July 06, 2026

2026 Annual Analytical Reactivity Testing with CDC Human Influenza Virus Panel on BinaxNOW™ Influenza A&B Card 2 Report

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SCIENTISTS

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OBJECTIVE

The purpose of this evaluation was to conduct an annual review of analytical reactivity performance of the BinaxNOW™ Influenza A&B Card 2 device with contemporary strains of human influenza virus supplied by the CDC. Results were obtained both visually for test and control line development and with the DIGIVAL Reader. Note: The DIGIVAL BinaxNOW™ Influenza A & B Card 2 is FDA cleared for use with the DIGIVAL Reader only. No visual ICT scores were recorded.

BACKGROUND

This testing was conducted in accordance with the FDA's required annual Analytical Reactivity testing for influenza virus antigen detection systems (Federal Code of Regulations, 866.3328). Each year the CDC provides a panel of virus for manufacturers to use to check the analytical reactivity of their test devices against contemporary strains of influenza. This report has been developed in accordance with requirements contained in the procedure provided with the CDC test panel. Panel documentation will be added as supporting materials to this report in CO-10241175.

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MATERIALS

Material	Part Number	Lot Number	Expiration Date
BinaxNOW™ Influenza A & B Card 2 pouched devices	575-430R	1136070	2026-11
DIGIVAL Reader	EQ006001	1911400801	N/A
		1911400757	N/A
Flash drive for data collection	N/A	N/A	N/A
BinaxNOW™ Flu A&B Positive Control Swab	416-415	0001142853	2027-08-25
BinaxNOW™ Viral Negative Control Swab	400-416	0001171982	2027-11-17
Elution Solution	400-001	0000905240	2027-07-30
		0001180546	2028-10-08
Puritan sterile foam tipped swab	Ref# 25-1506	S1447	2030-01-01
Calibrated pipettes and appropriately sized pipette tips	N/A	20A10263	2026/07/31
		04N78129	2026/07/31
		L12150M	2026/07/31
Timer(s)	N/A	N/A	N/A
CDC Human Influenza Virus Panel	Cat. No. VP2026	VP2026-001	2027-06-01

The following Influenza strains are included in the CDC Human Influenza Virus Panel for 2026, CoAs for the panel and individual viruses can be found in the Supporting Documents for CO-10241175:

Influenza Virus	Influenza Strain Designation
A (H1N1)pdm09	A/Missouri/11/2025
	A/Victoria/4897/2022
A (H3N2)	A/Michigan/105/2025
	A/Wisconsin/160/2024
B (Victoria lineage)	B/Tokyo/EIS13-175/2025
	B/Austria/1359417/2021

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METHODS

Part I – Sample Preparation

- **Note**: Virus panel was inactivated using β-Propiolactone. Samples were still handled under BSL2 conditions as a precaution per direction from the CDC.
  - Virus stock was thawed at 2-8°C refrigerated and used within 4 hours of thawing.
  - A five-fold dilution series of each virus was prepared using Elution Solution (PN 400-001) in sufficient volume to run at least five 50 µl swab replicates on the Influenza A&B Card test.
  - Mock swabs were prepared by applying 50 µL of sample to the swab head using gentle scratching of foam with pipette tip to facilitate sample absorption. Care was used to make sure sample was not sprayed off the swab head or allowed to roll off the foam as it was applied to the swab.
  - Each dilution was tested N=5 for each condition as per instructions in the Product Insert (Doc # IN575000).

Part II – Daily Control Testing

- The following daily assay control testing was conducted as outlined in the BinaxNOW™ Influenza A & B Card 2 Instrument Assay Procedure (F-2057-SCR) and the DIGIVAL Operations Procedure (F-2101-SCR).
  - BinaxNOW™ Influenza A&B Positive Control Swab (N=1)
  - BinaxNOW™ Viral Negative Control Swab (N=1)
- Daily assay control testing was conducted on each day of the study when the BinaxNOW Influenza A&B Card 2 testing was performed for all readers used, prior to beginning sample testing.
- For all control testing, all BinaxNOW™ Influenza A&B Card 2 devices were read with the DIGIVAL at 15 minutes for positive controls and negative controls.

Part III – Test Procedure

- Addition of the sample to each device was staggered to ensure that test devices were read on the DIGIVAL Reader at 15 minutes.
- For each viral strain included in the panel, testing of all dilutions was performed until there was non-reactivity at two consecutive five-fold dilution levels in Elution Solution demonstrated by obtaining negative Reader results on all 5 replicates at each level.

ACCEPTANCE CRITERIA

Daily Assay/Control Procedure Results:

- BinaxNOW™ Influenza A/B Positive Control swab must produce positive Flu A and Flu B results on the DIGIVAL at 15 minutes.
- BinaxNOW™ Viral Negative Control swab must produce negative results for Flu A and Flu B on the DIGIVAL at 15 minutes.
- All BinaxNOW™ Influenza A & B Card 2 device control lines must produce a valid response on the DIGIVAL for 99% of all samples tested.

Panel Testing Results:

- All BinaxNOW™ Influenza A & B Card 2 device control lines must produce a valid response on the DIGIVAL for 99% of all samples tested. The minimum reactive concentrations for Reader testing will be obtained and reported.
- All valid test results will be accepted.

RESULTS

Important: The BinaxNOW™ Influenza A & B Card 2 is FDA cleared for use with only the DIGIVAL. No visual scores were recorded.

All daily control testing produced valid results, see Supporting Materials. Positive control swabs produced positive results on Flu A and Flu B lines at 15 minutes per acceptance criteria. Negative control swabs produced negative results on Flu A and Flu B lines at 15 minutes per acceptance criteria. See Table 1 below.

Table 1: Daily Control Testing Results

Date	Daily Control Swab Testing	DIGIVAL Reader	Control (Valid or Invalid)	Flu A Capture Line	Flu B Capture Line
23JUN2026	Negative Swab	1911400801	Valid	Negative	Negative
23JUN2026	Positive Swab	1911400801	Valid	Positive	Positive
23JUN2026	Negative Swab	1911400757	Valid	Negative	Negative
23JUN2026	Positive Swab	1911400757	Valid	Positive	Positive
24JUN2026	Negative Swab	1911400801	Valid	Negative	Negative
24JUN2026	Positive Swab	1911400801	Valid	Positive	Positive
24JUN2026	Negative Swab	1911400757	Valid	Negative	Negative
24JUN2026	Positive Swab	1911400757	Valid	Positive	Positive

FDA specified results are provided in Table 2. This shows the minimum reactivity level, highlighted in green, for each of the six viruses in the CDC panel. Minimum reactivity level is defined as the final dilution that yielded positive results on the DIGIVAL proceeded by an additional two five-fold serial dilutions that yield only negative results at n=5 replicates.

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All raw data and dilution preparation info pertaining to this testing is located in Supporting Materials. Dilutions were completed according to the I-0601-SCR schematic. Exact quantities are specified in the protocol and no calculations were required.

CONCLUSIONS

This study effectively reviewed the analytical reactivity performance of the BinaxNOW™ Influenza A/B Card 2 device against contemporary strains of human influenza virus provided by the CDC. All six of the strains were definitively detected by the test at different levels of concentration, thus identifying the minimum reactivity level for each strain (see Table 2).

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Table 2: Reactivity Testing Results by Virus

Influenza Virus (Type/Subtype)	Virus Strain Name	Stock Concentration (EID50/mL)	Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at each Dilution							
			1.3x10^7	2.5x10^6	5.0x10^5	1.0x10^5	2.0x10^4	4.0x10^3	8.1x10^2	1.6x10^2
A/H1N1pdm09	A/Missouri/11/2025	10^7.8	5/5	5/5	5/5	5/5	5/5	1/5	0/5	0/5

Influenza Virus (Type/Subtype)	Virus Strain Name	Stock Concentration	Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at each Dilution							
			3.6x10^8	7.1x10^7	1.4x10^7	2.8x10^6	5.7x10^5	1.1x10^5	2.3x10^4	4.6x10^3
A/H1N1pdm09	A/Victoria/4897/2022	10^9.25	5/5	5/5	5/5	5/5	3/5	0/5	0/5	N/A

Influenza Virus (Type/Subtype)	Virus Strain Name	Stock Concentration	Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at each Dilution							
			6.3x10^7	1.3x10^7	2.5x10^6	5.1x10^5	1.0x10^5	2.0x10^4	4.0X10^3	8.1X10^2
A/H3N2	A/Michigan/105/2025	10^8.5	5/5	5/5	5/5	5/5	0/5	0/5	N/A	N/A

Influenza Virus (Type/Subtype)	Virus Strain Name	Stock Concentration	Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at each Dilution							
			1.1x10^8	2.2x10^7	4.5x10^6	9.0x10^5	1.8x10^5	3.6x10^4	7.2x10^3	1.4x10^3
A/H3N2	A/Wisconsin/160/2024	10^8.75	5/5	5/5	5/5	5/5	5/5	0/5	0/5	N/A

Influenza Virus (Type/Subtype)	Virus Strain Name	Stock Concentration	Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at each Dilution							
			1.1x10^8	2.2x10^7	4.5x10^6	9.0x10^5	1.8x10^5	3.6x10^4	7.2x10^3	1.4x10^3
B/Victoria-Lineage	B/Tokyo/EIS13-175/2025	10^8.75	5/5	5/5	5/5	5/5	0/5	0/5	N/A	N/A

Influenza Virus (Type/Subtype)	Virus Strain Name	Stock Concentration	Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at each Dilution							
			6.3x10^7	1.3x10^7	2.5x10^6	5.1x10^5	1.0x10^5	2.0x10^4	4.0X10^3	8.1X10^2
B/Victoria-Lineage	B/Austria/1359417/2021	10^8.5	5/5	5/5	5/5	5/5	0/5	0/5	N/A	N/A

The concentrations highlighted in green show the minimum reactive concentration for each virus where at least one replicate out of five was detected by the test.