Declaration on PEI Evaluation

To whom it may concern,

We, Nanjing Vazyme Medical Co., Ltd., as the manufacture of "Vazyme SARS-CoV-2 Antigen Detection Kit (Colloidal Gold-Based) (AT-No. AT255/20)", hereby in response to the report "Comparative evaluation of the sensitivities of SARSCoV-2 antigen rapid tests" revealed by PEI on 12 January, 2022, we make the following clarification:

1) We fully respect Paul-Ehrlich-Institut (PEI) as an authoritative and professional inspection agency in SARS-CoV-2 detection area. However, due to serious pandemic and massive test kits to be evaluated, PEI used the same specimen and protocol to compare kits from different company, which is different from the specimen requirement and protocol described in the "instruction of use" of Vazyme's test. Specifically, PEI used pooled samples with VTM as a transport media, and the pooled samples were transferred to each lab under frozen condition. However, Vazyme's kit only accept fresh sample from subject (unfrozen), and the sample can only be dissolved in transport media provided within the kit. The ingredient in VTM provided by other company and the sample frozen would cause unpredicted impact on the test kit, which may reduce the sensitivity of the product.

2) Vazyme has conducted clinical and analytical performance validation on above-mentioned product in many countries around the world, for example Greece and Italy. The clinical results are as follows:

<table>
<tr><th>Main Research</th><th>Sample Type</th><th>Specificity</th><th colspan="3">Sensitivity</th></tr>
<tr><td rowspan="3">Locus Medicus Lab in Athens, Greece</td><td rowspan="3">Nasal swab</td><td rowspan="3">100% (596/596)
95%CI: 99.06% - 100.00%</td><td rowspan="3">98.44% (596/596)
95%CI: 95.5%-99.47%</td><td>Ct≤25</td><td>100% (110/110)
95%CI:96.74%-100.00%</td></tr>
<tr><td>25＜Ct≤30</td><td>100% (42/42)
95%CI:91.62% -100.00%</td></tr>
<tr><td>Ct＞30</td><td>92.5% (40/40)
95%CI:80.14% -97.42%</td></tr>
<tr><td rowspan="3">Alabiso Lab – Salus, Life Brain Group, in Roma, Italy</td><td rowspan="3">Nasal swab</td><td rowspan="3">100% (1000/1000)
95%CI: 99.59% - 100.00%</td><td rowspan="3">100% (1000/1000)
95%CI: 95.25%-100.00 %</td><td>Ct≤25</td><td>100% (44/44)
95%CI: 91.97%-100.00%</td></tr>
<tr><td>25＜Ct≤30</td><td>100% (29/29)
95%CI: 88.3%-100.00%</td></tr>
<tr><td>Ct＞30</td><td>100% (4/4)
95%CI: 51.01%-100.00%</td></tr>
</table>

3) Vazyme SARS-CoV-2 Antigen Detection Kit (Colloidal Gold-Based) (AT-No. AT255/20) has been approved by the competent authorities of health or other relevant

accredited organization of many countries, for example German, France, Belgium, Turkey, Italy, Greece, Croatia, Bulgaria, Latvia, Ukraine, Hungary, Austria, Russia, Moldova, Slovakia, Indonesia, India, Thailand, Malaysia, Saudi Arabia, Cambodia, Vietnam, Peru, Ecuador, etc.

4) Vazyme SARS-CoV-2 Antigen Detection Kit (Colloidal Gold-Based) for self-testing (the same design as the above-mentioned product) has got the EC certificate issued by the Notified Body PCBC, please refer to **Annex I "EC Certificate"**. And this self-testing product also has been approved and listed by MOH of France, please refer to **Annex II "Listing approval of France".**

Yours sincerely,

Nanjing Vazyme Medical Co., Ltd.
22/Jan/2022

Annex I "EC Certificate"

CERTIFICATE

EC Certificate No. 1434-IVDD-463/2021
EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Nanjing Vazyme Medical Technology Co., Ltd
Floor 1-3, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, China.

in vitro diagnostic medical devices
for self-testing

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate: from 30.09.2021 to 27.05.2024

The date of issue of the Certificate: 30.09.2021

The date of the first issue of the Certificate: 30.09.2021

CE 1434

Issued under the Contract No. MD-56/2021
Application No: 563/2021
Certificate bears the qualified signature.
Warsaw, 30.09.2021
Module A1
FBM-30-E_10

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.10.01 09:32:52 +02'00'
Vice-President

POLISH CENTRE FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

Annex II "Listing approval of France"

查询链接：Plateforme COVID-19 (sante.gouv.fr)）

NOM	FABRICANT	DISTRIBUTEUR	CE	UE	CNR	SOUS-TYPE DE TEST	CIBLES	TYPE DE PRÉLÈVEMENT
Kit de détection de l'antigène du syndrome respiratoire aigu sévère du coronavirus 2 (SARS-CoV-2)	Nanjing VAZYME medical technology		✓	✓	✓	Antigénique non automatisé (dont TROD)		Nasopharyngé
2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit	Nanjing Vazyme Medical Technology	Meilleure Health International	✓	✓	✓	RT PCR simple	N, ORF1ab	Nasopharyngé
Kit de détection de l'antigène du syndrome respiratoire aigu sévère du coronavirus 2 (SARS-CoV-2)	Nanjing Vazyme Medical Technology		✓	✓	✓	Autotest	N, S	Nasal
2019-nCoV IgG/IgM detection kit	Nanjing Vazyme Medical technology Co. Ltd	MDL Medical	✓	✓	✓	Sérologie rapide (dont TDR et TRC	IgG, IgG protéine N	Sang total
2019-nCoV IgG/IgM detection kit	Nanjing Vazyme Medical technology Co. Ltd	SAM SARL	✓	✓	✓	Sérologie rapide (dont TDR et TRC	IgG, IgG protéine N	Sang total
2019-nCoV IgG/IgM detection kit	Nanjing Vazyme Medical technology Co.	Artimport	✓	✓	✓	Sérologie rapide (dont TDR et TRC	IgG, IgG protéine N	Sang total