Testing Solutions for Rapidly Detecting Influenza A&B

Best-in-Class Flu Diagnostics from the Fisher Healthcare Portfolio







- Sensitive True molecular test eliminates need for negative confirmation
- Precise Accurate results help to avoid unnecessary antibiotic use

Abbott ID NOW (formerly Alere i)

The Abbott[™] ID NOW[™] System uses isothermal nucleic acid amplification technology to detect influenza A and B viral nucleic acids. The CLIA-waived method includes all of the necessary testing components, and the analyzer offers barcode technology and LIS connectivity. This multi-assay platform includes Influenza A and B, RSV, and Strep A.

Cat. No. 23-046-617 and 23-046-634

Operational Outcomes

- Simple Easy-to-use, CLIA-waived test
- Fast Results available within 13 minutes

Financial Outcomes

- Effective Fast, accurate results reduce downstream costs
- Flexible Multiple purchase options



Quidel Solana

The Quidel[™] Solana[™] Molecular Platform provides Influenza A and B results in 45 minutes and multiplexes up to 12 tests per run. The CLIA-moderate assay includes access to the Power of Virena and offers LIS/EMR connectivity. This multi-assay platform offers a variety of diagnostics, from bacterial infections to infectious diseases.

Cat. No. 23-043-111 and 23-043-107

Clinical Outcomes

- Precise Highly sensitive molecularbased test for accurate results
- Safe Helps to reduce the risk of unnecessary antibiotic use

Operational Outcomes

- Flexible Offers STAT or batch testing
- Simple Share results via LIS connectivity

Financial Outcomes

- Efficient High sensitivity reduces the need for repeat testing
- Affordable Multiple placement and purchase options; no need for multiple instrument platforms



Confidence in making the right

test - no confirmation needed

Lab-standard sensitivity and

treatment decision at the time of the

Clinical Outcomes

specificity

Roche cobas Liat System

In just three steps, the Roche cobas[™] Liat[™] assays and analyzer automate the entire nucleic acid test (NAT) process: reagent preparation, target enrichment, inhibitor removal, nucleic acid extraction, amplification, real-time detection, and result interpretation. The system is CLIA-waived for Influenza A/B, RSV, and Strep A.

Cat. No. 23-312-198 and 23-312-200

Operational Outcomes

- Fast, easy operation with three simple steps
- Walkaway workflow and test results in 20 minutes or less
- Closed System concept, ideal for moving molecular out of the lab with decreased risk for contamination

Financial Outcomes

- No confirmation required
- Molecular CPT codes generally allow for higher reimbursement rate
- Capital and Placement options
 available



- Accurate clear information helps physicians provide targeted treatment
- Reliable precise results help reduce inappropriate use of antibiotics

Sekisui Diagnostics Silaris

Influenza A&B Test

The Sekisui[™] Silaris[™] Influenza A&B Test is a molecular diagnostic test that uses the polymerase chain reaction (PCR) and lateral flow technology to qualitatively detect the presence of antibodies to influenza A and B viruses in approximately 30 minutes. The CLIA-waived test is performed on nasal swab specimens using the Silaris Dock device. Reagents can be stored at room temperature.

Cat. No. 22-321-116 and 22-321-115

Operational Outcomes

- Easy CLIA-waived test for pointof-care diagnosis and treatment
- Efficient fast turnaround allows for prompt infection control measures

Financial Outcomes

- Simple test reduces costs and need to send samples to a core or reference lab
- Affordable cost effective with minimal capital outlay

Analyzers



Clinical Outcomes

- Accurate objective results for more reliable diagnoses
- Effective eliminates the variability of visually read tests

Abbott DIGIVAL Reader

Abbott[™] DIGIVAL[™] Reader is a benchtop instrument that can objectively interpret results by using a camera to detect the presence of and identify a completed lateral flow assay, analyze the intensity of the test and control line, and display the results (positive, negative, or invalid) on the color touchscreen.

Cat. No. 23-046-680 and 23-046-682

Operational Outcomes

- Simple intuitive design for ease of use
- Flexible choice of "read now" and "walk away" modes

Financial Outcomes

 Affordable — cost-effective assay and platform



Clinical Outcomes

- Accurate High positive and negative percent agreement
- Fast Get results in 10 minutes for prompt diagnosis

BD Veritor Plus System

The BD[™] Veritor[™] Plus System is a rapid chromatographic immunoassay analyzer for the qualitative detection of Influenza A and B viral nucleoprotein antigens. The system is CLIA waived for nasal and nasopharygeal swabs and offers two modes: Analyze Now and Walk Away. This multi-assay platform includes Influenza A and B, RSV, and Strep A.

Cat. No. B256066, B256041, and B256045

Operational Outcomes

- Easy No need to incubate samples before testing
- Flexible Works with multiple sample types and workflow options
- Safe Print or download results to reduce the risk of reporting errors

Financial Outcomes

 Economical — Expanded storage holds up to 3,500 results, so you spend less on additional analyzers



Quidel Sofia 2

The Quidel[™] Sofia[™] 2 Analyzer accurately detects Influenza A and B from nasal swabs, nasopharyngeal swabs, and nasal aspirate/wash samples. Its CLIA-waived procedure can produce dual test results from a single sample. The instrument features an easy-to-use interface with customizable settings.

Cat. No. 23-043-086 and 23-043-070

Clinical Outcomes

- Clear Eliminates the subjectivity of visually interpreted results
- Fast Positive results in as little as three minutes
- Efficient Make real-time treatment decisions for public health surveillance

Operational Outcomes

- Convenient Offers "read now" and "walk away" options
- Adaptable Multi-assay platform is approved for influenza A and B, RSV, Strep A, Lyme, and hCG

Financial Outcomes

- Flexible Multiple placement or direct purchase options
- Economical Prompt, type-specific results to help reduce unnecessary testing and overuse of antibiotics



- Best-in-class Flu A sensitivity
- Definitive results reduce human error and repeat testing

Sekisui Diagnostics Acucy

Influenza A&B Test Kit

Accurate, simple, and affordable solution to Influenza A&B testing. Acucy[™] Influenza A&B offers a best-in-class Flu A performance and provides an easy-to-use CLIA-waived procedure as well as definitive and standardized results. The included QC (2 additional tests for QC in each kit) removes the additional expense of performing external QC testing making this analyzer even more cost competitive.

Cat. No. 22-321-25 and 22-321-28

Operational Outcomes

- Results within 15 minutes
- Read-Now mode for high throughput

Financial Outcomes

- No long-term contract
- QC included = major cost savings



Quidel QuickVue Influenza A&B Test

The Quidel[™] QuickVue[™] Influenza A+B Test detects and differentiates influenza A and B antigens directly from nasal swab and nasopharyngeal swab specimens. A single sample can be used to run both the QuickVue Influenza A+B Test and the QuickVue RSV10 Test.

Cat. No. 23-043-058

Clinical Outcomes

- Accurate reliable results allow clinicians to take action with confidence
- Fast reduce wait time and improve patient satisfaction

Operational Outcomes

- Simple CLIA-waived testing doesn't require additional training
- Flexible Works with multiple sample types
- Easy Test with only 30 to 60 seconds of hands-on time

Financial Outcomes

• Economical — Accurate, costeffective detection



Clinical Outcomes

• Accurate — reliable results allow clinicians to take action with confidence



The Thermo Scientific[™] Xpect[™] Flu A & B Test detects influenza A and B antigens from human nasal wash, nasal swab, and throat swab specimens. It helps maintain efficiency and productivity with a simple two-step procedure that offers accurate results in as little as 15 minutes.

Cat. No. R24600

Operational Outcomes

- Flexible Multiple specimen storage, collection, and transportation options
- Efficient Less than one minute of hands-on time and a walk-away procedure

Financial Outcomes

• Economical — Accurate, cost-effective detection



Meridian Bioscience ImmunoCard STAT!

Influenza A&B Test

The Meridian Bioscience[™] ImmunoCard STAT![™] FLU A&B Test is a CLIA-waived lateral flow immunoassay for the detection of Influenza A and B from nasal and nasopharyngeal swabs. It can also be used to test nasal aspirate and wash specimens.

Cat. No. 23-315-126

Clinical Outcomes

- Accurate Reliable results allow clinicians to take action with confidence
- Simple CLIA-waived testing
- doesn't require additional training
 Fast Results in 10 to 15 minutes

Financial Outcomes

• Economical — Accurate, costeffective detection



- Accurate High positive and negative percent agreement
- Fast Short turnaround time for prompt diagnosis

Sekisui OSOM Ultra

The Sekisui[™] OSOM[™] Ultra Influenza *in vitro* rapid qualitative test detects Influenza A and B nucleoprotein antigens directly from nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens obtained from patients with signs and symptoms of respiratory infection.

Cat. No. 22-321-105

Operational Outcomes

- Simple Four easy steps for results in 15 minutes
- Flexible Works with multiple sample types

Financial Outcomes

- Economical No capital costs
- Affordable Priced competitively with other rapid diagnostic tests

Germaine Laboratories BioSign

Flu A&B Test



The Germaine[™] Laboratories BioSign[™] Flu A&B Test can detect the presence of influenza A and B antigens from a single specimen. The method is CLIA waived when used with nasal or nasopharyngeal swabs and CLIA moderate for nasal wash/aspirate specimens. This rapid test can produce results in 10 to 15 minutes.

Cat. No. 23-111-369

Clinical Outcomes

- Accurate reliable results allow clinicians to take action with confidence
- Fast reduce wait time and improve patient satisfaction

Operational Outcomes

- Simple CLIA-waived tests produce results in 15 minutes
- Flexible format and procedure allow testing in a variety of clinical settings

Financial Outcomes

- Economical no capital costs
- Affordable priced competitively with other rapid diagnostic tests



LifeSign Status

Influenza A&B Test

The LifeSign[™] Status Influenza A and B test qualitatively detects influenza A and B as well as H1N1 (swine flu). The test is CLIA waived for nasal swab samples, and the kit includes flocked swabs for better specimen collection.

Cat. No. 23-264-783

Clinical Outcomes

- Accurate Differentiates between influenza A and B with results that compare well to PCR
- **Operational Outcomes**
- Simple Features onboard sample extraction and an easy-to-read flip design
- Flexible Works with multiple sample types

Financial Outcomes

• Economical - no capital costs

Visual Read Lateral Flow Tests

FLU MATRIX	Quidel QuickVue Influenza A&B Test	Thermo Scientific Xpect	Meridian Bioscience Immunocard STAT!
Catalog Number	23-043-058	R24600	R24600
Specimen Type	Nasal SwabNasopharyngeal Swab	Nasal SwabNasal WashThroat Swab	Nasal SwabNasopharyngeal SwabNasal Aspirate/Wash
CLIA Status	Waived	Moderate	Waived (nasal and nasopharyngeal swabs); Moderate (wash/aspirate)
Test Methodology	Lateral Flow	Lateral Flow	Lateral Flow
Instrument Connectivity	No	N/A	No
Time to Result	10 minutes or sooner	15 minutes	15 minutes or sooner
Recommend Negative Confirmation	Yes	Yes	Yes
Comparison Method	PCR	Culture and PCR for discrepants	Culture and PCR
Sensitivity: A/B (May depend on sample type)	81.9%/80.9%	A+92.2% / B=97.8%	95.3% / 91.6% (culture) 89.2% / 86.4% (PCR)
Specificity: A/B (May depend on sample type)	97.8%/99.1%	100%	85.7% / 97.5% (culture) 99.4% / 99% (PCR)
Tests Per Kit	25	20	32
CPT Codes***	87502 (Flu A and B)	87502 (Flu A and B)	FLU A (swab) - 87804QW, FLU B (swab) - 87804QW-59, FLU A (wash/aspirate) - 87804, FLU B (wash/aspirate) - 87804-59
Meets FDA Flu Reclassification Requirements	Yes	Yes	Yes
Other Tests Available	None	None	None



Visual Read Lateral Flow Tests

FLU MATRIX	Sekisui OSOM Ultra	Germaine Labs BioSign Influenza A&B Test	LifeSign Status Influenza A&B Test
Catalog Number	22-321-105	23-111-369	23-264-783
Specimen Type	 Nasal swab Nasopharyngeal swab Nasopharyngeal wash/aspirate 	 Nasal swab Nasopharyngeal swab Nasopharyngeal wash/aspirate 	 Nasal swab Nasopharyngeal swab Nasopharyngeal wash/aspirate
CLIA Status	Waived (nasal and nasopharyngeal swabs) Moderate (wash/aspirate)	Waived (nasal and nasopharyngeal swabs) Moderate (wash/aspirate)	Waived (nasal and nasopharyngeal swabs) Moderate (wash/aspirate)
Test Methodology	Lateral flow	Lateral flow	Lateral flow
Instrument Connectivity	No	No	No
Time to Result	10 minutes (positive)15 minutes (confirm negative)	10 minutes (positive)15 minutes (confirm negative)	10 minutes (positive)15 minutes (confirm negative)
Recommend Negative Confirmation	Yes	Yes	Yes
Comparison Method	Culture, PCR	RT-PCR	Culture, PCR
Sensitivity: A/B (May depend on sample type)	91.2%/82.4% (culture) 89.2%/86.4% (PCR)	96.7% (both A and B)	89.2-95.3%/82.4-91.6%
Specificity: A/B (May depend on sample type)	75.2%/88.3% (culture) 99.4%/99% (PCR)	91% (both A and B)	75.2–99.4%/88.3–99%
Tests Per Kit	25 (plus two for QC)	25	22 (includes positive and negative QC swabs)
CPT Codes***	87804QW/87804QW-59	Influenza A 87084QW Influenza B 87084QW-59	87804 87804-59 (Used to indicate separate test)
Meets FDA Flu Reclassification Requirements	Yes	Yes	Yes
Other Tests Available	N/A	N/A	N/A

Analyzers

FLU MATRIX	Abbott DIGIVAL	BD Veritor Plus System	Quidel Sofia and Sofia 2	Sekisui Acucy
Catalog Number	23-046-682	B256045 (Waived) B256041 (Moderate)	23-043-070	22-321-128
Specimen Type	Nasal swabNasopharyngeal swab	Nasal swabNasopharyngeal swab	 Nasal swab Nasopharyngeal swab Nasopharyngeal wash/ aspirate 	 Nasal Swab Nasopharyngeal Swab
CLIA Status	Waived	Waived and moderate	Waived and moderate	Waived
Test Methodology	Lateral flow	Digital immunoassay (DIA)	Fluorescent immunoassay	Lateral Flow Reader
Instrument Connectivity	Yes — bidirectional	Veritor: No Veritor Plus: Yes	Yes, with real-time mapping and tracking capabilities	USB Drive and Third-Party
Time to Result	15 minutes	10 minutes	 3 minutes (positive, Sofia 2) 15 minutes (negative, Sofia and Sofia 2) 	15 minutes
Recommend Negative Confirmation	Yes	Yes	Yes	Yes
Comparison Method	PCR	PCR	Culture	Composite comparator (culture and molecular)
Sensitivity: A/B (May depend on sample type)	87%/95.7%	81–83%/80–86%	90–99%/88–90%	A: 96.4% B: 82.3%
Specificity: A/B (May depend on sample type)	95.1%/99.5%	97–98%/99–100%	95–96%/96–97%	A: 96.0% B: 98.1%
Tests Per Kit	22	30	25	25
CPT Codes***	87804 x 2	87804 (Flu A and B) 87807 (RSV) 87880 (Strep A)	87804QW (Flu A and B) 87807QW (RSV) 87880 (Strep A) 87880QW (Strep A+) 84703 (hCG) 86618QW 86618QW 86618QW 86618QW (Sofia 2 Lyme IgM) 86618QW-59 (Sofia 2 Lyme IgG)	87804QW
Meets FDA Flu Reclassification Requirements	Yes	Yes	Yes	Yes
Other Tests Available	None Currently	RSVStrep A	 hCG (Sofia) RSV (Sofia, Sofia 2) Strep A (Sofia, Sofia 2) Lyme (Sofia, Sofia 2) 	Non currently

Molecular Instruments

FLU MATRIX	Abbott ID Now (formerly Alere i)	Quidel Solana	Sekisui Silaris	Roche cobas Liat System
Catalog Number	23-046-634	23-043-107	22-321-116	23-312-198 23-312-199 23-312-200
Specimen Type	Nasal swabNasopharyngeal swab	Nasal swabNasopharyngeal swab	Nasal swab	Nasopharyngeal
CLIA Status	Waived	Moderate	Waived	Waived
Test Methodology	Nucleic acid amplification	Helicase-dependent amplification (HDA)	Reverse transcription- polymerase chain reaction (RT-PCR)	Real-Time PCR
Instrument Connectivity	Yes — uni- and bidirec- tional	Yes, with real-time mapping and tracking capabilities	No	Yes (with RALS, Telcor, or cobas 1000)
Time to Result	 5 minutes (positive) 13 minutes (confirm negative)	 45 minutes (per run of 1–12 tests) 	30 minutes	20 minutes
Recommend Negative Confirmation	No	No	No — uses reference method	No
Comparison Method	Molecular	Culture, PCR	FDA-approved molecular (Abbott ID Now)	Culture and PCR for discrepants
Sensitivity: A/B (May depend on sample type)	96.3%/100% (direct) 92.8%/100% (VTM)	98.6.%/100% (culture) 97.2%/100% (PCR)	97%/94%	A=100% / B=100%
Specificity: A/B (May depend on sample type)	97.4%/97.1% (direct) 98.5%/97.7% (VTM)	95.1.%/99.3% (culture) 96.7%/98.9% (PCR)	94%/99%	A = 96.8% / B=94.1%
Tests Per Kit	24	48	25	20

continued on next page

Molecular Instruments

CPT Codes***	87502	87493 (C. diff) 87529 x 2/87798 (HSV 1&2/ VZV) 87651/87998 (GAS/Strep Complete) 87661 (Trichomonas) 87502 (Flu A and B) 187798 x 2 (Bordetella Complete) 87077/87653 (Group B Strep: Vaginal/Rectal Swab) 87798 x 2 (RSV and hMPV)	87502QW (Influenza DNA Amp Probe)	87502 (Flu A and B)	
Meets FDA Flu Reclas- sification Requirements	Yes	Yes	Yes	Yes	Y
Other Tests Available	• RSV • Strep A	 C. difficile HSV 1&2/VZV Strep A, Strep Complete (A,C,G) RSV/hMPV Trichomonas Group B Strep Bordatella pertussis 	None currently	None currently	

*Approved VTM: BD/Copan VTM, Remel M4, Remel M4RT, Remel M5, Remel M6, or Copen ESwab

**Modifier, -QW, used to reflect CLIA-waived status for test

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As of November 11, 2019, these products meet FDA reclassification requirements. Policies regarding reclassification can vary and change over time, therefore it is the individual provider's responsibility to preform due diligence and make an individual determination regarding a product's classification.



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