JOY MED JOY TEST

CLINICAL SUMMARY FOR PHYSICIANS PROTOCOL CPSP 250821-09

Clinical Evaluation of the JOYTEST Respiratory Panel

Multicentre study in Germany (Mühlheim am Main / Hanau / Heidelberg)

Anhui DeepBlue Medical Technology manufactures professional JOYTEST respiratory tests for JOYMED, from the basic 3-in-1 to the exclusive 12-in-1. The study was commissioned for the new 11-in-1 panel.
(Performance data for each JOYTEST model are provided in its instructions for use)

11	1,405	95–98%
respiratory targets assessed	specimens in the main analysis	sensitivity by target

Study Sites and Methods

Dr Haidong Teng's practice (Mühlheim am Main) and the Klinikum Hanau laboratory handled sampling and antigen testing. MVZ Labor Dr. Limbach & Kollegen (Heidelberg) ran reference RT-PCR (Seegene Allplex RV Master Assay and Allplex Respiratory Panel 4). Dr Stephan Johannes Korn was the principal investigator.

The protocol specifies a nasal swab for antigen testing and a paired nasopharyngeal swab for RT-PCR. Of 1,575 specimens evaluated, the main set included 1,100 PCR-positive specimens and 305 specimens negative for all targets. **PCR-positive specimens were collected within seven days of symptom onset.** [1]

11-in-1 Panel Results vs RT-PCR

Target	Detected / PCR+	Sensitivity	95% CI for sensitivity
SARS-CoV-2	97 / 100	**97%**	91.55–98.97%
Influenza A	96 / 100	**96%**	90.16–98.43%
Influenza B	95 / 100	**95%**	88.82–97.85%
Respiratory syncytial virus (RSV)	97 / 100	**97%**	91.55–98.97%
Adenovirus	98 / 100	**98%**	93.00–99.45%
Human metapneumovirus (hMPV)	96 / 100	**96%**	90.16–98.43%
Parainfluenza virus (PIV)	96 / 100	**96%**	90.16–98.43%
Mycoplasma pneumoniae	97 / 100	**97%**	91.55–98.97%
Rhinovirus	95 / 100	**95%**	88.82–97.85%
Streptococcus pneumoniae	95 / 100	**95%**	88.82–97.85%
Legionella pneumophila	96 / 100	**96%**	90.16–98.43%

Observed specificity was 100% per target (0 false positives out of 1,305 per target, 95% CI 99.71–100%). The antigen test missed 2–5 of 100 PCR-positive specimens, depending on the target. CI denotes confidence interval [1]. **Study framework.** The manufacturer's report cites Annex XIII to Regulation (EU) 2017/746 (IVDR) and ISO 20916:2019 good study practice [1].

Clinical Data for JOYTEST 12-in-1

The German study evaluated the 11-in-1 panel and began before JOYMED added JOYTEST 12-in-1 to its range. The 12-in-1 version adds detection of *B. pertussis*. Its instructions for use report 98.23% positive agreement (111/113, 95% CI 93.78–99.51%) and 235/235 negative agreement with the comparator kit for this target [2].

References

[1] Anhui DeepBlue Medical Technology Co., Ltd. *Eleven Respiratory Pathogens Antigen Test Kit (LFA) Clinical Performance Study Report.* CPSP 250821-09, v. 1.0, 17 June 2026, pp. 6–8, 17, 20, 22–27 and 32. REF RP1111NNP-X and RP1111NST-X.
[2] **JOYTEST 12-in-1 instructions for use, Czech edition** (JOY121P1), IFU-RP12Ag-NNP-01, rev. A/0, 18 August 2025, pp. 1–3 and section 4.9.
[3] Anhui DeepBlue Medical Technology Co., Ltd. Instructions for use for the nine-target respiratory panel, IFU-RP9Ag-NNP-01, rev. A/0.

The full original report and model-specific instructions for use are available on request. JOYMED prepared this summary with the manufacturer's written permission.

Prague, 24 November 2026 **Tereza Šnoblová,** Managing Director, JOYMED.cz s.r.o.