



RSV-4-in-1 1_Primary RSV-4-in-1 2_Secondary RSV-4-in-1 3_Secondary RSV-4-in-1 4_Secondary RSV-4-in-1 5_Secondary RSV-4-in-1 6_Secondary RSV-4-in-1 7_Secondary

Download high resolution images

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PRODUCT NAME

iHealth® Flu A/Flu B/COVID-19/RSV 4-in-1 Rapid Test OTC
iHealth® Flu A/Flu B/COVID-19/RSV 4-in-1 Rapid Test POC

KEY FEATURES

FDA 510(K)-CLEARED 15-MINUTE 4-IN-1 ANTIGEN RAPID TEST

- **Over-the-Counter (OTC) At-Home Use**
Quickly test for COVID-19, Flu A, Flu B, and RSV with clear results in about 15 minutes.
- **Professional Point-of-Care (POC) Use**
FDA-authorized for clinical and point-of-care settings, delivering reliable 15-minute results to support timely, informed clinical decisions.

MADE FOR AGES 6 MONTHS AND UP

- For individuals 6 months to 13 years, nasal swab collection must be performed by an adult
- For individuals 14 years and older, nasal swabs may be self-collected

ONE TEST. 5 DROPS. SAME EASY STEPS. BROADER DETECTION

Detect multiple respiratory viruses with one sample and just 5 drops. Using the simple 4 easy steps you already know from our at-home COVID-19 and 3-in-1 combo tests, get fast reliable answers whenever symptoms appear.

CONVENIENT ON-THE-GO TESTING

Compact and portable for quick testing anytime, anywhere—at home, before travel, or after potential exposure. A reliable 4-in-1 test you can trust—for peace of mind when it matters most.

DESCRIPTION

OTC Use

The iHealth® Flu A&B/COVID-19/RSV Rapid Test is intended for over-the-counter (OTC) use for the qualitative detection of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV) protein antigens in anterior nasal (nares) swab samples.

The test is intended for non-prescription home use by individuals 14 years of age or older testing themselves, or by adults testing individuals 6 months of age or older. It is intended for use in individuals with signs and symptoms of respiratory tract infection within the first six (6) days of symptom onset, when tested at least twice over a three-day period, with a minimum of 48 hours between tests.

POC Use

The iHealth® Flu A&B/COVID-19/RSV Rapid Test Pro is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A, influenza B, and RSV protein antigens directly from anterior nasal swab samples.

This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Regulatory Status

The iHealth® Flu A&B/COVID-19/RSV Rapid Test and iHealth® Flu A&B/COVID-19/RSV Rapid Test Pro are FDA cleared under 510(k) (K251085).

SPECIFICATIONS

• 24 Packs/Carton, 2 Tests/Pack

UPC#	850078377104
SKU#	CFR-2
Model #	ICR-3000
Packs Per Carton	24
Tests Per Pack	2
Single Package Dimensions(LxWxH)	6.18 x 3.19 x 0.71 Inches
Single Package Weight(lb)	0.12
Carton Dimension(LxWxH)	9.6 x 6.8 x 7.5 Inches
Carton Weight (lb)	3.7

• 12 Packs/Carton, 25 Tests/Pack

UPC#	850078377180
SKU#	CFR-P-25
Model #	ICR-3000P
Packs Per Carton	12
Tests Per Pack	25
Single Package Dimensions(LxWxH)	6.30 x 5.31 x 4.45 Inches
Single Package Weight(lb)	0.93
Carton Dimension(LxWxH)	19.7 x 11.6 x 10.0 Inches
Carton Weight (lb)	13.0

CLINICAL PERFORMANCE

• SARS-COV-2 PERFORMANCE

iHealth® Flu A/Flu B/COVID-19/RSV 4-in-1 Rapid Test	Comparator Method		
	Positive	Negatives	Total
Positive	67	1	68
Negative	8	1043	1051
Total	75	1044	1119

Positive Agreement (PPA) = 89.3% (67/75), 95% CI (80.3%, 94.5%)

Negative Agreement (NPA) = 99.9% (1043/1044), 95% CI (99.5%, 100.0%)

• INFLUENZA A PERFORMANCE

iHealth® Flu A/Flu B/COVID-19/RSV 4-in-1 Rapid Test	Comparator Method		
	Positive	Negatives	Total
Positive	205	4	209
Negative	29	881	910
Total	234	885	1119

Positive Agreement (PPA) = 87.6% (205/234), 95% CI (82.8%, 91.2%)

Negative Agreement (NPA) = 99.5% (881/885), 95% CI (98.8%, 99.8%)

• INFLUENZA B PERFORMANCE

iHealth® Flu A/Flu B/COVID-19/RSV 4-in-1 Rapid Test	Comparator Method		
	Positive	Negatives	Total
Positive	36	0	36
Negative	3	1080	1083
Total	39	1080	1119

Positive Agreement (PPA) = 89.3% (67/75), 95% CI (80.3%, 94.5%)

Negative Agreement (NPA) = 99.9% (1043/1044), 95% CI (99.5%, 100.0%)

• RSV PERFORMANCE

iHealth® Flu A/Flu B/COVID-19/RSV 4-in-1 Rapid Test	Comparator Method		
	Positive	Negatives	Total
Positive	149	12	161
Negative	21	937	958
Total	170	949	1119

Positive Agreement (PPA) = 87.6% (149/170), 95% CI (81.9%, 91.8%)

Negative Agreement (NPA) = 98.7% (937/949), 95% CI (97.8%, 99.3%)

RESOURCES

↓ DOWNLOADS

- Product Images (ALL)
- FDA EUA Letter
- Quick Start Guide for Consumers
- Health Provider Instructions for Use
- iHealth Logo

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