Qorvo Biotechnologies Omnia™ SARS-CoV-2 Antigen Test

Low Limit of SARS-CoV-2 Detection

Qorvo Biotechnologies pairs rapid turnaround time with differentiated detection technology using Bulk Acoustic Wave (BAW) technology to deliver a new generation of immunoassay diagnostic performance.

- Self-contained, single-use test cartridge with immunoassay reagents for use on the Qorvo Omnia™ Instrument
- Qualified sample type is nasal swabs

Simple 3-Step Testing Process:

Load sample onto test cartridge

Insert test cartridge into Qorvo Omnia Instrument

Results available in approximately 20 minutes

Interpretation of Results

Internal Control	Nucleocapsid AU/mL	Displayed Result	Test Result Interpretation
Invalid	Not displayed	INVALID	Invalid test. Test again with a new specimen and new cartridge.
Valid	<1.0	NEGATIVE	Presumptive Negative for SARS-CoV-2 (no antigen detected)
Valid	≥1.0	POSITIVE	Positive for SARS-CoV-2 (antigen present)

Clinical Performance

Qorvo Omnia SARS-CoV-2 Antigen Results	Comparator Method		
	Positive	Negative	Total
Positive	51[1]	0	51
Negative	6[1]	32	38
Total	**57**	**32**	**89**

[1] Four positive results enriched this study with different yet comparable RT-PCR Comparative Methods to ensure required testing of low positive specimens

Positive Percent Agreement (PPA)	89.47%	(95% CI: 78.88%-95.09%)
Negative Percent Agreement (NPA)	100%	(95% CI: 89.28%-100%)

Days From Onset	Cumulative Omnia SARS-CoV-2 Antigen Positive	Cumulative RT-PCR Positive	PPA
0	1	1	100.0%
1	6	6	100.0%
2	13	15	86.7%
3	24	28	85.7%
4	43	49	87.8%
5	45	51	88.2%
6	51	57	89.5%

For more information, visit www.qorvobiotech.com

This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. 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.

Ordering Information

QPR8302:	80 each of test cartridges, nasal swabs, Lysis buffer vials and dropper caps
QPR8302.QC:	Positive Antigen quality control, 6 vials @ 1.6mL each