

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2108538	(X3) Date Survey Completed 09/23/2020
Name of Provider or Supplier Get Well Urgent Care Madison Heights	Street Address, City, State 350 East 12 Mile Rd, Madison Heights, MI	
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
D0000	The purpose of this unannounced survey was for complaint #MI00114441. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003).
D1000	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c)</p> <p>Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to ensure all authorized fact sheets were included with patient test result reports required by the manufacturer for 2 (July 2020 to September 2020) of 2 months the laboratory has been testing COVID-19 specimens. Findings include: 1. A review of the laboratory's "Quidel Sofia 2 SARS Antigen FIA" package insert revealed a section stating, "Authorized laboratories and patient care settings using your product will include with test result reports, all authorized fact sheets." 2. An interview on 9/23/20</p>

at 10:06 am with the Office Manager revealed the laboratory did not distribute the authorized fact sheets with patient test result reports.