as CLIA waived effective 07/02/2024. 4. A review of a patient activity log from 09/17/2024 through 12/31/2024 revealed that the laboratory had tested approximately 265 patients, and three of the patients tested were under two years old. 5. An interview with the technical consultant on 01/15/2025 at 11:30 a.m. confirmed the survey findings. Word Key: COVID-19 - Severe acute respiratory syndrome Coronavirus (SARS-CoV-2) Ag - Antigen CLIA - Clinical Laboratory Improvement Amendments</p>