

Covid 19 Test Kit Pre-purchase Questionnaire -

Product Name	
Name of Test Kit (on packaging & documentation)	COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P) ICOV4212
Supplier (Name & address)	Happy Business Services Zrt. Budapest 1137, Szent István krt. 18.
Manufacturer	
Name & address	Hangzhou Clongene Biotech Co., Ltd. No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, 311121 Hangzhou, China
Website	http://en.clongene.com/
Manufacturing site accreditation	EN ISO 13485:2016; ISO 45001:2018; ISO 9001:2015; ISO 14001:2015;
For tests manufactured outside the EU, name & address of the 'Responsible Person'	EU representative of the manufacturer: Shanghai International Holding Corp.GmbH (Europe) Eiffestrasse 80, D-20537 Hamburg, Germany
Regulatory Status	
Product can be used only by doctors or medically qualified persons.	Usage performed by unqualified persons cannot be considered safe. The product is not suitable for self-testing or for use in home environment!
A Hungarian User's Manual is enclosed with every single test.	On the grounds of the Hungarian User's Manual the test can be used by health professionals without any additional training.
Eu and national registration	
Has it been certified by an EU Notified Body. If Y please give details	Y Registered in EUDAMED and in DIMDI by the EU representative of the manufacturer in Germany
Date of approval	22 March, 2020 by German authorities
Approval/registration number	DE/CA05/IvD-238321-1330-00 in DIMDI and EUDAMED
Has it been approved by OGYÉI?	Y
Date of registration	23 March, 2020 by OGYÉI
Registration number	HU/CA01/17106/20 by OGYÉI
Regulation of usage	
Product can be used only by doctors or medically qualified persons.	Usage performed by unqualified persons cannot be considered safe. The product is not suitable for self-testing or for use in home environment!
A Hungarian User's Manual is enclosed with every single test.	On the grounds of the Hungarian User's Manual the test can be used by health professionals without any additional training.
Sample type e.g. <i>blood prick, swab</i>	human whole blood/serum/plasma
Are all consumables included	Y
Recommended time to take test for most accurate result (days post symptoms)	According to the medical literature the symptoms appear between 5-14 days after the infection. However, not having any symptoms may mean that the

	patient is already infected, and the body has already started to develop the specific antibodies. In case of symptoms the specific antibody is already present in the blood.
Time taken to get result	15 minutes
What is the end point of the test & how does the user interpret it	<p>Qualitative analysis of the presence of IgM/IgG in the sample. Control included.</p> <p>If the control line is present:</p> <ul style="list-style-type: none"> - Neither IgM nor IgG line is present: negative. - IgM line is present: positive for IgM. - IgG line is present: positive for IgG - Both IgM and IgG line are present: positive for IgM and IgG. <p>If the control line is not present:</p> <ul style="list-style-type: none"> - Test is invalid, regardless of any other lines present.
Disposal of used kit	<p>All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.</p> <p>The used test cassette should be discarded according to federal, state and local regulations.</p>
Test Kit Details	
Device type <i>e.g. Lateral Flow Cassette</i>	Lateral flow chromatographic immunoassay cassette
Target <i>e.g. IgM, IgG</i>	IgM and IgG
Specificity (each target)	<p>IgM: 98.89%;</p> <p>IgG: see below</p>
Sensitivity (each target)	<p>IgM: 87.01%</p> <p>IgG: 97.40% (positive rate of the 77 [positive] patients during the convalescence period.)</p>
Required storage conditions	Store between 4-30 °C
Shelf life of kit	2 years

Declaration:

I confirm that the information given in this form is true, complete and accurate:

Name	Signature	Company	Date
P.hd. Dr. Rényi Gábor		Happy Business Services Zrt	05.04.2020