

Testing of SARS-CoV-2 rapid antigen tests detection of new variants in DK (Omicron BA.4 and BA.5)

To whom it may concern:

COVID-19 pneumonia is still raging around the world, and waves of new mutant strains in epidemic proportions are challenging rapid antigen tests (RAT) based on the principles of immunochromatography. On 28 July 2022, the Statens Serum Institut (SSI) in Denmark published a study that tested the ability of some Danish public authorities procured and used COVID-19 self-testing reagents to detect Omicron BA.4 and BA.5 variants. The Boson Rapid SARS-CoV-2 Antigen Test Card was tested positive at three dilution gradients of 1:10, 1:100 and 1:1000 for three strains of BA.4, BA.5 and the wild-type strain. The clinical report can be viewed through the following links:

<https://en.ssi.dk/-/media/arkiv/subsites/covid19/diagnostik/afprvning-af-sarscov2-antigen-tests-for-pvisning-af-nye-varianten-i-dk-omikron-ba4-og-ba5.pdf?la=en>

Results of testing of antigen test-kits week 30 2022:

Name of test	Manufacturer/ supplier	Variant	Dilution of variant			
			1:10	1:100	1:1.000	1:10.000
Flowflex SARS-CoV-2 Antigen	Acon Biotech	Wild-type	+	+	+	-
Rapid Test (self testing)		BA.4	+	+	+	nd
		BA.5	+	+	+	nd
BIOSYNEX COVID-19 Antigen selvtestkit	BIOSYNEX	Wild-type	+	+	-	-
		BA.4	+	+	(+)	nd
SARS-COV-2 Antigen Self test Nasal	Roche	BA.5	+	+	(+)	nd
		Wild-type	+	+	-	-
Rapid SARS-COV-2 Antigen Test Card	Boson Biotech	BA.4	+	+	-	nd
		BA.5	+	+	-	nd
		Wild-type	+	+	+	-

(+): weak positive

-: negative

nd: not done

When testing showed the same results for all duplicates, the table only shows one result for every dilution/variant.

Different results for the duplicates are shown as (+)/-.

Statement

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We Xiamen Boson Biotech Co., Ltd., a manufacturer of various types of Diagnostic Kits, having factories at 90-94 Tianfeng Road, Jimei North Industrial Park, Xiamen, P.R.C. do hereby confirm that Omicron evolved from the previous BA.1 variant into different subvariants of BA.2, BA.3, BA.4 and BA.5. The biggest difference between the different Omicron subvariants occurs on the S protein, with very little difference on the N protein, as shown in the table below:

	BA.1	BA.2	BA.3	BA.4	BA.5
N protein mutation sites	P13L del31/33 R203K G204R	P13L del31/33 R203K G204R S413R	P13L del31/33 R203K G204R S413R	P13L del31/33 P151S R203K G204R S413R	P13L del31/33 R203K G204R S413R

The Boson Rapid SARS-CoV-2 Antigen Test Card detects the N protein of the SARS-CoV-2 virus. As shown in the table above, the N protein variation sites of BA.2, BA.3, and BA.5 are completely identical, and only differ from BA.1 in the 413th amino acid. Boson internally evaluated the detection of BA.1, and external research included the detection of BA.1 and BA.2 (Denmark Statens Serum Institut), and the results were all detectable. The results of Omicron BA.2 can be found at

<https://en.ssi.dk/-/media/arkiv/subsites/covid19/diagnostik/afprvning-af-sars-cov-2-antigentests-fo-r-pvisning-af-varianter.pdf?la=en>. BA.4 and BA.2, BA.3, BA.5 are different except for the 151st amino acid, and other N protein variation sites are completely identical. Due to the amino acid mutation at position 151 of BA.4 lie without the epitope region for Boson Rapid SARS-CoV-2 Antigen Test Card, So Boson reagent can also detect BA.3, BA.4 and BA.5.

XIAMEN BOSON BIOTECH CO., LTD

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