VAN OOSTVEEN MEDICAL B.V.
MEDICAL DISPOSABLES

Romed

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STATEMENT

To whom it may concern

We, Van Oostveen Medical B.V., with recognized reputation in production of Romed medical products, having their head office at Herenweg 269, 3648 CH WILNIS – HOLLAND, hereby declare that following products distributed by us:

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)
Coronavirus Ag Rapid Test Cassette (Swab)

have been placed on the European Market, based on the following performance characteristics (which are also included in the IFU included in each test kit

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)
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.

Coronavirus Ag Rapid Test Cassette (Swab)

Method		PCR		Total Results
Coronavirus Ag Rapid Test Cassette	Results	Positive	Negative	
	Positive	39	0	39
	Negative	6	116	122
Total Results		45	116	161

Relative Sensitivity: 86.7%
Relative Specificity: 100%
Accuracy: 96.3%

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Post Market Clinical Information - COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)

The antibody test was placed on the market first, and there is already Post Market Clinical Information available for this product. It 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.

Wilnis, 14 September 2020
For: VAN OOSTVEEN MEDICAL B.V. – ROMED – HOLLAND

Silvia Hodorogea, MSc
Romed Quality Assurance