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Declaration of PEI Evaluation

To whom it may concern,

We, Hangzhou Clongene Biotech Co., Ltd. as the manufacturer of CLUNGENE COVID-19 Antigen Rapid Test (AT-No.: AT079/20). In response to the PEI evaluation results of Comparative evaluation of the sensitivities of SARSCoV-2 antigen rapid tests which update on 12 January, 2022, hereby views as follows:

1) We accept and respect the evaluation scheme performed by PEI, a governmental and professional authority in Germany. However, the method of adding specimen in the PEI evaluation protocol is different from the CLUNGENE COVID-19 Antigen Rapid Test. The COVID-19 Antigen Rapid Test produced by Hangzhou Clongene Biotech Co., Ltd. has two adding methods: 1. Direct Swab (Dry swab)，after taking the Specimen with the swab, it was performed with 300 uL of extraction reagent; 2. Viral Transport Media (VTM) solution containing specimen, taking 300uL of the VTM solution containing specimen mix with 300 uL of extraction reagent .The adding specimen method of PEI is to take 50 uL of the VTM solution containing specimen and attach it to the swab, and then perform it with 300 uL of extraction reagent. As we can be seen from the above, the evaluation method of PEI is different from the method of adding specimen of CLUNGENE, which may cause the specimen to be adsorbed by the swab, thereby reducing the sensitivity of the product.

2) COVID-19 Antigen Rapid Test (Nasal Swab) was validated by the joint PHE Porton Down and University of Oxford SARS-CoV-2 lateral flow antigen test validation cell in the UK and be listed in the Table: summary of lateral flow devices that have passed phase 3a validation by the Department of Health and Social Care (DHSC) on 29 September 2021. COVID-19 Antigen Rapid Test (Nasal Swab) showed very high sensitivity and specificity compared to RT-PCR.
https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/outcome-of-the-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices

3) CLUNGENE COVID-19 Antigen Rapid Test for self-testing (ARTG: 333341) has been approved by

TGA in January 2022. CLUNGENE COVID-19 Antigen Rapid Test for self-testing showed very high sensitivity compared to RT-PCR.

https://www.tga.gov.au/covid-19-rapid-antigen-self-tests-are-approved-australia

For each test a comment on the clinical sensitivity is assigned as follows:

- **Acceptable sensitivity** - clinical sensitivity greater than 80% PPA
- **High sensitivity** - clinical sensitivity greater than 90% PPA
- **Very high sensitivity** - clinical sensitivity greater than 95% PPA

COVID-19 self-tests (home use) approved by TGA

*Clicking on the name of the test will link to the instructions on how to use it.

PDF Instructions on how to use the test are provided as a supplementary resource for the visually read tests listed below and do not meet disability access requirements.

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Name of self-test* and how to use the test	Sample type used	Australian Sponsor (supplier)	Manufacturer	ARTG	Clinical Sensitivity	Date Approved
Clungene Covid-19 Antigen Rapid Test for self-testing (pdf,703kb)	Nasal swab	APAC Security Pty Ltd	Hangzhou Clongene Biotech Co Ltd (China)	333341	Very high sensitivity	7 January 2022

4) COVID-19 Antigen Rapid Test has also conducted clinical validation in many countries around the world, for example Greece, Poland, Malaysia, Germany and Thailand. The specific clinical data of each country are as follows:

Main Research	Sample Type	Specificity	Sensitivity	
Locus Medicus S.A. in Greece	Nasopharyngeal swab	100% (456/456) 95%CI: 99.2%-100%	Ct≤25:	100% (81/81) 95%CI: 95.5%-100%
			25＜Ct≤30:	100% (23/23) 95%CI: 85.7%-100%
			Ct＞30:	75% (12/16) 95%CI: 50.5%-89.8%
			Total sensitivity:	96.7% (116/120) 95%CI: 91.7%-98.7%
	Nasal swab	100% (456/456) 95%CI: 99.2%-100%	Ct≤25:	100% (74/74) 95%CI: 95.1%-100%
			25＜Ct≤30:	100% (21/21) 95%CI: 84.5%-100%
			Ct＞30:	77.8% (21/27) 95%CI: 59.2%-89.4%
			Total sensitivity:	95.1% (116/122) 95%CI: 89.7%-97.7%
Centralne Laboratorium Kliniczne Uniwersyteckie Centrum Kliniczne in Poland	Nasal swab	100% (450/450) 95%CI: 99.2%-100%	Ct≤25:	97.5% (77/79) 95%CI: 91.2%-99.3%
			25＜Ct≤30:	95.7% (22/23) 95%CI: 79.0%-99.2%
			Ct＞30:	75% (6/8)

Main Research	Sample Type	Specificity	Sensitivity	
				95%CI: 40.9%-92.9%
			Total sensitivity:	95.5% (105/110) 95%CI: 89.8%-98.0%
Tropical Infectious Diseases Research & Education Centre (TIDREC) and University of Malaya in Malaysia	Nasal swab	100% (30/30) 95%CI: 88.6%-100%)	Ct≤30:	100% (30/30) 95%CI: 88.6%-100%
Research & Consulting Dr. Doll GmbH in Germany	Nasal swab	100% (320/320) 95%CI: 98.8%-100%	Ct≤25:	98.8% (79/80) 95%CI: 93.3%-99.8%
			25＜Ct≤30:	92.9% (26/28) 95%CI: 77.4%-98.0%
			Ct＞30:	70% (7/10) 95%CI: 39.7%-89.2%
			Total sensitivity:	94.9% (112/118) 95%CI: 89.4%-97.7%
Ramathibodi Hospital in Thailand	Nasopharyngeal swab	100% (240/240) 95%CI: 98.4%-100%	Ct≤25:	100% (87/87) 95%CI: 95.8%-100%
			25＜Ct≤30:	100% (33/33) 95%CI: 89.6%-100%
			Ct＞30:	60% (3/5) 95%CI: 23.1%-88.2%
			Total sensitivity:	98.4% (123/125) 95%CI: 94.4%-99.6%

Yours sincerely,

Hangzhou Clongene Biotech Co., Ltd.