Ksmart®
SARS-CoV-2 IgG/IgM Antibody Rapid Test

13.09.21 - Preben Joffe, Medical Director, Consultant in internal medicine & nephrology

Ksmart® & LabPad® Evolution
Ksmart® is a medical device that in relation with COVID-19 can be used for detecting IgG and IgM of SARS-CoV-2 as a rapid test. It is basically an automated rapid immunochromatographic assay to be used with the reader **LabPad® Evolution** designed for diagnostic rapid testing.
Ksmart® was given its name as it is shaped as a key including tree zones of importance:
Zone 1 = sample well,
Zone 2 = testing strip and
Zone 3 = for data given in a QR code.

Ksmart®:

LabPad® Evolution is a Point of Care diagnostic reader of several different biologic tests. It is small, portability (270g weight), powered by chargeable batteries, easy to use (3 buttons interface) and uses Bluetooth and USB for data transmission.

LabPad® Evolution:

Practically, the Ksmart® must be inserted into the top of the LapPad Evolution reader in order to

measure human SARS-CoV-2 Spike protein IgG and IgM antibodies:

Detection of antibodies against SARS-CoV2

The Ksmart® SARS-CoV-2 IgG/IgM rapid test *semiquantitatively* detects IgG to the Spike protein of SARS-CoV-2 whereas the detection of IgM to the same protein of SARS-CoV-2 is measured *qualitatively*. The test is therefore a valued parameter of the humoral immune response to SARS-CoV-2 antigens following COVID-19 or after vaccinations against SARS-CoV2.

Ksmart® is for single use and consists of

- *a test area* made of a nitrocellulose membrane strip,
- *a control line* and
- *two results lines* for IgM and IgG, respectively.

The control line consists of goat anti-rabbit IgG while the test lines carry anti-human IgM and IgG monoclonal antibodies.

During testing, the serum or capillary blood reacts with SARS-COV-2 recombinant antigen coated particles in Zone 1 of the Ksmart®. The mixture then migrates on the membrane by capillary action and reacts with the coated anti-human IgM at the first test line region located in Zone 2. If the sample contains SARS-COV-2 IgM antibodies, a colored line will appear. Thereafter, the mixture reacts with the coated anti-human IgG antibody at the second test line (also at Zone 2) and in case the sample contains SARS-COV-2 IgG, a colored line appears.
As a procedural control, a control line will appear in the control line region (Zone 2) if the proper volume of sample has been added and membrane wicking has occurred.
The result of the Ksmart® SARS-COV-2 IgG/IgM rapid test must be read out by the matching LabPad® Evolution analyzer measuring the optical density of the colored lines.

IgG

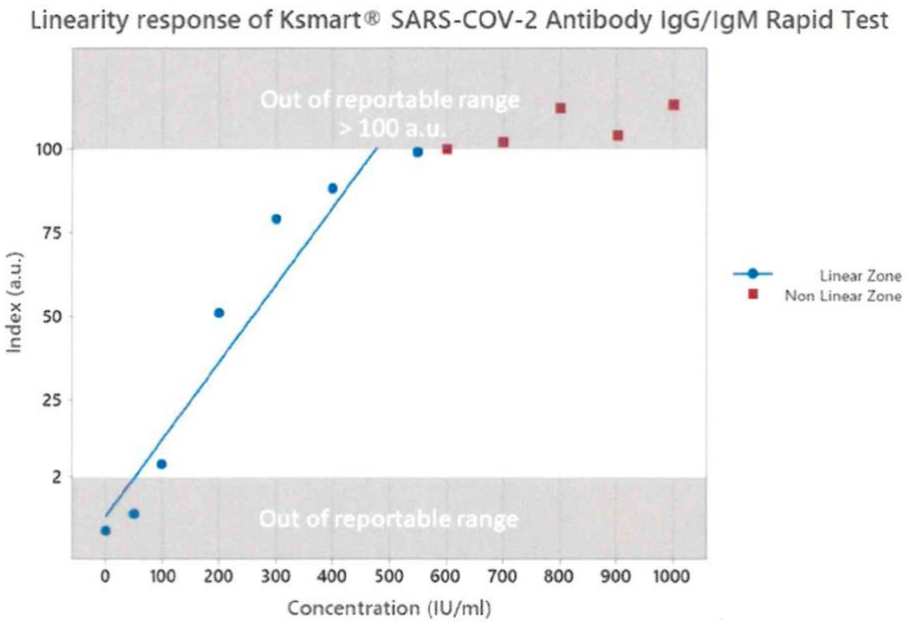
In case of a positive result to SARS-CoV-2 IgG the reportable range is expressed as an index in the range of 2-100 arbitrary unit (a.u).

Index 2 a.u. corresponds to a diluted pool of SARS-CoV-2 positive samples measured at 70 UI/ml while index 100 a.u. corresponds to a diluted pool of SARS-CoV-2 positive samples measured at 550 UI/ml.
Thus, the range of the Ksmart® is 70-550 UI/ml and

- <2 a.u. = a low positive result to SARS-CoV-2 antibodies IgG
- >100 a.u. = a strong positive result to SARS-CoV-2 antibodies IgG
- Negative = no detectible SARS-COV-2 antibodies IgG

In clinical terms the following can be applied:

- **A concentration of approximately 35-40 a.u. or more indicates a *HIGH likelihood* that one is protected from SARS-CoV-2.**
- **A concentration of approximately 6-34 a.u. indicates a *MEDIUM likelihood* that one seems protection from SARS-CoV-2**
- **A concentration of approximately 5 a.u. or less indicates a LOW likelihood that one is protection from SARS-CoV-2**



IgM
The result is reported *qualitatively* as being positive or negative depending on the present or the lack of SARS-COV-2 IgM.