



CorDx COVID-19 Antigen

The CorDx COVID-19 Antigen Test is an easy-to-use test device that delivers accurate and reliable results in just 10 minutes. Designed with safety and user-friendliness in mind. With features such as lower nasal sample collection and simple sample extraction, users can safely self-test at the convenience of their own home. Clinically evaluated against the Omicron variants and independently tested against the BQ.1/ BQ.1.1 variants.



Features and Benefits

- Results in 10 minutes.
- Extensively validated through strict EUA clinical study during time of Extremely High Omicron prevalence.
- Evaluated against BQ.1/ BQ.1.1 variants.
- High sensitivity, specificity and accuracy.
- Safe and efficient sample extraction.
- Built-in tube holders on the kit box.
- **Two USA** manufacturing sites. One China manufacturing site.
- 15-month shelf life.



Test Kit Package Includes:

		Number of tests/kit	2 tests/ kit	20 tests/ kit
Reagent/ Material	Test cassette		2	20
	Swab		2	20
	Tube with sample processing solution		2	20
	Tube holder (back of box)		2	2
	User Instructions		1	1

Performance Specifications:

Based on a multi-site clinical study conducted in the United States during the Omicron wave (March 2022):

Subjects	Comparator Positives	Comparator Negatives	Total
CorDx COVID-19 Ag Test Positives	35	1	36
CorDx COVID-19 Ag Test Negatives	4	343	347
Total	39	344	383
Positives Percent Agreement= 89.7%			
Negatives Percent Agreement= 99.7%			

SKU and Package Configuration:

Product Number	Package Configuration
CO-291-2	2 tests / kit box
CO-291-20	20 tests / kit box

Shipping Dimensions:

(2 Tests)

Item	Quantity	Length (inch)	Width (inch)	Height (inch)	Weight (lbs)
Kit Box	2 Tests	6.5	3	0.71	0.09
Carton	256 Kit Boxes (512 Tests)	23.2	13.6	12.6	24.03
Pallet	30 Cartons (15360 Tests)	48	43	77	752

(20 Tests)

Item	Quantity	Length (inch)	Width (inch)	Height (inch)	Weight (lbs)
Kit Box	20 Tests	7.87	5.2	3.31	0.58
Carton	32 Kit Boxes (640Tests)	21.97	14.37	16.93	20.55
Pallet	25 Cartons (16000 Tests)	48	40	73	548

EUA Number: EUA220303

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARSCoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

Inclusivity

The CorDx COVID-19 Ag Test was validated against the Delta and Omicron variants. Independent testing by the RaDx variant task force confirmed the test's ability to detect the BQ.1/ BQ.1.1 variants.

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For additional information

email: orders@bigbenmedical.com

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