

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2233521	(X3) Date Survey Completed 03/03/2022
Name of Provider or Supplier Being Human Medical, Llc, Am Laboratory	Street Address, City, State 6027 N Cicero Ave, Chicago, IL	
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
D6087	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on interview, observation, and record review, the laboratory director failed to ensure that laboratory personnel are performing SARS-CoV-2 antigen testing as required for accurate and reliable testing at one of two sites surveyed. Findings: 1. During a tour of site B on March 3, 2022 at approximately 11:30 A.M., the surveyor observed the Indicaid (Trademark) COVID-19 Rapid Antigen Test in use. 2. During interview on March 3, 2022 at approximately 11:35 A.M., Testing Personnel #2 (TP2) stated that the antigen test was read 10-15 minutes after the sample was added to the cassette. 3. On March 3, 2022 at approximately 11:36 A.M., the surveyor observed the timer at site B was set for 15 minutes. 4. The surveyor requested the manufacturer's instructions for the Indicaid (Trademark) COVID-19 Rapid Antigen Test at approximately 11:37. TP2 was unable to locate the instructions. 5. Review of the Indicaid (Trademark) COVID-19 Rapid Antigen Test Instructions for Use obtained at site A stated "Read the test line (T) and control line (C) results promptly at 20 minutes, and not earlier to ensure proper test performance." 6. At approximately 11:52 A.M. on March 3, 2022, TP2 stated that site B started using the Indicaid (Trademark) COVID-19 Rapid Antigen Test approximately three weeks ago.</p>