U.S. FOOD & DRUG ADMINISTRATION

April 22, 2021

Garry A. Courtney
Director, Regulatory Affairs
Megna Health, Inc.
436 Creamery Way, Suite 200
Exton, PA 19341

Device:	Rapid COVID-19 IgM/IgG Combo Test Kit
EUA Number	EUA200308
Company:	Megna Health, Inc.
Indication:	This test is indicated for the following indications for use: For certain authorized laboratories (see below) – Qualitative detection and differentiation of Immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies to SARS-CoV-2 in human serum and acid citrate dextrose (ACD) plasma. Intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. For certain authorized laboratories (see below) – Qualitative detection and differentiation of Immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies to SARS-CoV-2 in fingerstick whole blood. Intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing of serum and plasma is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests. Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings