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## Declaration Letter

**MANUFACTURER** GREENCROSS MEDICAL SCIENCE Co., Ltd  
26, Mugeuk-ro 65beon-gil, Geumwang-eup, Eumseong-gun,  
Chungcheongbuk-do, 27632, REPUBLIC OF KOREA

**Product** GENEDIA W COVID-19 Ag

**CLASSIFICATION** Others IVD / Non List A, Non List B and not for self-testing

**We, GCMS declares that** LoD of heat-inactivated SARS-CoV-2 Virus on the GENEDIA W COVID-19 Ag is  $3.38 \times 10^3$  TCID<sub>50</sub>/mL ( $0.22 \times 10^6$  genome copies/mL) for spiked loading concentration on swab and  $7.50 \times 10^2$  TCID<sub>50</sub>/mL ( $4.88 \times 10^4$  genome copies/mL) for final working concentration.

Virus Stock Concentration	Spiked Loading Concentration on Swab	Final Working Concentration	Number of positive result/Total	Positive rate (%)
$6.45 \times 10^6$ TCID <sub>50</sub> /mL ( $4.2 \times 10^8$ genome copies/mL)	$3.38 \times 10^3$ TCID <sub>50</sub> /mL ( $0.22 \times 10^6$ genome copies/mL)	$7.50 \times 10^2$ TCID <sub>50</sub> /mL ( $4.88 \times 10^4$ genome copies/mL)	60/60	100 %

Green Cross Medical Science Corporation

Representative Director

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**Dr. Eun-Uk AHN**

President  
Green Cross Medical Science Corporation