

Table 2: Characteristics of Rapid Influenza Diagnostic Tests (Antigen Detection Only)¹

Procedure (Manufacturer/Distributor)	Influenza Virus Types Detected	Approved Specimens²	CLIA Waived³	Uses Analyzer Reader Device
BD Directigen™ EZ Flu A+B⁴ (Becton-Dickinson & Co.)	A and B	NP ⁵ wash/aspirate/swab Throat swab	No	No
BD Veritor™ System for Rapid Detection of Flu A+B⁴ (CLIA-waived), (Becton Dickinson & Co.)	A and B	NP ⁵ swab/ nasal swab	Yes	Yes
BD Veritor™ System for Rapid Detection of Flu A+B⁴ (Moderately Complex), (Becton Dickinson & Co.)	A and B	NP ⁵ wash/aspirate	No	Yes
Binax NOW® Influenza A&B⁴ Test (Alere Scarborough, Inc.)	A and B	NP ⁵ swab, Nasal wash/aspirate/swab	Yes	No
BioSign® Flu A+B⁴ or OraSure QuickFlu Rapid A+B Test or Polymedco Poly stat Flu A&B Test or LifeSign LLC Status Flu A&B (Princeton BioMedtech Corp.)	A and B	NP ⁵ swab/aspirate/wash, nasal swab	No	No
ClearView Exact II Influenza A&B Test or	A and B	Nasal swab	Yes	No

Alere Influenza A&B Test (Alere Scarborough, Inc.)				
OSOM® Influenza A&B⁴ Test (Sekisui Diagnostics)	A and B	Nasal swab	No	No
QuickVue® Influenza A/B Test⁶ (Quidel Corp.)	A and B	Nasal wash/aspirate/swab	Yes	No
QuickVue® Influenza A+B Test⁴ (Quidel Corp.)	A and B	NP ⁵ swab Nasal wash/aspirate/swab	Yes	No
RAMP Influenza A/B Assay or 3M™ Rapid Detection Flu A+B Test⁴ (Response Biomedical Corp.)	A and B	NP ⁵ swab/aspirate Nasal wash/aspirate	No	Yes
SAS™ FluAlert A&B Test⁴ (SA Scientific, Inc.)	A and B	Nasal wash/aspirate	No	No
SAS™ Influenza A Test⁴ (SA Scientific, Inc.)	A only	Nasal wash/aspirate	Yes	No
SAS™ Influenza B Test^{4,6} (SA Scientific, Inc.)	B only	Nasal wash/aspirate	Yes	No

Sofia® Analyzer and Influenza A+B FIA⁴ (CLIA-waived) (Quidel Corp.)	A and B	NP ⁵ swab Nasal swab	Yes	Yes
Sofia® Analyzer and Influenza A+B FIA⁴ (Quidel Corp.)	A and B	NP ⁵ aspirate/ wash	No	Yes
TRU FLU®⁴ (Meridian Bioscience, Inc.)	A and B	NP ⁵ aspirate/swab Nasal wash/swab	No	No
XPECT™ Influenza A/B⁴ (Remel Inc./Thermo Fisher Scientific)	A and B	Nasal wash/swab Throat swab	No	No

1. List may not include all test kits approved by the U.S. Food and Drug Administration. Discontinued tests not included.
2. Approved respiratory specimens according to manufacturer's package insert. Note that test performance may vary if other respiratory specimens are used.
3. Ref: <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>
4. Distinguishes between influenza A and B virus infections.
5. NP = nasopharyngeal.
6. Does not distinguish between influenza A and B virus infections when used alone.

Disclaimer: Use of trade names or commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention or the Department of Health and Human Services.