2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Plasma/ Serum) Package Insert

[Image of packaging]

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1. INTRODUCTION
The 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Plasma/ Serum) is a qualitative immunochromatography assay for the detection of 2019-nCoV IgG and IgM antibodies in whole blood, plasma or serum of human subjects. This test is composed of two components: an IgG component and an IgM component. The IgG component anti-human IgG is coated in test line region. The control line region contains anti-human IgG. The specimen is added to the test cassette, and the reaction is monitored visually. The test results are classified as negative (absence of visible line in control region) or positive (visible line in control region). The test cassette is intended for use in clinical laboratories or other settings where rapid results are needed. This test is only for use in individuals aged 18 years and older who have been diagnosed with COVID-19. It is not intended for self-testing.

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