VAN OOSTVEEN MEDICAL B.V.
MEDICAL DISPOSABLES

Romed

Herenweg 269
3648 CH Wilnis
The Netherlands
Tel. +31 297 28 21 01
Fax +31 297 28 83 16
E-mail info@romed.nl
www.romed.nl

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)

- Has been registered in the EU, in Germany (Hamburg) on 30-03-2020, registration number DE/CA05/IvD-238321-1331-00.
- Has received an Emergency Use Authorization from the FDA. This has been based on the Serology Test Evaluation Report released by the FDA on 28-05-2020
- 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.

Coronavirus Ag Rapid Test Cassette (Swab)

- Has been registered in the EU, in Germany (Hamburg) on 14-04-2020, registration number DE/CA05/IvD-238321-1355-00.

Wilnis, 11 September 2020
For: VAN OOSTVEEN MEDICAL B.V. – ROMED – HOLLAND

Silvia Hodorogea, MSc
Romed Quality Assurance