**Application procedure for manufacturers seeking a recommendation of SARS-CoV-2antibody tests during the COVID-19 outbreak in Belgium.**

**- update 01/04/2022 -**

1. Minimal eligibility criteria and the application form for **antibody tests** can be found in **Annex 1** to this communication. The manufacturer submits the completed application form in Annex 1, together with all required documents, to [**serology@fagg-afmps.be**](mailto:serology@fagg-afmps.be). Use the e-mail subject: recommendation - “name manufacturer” - “name device”.
2. 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;
   * Completed application form (Annex 1).
3. The FAMHP and Sciensano verify the request. Only complete requests will be processed. The FAMHP reserves the right to request additional documents.
4. After positive evaluation of the provided documentation, the test will be listed in a table of recommended tests on this [website](https://www.fagg-afmps.be/nl/MENSELIJK_gebruik/gezondheidsproducten/medische_hulpmiddelen_hulpstukken/covid_19/tests).

**Annex 1 – Form to be completed when applying for a recommendation of a SARS-CoV-2 antibody test**

**Important note:** be aware that the Belgian competent authority will remove tests from the list in case false or misleading information was provided. If tests do not comply with the IVD Directive 98/79/EC (as transposed in the Royal Decree from 14 November 2001 – [Dutch](http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=2001111446&table_name=wet) - [French](http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2001111446&table_name=loi)), additional action will be taken!

**Minimal eligibility criteria:**

|  |  |
| --- | --- |
| **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). |
| **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. |

**Form to be completed by the applicant:**

Clearly provide the information asked for in every line. Incomplete forms will not be processed! Send the completed form and all other required documents to [serology@fagg-afmps.be](mailto:serology@fagg-afmps.be). Use the following e-mail subject: Recommendation - “name manufacturer” - “name device”.

|  |  |
| --- | --- |
| **Intended Use** | *Provide a short, clear description of the intended use.* |
| **Instructions for Use** | In line with [IVDD (98/79/EC)](https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31998L0079) Annex 1 requirements? Yes:  **(in English or in all 3 official Belgian languages)** |
| **Labelling** | In line with IVDD (98/79/EC) Annex 1 requirements? Yes:  **(in English or in all 3 official Belgian languages)** |
| **Manufacturing** | Conforms to EN ISO 13485:2016? Yes:  No: |
| **Declaration of Conformity** | In line with IVDD (98/79/EC) Annex 3 requirements? Yes: |
| **Target population** | *Specify the target population for the test: e.g. suspected or confirmed patients, vaccinated people, general population.* |
| **Target antibody/antibodies** | *Indicate which class or combination of antibody/antibodies is/are captured.* |
| **Specimen types, clinical sensitivity and specificity**  *Note*: when more than one specimen type can be used, please include the overall AND individual sensitivity and specificity values and the corresponding number of samples tested. This way also the validation of specimen types can be checked. | |  |  |  |  | | --- | --- | --- | --- | | **Specimen** | **Sensitivity in % (compared to RT-PCR)**  **and**  **Number of samples tested** | **Specificity in % (compared to RT-PCR)**  **and**  **Number of samples tested** | **Not Applicable** | | **Overall** |  |  |  | | Whole blood | *Specify anticoagulants* | |  | |  |  | | Plasma | *Specify anticoagulants* | |  | |  |  | | Serum |  |  |  | | Other (please specify) |  |  |  | |
| **Validation of specimen types** | *Only complete in case not all specimen types were compared to RT-PCR. Specify which samples were compared and how many.* |
| **Cross-reactivity** | |  |  | | --- | --- | | **Virus** | **Tested and mentioned in IFU?** | | HCoV-HKU1 | Yes: | | HCoV-NL63 | Yes: | | HCoV-OC43 | Yes: | | HCoV-229E | Yes: | | Other coronavirus? | Yes:  - Which? | | Influenza A | Yes: | | Influenza B | Yes: | | Parainfluenza | Yes: | | Other viruses and micro-organisms | *List those that were tested* | |  |  | |
| **Interference** | *List substances tested* |
| **Precision (repeatability and reproducibility)** | Short summary present in IFU? Yes:  No: |
| **Reference number** | *Provide the reference/catalogue number of the test AND, if applicable, the corresponding ID number from the* [*JRC database*](https://covid-19-diagnostics.jrc.ec.europa.eu/devices/)*.* |

**The undersigned declares that all information provided is correct and understands that the Belgian competent authority will remove tests from the list in case false or misleading information was provided. If tests do not comply with the IVD Directive 98/79/EC (as transposed in the Royal Decree from 14 November 2001 –** [**Dutch**](http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=2001111446&table_name=wet) **-** [**French**](http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2001111446&table_name=loi)**),  additional action will be taken.**

**Date:**

**Name:**

**Function:**

**Signature:**