



Influenza A&B testing

The littlest things can deliver accuracy and speed

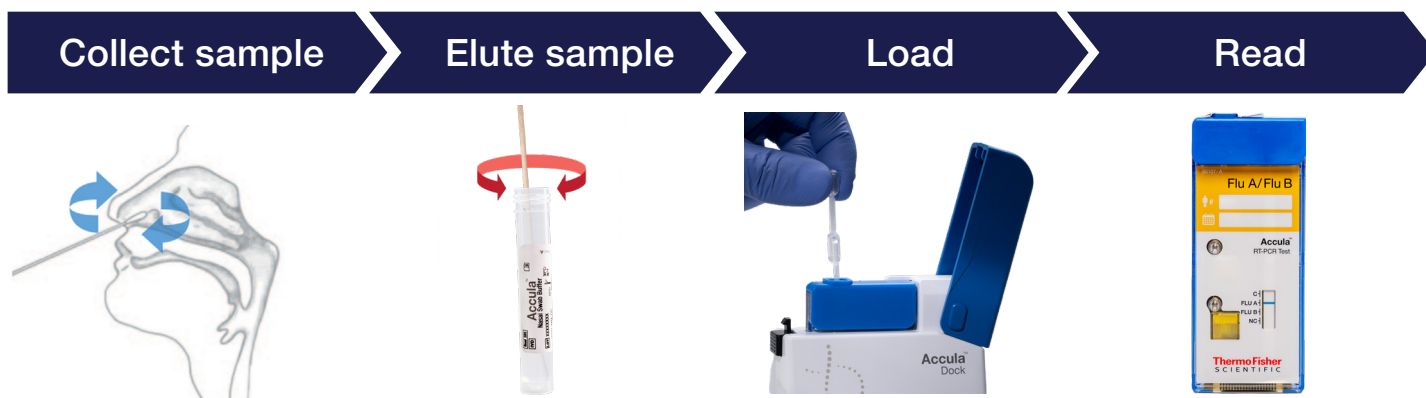
The Thermo Fisher Scientific™ Accula™ Flu A/Flu B Test is a rapid diagnostic test that combines the accuracy¹ of RT-PCR with the simplicity, convenience, and procedural familiarity of traditional rapid immunoassays. The Accula Flu A/Flu B Test has received 510(k) clearance from the US Food And Drug Administration (FDA) for the qualitative and differential detection of influenza A and influenza B viral RNA in Clinical Laboratory Improvement Amendments (CLIA) waived environments. Designed for use with the palm-sized Thermo Fisher Scientific™ Accula™ Dock, the Accula Flu A/Flu B Test provides reliable results in approximately 30 minutes.

The Accula Flu A/Flu B Test and Dock feature:

- **PCR technology**—97% sensitivity and 94% specificity for Flu A; 94% sensitivity and 99% specificity for Flu B
- **Simple sample collection**—prepare and load nasal swab samples in seconds
- **Fast results**—qualitative, rapid PCR-based test provides visual results in approximately 30 minutes
- **Easy storage**—reagents stored at room temperature (15°C to 30°C, 59°F to 86°F); eluted samples in Thermo Fisher Scientific™ Accula™ Buffer may be kept at room temperature for up to 2 hours
- **Compact design**—dock fits in the palm of your hand; ideal size for clinical settings

¹Refer to performance tables on pg. 2

~30 minutes for actionable results, accessibility, and RT-PCR accuracy



Features and benefits

Part Numbers:	Accula™ Flu A/Flu B Test: FAB1100CW
	Accula™ Flu A/Flu B Control Kit: FAB1100CW-C
	Accula™ Dock: D2000
Specimen Type:	Nasal Swab
CLIA Status:	Waived
Test Methodology:	Rapid RT-PCR
Time to result:	~30 Minutes
Tests per kit:	25 tests
Other tests available:	Accula™ SARS-CoV-2 Test
Electrical requirements:	Dock Power Input: 12 VDC \pm 1 VDC, 1 A max.
	AC Power Adapter Input: 100 - 240 VAC, 50/60 Hz
	AC Power Adapter Output: 12 VDC, 2.08 A, 25 W max.
Useful life (Dock):	5,000 Runs

Performance

Flu A performance against molecular comparator method

Accula™ Flu A/Flu B Test Flu A	Comparator		
	Positive	Negative	Total
Positive	289	60 ^[1]	349
Negative	9 ^[2]	900	909
Total	298	960	1258
Sensitivity:	97% (95% CI: 94.4% – 98.4%)		
Specificity:	94% (95% CI: 92.0% – 95.1%)		

^[1] FLU A was detected in 47/60 false positive specimens using an alternative FDA-cleared molecular influenza assay.

^[2] FLU A was not detected in 3/9 false negative specimens using an alternative FDA-cleared molecular influenza assay.

Flu B performance against molecular comparator method

Accula™ Flu A/Flu B Test Flu B	Comparator		
	Positive	Negative	Total
Positive	126	14 ^[1]	140
Negative	8 ^[2]	1110	1118
Total	134	1124	1258
Sensitivity:	94% (95% CI: 88.7% – 97.0%)		
Specificity:	99% (95% CI: 97.9% – 99.3%)		

^[1] FLU B was detected in 9/14 false positive specimens using an alternative FDA-cleared molecular influenza assay.

^[2] FLU B was not detected in 5/8 false negative specimens using an alternative FDA-cleared molecular influenza assay.

For questions, email USSD2.customercare@thermofisher.com
 or go to [thermofisher.com/acculaflu](https://www.thermofisher.com/acculaflu)

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