
	HMPV Rapid Test (RAPG-HMPV-001) Clinical Study Report	CS-RAPG-HMPV-001
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Clinical Study Report

HMPV RAPID TEST RAPG-HMPV-001

The signature below certifies that this revision of the document has been reviewed and accepted for its accuracy on the stated date.

	Signature	Position	Date
Approved by		Quality Manager	11/10/2023

Purpose of the test

To evaluate the quality and suitability for clinical application of the HMPV Rapid Test produced by Biopanda Reagents using clinical specimens, comparison methods, and statistical analysis.

Overall design of the test

The Biopanda HMPV Rapid Test and the contrast device will be used on a parallel study using the same clinical specimens.

Study method

Specimen size

The target total specimen size of this clinical test is confirmed as 170 cases.

Specimen selection

The Biopanda HMPV Rapid Test qualitatively detects human metapneumovirus antigens in nasopharyngeal swab samples. Suitable specimens for the Biopanda device and the contrast device are nasopharyngeal swab samples. The collection of specimens was operated following the requirements from the instructions for use of the Biopanda device and the contrast device. The testing of the specimens and the reading of the results was also in compliance with the instructions of the Biopanda device and the contrast device.

The selection of the contrast device and the confirming method

Biopanda device: HMPV Rapid Test

Contrast device: Commercially available RT-PCR

Results of the clinical test

		RT-PCR		Total
		Positive	Negative	
Biopanda HMPV Rapid Test	Positive	55	1	56
	Negative	5	109	114
Total		60	110	170

Relative Sensitivity: 91.7% (95%CI*: 81.6% - 97.2%)

Relative Specificity: 99.1% (95%CI*: 95.0% - 100%)

Overall Accuracy: 96.5% (95%CI*: 92.5% - 98.7%)

*Confidence Intervals

Conclusions:

The clinical study was based on 170 specimens in total, comparing the Biopanda device and the contrast device. According to above table, the relative sensitivity rate between Biopanda's HMPV Rapid Test and the contrast device is 91.7%, relative specificity rate is 99.1%, and overall accuracy rate is 96.5%. Therefore, the Biopanda HMPV Rapid Test performs well and can be used in clinical settings for diagnostic purposes.