VAN OOSTVEEN MEDICAL B.V.
MEDICAL DISPOSABLES

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CLINICAL RESULTS

– ROMED COVID-19 IGG/IGM RAPID TEST CASSETTE (WHOLE BLOOD/SERUM/PLASMA)

1. INITIAL FACTORY CLINICAL PERFORMANCE STUDY

The Romed COVID-19 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) has been evaluated with the 113 blood samples obtained from patients exhibiting pneumonia or respiratory symptoms. The results were compared to RT-PCR or clinical diagnosis (including chest Computed Tomography and clinical signs etc.) of "Diagnosis and treatment of novel coronavirus pneumonia".

Regarding the IgM test, the result comparison to RT-PCR.

Method		RT-PCR		Total
		Positive	Negative	
COVID-19 IgG/IgM Rapid Test	Positive	87	0	87
	Negative	12	14	26
Total		99	14	113

Regarding the IgG test, we have counted the positive rate of the 36 of 113 patients during the convalescence period.

Method		Number of patients during the convalescence period	Total
COVID-19 IgG/IgM Rapid Test	Positive	35	35
	Negative	1	1
Total		36	36

The sensitivity of IgM test is 87.9% (87/99) and specificity is 100%(14/14) comparison to RT-PCR.
The sensitivity of IgG test is 97.2% 35/36 during the convalescence period, and specificity is 100% 14/14.

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2. CLINICAL PERFORMANCE STUDY – THE NETHERLANDS

The antibody test has been evaluated in the Netherlands by the Serology Taskforce, which is part of the Dutch National Testing Capacity Coordination Structure (Landelijke Coördinatiestructuur Testcapaciteit, LCT) The current version of their report regarding the status of the validation of point-of-care serology tests for diagnostics of SARS-CoV-2 is version 8 of 15 July 2020. The summary of the results for this product is as follows:

a. The IgG sensitivity (100%, n=63) meets the predetermined criteria for diagnosis in patients with severe infections where samples were collected >14 days after onset of illness. The IgM sensitivity (88.9%), or IgM/IgG combined reported only (90.5%, n=21) do not meet the predetermined criteria for diagnosis in patients with severe infections where samples were collected >14 days after onset of illness. Confirmation with a larger number of samples is needed.
b. The IgM and IgG sensitivities are 52.9% and 47.1% (n=17) or 60.1% for IgM/IgG combined reported only (n=158) for patients where samples were collected ≤14 days after onset of illness. Confirmation with a larger number of samples is needed.
c. The sensitivities for IgM and IgG (94.6% and 93.2%, n=74), or for IgM/IgG combined reported only (77.8%, n=9) do not meet all predetermined criteria in populations with mild symptoms or asymptomatic infections where samples were collected after >14 days. Confirmation with a larger number of samples is needed.
d. The IgG specificity (98.6%, n=136) meets the predetermined criteria, while the IgM specificity (92.6%) and IgM/IgG combined reported only (97.3%, n=73) do not meet the predetermined criteria. Confirmation with a larger number of samples is needed.

3. CLINICAL PERFORMANCE STUDY - US

The antibody test has also been placed on the US market and it has been evaluated by the US FDA. In their evaluation, the US FDA have used 30 positive samples and 80 negative samples. The positive samples have been collected between 19 and 36 days after onset of symptoms.

Measure	Estimate	Confidence Interval
IgM Sensitivity	100% (30/30)	(88.7%; 100%)
IgM Specificity	100% (80/80)	(95.4%; 100%)
IgG Sensitivity	96.7% (29/30)	(83.3%; 99.4%)
IgG Specificity	97.5% (78/80)	(91.3%; 99.3%)
Combined Sensitivity	100% (30/30)	(88.7%; 100%)
Combined Specificity	97.5% (78/80)	(91.3%; 99.3%)
Combined PPV for prevalence = 5.0%	67.8%	(35%; 88.4%)
Combined NPV for prevalence = 5.0%	100%	(99.4%; 100%)
Cross-reactivity with HIV+	0.0% (0/10), not detected	

The sensitivity and the specificity determined by the US FDA evaluation is higher than the values determined by the Dutch taskforce, however this is likely due to the number of days after symptom onset when the samples have been collected.

We can conclude that in order to meet the predetermined criteria, the tests need to be performed with samples collected at least 14 days after symptom onset, however the accuracy will be further improved if additional time passes.

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CROSS REACTIVITY

Cross-reactivity of the Romed COVID-19 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) was evaluated using serum samples which contain antibodies to the pathogens listed below. A total of 120 specimens from 24 different categories were tested. No false Positives were found with the following:

Sample Categories	Tested Sample Number
Influenza A virus IgG	5
Influenza B virus IgG	5
Respiratory syncytial virus IgG	5
Adenovirus IgG	5
Rhinovirus IgG	5
Human metapneumovirus IgG	5
Mycoplasma pneumoniae IgG	5
Chlamydia pneumoniae IgG	5
HCV IgG	5
Haemophilus influenza IgG	5
HBV core antibody IgG	5
Bacterial pneumonia	5
Influenza A virus IgM	5
Influenza B virus IgM	5
Respiratory syncytial virus IgM	5
Adenovirus IgM	5
Rhinovirus IgM	5
Human metapneumovirus IgM	5
Mycoplasma pneumoniae IgM	5
Chlamydia pneumoniae IgM	5
HCV IgM	5
Haemophilus influenza IgM	5
HBV core antibody IgM	5
Antinuclear antibodies (ANA)	5

INTERFERING SUBSTANCES

Low titer COVID-19 antibody positive serum samples and COVID-19 antibody negative serum samples were spiked with one of the following substances to specified concentrations and tested in multiple replicates. No false Positives or false Negatives were found with the following:

Name of Substances	Concentration
Ascorbic Acid	20 mg/dL
Hemoglobin	1000 mg/dL
Bilirubin	10 mg/dL
Albumin	2000 mg/dL
Triglyceride	500 mg/dL

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CLASS SPECIFICITY

A Class Specificity Study was conducted to determine the impact of DTT treatment on the detection of IgM and/or IgG positive samples by the Romed COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma). IgM samples treated with DTT showed no visible IgM line with the Romed COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma), whereas the IgG samples were not affected by DTT treatment. Test results with IgM positive samples after DTT treatment showed 100% agreement to the expected results. Test results with IgG positive samples after DTT treatment showed 100% agreement to the expected results. The results observed confirm the class specificity of the test.

STUDY OF: VENOUS WHOLE BLOOD AND PLASMA SPECIMENS WITH ANTICOAGULANTS

To evaluate if various anticoagulants have an effect on the results of the Romed COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma), negative plasma specimens and positive plasma specimens (with 2 different low positive IgG and IgM concentrations) were mixed with three different anticoagulants (lithium heparin, EDTA, sodium citrate) in separate tubes and tested in triplicate in plasma only or spiked into venous whole blood. IgG and IgM were correctly identified in all spiked whole blood specimens by the test, similar to results obtained with the plasma only specimens. There was a 100% concordance rate with expected results when IgM or IgG positive venous whole blood specimens or plasma specimens were tested with anticoagulants.

Wilnis, 5 November 2020
For: VAN OOSTVEEN MEDICAL B.V. – ROMED – HOLLAND

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