Application procedure for manufacturers seeking a recommendation of antibody or antigen tests during the COVID-19 outbreak in Belgium.

- update 03/10/2020 -

1. Minimal eligibility criteria for **antibody tests** can be found in **Annex 1** to this communication. The manufacturer submits its application for recommendation to **serology@fagg-afmps.be**. Use the following phrase in the subject line: recommendation - "name manufacturer" - "name device".

2. Minimal eligibility criteria for **antigen tests** can be found in **Annex 2** to this communication. The manufacturer submits its application for recommendation to **antigen@fagg-afmps.be**. Use the following phrase in the subject line: recommendation - "name manufacturer" - "name device".

3. Requests shall be accompanied by:
   - A declaration of conformity with the IVD Directive (98/79/EC);
   - Notified body certificate (if applicable);
   - A list of (harmonized) standards that have been applied;
   - Relevant standard certificates (e.g. EN ISO 13485:2016) (if applicable);
   - Instructions for use;
   - Labels;
   - Information on the instrumentation that needs to be used with the test (e.g. open or closed platform test);
   - Any relevant validation data that pertain to the test.
4. The FAMHP and Sciensano verify the request. Only complete requests will be processed.
5. After positive evaluation of the provided documentation, the test will be listed in a table of recommended tests on the following website: https://www.fagg.be/sites/default/files/content/belgian_validation.xlsx.

Annex I – Eligibility criteria for SARS-CoV-2 antibody tests.

Intended Use	Determination of the immune status against SARS-CoV-2. Detection of SARS-CoV-2-specific antibodies in plasma, serum, venous or capillary blood. Not suitable for diagnosing active infections.
Instructions for Use	In line with IVDD (98/79/EC) Annex 1 requirements.
Labelling	In line with IVDD (98/79/EC) Annex 1 requirements.
Manufacturing	Conforms to EN ISO 13485:2016.
Target population	Specify the target population for the test: e.g. suspected or confirmed patients, general population.
Target user	Healthcare professional or lay user.
Method	Provide a short, clear description of the method principle.
Target antigen(s)	Indicate which viral antigen(s) is used to capture antibodies.
Specimen	Specify which specimen types can be used with the test.
Validation of specimens	Demonstrate equivalency between intended specimen types.
Cross-reactivity	Assessment of cross reactivity with other pathogens likely present in the surrounding area including, where possible, other common pathogenic coronaviruses. The effect of the following infections should be evaluated: • Infections with the common human pathogenic coronaviruses like HCoV-HKU1, -NL63, -OC43, or -229E; • Infections with influenza viruses and other respiratory viruses; • Acute bacterial pneumonia. The effect of the following vaccinations could be evaluated: • Vaccination against influenza viruses.
Interference	Assessment of possible interference from substances/conditions. E.g. autoantibodies, triglycerides, bilirubin, common medicines and medicines used to alleviate or treat infections. Indicate at what concentrations possible interfering substances have been evaluated.
Precision	Both repeatability and reproducibility should be assessed.
Cut-off value	If applicable, provide a rationale for the chosen cut-off value.
Clinical sensitivity	Comparison with results from a validated molecular test using nasopharyngeal samples should be performed. The time delay between symptoms onset or a positive molecular test and the antibody test should be stated. For samples taken later than 14 days after onset of symptoms: sensitivity ≥ 97% (with 95% confidence intervals).
Clinical specificity	≥ 98,5 % (with 95% confidence intervals).
Controls	Rapid tests[1] shall include a procedural control detecting the capability of the assay. Other tests: when not included in the kit, specify which external controls have been validated and indicate within which predetermined limits control results should fall.

Instrumentation	If applicable, indicate what instrumentation and software is needed to run/read the test and provide at least one validated combination for tests that can be run/read on multiple platforms.

[1] Rapid tests are defined as qualitative or semi-quantitative tests, which involve non-automated procedures and have been designed to provide a fast result.

Annex II – Eligibility criteria for SARS-CoV-2 antigen tests.

Intended Use	Determination of the presence of SARS-CoV-2 by detection of viral antigen(s).
Instructions for Use	In line with IVDD (98/79/EC) Annex 1 requirements.
Labelling	In line with IVDD (98/79/EC) Annex 1 requirements.
Manufacturing	Conforms to EN ISO 13485:2016.
Target population	Specify the target population for the test: e.g. suspected patients, general population.
Target user	Healthcare professional or lay user.
Method	Provide a short, clear description of the method principle.
Target antigen(s)	Indicate which viral antigen(s) is captured.
Specimen	Specify which specimen types can be used with the test.
Validation of specimens	If applicable, demonstrate equivalency between intended specimen types.
Cross-reactivity	Assessment of cross reactivity with other pathogens likely present in the surrounding area including, where possible, other common pathogenic coronaviruses. The effect of the following infections should be evaluated: • Infections with the common human pathogenic coronaviruses like HCoV-HKU1, -NL63, -OC43, or -229E; • Infections with influenza viruses and other respiratory viruses; • Acute bacterial pneumonia.
Precision	Both repeatability and reproducibility should be assessed.
Cut-off value	If applicable, provide a rationale for the chosen cut-off value.
Clinical sensitivity	≥ 90 % (with 95 % confidence intervals). Comparison with a validated molecular test using nasopharyngeal samples should be performed. If possible, specify the range of Ct-values that correspond to antigen test sensitivity values (e.g. sensitivity for Ct≤25 and sensitivity for Ct>25). Indicate during which period (days after symptoms onset) samples should be taken.
Clinical specificity	≥ 99 % (with 95 % confidence intervals).
Controls	Rapid tests[1] shall include a procedural control detecting the capability of the assay. Other tests: when not included in the kit, specify which external controls have been validated and indicate within which predetermined limits control results should fall.
Instrumentation	If applicable, indicate what instrumentation and software is needed to run/read the test and provide at least one validated combination for tests that can be run/read on multiple platforms.

[1] Rapid tests are defined as qualitative or semi-quantitative tests, which involve non-automated procedures and have been designed to provide a fast result.