



NIV/DVG/ER/E-137

27th August, 2020

**PERFORMANCE EVALUATION REPORT FOR ANTIBODY-BASED RAPID
DIAGNOSTIC KIT**

- **Name of the kit :-** COVID-19 IgG/IgM Rapid Test
- **Name of the manufacturer:-** Meril Diagnostics Pvt. Ltd.
- **Batch numbers :-** 1) MRD-116 2) MRD-117 3) MRD-118
- **Application:-** Rapid Immunoassay for qualitative detection of antibodies (IgG and IgM) to SARS-COV-2 virus in whole blood/serum/plasma
- **Kit components:-** Individually packed test devices with desiccant, buffer, disposable capillary tubes, package insert
- **Sample Panel**
 - **Positive samples :-** 100 (Serum/Plasma samples of patients who tested positive in COVID-19 RTPCR)
 - **Negative samples (provide details) :-** 100 (Serum/Plasma samples from patients who tested negative in COVID-19 RTPCR, healthy individuals (collected before COVID-19 outbreak) and patients with confirmed Influenza A, Influenza B, Measles, Rubella and Chikungunya infections)
- **Results**

COVID-19 IgG/IgM Rapid Test

Batch	MRD-116 (IgG/IgM)			MRD-117 (IgG/IgM)			MRD-118 (IgG/IgM)		
	Positive	Negative	Total	Positive	Negative	Total	Positive	Negative	Total
Positive	97	02	99	95	03	98	95	05	100
Negative	03	98	101	05	97	102	05	95	100
Total	100	100	200	100	100	200	100	100	200

Batch	MRD-116 (IgG/IgM)		MRD-117 (IgG/IgM)		MRD-118 (IgG/IgM)	
	Estimate (%)	95% CI	Estimate (%)	95% CI	Estimate (%)	95% CI
Sensitivity	97	91.48 – 99.38	95	88.72 – 98.36	95	88.72 – 98.36
Specificity	98	92.96 – 99.76	97	91.48 – 99.38	95	88.72 – 98.36





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Disclaimers

1. ICMR's validation process does not approve / disapprove the kit design.
2. ICMR's validation process does not certify user friendliness of the kit / assay.
3. Validation of a kit by ICMR is not an assurance that the kit specifications would be included in the tendering process.

Note: This report is exclusively for COVID-19 IgG/IgM Rapid Test [Lot No: - 1) MRD-116 2) MRD-117 3) MRD-118] manufactured by Meril Diagnostics Pvt. Ltd. (Supplied by Meril Diagnostics Pvt. Ltd.)

Evaluation Done on 25th August, 2020

Evaluation Done by

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