



Canadian Journal of Health Technologies

May 2024 Volume 4 Issue 5

CADTH Horizon Scan

Point-of-Care Tests for COVID-19 and Influenza in Canada

Key Messages

What Is the Issue?

- Health care providers rely on laboratory tests to differentiate between respiratory illnesses that manifest in similar symptoms, such as COVID-19 and influenza. However, samples may travel to centralized laboratories to process, delaying test results and treatment.
- Point-of-care tests (POCTs) allow for diagnosis at the site of care but at the expense of diagnostic performance. Several commercial POCTs, specifically for COVID-19, have become increasingly available in Canada since the start of the pandemic. Decision-makers will need to consider which commercial POCT can meet their jurisdiction's testing needs.

POCTs in Canada and Their Potential Impact

- Some POCTs, called "Multiplex tests," can detect and differentiate between certain illnesses using a single sample. Some studies suggest that using POCTs for respiratory illness in hospitals and emergency departments can expedite diagnosis, improve patient flow, reduce admissions, and shorten the length of stay.
- Commercial POCTs vary in diagnostic performance, complexity, and costs. There are at least 37 authorized POCTs for COVID-19, influenza, or both in Canada. All devices accept a nasal, nasopharyngeal sample, or both sample types for testing. Some tests require a reader or analyzer to use test kits for diagnosis.
- POCTs can provide results in 1 hour or less. However, laboratory testing (i.e., nucleic acid amplification tests) remains the standard of care to diagnose COVID-19 and influenza, given their better diagnostic performance compared to POCTs.

What Else Do We Need to Know?

- Confirmatory laboratory tests can reaffirm the diagnosis from POCTs. However, budget impact analyses and clinical studies on authorized tests in Canada do not consider how confirmatory lab tests impact findings on POCT use. Future studies should investigate the cost-effectiveness of POCTs with confirmatory testing, as well as the impact of incorrect diagnosis from POCT on patient outcomes.
- Rural and remote communities may benefit from POCTs for respiratory illness, given their distance to centralized laboratories.

Background

POCTs provide timely diagnosis at the site of care and avoids delays in treatment.¹⁻³ These tests can also support disease control and surveillance, and ease demand on centralized laboratories.¹ POCTs can be classified into 1 of the 2 categories:²

- **Antigen-based tests or immunoassays:** These tests detect antigens or antibodies of a particular disease or disease state.
- **Molecular-based testing:** These devices detect DNA or RNA sequences that suggest the presence of the disease. This category encompasses, nucleic acid amplification tests (NAATs), such as reverse-transcription polymerase chain reaction (RT-PCR) and isothermal amplification.

Some authorized POCTs are referred to as “multiplex,” which means they can diagnose more than 1 condition using a single test.² Multiplex POCTs can be practical in cases where different illnesses manifest with similar symptoms. This can be the case for respiratory illnesses, like COVID-19 and influenza.^{4,5} Both can result in symptoms such as fever, chills, cough, sore throat, fatigue, headache, muscle ache, and gastrointestinal symptoms.⁵ Health care providers can avoid delays in treatment and using multiple tests to diagnose and differentiate between respiratory illnesses.⁴

Health systems have implemented POCTs to slow and reduce the spread of COVID-19.¹ In 2020, the federal Minister of Health signed an interim order allowing expedited access to COVID-19 medical devices, including diagnostics.³ In the same year, the seasonal influenza epidemic was suppressed due to measures to curb the spread of COVID-19.⁶ However, public health surveillance found that the following influenza epidemic (i.e., 2022 to 2023) returned to prepandemic levels and coincided with early respiratory syncytial virus (RSV) activity and the ongoing circulation of COVID-19.⁶ POCTs, including multiplex tests, may help health care providers differentiate between COVID-19 and influenza, as well as other respiratory illnesses, at the site of care without having to wait for samples to reach a laboratory for test results.

This report identifies and provides an overview of POCTs authorized in Canada for COVID-19 or influenza A and B.

It also includes POCTs that can detect and distinguish between SARS-CoV-2 and influenza A and B. The diagnostic accuracy can vary substantially across commercial devices.⁴ Hence, we summarized the accuracy of identified authorized devices, as well as their costs and time to results, when available from the literature, public websites, and product inserts. To note, CADTH published a horizon scan in 2021 focused on multiplex testing modalities available for COVID-19 and influenza, but it was not specific to POCTs, nor did it include stand-alone tests authorized by Health Canada.⁷ This report focuses on POCTs designated for health care professional use, and it does not include tests intended for self-testing only.⁸

POCTs for COVID-19 and Influenza in Canada

The number of authorized POCTs for COVID-19 in Canada has increased since the start of the pandemic.^{9,10} By March 2021, Health Canada had approved 6 POC rapid NAATs and 6 immunoassays for COVID-19 diagnosis.⁹ At the time of writing this report (February 2024), we identified 37 relevant authorized POCTs in Canada, specifically:

- 11 multiplex tests for COVID-19 and influenza¹¹⁻²¹ (5 tests^{11,13-15,20} can also diagnose other respiratory viruses, such as RSV and adenovirus)
- 17 for COVID-19 only²²⁻³⁸
- 9 for influenza only.³⁹⁻⁴⁷

The media has reported POCT use for COVID-19 in various care settings across Canada. For example, Saskatchewan uses the Abbot Panbio Test and BD Veritor for surveillance in long-term care.⁴⁸ In 2021, they also piloted the use of Abbott ID NOW in emergency departments (EDs).⁸ Alberta provided primary care clinics with POCTs for influenza, COVID-19, and RSV in partnership with Becton, Dickinson.⁴⁹

[Table 1](#) details information from product inserts related to multiplex POCTs for COVID-19 and influenza, whereas POCTs for COVID-19 only and influenza only are summarized in [Tables 2](#) and [3](#), respectively. We retained the language used around accuracy outcomes found in product inserts (e.g., positive and negative percent agreement versus sensitivity and specificity).

[Appendix 2](#) provides a list of accuracy or diagnostic test accuracy (DTA) studies we identified for authorized devices.

Multiplex POCTs for Influenza and COVID-19

We identified 11 authorized multiplex POCTs for COVID-19 and influenza A and B.¹¹⁻²¹ Of the 11 tests, 6 are molecular-based (5 RT-PCR and 1 isothermal amplification)¹¹⁻¹⁶ and 5 are antigen-based (i.e., 4 lateral flow immunoassays and 1 immunofluorescence).¹⁷⁻²¹ The time to results range from 13 to 60 minutes. Many of the identified multiplex tests require a nasopharyngeal or nasal sample, while some tests can accept either sample types.

The performance of POCT can differ across sample types. For nasal samples, the positive percent agreement (PPA) and sensitivity of the POCTs ranged from 86.7% to 100% for COVID-19, 93.6% to 100% for influenza A, and 93.3% to 100% for influenza B. These outcomes provide insight on the test's ability to detect the presence of illness. The negative percent agreement (NPA) and specificity was generally high (above 97%) using nasal samples across the POCTs. These outcomes provide insight on the test's ability to detect the lack of a particular illness.

For nasopharyngeal samples, the PPA and sensitivity ranged from 91.7% to 98% for COVID-19, 93.6% to 100% for influenza A, and 93.3% to 100% for influenza B. The NPA and specificity of the multiplex POCTs was 96% or higher for COVID-19 and influenza across identified POCTs using nasopharyngeal samples.

Table 1: Overview of POCT Multiplex Tests for COVID-19 and Influenza A and B

Product name and	Specimen type	Accuracy (95% CI)			Time to result (minutes)
		SARS-CoV-2	Influenza A	Influenza B	
RT-PCR (molecular based)					
ID NOW ¹¹	Nasopharyngeal, anterior nasal ^a	Nasal or Nasopharyngeal PPA = 91.7% (87.8% to 94.4%) NPA = 98.4% (97.1% to 99.1%)	Nasal or Nasopharyngeal PPA = 93.6% (93.3% to 98.2%) NPA = 97.4% (96% to 98.4%)	Nasal or Nasopharyngeal PPA = 100% (96.3% to 100%) NPA = 97.1% (95.9% to 98.1%)	13 or less
Cobas SARS-CoV-2 and Influenza A/B ¹²	Nasopharyngeal, nasal	Nasopharyngeal PPA = 96.3% (89.5% to 98.7%) NPA = 99.6% (99 to 99.9%) Nasal PPA = 100% (95.1% to 100%) NPA = 99.6% (99% to 99.9%)	Nasopharyngeal PPA = 98.3% (95.1% to 99.4%) NPA = 96% (94.7% to 97.0%) Nasal: NR	Nasopharyngeal PPA = 95.2% (84.2% to 98.7%) NPA = 99.4% (98.8% to 99.7%) Nasal: NR	20
Xpert Xpress SARS-CoV-2/Flu/RSV ¹³	Nasopharyngeal, nasal, nasal wash/aspirate ^a	Nasopharyngeal PPA = 97.9% (88.9% to 99.6%) NPA = 100% (98.1% to 100%) Nasal: NR	Nasopharyngeal PPA = 100% (92.6% to 100%) NPA = 100% (98% to 100%) Nasal: NR	Nasopharyngeal PPA = 100% (92.3% to 100%) NPA = 99% (93.6% to 99.7%) Nasal: NR	NR
The BioFire Respiratory Panel 2.1 ¹⁴	Nasopharyngeal, nasal ^a	Nasopharyngeal PPA = 98% (89.3% to 99.6%) ^b NPA = 100% (92.7% to 100%) ^b Nasal: NR	PPA = 100% (95.3% to 100%) ^c NPA = 100% (99.7% to 100%) ^c	PPA = 100% (78.5% to 100%) ^c NPA = 99.9% (99.5% to 100%) ^c	45 (the whole testing procedure)
QIAstat-Dx Respiratory SARS-CoV-2 Panel ¹⁵	Nasopharyngeal ^a	PPA = 100% (85.8% to 100%) ^d NPA = 100% (85.8% to 100%) ^d	Sensitivity or PPA = 99.2% (97% to 99.8%) ^d Specificity or NPA = 99.5% (99% to 99.7%) ^d	Sensitivity or PPA = 94.6% (89.2% to 97.3%) ^d Specificity or NPA = 99.9% (99.7% to 100%) ^d	60
Isothermal amplification (molecular based)					
Lucira COVID-19 and Flu Test ¹⁶	Nasopharyngeal, nasal	Nasal PPA = 98.2% (93.6% to 99.5%) NPA = 100% (98.7% to	Nasal PPA = 100% (93.9% to 100%) NPA = 99.7% (98.4% to	Nasal PPA = 97.6% (87.4% to 99.6%) NPA = 99.5% (98% to	30

Product name and	Specimen type	Accuracy (95% CI)			Time to result (minutes)
		SARS-CoV-2	Influenza A	Influenza B	
		100%) Nasopharyngeal: NR	99.9%) Nasopharyngeal: NR	99.8%) Nasopharyngeal: NR	
Lateral flow immunoassays (antigen based)					
The Rapid Response Influenza AB + COVID-19 Antigen (3 in 1) ¹⁷	Nasopharyngeal, anterior nasal	Nasopharyngeal Sensitivity = 94.7% (88.1% to 97.7%) Specificity = 99.7% (98.3% to 99.9%) Nasal Sensitivity = 93.6% (86.8% to 97.0%) Specificity = 99.7% (98.3% to 99.9%)	Nasopharyngeal Sensitivity = 96.2% (87.2 to 99.0%) Specificity = 100% (99% to 100%) Nasal Sensitivity = 94.3% (84.6 to 98.1%) Specificity = 99.7% (98.5% to 100%)	Nasopharyngeal Sensitivity = 93.3% (78.7% to 98.2%) Specificity = 99.7% (98.6% to 100%) Nasal Sensitivity = 93.3% (78.7% to 98.2%) Specificity = 99.5% (98.2% to 99.9%)	15
Status COVID-19/Flu A&B ¹⁸	Nasopharyngeal, anterior nasal	Nasopharyngeal PPA = 93.1% (83.6% to 97.3%) NPA = 100% (97.7% to 100%) Anterior Nasal PPA = 91.7% (64.6% to 98.5%) NPA = 100% (96% to 100%)	Nasopharyngeal PPA = NA ^e NPA = 100% (98.3% to 100%) Anterior Nasal PPA = 94.7% (85.6% to 98.2%) NPA = 100% (92.4% to 100%)	Nasopharyngeal PPA = NA ^e NPA = 100% (98.3% to 100%) Anterior Nasal PPA = NA ^e NPA = 100% (98.1% to 100%)	15
COVID-19 and Influenza A/B Antigen Combo Test ¹⁹	Nasopharyngeal, nasal	Nasopharyngeal Sensitivity = 95% (88.8% to 97.8%) Specificity = 99.8% (98.6% to 100%) Nasal Sensitivity = 94% (87.5% to 97.2%) Specificity = 99.5% (98.2% to 99.9%)	Nasopharyngeal Sensitivity = 96.2% (87.2% to 99%) Specificity = 100% (99.2 to 100%) Nasal Sensitivity = 94.3% (84.6% to 98.1%) Specificity = 99.8% (98.8% to 100%)	Nasopharyngeal Sensitivity = 94.3% (81.4% to 98.4%) Specificity = 99.8% (98.3% to 100%) Nasal Sensitivity = 94.3% (81.4% to 98.4%) Specificity = 98.8% (98.8% to 100%)	15
The BD Veritor System for Rapid Detection of SARS-CoV-2 and Flu A+B ²⁰	Anterior nasal ^a	PPA = 86.7% (75.8% to 93.1%) NPA = 99.5% (97.4% to 99.95%)	PPA = 100% (91.2% to 100%) ^f NPA = 100% (100% (95.2% to 100%) ^e	PPA = 100% (90% to 100%) ^f NPA = 100% (95.5% to 100%) ^f	15
Immunofluorescence (antigen based)					
The Sofia 2 Flu + SARS Antigen FIA ²¹	Nasal, Nasopharyngeal, nasopharyngeal aspirate/wash	Nasal PPA = 95.2% (84.2% to 98.7%)	Nasal PPA = NA ^e NPA = 100% (97.7% to 100%)	Nasal PPA = NA ^e NPA = 100% (97.7% to 100%)	15

Product name and	Specimen type	Accuracy (95% CI)			Time to result (minutes)
		SARS-CoV-2	Influenza A	Influenza B	
		NPA = 100% (96.9% to 100%) Nasopharyngeal: NR	100%) Nasopharyngeal: NR	to 100%) Nasopharyngeal: NR	

NPA = negative predictive agreement; NR = not reported; PPA = positive predictive agreement; RT-PCR = reverse-transcriptase polymerase chain reaction;

Note: The reference standard for accuracy evaluations was RT-PCR or transcription PCR, unless specified otherwise.

^aThe test can detect other respiratory illnesses, such as RSV or adenovirus.

^bThe product's accuracy was compared to 3 emergency use authorized assays.

^cUnknown specimen type.

^dThe product's accuracy was compared to a validated molecular comparator assay or contrived positive samples.

^eNo participants from the study's sample were positive for the respiratory disease.

^fThe product's accuracy was compared to BD Veritor system Rapid detection of Flu A + B, which was reported to be 100% concordant with historical reference RT-PCR results.

POCTs for COVID-19

We identified 17 POCTs for COVID-19 only.²²⁻³⁸ Of the 17 devices, 1 is a molecular-based test, specifically RT-PCR.²² The remaining tests are lateral flow immunoassays (antigen-based tests).²³⁻³⁸ Like the multiplex tests, a majority of devices use nasopharyngeal or nasal samples for diagnosis, while some accept both sample types. The time to results ranges from 15 to 30 minutes.

For nasal samples, the PPA and sensitivity ranged from 85% to 100%, whereas the NPA and specificity ranged from 92% to 100%. For nasopharyngeal samples, the PPA and sensitivity ranged from 91.67% to 100%, whereas the NPA and specificity ranged from 96.5% to 100%. The only identified test that accepts saliva samples is PCL COVID19 Ag Gold. With saliva samples, the PPA and NPA of PCL COVID19 Ag Gold was 94.44% and 100%, respectively.²⁷

Table 2: Overview of Stand-Alone POCT for COVID-19 Only

Product name	Specimen type	Accuracy (95% CI)	Time to result (minutes)
RT-PCR (molecular based)			
The Xpert Xpress CoV-2 plus ²²	Nasopharyngeal, anterior nasal, midturbinate, oropharyngeal, nasal wash/aspirate	Nasopharyngeal PPA = 100% (95.4% to 100) NPA = 96.5% (90.1% to 98.8%) Nasal PPA = 100% (92.3% to 100%) NPA = 100% (94.4% to 100%)	30
Isothermal amplification (molecular based)			
Cue COVID-19 Point-of-care Molecular Test ²³	Anterior nasal	PPA = 100% (NR) NPA = 92% (NR)	20

Product name	Specimen type	Accuracy (95% CI)	Time to result (minutes)
Lateral flow immunoassays (antigen based)			
The Wondfo 2019-nCoV Antigen Test ²⁴	Nasal	PPA = 85.5% (73.8% to 92.4%) NPA = 100% (92.3% to 100%)	15
SARS-CoV-2 Antigen Rapid Test ²⁵	Nasal	Relative Sensitivity: 96.50% (92.03% to 98.86%) Relative Specificity: 99.20% (97.13% to 99.90%)	10
Flowflex COVID-19 Antigen Rapid Test ²⁶	Nasal	PPA = 93% (78% to 99%) NPA = 100% (95% to 100%)	15
PCL COVID19 Ag Gold ²⁷	Nasal, nasopharyngeal, saliva	Nasopharyngeal PPA = 91.67% (77.53% to 98.25%) NPA = 100% (94.72% to 100%) Nasal PPA = 91.67% (77.53% to 98.25%) NPA = 100% (94.72% to 100%) Saliva PPA = 94.44% (81.34% to 99.32%) NPA = 100% (94.72% to 100%)	10
Medsup COVID-19 Rapid Antigen Test ²⁸	Nasal	Relative sensitivity = 97.1% (93.1% to 98.9%) Relative specificity = 99.5% (98.2% to 99.9%)	15
iStatix COVID-19 Antigen Test ²⁹	Anterior nasal	PPA = 91.43% (76.94% to 98.20%) NPA = 100% (94.04% to 100%)	15
SGTi-flex COVID-19 Ag ³⁰	Nasopharyngeal, nasal	Nasopharyngeal PPA = 91.67% (81.93% to 96.39%) NPA = 99.38% (96.55% to 99.89%) Nasal PPA = 88.33% (77.82% to 94.23%) NPA = 100% (91.24% to 100%)	15
The InteliSwab COVID-19 Rapid Test Pro ³¹	Anterior nasal	PPA = 85% (74% to 92%) ^{a,b} NPA = 98% (93% to 100%) ^{a,b}	30
Artron COVID-19 Antigen Test ³²	Nasopharyngeal, nasal	Nasopharyngeal Sensitivity = 97.22% (92.10% to 99.42%) Specificity = 99.7% (99.98% to 99.97%) Nasal Sensitivity = 91.30% (82.03% to 96.74%) Specificity = 99.56% (97.57% to 99.99%)	15
The QuickVue SARS Antigen Test ³³	Anterior nasal	PPA = 96.6% (88.3% to 99%) NPA = 99.3% (96% to 99.9%)	10
STANDARD Q COVID-19 Ag Test ³⁴	Nasopharyngeal	Nasopharyngeal Sensitivity = 99.3% (98.4 to 99.7%) Specificity = 97.9% (94.8 to 99.2%)	15

Product name	Specimen type	Accuracy (95% CI)	Time to result (minutes)
COVID-19 Antigen Rapid Test Device ³⁵	Nasopharyngeal, nasal	Nasopharyngeal PPA = 94.3% (84.6% to 98.1%) NPA = 98.3% (95.1% to 99.4%) Nasal PPA = 92.3% (83.2% to 96.7%) NPA = 100% (96.7% to 100%)	15
The Rapid Response COVID-19 Antigen Rapid Test ³⁶	Nasopharyngeal, nasal	Nasopharyngeal Sensitivity = 95.8% (79.8% to 99.3%) Specificity = 100% (84.5% to 100%) Nasal Sensitivity = 90.2% (78.6% to 96.2%) Specificity = 100% (96.5% to 100%)	15
Panbio COVID-19 Ag Rapid Test ³⁷	Nasal	Sensitivity = 98.1% (93.2% to 99.8%) Specificity = 99.8% (98.6% to 100%)	15
The Sofia SARS Antigen FIA ³⁸	Nasal	PPA = 96.7% (83.3% to 99.4%) NPA = 100% (97.9% to 100%)	15

NPA = negative predictive agreement; NR = not reported; PPA = positive predictive agreement; RT-PCR = reverse-transcriptase polymerase chain reaction.

Note: The reference standard for accuracy evaluations was RT-PCR or PCR unless specified otherwise.

^aThe participants self-collected their samples for testing.

^bThe product's accuracy was compared to a highly sensitive molecular FDA emergency use authorized SARS-CoV-2 assay.

POCTs for Influenza A and B

We identified 9 POCTs for Influenza A and B authorized by Health Canada.³⁹⁻⁴⁷ Of the 9, 2 are molecular based, specifically 1 RT-PCT and 1 isothermal amplification test.^{39,40} Seven are immunoassays and antigen-based.⁴¹⁻⁴⁷ All devices use nasopharyngeal or nasal samples and some can accept both sample types. One test also accepts samples from the throat.⁴³ Time to results ranges from 10 to 30 minutes.

For nasal samples, the PPA and sensitivity ranged from 86.1% to 94% and 70% to 100% for influenza A and influenza B, respectively. The NPA and specificity with nasal samples ranged from 92% to 100% and 92.5% to 100% for influenza A and influenza B, respectively.

For nasopharyngeal samples, the PPA and sensitivity ranged from 83% to 99% and 62% to 100% for influenza A and influenza B, respectively. The NPA and specificity with nasopharyngeal samples ranged from 89% to 98.8% and 94.3% to 99.7% for influenza A and influenza B, respectively.

The product insert for X/pect Flu A&B reported the performance with samples from the throat.⁴³ It reported a sensitivity and specificity of 100% with throat samples for influenza A and B.⁴³

Table 3: Overview of Stand-Alone POCT for Influenza A and B

Product name	Specimen type	Accuracy (95% CI)		Time to result (minutes)
		Influenza A	Influenza B	
RT-PCR (molecular based)				
Xpert Xpress Flu/RSV ³⁹	Nasopharyngeal, nasal	Nasopharyngeal PPA = 98.1% (93.3% to 99.5%) NPA = 98.8% (98.2% to 99.2%)	Nasopharyngeal PPA = 100% (95.3% to 100%) NPA = 99.7% (98.6% to 99.4%)	30
Isothermal amplification (molecular based)				
EasyNAT Rapid Flu Assay ⁴⁰	NR	NR	NR	NR
Immunoassay (antigen based)				
QuickVue Influenza A+B Test ⁴¹	Nasopharyngeal, nasal, nasal wash, nasal aspirate	Nasopharyngeal Sensitivity = 83% Specificity = 89% Nasal Sensitivity = 94% Specificity = 92%	Nasopharyngeal Sensitivity = 62% Specificity = 98 Nasal Sensitivity = 70% Specificity = 97%	10
Immunocard STAT! Flu A&B ⁴²	Nasopharyngeal, nasal, nasopharyngeal aspirate or wash	Combined nasal and nasopharyngeal Sensitivity = 92.2% Specificity = 94.2%	Combined nasal and nasopharyngeal Sensitivity = 90% Specificity = 94.3%	10 to 15
X/pect Flu A&B ⁴³	Nasal, throat, nasal wash	Nasal Sensitivity = 88.9% Specificity = 100% Nasal wash Sensitivity = 92.5% (79.6% to 98.4%) Specificity = 100% (98.2 to 100%) Throat Sensitivity = 100% (69.2 to 100%) Specificity = 100% (83.2% to 100%)	Nasal Sensitivity = 83.3% Specificity = 100% Nasal wash Sensitivity = 100% Specificity = 100% Throat Sensitivity = 100% (39.8% to 100%) Specificity = 100% (86.8% to 100%)	15
BinaxNow Influenza A/B with DIGIVAL ⁴⁴	Nasal, nasopharyngeal	Combined nasal and nasopharyngeal Sensitivity = 84.3% (77.2% to 89.5%) Specificity = 94.7% (92.1% to 96.4%)	Combined nasal and nasopharyngeal Sensitivity = 89.5% (77.2% to 89.5%) Specificity = 94.7% (92.1% to 96.4%)	15

Product name	Specimen type	Accuracy (95% CI)		Time to result (minutes)
		Influenza A	Influenza B	
Influenza A and B Test Kit ⁴⁵	Nasopharyngeal, nasal	Nasal Sensitivity = 86.1% (NR) Specificity = 94.2% (NR)	Nasal Sensitivity = 80.2% (NR) Specificity = 92.5% (NR)	20
STANDARD F Influenza A/B FIA ⁴⁶	Nasopharyngeal, nasal	NR	NR	10
Sofia Influenza A+B FIA ⁴⁷	Nasopharyngeal, nasal, nasopharyngeal aspirate/wash	Nasopharyngeal and nasal Sensitivity = 93% (NR) ^a Specificity = 95% (NR) ^a Nasopharyngeal aspirate and wash Sensitivity = 99% (NR) ^a Specificity = 96% (NR) ^a	Nasopharyngeal and nasal Sensitivity = 90% (NR) ^a Specificity = 96% (NR) ^a Nasopharyngeal aspirate and wash Sensitivity = 88% (NR) ^a Specificity = 96% (NR) ^a	15

NPA = negative predictive agreement; NR = not reported; PPA = positive predictive agreement; RT-PCR = reverse-transcriptase polymerase chain reaction.

Note: The reference standard for accuracy evaluations was RT-PCR or PCR unless specified otherwise.

^aAccuracy was evaluated against cell culture.

How Do POCTs Change Care for Influenza and COVID-19?

Diagnosis informs patient management, such as treatment, patient flow, and infection control measures.⁴ Laboratory tests take longer than POCTs due to the time for samples to travel to a laboratory. In Saskatchewan, EDs observed a decrease in wait times for COVID-19 results to 22 minutes from 12 to 24 hours with Abbott ID Now.⁸ They noticed an improvement in patient flow and reduced time spent in the ED for patients.⁸ A prospective, nonrandomized study in UK EDs noticed a similar impact with QIAstat-Dx Respiratory SARS-CoV-2 Panel.⁵⁰ The study's results showed a lower median wait time of 1.7 hours for results in the POCT group compared to 23.1 hours observed in laboratory PCR.⁵⁰ The authors also observed improvements in patient flow, such as reduced bed moves and time spent in assessment areas.⁵⁰

Some of the literature that evaluates the impact of POCTs for influenza A and B show similar findings. POCTs help physicians and patients follow best practices regarding treatment timelines. The Association for the Advancement of Medical Instrumentation suggests that treatment should be initiated within 12 hours of illness onset to ensure optimal results.⁵¹ Specific treatments for respiratory illnesses each have recommended initiation periods that may require more rapid diagnosis. For example, Tamiflu, a prescription medication for the flu, should be initiated within 48 hours of symptom onset.⁵² The product insert for Paxlovid states that it should be initiated within 5 days of COVID-19 symptom onset.⁵³ A prospective cohort in UK university hospitals found that Xpress Flu/RSV saved a median time of 27.1 hours waiting for results.⁵⁴ The authors noted that the respiratory clinic at the hospital saved the most time during this study.⁵⁴ The respiratory clinic needed to send samples to an offsite laboratory, whereas other units assessed could send their samples to an onsite laboratory.⁵⁴ Other studies found that POCTs for influenza can reduce the

treatment prescribed (e.g., antivirals),⁵⁴⁻⁵⁶ follow up tests for patients,^{56,57} and hospital admissions and length of stay.^{54,56,57} However, we did not identify any studies assessing patient outcomes in care settings in Canada.

Individuals living in rural or remote communities with suspected respiratory illness can benefit from POCTs. Laboratories may not be as readily available in these areas. Samples can travel far distances to reach laboratories, which can delay treatment for individuals with respiratory illness.⁵⁸ During the COVID-19 pandemic, individuals living in northern, remote, and isolated communities waited around 7 to 10 days for their COVID-19 test results.⁵⁸ The Canadian Public Health Laboratory Network advocated for the distribution of POC supplies to these communities, given the lack of infrastructure to support timely laboratory-based testing.⁵⁸ For instance, Ontario Health's test strategy uses molecular POCTs in regions of the province that have a longer turnaround time for COVID-19 results, including rural and remote communities.⁵⁹

How Much Does It Cost?

The price of the commercial POCTs vary. POCTs differ in complexity and some tests require the 1-time purchase of a reader or analyzer, in addition to test kits. For example, the BD Veritor Plus analyzer costs \$749,⁶⁰ and the Cue COVID-19 reader costs \$314.⁶¹

The price of commercial multiplex POCTs ranges from \$8 to \$59.18 per test. For COVID-19, the prices range from \$2.13 to \$81.33 per test. We only identified the price of 1 commercial influenza POCT, which costs \$23 per test.⁶² [Table 4](#) summarizes the prices of each POCT per test in Canadian dollars when available from public websites. To note, health care facilities may pay a different price than the costs reflected in public websites.

Table 4: Price of Commercial POCTs

Type of test	Commercial test	Price per test (CA)
Multiplex tests (for COVID-19 and influenza)	cobas SARS-CoV-2 and Influenza A/B ⁷	\$59.18 ^a
	Lucira COVID-19 and Flu Test ⁶³	\$98
	The Rapid Response Influenza AB + COVID-19 (Antigen – 3 in 1) ⁶⁴	\$8
	Status COVID-19/Flu A&B ⁶⁵	\$23
	The BD Veritor System for Rapid Detection of SARS-CoV-2 and Flu A+B ⁶⁶	\$43 ^a
	The Sofia 2 Flu + SARS Antigen FIA ⁶⁷	\$30.80 ^a
COVID-19 POCTs	Cue COVID-19 Point-of-care Molecular Test ⁶⁸	\$81.33 ^a
	Flowflex COVID-19 Antigen Rapid Test ⁶⁹	\$5
	Medsup COVID-19 Rapid Antigen Test ⁷⁰	\$2.13
	iStat COVID-19 Antigen Test ⁷¹	\$19

Type of test	Commercial test	Price per test (CA)
	Artron COVID-19 Antigen Test ⁷²	\$9
	STANDARD Q COVID-19 Ag Test ⁷³	\$11
	The Rapid Response COVID-19 Antigen Rapid Test	\$5
	Panbio COVID-19 Ag Rapid Test ⁷⁴	\$19.96
Influenza POCTs	QuickVue Influenza A+B Test ⁶²	\$23

CA = Canadian dollars; POCT = point-of-care test.

*The price does not include the associated reader or analyzer.

From the literature, we also identified 4 budget impact analyses for authorized POCTs in Canada.^{56,57,75,76} The budget impact analyses reported the following findings:

- A traumatological ED in Germany saved a total of 2,631.25€ per person with surgery and 729.01€ per person without surgery using **Abbott ID Now**.⁷⁵
- A pediatric ED in France saved a total of 69,000€ per season using **The BD Veritor System for Rapid Detection of Flu A and B**.⁵⁶
- Another ED in France calculated cost savings of 2,770€ during 2013 to 2014 season and 3,420€ during the 2014 to 2015 using **Sofia Influenza A+B**.⁵⁷
- An ED in the Netherlands observed a mean cost saving of 1,166€ per individual positive for influenza and 2,203€ per individual negative for influenza using **Cobias Liat (for Influenza)**.⁷⁶

A study evaluated the cost-effectiveness of POCTs for diagnosing influenza in EDs in Canada.⁷⁷ The investigators used a decision-analytic model using a lifetime horizon perspective to assess rapid tests, digital immunoassays, NAATs, clinical judgment, and batch PCR from a single health care payer perspective.⁷⁷ Of the 3 rapid diagnostic tests, rapid NAATs resulted in the largest net health benefit at a cost-effectiveness threshold of \$50,000.⁷⁷

Considerations

Confirmatory Laboratory Tests

Compared to laboratory-based tests, POCTs have inferior sensitivity, with performance varying across commercial tests.^{4,78} A confirmatory laboratory test can rule out false negatives from POCTs.⁷⁹ The Canadian Society of Clinical Chemists and the Canadian Public Health Laboratory Network recommend POCTs in circumstances where laboratory tests are not available or turnaround time for lab test results can impact patient outcomes.^{9,80} Laboratory tests remain the preferred method to diagnose COVID-19.^{9,59,80}

The studies above did not consider the costs of POCT programs with confirmatory testing and how false negatives from POCTs impact patient clinical outcomes. Nonetheless, POCTs can help patients and care providers meet recommended timelines for starting treatment by decreasing the turnaround time for results, especially for diagnostic centres far from laboratories.^{10,54}

Implementing a POCT Program

The Canadian Public Health Laboratory Network released a statement in 2022 highlighting implementation considerations for POC diagnostic programs, such as:⁹

- validation of the POCT against gold standard or standard of care
- training and risk assessment for health care providers performing and interpreting the results
- establishing a quality assurance or control program.

Self-Testing

Some of the authorized POCTs we identified can also be used to self-test at home.^{16,23,31} The performance of the test can differ when the test is administered by a health care professional versus when the sample is collected by a lay user. For example, the PPA and NPA of the Cue COVID-19 Point-of-care Molecular Test was 100% and 92%, respectively, when used at the POC.²³ In contrast, the PPA and NPA of the same test when used by lay users was 97.4% and 99.1%, respectively.²³

Conclusion

The landscape of diagnostic tests for COVID-19 and other respiratory illnesses continues to evolve. Respiratory illnesses, such as COVID-19 and influenza, can manifest in similar symptoms, making it difficult for physicians to rely on their clinical judgment for diagnosis and treatment.^{4,5} We identified 28 authorized POCTs able to detect COVID-19¹¹⁻³⁸ and 20 POCTs that can detect influenza.³⁹⁻⁴⁷ Eleven tests are multiplex, with the ability to distinguish between COVID-19 and influenza.¹¹⁻²¹

As seasonal influenza epidemics return and COVID-19 continues to circulate,⁶ health care providers can use POCTs to initiate treatment in a timely manner, as well as improve patient flow in health centres.⁵⁴⁻⁵⁷

However, commercial tests authorized in Canada vary in performance, time to results, and costs.^{4,56,57,75,76} Additionally, laboratory tests, specifically NAATs, remain the standard of care for diagnosing COVID-19 and influenza.^{9,79,80} Confirmatory laboratory tests are still needed to rule out inaccurate diagnosis from POCTs.^{9,79,80} Nonetheless, POCTs may benefit rural and remote areas by avoiding delays in treatment given their distance from laboratories.⁵⁸ Future studies should factor in confirmatory tests in their cost calculations, as well as the impact of inaccurate diagnosis from POCTs on clinical flow and patient outcomes.

References

1. 2. Point-of-Care Testing. In: 2022 Health technology trends to watch: top 10 list. (*CADTH horizon scan*). Ottawa (ON): CADTH; 2022: <https://www.cadth.ca/2-point-care-testing>. Accessed 2024 Feb 20.
2. Larkins MC, Thombare A. Point-of-care testing. Treasure Island (FL): StatPearls Publishing; 2023: <https://www.ncbi.nlm.nih.gov/books/NBK592387/>. Accessed 2024 Feb 20.
3. Testing devices for COVID-19: point-of-care and self-testing devices. Ottawa (ON): Health Canada; 2023: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/testing/home-devices.html>. Accessed 2024 Feb 20.
4. Aoki FY, Papenburg J, Mubareka S, Allen UD, Hatchette TF, Evans GA. 2021-2022 AMMI Canada guidance on the use of antiviral drugs for influenza in the COVID-19 pandemic setting in Canada. *J Assoc Med Microbiol Infect Dis Can*. 2022;7(1):1-7. [PubMed](#)
5. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Key features of influenza, SARS-CoV-2 and other common respiratory viruses. 2nd ed. Toronto (ON): King's Printer for Ontario; 2024: https://www.publichealthontario.ca/-/media/Documents/1/2023/influenza-sars-cov2-respiratory-viruses-key-features.pdf?rev=f7e4dab95a6e4c6e94069795243e341a&sc_lang=en. Accessed 2024 Feb 20.
6. Schmidt K, Ben Moussa M, Buckrell S, et al. National Influenza Annual Report, Canada, 2022-2023: Canada's first fall epidemic since the 2019-2020 season. *Can Commun Dis Rep*. 2023;49(10):413-424. [PubMed](#)
7. Li Y, Walter M. Combined testing for severe acute respiratory and syndrome coronavirus 2 and influenza. (*CADTH horizon scan*). Ottawa (ON): CADTH; 2021: <https://www.cadth.ca/sites/default/files/covid-19/EN0029%20Combined%20COVID%20flu%20tests%20v.7.0.pdf>. Accessed 2024 Feb 20.
8. Point of care testing now in use in Saskatchewan. Thornhill (ON): Canadian Healthcare Technology; 2021: <https://www.canhealth.com/2021/02/10/point-of-care-testing-now-in-use-in-saskatchewan/>. Accessed 2024 Feb 20.
9. Taher J, Randell EW, Arnoldo S, et al. Canadian Society of Clinical Chemists (CSCC) consensus guidance for testing, selection and quality management of SARS-CoV-2 point-of-care tests. *Clin Biochem*. 2021;95:1-12. [PubMed](#)
10. Respiratory Virus Infections Working Group. Canadian Public Health Laboratory Network: prioritized support for northern, remote and isolated communities in Canada. *Can Commun Dis Rep*. 2020;46(10):322-323. [PubMed](#)
11. ID NOW COVID-19 2.0: product insert. Scarborough (ME): Abbott Diagnostics Scarborough, Inc.; 2022: <https://www.fda.gov/media/158402/download?attachment>. Accessed 2024 Feb 23.
12. cobas Sars-CoV-2 & Influenza A/B. Branchburg (NJ): Roche Molecular Systems, Inc.; 2022: <https://www.fda.gov/media/141887/download>. Accessed 2024 Feb 23.
13. Xpert Xpress SARS-CoV-2/Flu/RSV: instructions for use. Sunnyvale (CA): Cepheid; 2021: <https://www.fda.gov/media/142438/download>. Accessed 2024 Feb 24.
14. BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ). Salt Lake City (UT): BioFire Diagnostics, LLC; 2022: <https://www.fda.gov/media/142696/download>. Accessed 2024 Feb 23.
15. QIAstat-Dx Respiratory SARS-CoV-2 Panel: instructions for use (handbook). Germantown (MD): QIAGEN LLC; 2021: <https://www.qiagen.com/ca/resources/download.aspx?id=e199b16c-0cb0-4406-a22c-a26377a8f8ee&lang=en>. Accessed 2024 Mar 07.
16. Lucira COVID-19 & Flu Test: instruction for use. Emeryville (CA): Lucira Health, Inc.; 2023: <https://health-products.canada.ca/ifu/20230721a1ea6387a6ad3b9eb72ddf22a70d5dfc.pdf>. Accessed 2024 Feb 23.
17. Rapid Response Influenza AB + COVID-19 Antigen – 3 in 1 Test: product insert. Pickering (ON): BTNX, Inc.; 2023: <https://health-products.canada.ca/ifu/20231227371351680c76f2aecdd191c2ecffa97a1.pdf>. Accessed 2024 Feb 23.
18. Status COVID-19/Flu A&B: rapid immunoassay for direct detection and differential diagnosis of SARS-CoV-2, influenza type A, and type B antigens. Monmouth Junction (NJ): Princeton BioMeditech Corporation; 2023: <https://health-products.canada.ca/ifu/20231204bc95b0563db751f9700c0812d7c0306c.pdf>. Accessed 2024 Feb 23.

19. COVID-19 & Influenza A/B Antigen Combo Test, version 5.1. Zhejiang (CN): Assure Tech. (Hangzhou) Co., Ltd.; 2023 Oct 30: <https://health-products.canada.ca/ifu/2023111443295e6f80f291d3e7a6f35923b077b9.pdf>. Accessed 2024 Feb 23.
20. BD Veritor System for rapid detection of SARS CoV 2 & Flu A+B. Sparks (MD): Becton, Dickinson and Company; 2023: <https://www.fda.gov/media/147016/download>. Accessed 2024 Feb 24.
21. Sofia 2 Flu + SARS Antigen FIA. San Diego (CA): Quidel Corporation: <https://health-products.canada.ca/ifu/2023040434bbd6d2718a3896a23387b8b7276917.pdf>. Accessed 2024 Feb 23.
22. Xpert Xpress CoV-2 plus: instructions for use. Sunnyvale (CA): Cepheid; 2023 Feb: <https://health-products.canada.ca/ifu/20230804c580452e8cecea6574a8e87c07d5e7fb.pdf>. Accessed 2024 Feb 23.
23. Cue COVID-19 Test instructions for use. San Diego (CA): Cue Health Inc.; 2022: [https://cuehealth.com/static/docs/home-otc/canada/Cue_COVID-19_OTC_Test_Instructions_For_Use_\(IFU\)_Canada-en.pdf](https://cuehealth.com/static/docs/home-otc/canada/Cue_COVID-19_OTC_Test_Instructions_For_Use_(IFU)_Canada-en.pdf). Accessed 2024 Mar 06.
24. Wondfo 2019-nCoV Antigen Test (Lateral Flow Method). Guangzhou (CN): Guangzhou Wondfo Biotech Co., Ltd; 2023: <https://health-products.canada.ca/ifu/20230824df9a0cf2f2d56500b5e82462700fd06a.pdf>. Accessed 2024 Feb 23.
25. SARS-CoV-2 Antigen Control: package insert. Zhejiang (CN): Hangzhou AllTest BioTech Co., Ltd.; 2023: <https://health-products.canada.ca/ifu/202306119f4a8d7578a11809a138ba4897e17241.pdf>. Accessed 2024 Feb 23.
26. Flowflex COVID-19 Antigen Rapid Test: package insert. San Diego (CA): ACON Laboratories, Inc.; 2023: <https://health-products.canada.ca/ifu/20230413ed87b7c5ccc001636ef6f831d2dbc3a1.pdf>. Accessed 2024 Feb 23.
27. PCL COVID19 Ag Gold: instructions for use. Seoul (KR): PCL, Inc.; 2023 Feb 24: <https://health-products.canada.ca/ifu/202306091db1fce19e3835c9948cea8d99ae1484.pdf>. Accessed 2024 Feb 23.
28. COVID-19 Rapid Antigen Test: package insert. Montreal (QC): MedSup Medical; 2022 Mar 29: <https://health-products.canada.ca/ifu/202207203567224a289ee4f4408e2e5254e3b040.pdf>. Accessed 2024 Feb 23.
29. iStatix COVID-19 Antigen Test. Richmond (BC): bioLytical Laboratories, Inc.; 2022 Dec 21: <https://health-products.canada.ca/ifu/20230712b3ee1156b35cd034b8e77eff0496b71f.pdf>. Accessed 2024 Feb 23.
30. SGTi-flex COVID-19 Ag. Chungcheongbuk-do (KR): Sugentech Inc.; 2023: <https://health-products.canada.ca/ifu/2023061125a6e006cc548aba7cf7d960367804d7.pdf>. Accessed 2024 Feb 23.
31. IntelliSwab Covid-10 Rapid Test Pro: healthcare provider instructions for use. Bethlehem (PA): Orasure Technologies, Inc.; 2023: <https://www.fda.gov/media/149918/download>. Accessed 2024 Feb 24.
32. Artron COVID-19 Antigen Test: instruction for use. Burnaby (BC): Artron Laboratories Inc.; 2023 Feb 15: <https://health-products.canada.ca/ifu/202303033bb6b14f8a2984a5190367f05b742045.pdf>. Accessed 2024 Feb 23.
33. QuickVue SARS Antigen Test. San Diego (CA): Quidel Corporation: <https://health-products.canada.ca/ifu/20230404c551c30fcb7e7ab62909775189598c59.pdf>. Accessed 2024 Feb 23.
34. STANDARD Q COVID-19 Ag Test. Gyeonggi-do (KR): SD Biosensor, Inc.; 2022: <https://health-products.canada.ca/ifu/2022072012d0fb2e56e84176a889d3d6f5dcb54f.pdf>. Accessed 2024 Feb 23.
35. COVID-19 Antigen Rapid Test Device. Zhejiang (CN): Assure Tech. (Hangzhou) Co., Ltd.; 2022: <https://health-products.canada.ca/ifu/2023062742b342025cc20d0ce6c7434f0ed22c5a.pdf>. Accessed 2024 Feb 23.
36. Rapid Response COVID-19 Antigen Rapid Test Device: product insert, revision 4.18. Pickering (ON): BTNX, Inc.; 2023 May 12: <https://health-products.canada.ca/ifu/20231221f1eb368765ab820dd47dac6abaa52358.pdf>. Accessed 2024 Feb 23.
37. Panbio COVID-19 Ag Rapid Test Device (nasal). Jena (DE): Abbott Rapid Diagnostics Jena GmbH; 2021: <https://health-products.canada.ca/ifu/2023040451ae5edf40b6ac514f728924a3bbbbac.pdf>. Accessed 2024 Feb 23.
38. Sofia SARS Antigen FIA. San Diego (CA): Quidel Corporation: <https://health-products.canada.ca/ifu/202304042e42188e96ab4407cfd447c803f82de6.pdf>. Accessed 2024 Feb 23.
39. Xpert Xpress Flu/RSV. Sunnyvale (CA): Cepheid; 2020 Jan: <https://www.cepheid.com/content/dam/www-cepheid.com/documents/package-insert-files/Xpress-Flu-RSV-US-IVD-ENGLISH-Package-Insert-301-7239-Rev.%20D.pdf>. Accessed 2024 Mar 01.

40. Ustar: POCT Multi-Modules Nucleic Acid Amplification and Detection Analyzer. Zhejiang (CN): Ustar Biotechnologies (Hangzhou) Ltd.; 2023: https://cetest01.us-ca.ufileos.com/100001_2006075053/Brochure_EasyNAT%20System_EN_V1.1_20230227.pdf. Accessed 2024 Feb 26.
41. QuickVue Influenza A+B Test. San Diego (CA): Quidel Corporation; 2023: <https://techdocs.quidelortho.com/?country=Canada&language=English&docId=17843523&isauthenticated=public>. Accessed 2024 Mar 01.
42. Immunocard STAT! Flu A&B Monmouth Junction (NJ): PBM Princeton BioMeditech Corp.; 2022: https://www.meridianbioscience.com/uploads/782030_pi.pdf?country=CA. Accessed 2024 Mar 01.
43. Remel X/pect Flu A & B. Lenexa (KS): Remel Inc.; 2020: <https://www.thermofisher.com/document-connect/document-connect.html?url=https://assets.thermofisher.com/TFS-Assets%2FMBD%2FInstructions%2FIFU24600%20.pdf>. Accessed 2024 Mar 01.
44. BinaxNOW Influenza A & B Card 2 with DIGIVAL. Scarborough (ME): Abbott Diagnostics Scarborough, Inc.; 2022: <https://ensur.invmed.com/ensur/contentAction.aspx?key=ensur.352421.S2R4E4A3.20180810.7555.4173048>. Accessed 2024 Mar 01.
45. Artron Influenza A and B (FLU A&B) Test Kit: instructions for use. Burnaby (BC): Artron Laboratories Inc.; 2022 Dec 15: https://rapidtestandtrace.ca/wp-content/uploads/2023/05/IFU-A03-41-422-FluA_B-V22-01.pdf. Accessed 2024 Mar 01.
46. SD Biosensor. STANDARD F Influenza A/B FIA. 2021; https://www.sdbiosensor.com/product/product_view?product_no=173#. Accessed 2024 Mar 01.
47. Sofia Influenza A+B FIA. San Diego (CA): Quidel: <https://cliawaived.com/amfile/file/download/file/609/product/4614/>. Accessed 2024 Mar 6.
48. Vescera Z. COVID-19: SHA to 'accelerate' rapid testing in long-term care. Saskatoon (SK): Saskatoon Star Phoenix; 2021: <https://thestarphoenix.com/news/saskatchewan/covid-19-sha-to-accelerate-rapid-testing-in-long-term-care>. Accessed 2024 Feb 20.
49. Herring J. Pilot to bring strep, flu, COVID testing to Alberta primary-care clinics. Calgary (AB): Calgary Herald; 2023: <https://calgaryherald.com/news/local-news/pilot-strep-flu-covid-testing-alberta-primary-care-clinics>. Accessed 2024 Feb 20.
50. Brendish NJ, Poole S, Naidu VV, et al. Clinical impact of molecular point-of-care testing for suspected COVID-19 in hospital (COVID-19POC): a prospective, interventional, non-randomised, controlled study. *Lancet Respir Med*. 2020;8(12):1192-1200. [PubMed](#)
51. Aoki FY, Allen UD, Mubareka S, Papenburg J, Stiver HG, Evans GA. Use of antiviral drugs for seasonal influenza: foundation document for practitioners-update 2019. *J Assoc Med Microbiol Infect Dis Can*. 2019;4(2):60-82. [PubMed](#)
52. Tamiflu, Genetech. Taking Tamiflu at the first sign of flu symptoms may reduce the amount of time you're sick. 2024; <https://www.tamiflu.com/taking-tamiflu.html#:~:text=Take%20Tamiflu%20within%2048%20hours,light%20snack%20or%20a%20meal>. Accessed 2024 Apr 11.
53. Paxlovid (nirmatrelvir; ritonavir): two 150 mg nirmatrelvir tablets co-packaged with 100 mg ritonavir tablet, oral use [product monograph]. Kirkland (QC): Pfizer Canada ULC; 2024 Jan 02: <https://covid-vaccine.canada.ca/info/pdf/paxlovid-pm-en.pdf>. Accessed 2024 Apr 11.
54. Morris TC, Bird PW, Horvath-Papp E, Dhillon JK, May S, Tang JW. Xpert Xpress Flu/RSV: validation and impact evaluation at a large UK hospital trust. *J Med Virol*. 2021;93(8):5146-5151. [PubMed](#)
55. O'Connell S, Conlan C, Reidy M, Stack C, Mulgrew A, Baruah J. The impact of point-of-care testing for influenza A and B on patient flow and management in a medical assessment unit of a general hospital. *BMC Res Notes*. 2020;13(1):143. [PubMed](#)
56. Cantais A, Mory O, Plat A, et al. Impact of bedside diagnosis of influenza in the paediatric emergency ward. *Clin Microbiol Infect*. 2019;25(7):898-903. [PubMed](#)
57. Diallo D, Hochart A, Lagree M, Dervaux B, Martinot A, Dubos F. Impact of the Sofia® Influenza A+B FIA rapid diagnostic test in a pediatric emergency department. *Arch Pediatr*. 2019;26(1):6-11. [PubMed](#)
58. Respiratory Virus Infections Working Group. Canadian Public Health Laboratory Network statement on point-of-care serology testing in COVID-19. *Can Commun Dis Rep*. 2020;46(5):119-120. [PubMed](#)
59. Ontario Health. COVID-19 test collection and analysis. 2022; <https://www.ontariohealth.ca/providing-health-care/clinical-resources-education/covid-19/testing-analysis>. Accessed 2024 Apr 11.
60. MedLee. BD Veritor Plus Analyser. 2024; <https://www.medlee.ca/products/rapid-test-kit-by-bd>. Accessed 2024 Mar 18.

61. Cue Health. Cue Reader. <https://cuehealth.com/product/cue-health-monitoring-system-reader>. Accessed 2024 Mar 18.
62. Fisher Scientific part of Thermo Fisher Scientific. Quidel QuickVue Influenza A+B Test. 2024; <https://www.fishersci.ca/shop/products/quidel-quickvue-influenza-a-b-test/23043058>. Accessed 2024 Mar 18.
63. Lucira Health Inc. Lucira COVID-19 & Flu Test. 2024; <https://checkit.lucirahealth.ca/products/lucira-covid-19-flu-test>. Accessed 2024 Mar 18.
64. BTNX Inc. Influenza AB + COVID-19 Antigen – 3 in 1 Test. 2024; <https://www.btnx.com/Product?id=2025>. Accessed 2024 Mar 18.
65. Northern Diagnostics. Status COVID-19/Flu A&B. 2022; <https://northerndiagnostics.com/status-covid-19-flu-ab/>. Accessed 2024 Mar 18.
66. MedLee Modern Medical Products. BD Veritor System for Rapid Detection of SARS-CoV-2. 2024; <https://www.medlee.ca/products/bd-veritor-system-for-rapid-detection-of-sars-cov-2>. Accessed 2024 Mar 18.
67. Fisher Scientific part of Thermo Fisher Scientific. Quidel Sofia 2 Flu+SARS Antigen FIA (25T). 2024; <https://www.fishersci.ca/shop/products/sofia-2-flu-sars-antigen-fia-25t/361058699>. Accessed 2024 Mar 18.
68. Cue Health. COVID-19 tests - 3 pack. 2022; <https://shop.cuehealth.ca/products/cue-covid-19-test-for-home-and-over-the-counter-otc-use-cartridge-3-pack>. Accessed 2024 Mar 18.
69. PPE Supply Canada. Flowflex COVID-19 Antigen Rapid Test Kit (expiry: Oct 2024). <https://www.ppe-supply.com/products/flowflex-covid-19-antigen-rapid-test>. Accessed 2024 Mar 18.
70. MedSup Medical. Medsup COVID-19 Rapid Antigen Self-Test. 2024; <https://www.medsupmedical.com/products/ms-tra-sd-5-medsup-covid-19-rapid-antigen-self-test>. Accessed 2024 Mar 18.
71. Rapid Test & Trace Canada by RT Medical. iStatist – COVID-19 Antigen Test (5 pack). 2024; <https://rapidtestandtrace.ca/product/istatis-covid-19-antigen-test/>. Accessed 2024 Mar 18.
72. The Canadian Shield. Artron COVID-19 Rapid Antigen Test kit (5-pack). 2024; <https://www.canadianshieldppe.ca/products/artron-covid-19-rapid-antigen-test-kit-5-pack>. Accessed 2024 Mar 18.
73. Rapid Test & Trace Canada by RT Medical. Standard-Q COVID-19 Rapid Antigen Test (25 pack). 2024; <https://rapidtestandtrace.ca/product/standard-q-sars-cov-2-rapid-antigen-test/>. Accessed 2024 Mar 8.
74. MedLee. Abbott Panbio Covid-19 Antigen Rapid Test Device. 2024; <https://www.medlee.ca/products/panbio-covid-19-ag-rapid-test-device>. Accessed 2024 Mar 18.
75. Stolberg-Stolberg J, Jacob E, Kuehn J, et al. COVID-19 rapid molecular point-of-care testing is effective and cost-beneficial for the acute care of trauma patients. *Eur J Trauma Emerg Surg*. 2023;49(1):487-493. [PubMed](#)
76. Marbus SD, Lutgens SPM, van Gageldonk-Lafeber AB, Hazenberg E, Hermans MHA, Suijkerbuijk AWM. Costs of a clinical pathway with point-of-care testing during influenza epidemic in a Dutch hospital. *Influenza Other Respir Viruses*. 2021;15(2):202-205. [PubMed](#)
77. Mac S, O'Reilly R, Adhikari NKJ, Fowler R, Sander B. Point-of-care diagnostic tests for influenza in the emergency department: a cost-effectiveness analysis in a high-risk population from a Canadian perspective. *PLoS One*. 2020;15(11):e0242255. [PubMed](#)
78. Canadian Public Health Laboratory Network Laboratory Directors Council and the Canadian Public Health Laboratory Network Respiratory Virus Infection Working Group. Interim guidance on the use of the Abbott Panbio COVID-19 Antigen Rapid Test. *Can Commun Dis Rep*. 2021;47(1):17-22. [PubMed](#)
79. Considerations for SARS-CoV-2 antigen testing for healthcare providers testing individuals in the community. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2023: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html#anchor_1631295313910. Accessed 2024 Mar 07.
80. Respiratory Virus Infections Working Group. Canadian Public Health Laboratory Network statement on point-of-care serology testing in COVID-19. *Can Commun Dis Rep*. 2022;48(1):1-3. [PubMed](#)

Appendix 1: Methods

Literature Search Strategy

An information specialist conducted a literature search on key resources including MEDLINE, the Cochrane Database of Systematic Reviews, the International HTA Database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevancy. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Search concepts were developed based on the elements of the research questions and selection criteria. The main search concepts were point-of-care (POC) tests, and COVID-19 or influenza. [CADTH-developed search filters](#) were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, indirect treatment comparisons, randomized controlled trials or controlled clinical trials, economic studies, guidelines, diagnostic accuracy, or the Canadian context. The search was completed on February 23, 2024 and limited to English-language documents published since January 1, 2019. An additional search was conducted using the brand names of POC tests approved by Health Canada for use with COVID-19 and influenza. CADTH-developed search filters were applied to limit retrieval to diagnostic accuracy, randomized controlled trials, or controlled clinical trials. The search was completed on February 23, 2024 and limited to English-language documents published since January 1, 2019.

Selection Criteria

One author screened the literature search results and reviewed potentially relevant studies and the product inserts of relevant POCTs. Studies were considered for inclusion if the intervention was an authorized POCTs for SARS-CoV-2 and influenza A and B. Grey literature were included when they provided additional information to that available in the published studies. To check if POCTs were authorized for use in Canada, the author used Health Canada's [list of authorized medical devices](#) and [Medical Devices Active Listing](#).

Appendix 2: DTA and Accuracy Studies by Authorized Device and Indication

Note that this appendix has not been copy-edited.

Tables 5 and 6 summarize the accuracy outcomes reported in identified DTA or accuracy studies. We included studies that compare a POCT to standard of care (i.e., RT-PCR or PCR). Any studies captured in systematic reviews were excluded.

Table 5: Studies with DTA or Accuracy Outcomes for COVID-19 by Device

Study	Setting, country (N)	Accuracy (95% CI)	
		Sensitivity or PPA	Specificity or NPA
Panbio COVID-19 Ag Rapid Test			
Gobena D, Gudina EK, Gebre G, Degfie TT, Mekonnen Z. Rapid antigen test as a screening tool for SARS-CoV-2 infection: Head-to-head comparison with qRT-PCR in Ethiopia. <i>Heliyon</i> . 2024 Jan 15;10(1):e23518. PubMed: PM38169801	Selected hospitals; Ethiopia (N = 1,364)	33.3% (31% to 36%)	99.3% (98.8% to 99.7%)
Boujemaa S, Suri GS, Kaur G. Diagnostic evaluation of Panbio TM antigen rapid diagnostic test for SARS-CoV-2: A systematic review and meta-analysis. <i>J Virol Methods</i> . 2023 11;321:114811. PubMed: PM37696303	Various settings; Various countries (49 studies*)	65% (64% to 66%)	99% (99% to 100%)
Fragkou PC, Moschopoulos CD, Dimopoulou D, et al. Performance of point-of care molecular and antigen-based tests for SARS-CoV-2: a living systematic review and meta-analysis. <i>Clin Microbiol Infect</i> . 2023 Mar;29(3):291-301. PubMed: PM36336237	Various settings; Various countries (38 studies*)	71% (65% to 76%)	99% (99% to 100%)
Gallardo-Alfaro L, Lorente-Montalvo P, Canellas M, et al. Diagnostic accuracy of Panbio TM rapid antigen test for SARS-CoV-2 in pediatric population. <i>BMC Pediatr</i> . 2023 08 29;23(1):433. PubMed: PM37644389	Various settings; Spain (N = 1142)	59.5% (48.2% to 69.9%)	99.8% (99.2% to 99.9%)
Haroun AE, Obtel M, El Hilali S, et al. COVID-19 in Morocco's region: Observational study of prevalence in symptomatic adults using the PANBIOS R rapid antigen test September 2021. <i>Influenza Other Respi Viruses</i> . 2023 05;17(5):e13142. PubMed: PM37180839	NR; Morrocco (N = 206)	69.4% (NR)	95.7%(NR)
Moreno-Contreras J, Espinoza MA, Cantu-Cuevas MA, et al. Saliva sampling and its direct lysis is an excellent option for SARS-CoV-2 diagnosis in pediatric patients: comparison with the PanBio COVID-19 antigen rapid test in symptomatic and asymptomatic children. <i>J Med Microbiol</i> . 2023 Nov;72(11). PubMed: PM38014762	Ambulatory care; Mexico (N = 498)	64.3% (56.3% to 72.2%)	96.6% (94.8% to 98.5%)
Ashagre W, Atnafu A, Wassie L, et al. Evaluation of the diagnostic performance of PanbioTM Abbott SARS-CoV-2 rapid antigen test for the detection of COVID-19 from suspects attending ALERT center. <i>PLoS One</i> . 2022;17(11):e0277779. PubMed: PM36413550	Hospital; Ethiopia (N = 120)	74.2% (63.3% to 85%)	100% (100%)

Study	Setting, country (N)	Accuracy (95% CI)	
		Sensitivity or PPA	Specificity or NPA
Brummer LE, Katzenschlager S, McGrath S, et al. Accuracy of rapid point-of-care antigen-based diagnostics for SARS-CoV-2: An updated systematic review and meta-analysis with meta-regression analyzing influencing factors. <i>PLoS Med.</i> 2022 05;19(5):e1004011. PubMed: PM35617375	Various settings; Various countries (N = 32,370)	71.9% (66.8% to 76.4%)	99.5% (99.2% to 99.7%)
Chen TH, Huang MY, Hsiao CH, Chien DK, Tsai W. Performance evaluation of Panbio™ COVID-19 rapid antigen test for SARS-CoV-2 detection in a low prevalence cohort. <i>Infect Dis.</i> 2022 12;54(12):944-946. PubMed: PM35837988	Hospital; Taiwan (N = 9,174)	23.1% (13.53% to 35.19%)	99.9% (99.77% to 99.93%)
Dinnes J, Sharma P, Berhane S, et al. Rapid, point-of-care antigen tests for diagnosis of SARS-CoV-2 infection. <i>Cochrane Database Syst Rev.</i> 2022 07 22;7:CD013705. PubMed: PM35866452	Various settings; Various countries (N = 1,204)	74.8% (67.6% to 80.8%)	99.7% (99.6% to 99.8%)
Hayer J, Kasapic D, Zemmrich C. Real-world clinical performance of commercial SARS-CoV-2 rapid antigen tests in suspected COVID-19: A systematic meta-analysis of available data as of November 20, 2020. <i>Int J Infect Dis.</i> 2021 Jul;108:592-602. PubMed: PM34015523	Various settings; Various countries (19 studies*)	76.9% (72.1% to 81.2%)	≥ 97 (NR)
ID NOW			
Han E, Lee S, Kim HS, et al. Analytical performance of the Abbott ID NOW 2.0 assay for SARS-CoV-2 detection in clinical samples from symptomatic patients. <i>Diagn Microbiol Infect Dis.</i> 2024 Mar;108(3):116164. PubMed: PM38157639	Medical Center; Korea (N = 792)	97.6% (93.6% to 99.3%)	100% (99.4% to 100%)
Thompson A, Hettle D, Hutchings S, et al. The diagnostic accuracy of the ID NOW COVID-19 point of care test in acute hospital admissions. <i>J Clin Virol.</i> 2024 Feb;170:105634. PubMed: PM38211537	Hospitals; UK (N = 12,821)	85.2% (82.2% to 87.9%)	99.6% (99.4% to 99.7%)
Babic N, Garner KS, Hirschhorn JW, Zebian R, Nolte FS. Evaluation of Abbott ID NOW COVID-19 POC test performance characteristics and integration in the regional health network workflows to improve health care delivery. <i>Clin Biochem.</i> 2023 Jul;117:69-73. PubMed: PM34896098	ED; South Carolina, US (N = 793)	94.5% (85.1% to 98.1%)	99.3% (96.4% to 99.9%)
Fragkou PC, Moschopoulos CD, Dimopoulou D, et al. Performance of point-of care molecular and antigen-based tests for SARS-CoV-2: a living systematic review and meta-analysis. <i>Clin Microbiol Infect.</i> 2023 Mar;29(3):291-301. PubMed: PM36336237	Various settings; Various countries (10 studies*)	86% (78% to 92%)	99% (98% to 99%)
Kepka Z, Briksi A, Hubacek P, Zajac M, Drevinek P. Characteristics of the ID-NOW TM test for the rapid detection of SARS-CoV-2. <i>Epidemiol Mikrobiol Imunol.</i> 2023;72(1):3-8. PubMed: PM37185021	ED; Czech Republic	76.74% (61.37% to 88.24%)	98.82% (96.59% to 99.76%)
Payne D, Williams C, Jacob J, et al. Comparison of an ID NOW COVID-19 Assay Used at the Point of Care to Laboratory-Based Nucleic Acid Amplification Tests. <i>J Clin Microbiol.</i> 2023 Jul 20;61(7):e0041323. PubMed: PM37395672	Mobile testing unit, community health center, tertiary care hospital; US	88.2% (NR)	99.1% (NR)

Study	Setting, country (N)	Accuracy (95% CI)	
		Sensitivity or PPA	Specificity or NPA
Stokes W, Venner AA, Buss E, Tipples G, Berenger BM. Prospective population-level validation of the Abbott ID NOW severe acute respiratory syndrome coronavirus 2 device implemented in multiple settings for testing asymptomatic and symptomatic individuals. <i>Clin Microbiol Infect.</i> 2023 Feb;29(2):247-252. PubMed: PM36096431	Various settings; Alberta, Canada (N = 129,112)	92.5% (92% to 93%)	99.5% (99.4% to 99.5%)
Stolberg-Stolberg J, Jacob E, Kuehn J, et al. COVID-19 rapid molecular point-of-care testing is effective and cost-beneficial for the acute care of trauma patients. <i>Eur J Trauma Emerg Surg.</i> 2023 Feb;49(1):487-493. PubMed: PM36066585	Acute trauma center; Germany (N = 1,133)	83.33% (35.88% to 99.58%)	99.82% (99.36% to 99.98%)
Teklemariam Z, Feleke D, Abdurahman A, et al. Evaluation of the performance of Abbott Panbio TM COVID-19 antigen rapid diagnostic test for the detection of severe acute respiratory syndrome coronavirus 2 at Harar, Eastern Ethiopia. <i>Front Med (Lausanne).</i> 2023;10:1135027. PubMed: PM37324158	Health institutions; Ethiopia (N = 236)	77.5% (61.6% to 89.2%)	98.5% (95.6% to 99.7%)
Barker KR, Small LN, Thai DV, Sohn KY, Rosella LC. Evaluating the Ability to ID (COVID-19) NOW: a Large Real-World Prospective Evaluation of the Abbott ID NOW COVID-19 Assay. <i>Microbiol Spectr.</i> 2022 06 29;10(3):e0051322. PubMed: PM35579469	Multisite community and academic hospital; Canada (N = 2,244)	89.9% (85.0% to 93.3%)	99.9% (99.7% to 100%)
Barnacle JR, Houston H, Baltas I, et al. Diagnostic accuracy of the Abbott ID NOW SARS-CoV-2 rapid test for the triage of acute medical admissions. <i>J Hosp Infect.</i> 2022 May;123:92 to 99. PubMed: PM35217130	ED; England, UK (N = 6,050)	83.1% (75.4% to 88.7%)	99.5% (99.3% to 99.6%)
Bousquet A, Larreche S, Bigaillon C, et al. Abbott R ID NOW TM COVID-19 rapid molecular assay vs. Hologic R Panther Aptima TM SARS-CoV-2 assay in nasopharyngeal specimens: results from 1-year retrospective study in an emergency department. <i>Diagn Microbiol Infect Dis.</i> 2022 Sep;104(1):115742. PubMed: PM35843113	ED; France (N = 3,980)	86.9% (81.4% to 92.4%)	99.7% (99.6% to 99.9%)
Burdino E, Cerutti F, Milia MG, et al. Fast and reliable real life data on COVID-19 triaging with ID NOW. <i>J Clin Virol Plus.</i> 2022 Feb;2(1):100065. PubMed: PM35262036	ED; Italy (N = 148)	83.9% (NR)	100% (NR)
Deslandes V, Clark E, Thiruganasambandamoorthy V, Desjardins M. Implementation of the Abbott ID Now COVID-19 assay at a tertiary care centre: a prospective pragmatic implementation study during the third wave of SARS-CoV-2 in Ontario. <i>Diagn Microbiol Infect Dis.</i> 2022 Mar;102(3):115609. PubMed: PM34933188	Tertiary care hospital ED; Ontario, Canada (N = 273)	93.8% (NR)	99.5% (NR)
Levesque S, Beauchemin S, Vallee M, et al. Evaluation of water gargle samples for SARS-CoV-2 detection using Abbott ID NOW COVID-19 assay. <i>J Med Virol.</i> 2022 09;94(9):4522 to 4527. PubMed: PM35535382	University laboratories; Quebec, Canada (N = 213)	91.6% (86.9% to 95%)	NR
Pattnaik D, Poddar N, Pathi BK, et al. Comparative Evaluation of Cartridge-Based Abbott ID NOW Test With Probe-Based Real-Time Reverse Transcription Polymerase Chain Reaction Assay for Detection of SARS-CoV-2. <i>Cureus.</i> 2022 Feb;14(2):e22470. PubMed: PM35223334	Tertiary care hospitals; India (N = 259)	87% (NR)	98% (NR)

Study	Setting, country (N)	Accuracy (95% CI)	
		Sensitivity or PPA	Specificity or NPA
Srivastava S, Singh P, Malhotra R, Mathur P. Comparison of Abbott ID NOW, a novel isothermal amplification based COVID-19 diagnostic method with RTPCR. <i>J Virol Methods</i> . 2022 06;304:114521. PubMed: PM35278535	Trauma Center; India (N = 72)	93.22% (83.82% to 97.93%)	100% (77.19% to 100%)
Burnes LE, Clark ST, Sheldrake E, et al. One swab, two tests: Validation of dual SARS-CoV-2 testing on the Abbott ID NOW TM. <i>J Clin Virol</i> . 2021 Aug;141:104896. PubMed: PM34174710	Acute care hospitals; Ontario, Canada (N = 179)	87.0% (0.74% to 0.94%)	99.7% (0.98% to 0.99%)
Farfour E, Asso-Bonnet M, Vasse M. The ID NOW COVID-19, a high-speed high-performance assay. <i>Eur J Clin Microbiol Infect Dis</i> . 2021 Sep;40(9):2041-2045. PubMed: PM33855651	ED; France (N = 48)	94.9% (NR)	100% (NR)
Goupil-Sormany I, Longtin J, Dumaresq J, et al. The PRONTO study: Clinical performance of ID NOW in individuals with compatible SARS-CoV-2 symptoms in walk-in centres-accelerated turnaround time for contact tracing. <i>Can Commun Dis Rep</i> . 2021 Dec 09;47(12):534 to 542. PubMed: PM35018141	Walk-in centres; Quebec, Canada (N = 2,372)	99% (97.5% to 99.7%)	99.2% (98.7% to 99.6%)
Stokes W, Berenger BM, Singh T, et al. Acceptable performance of the Abbott ID NOW among symptomatic individuals with confirmed COVID-19. <i>J Med Microbiol</i> . 2021 Jul;70(7). PubMed: PM34309503	Community centers and hospitals; Alberta, Canada (N = 133)	89.1% (82.0% to 94.1%)	NR
Thwe PM, Maiyo E, Ren P. Abbott ID now COVID-19 assay performance: a year in review. <i>Diagn Microbiol Infect Dis</i> . 2021 Dec;101(4):115536. PubMed: PM34634713	Academic hospital; US (N = 3,320)	70.3% (NR)	95.3% (NR)
Yoon SH, Yang S, Cho H, Eun S, Koo CM, Kim MK. Point-of-care testing for the detection of SARS-CoV-2: a systematic review and meta-analysis. <i>Eur Rev Med Pharmacol Sci</i> . 2021 Jan;25(1):503 to 517. PubMed: PM33506942	Various settings; Various countries (26 studies*)	75% (74% to 82%)	100% (98% to 100%)
The Sofia SARS Antigen FIA			
Cernila M, Logar M, Mozina H, Osredkar J. Comparison between the Sofia SARS Antigen FIA Test and the PCR Test in Detection of SARS-CoV-2 Infection. <i>Lab Med</i> . 2023 Mar 07;54(2):e44-e48. PubMed: PM35976956	Hospital; Slovenia (N = 818)	90% (55.5% to 99.75%)	97.52% (92.93% to 99.49%)
Lippi G, Henry BM, Plebani M. Pooled analysis of diagnostic performance of the instrument-read Quidel Sofia SARS antigen Fluorescent Immunoassay (FIA). <i>eJIFCC</i> . 2023 Jul;34(2):123-141. PubMed: PM37455844	NR; Various countries (24 studies)	78% (74% to 78%)	100% (100% to 100%)
Bornemann L, Dahne T, Fomenko A, et al. Performance of the Sofia SARS-CoV-2 rapid antigen test as frontline test in a university hospital, Germany. <i>Diagn Microbiol Infect Dis</i> . 2022 May;103(1):115663. PubMed: PM35331603	ED; Germany (N = 7,877)	62.9% (57.8% to 67.8%)	99.4% (99.2% to 99.5%)
Brummer LE, Katzenschlager S, McGrath S, et al. Accuracy of rapid point-of-care antigen-based diagnostics for SARS-CoV-2: An updated systematic review and meta-analysis with meta-regression analyzing influencing factors. <i>PLoS Med</i> . 2022 05;19(5):e1004011. PubMed: PM35617375	Various settings; Various countries (N = 9,739)	76.4%(70.9% to 81.2%)	99% (98.3% to 99.4%)

Study	Setting, country (N)	Accuracy (95% CI)	
		Sensitivity or PPA	Specificity or NPA
Dinnes J, Sharma P, Berhane S, et al. Rapid, point-of-care antigen tests for diagnosis of SARS-CoV-2 infection. <i>Cochrane Database Syst Rev</i> . 2022 07 22;7:CD013705. PubMed: PM35866452	Various settings; Various countries (N = 2,062)	82.4% (70.7% to 90.0%)	98.9% (98.3% to 99.3%)
The BioFire Respiratory Panel 2.1			
Fragkou PC, Moschopoulos CD, Dimopoulou D, et al. Performance of point-of care molecular and antigen-based tests for SARS-CoV-2: a living systematic review and meta-analysis. <i>Clin Microbiol Infect</i> . 2023 Mar;29(3):291-301. PubMed: PM36336237	Various settings; Various countries (1 study)	98% (89% to 100%)	100% (93% to 100%)
Park J, Kim SY, Lee J, Hong KH. Clinical Evaluation of BioFire COVID-19 Test, BioFire Respiratory Panel 2.1, and Cepheid Xpert Xpress SARS-CoV-2 Assays for Sample-to-Answer Detection of SARS-CoV-2. <i>Genes (Basel)</i> . 2023 01 16;14(1):16. PubMed: PM36672974	Hospital; Korea and Italy (N = 77)	100% (90.26% to 100%)	100% (91.4% to 100%)
Hirotsu Y, Maejima M, Shibusawa M, et al. Direct comparison of Xpert Xpress, FilmArray Respiratory Panel, Lumipulse antigen test, and RT-qPCR in 165 nasopharyngeal swabs. <i>BMC Infect Dis</i> . 2022 Mar 04;22(1):221. PubMed: PM35246055	Hospital; Japan (N = 165)	98% (95.6% to 98%)	100% (96.3% to 100%)
Xpert Xpress			
Oh AC, Suh HJ, Kim H, Lee JK, Hong YJ. Comparison of Xpert Xpress SARS-CoV-2 Assay Compared with Standard M nCoV Real-Time PCR: Prospective Study. <i>Clin Lab</i> . 2024 Feb 01;70(2):01. PubMed: PM38345984 . PubMed: PM38345984	NR; Korea (N = 357)	82.1% (NR)	95% (NR)
Fragkou PC, Moschopoulos CD, Dimopoulou D, et al. Performance of point-of care molecular and antigen-based tests for SARS-CoV-2: a living systematic review and meta-analysis. <i>Clin Microbiol Infect</i> . 2023 Mar;29(3):291 to 301. PubMed: PM36336237	Various settings; Various countries (5 studies*)	98% (95% to 99%)	96% (93% to 97%)
Hasanah M, Aulia FA, Wardhani P, Aryati. Comparison of SARS-CoV-2 virus detection using the Xpert Xpress rapid molecular test on Abbott M2000 Real-Time System: a cross-sectional study. <i>Ann Med Surg (Lond)</i> . 2023 Jun;85(6):2559-2563. PubMed: PM37363578	Tertiary hospital; Indonesia (N = 36)	100%(NR)	100% (NR)
Park J, Kim SY, Lee J, Hong KH. Clinical Evaluation of BioFire COVID-19 Test, BioFire Respiratory Panel 2.1, and Cepheid Xpert Xpress SARS-CoV-2 Assays for Sample-to-Answer Detection of SARS-CoV-2. <i>Genes (Basel)</i> . 2023 01 16;14(1):16. PubMed: PM36672974	Hospital; Korea and Italy (N = 77)	100% (90.26% to 100%)	100% (91.4% to 100%)
Cao XJ, Fang KY, Li YP, Zhou J, Guo XG. The Diagnostic Accuracy of Xpert Xpress to SARS-CoV-2: A systematic review. <i>J Virol Methods</i> . 2022 Mar;301:114460. PubMed: PM35032480	Various settings; Various countries (11 studies)	97% (0.96% to 0.98%)	97% (96% to 98%)
Hirotsu Y, Maejima M, Shibusawa M, et al. Direct comparison of Xpert Xpress, FilmArray Respiratory Panel, Lumipulse antigen test, and RT-qPCR in 165 nasopharyngeal swabs. <i>BMC Infect Dis</i> . 2022 Mar 04;22(1):221. PubMed: PM35246055	Hospital; Japan (N = 165)	99% (96.8% to 99%)	100% (96.6% to 100%).

Study	Setting, country (N)	Accuracy (95% CI)	
		Sensitivity or PPA	Specificity or NPA
Al-Hail H, Mirza F, Al Hashemi A, et al. Evaluation of automated molecular tests for the detection of SARS-CoV-2 in pooled nasopharyngeal and saliva specimens. <i>J Clin Lab Anal.</i> 2021 Aug;35(8):e23876. PubMed: PM34132419	Tertiary care hospital; Qatar	97.1% (85.1% to 99.9%) ^a	100% (98.1% to 100%) ^a
Lee J, Song JU. Diagnostic accuracy of the Cepheid Xpert Xpress and the Abbott ID NOW assay for rapid detection of SARS-CoV-2: A systematic review and meta-analysis. <i>J Med Virol.</i> 2021 07;93(7):4523-4531. PubMed: PM33913533	Various settings; Various countries (17 studies)	79% (69% to 86%)	100% (98% to 100%)
Morris TC, Bird PW, Horvath-Papp E, Dhillon JK, May S, Tang JW. Xpert Xpress Flu/RSV: Validation and impact evaluation at a large UK hospital trust. <i>J Med Virol.</i> 2021 08;93(8):5146-5151. PubMed: PM33559907	Various settings; US (N = 166)	98.7%(NR) ^b	100%(NR) ^b
Yoon SH, Yang S, Cho H, Eun S, Koo CM, Kim MK. Point-of-care testing for the detection of SARS-CoV-2: a systematic review and meta-analysis. <i>Eur Rev Med Pharmacol Sci.</i> 2021 Jan;25(1):503-517. PubMed: PM33506942	Various settings; Various countries (26 studies*)	99% (97% to 100%)	99%(94% to 100%)
Cobas Liat			
Fragkou PC, Moschopoulos CD, Dimopoulou D, et al. Performance of point-of care molecular and antigen-based tests for SARS-CoV-2: a living systematic review and meta-analysis. <i>Clin Microbiol Infect.</i> 2023 Mar;29(3):291-301. PubMed: PM36336237	Various settings; Various countries (2 studies*)	98% (72% to 100%)	97% (96% to 98%)
Park K, Sung H, Kim MN. Evaluation of the cobas Liat detection test for SARS-CoV-2 and influenza viruses following the emergence of the SARS-CoV-2 Omicron variant. <i>Diagn Microbiol Infect Dis.</i> 2023 Apr;105(4):115891. PubMed: PM36738537	Tertiary hospital; Korea (N = 1,147)	100% (NR)	100% (NR)
Cue COVID-19 Molecular Test			
Fragkou PC, Moschopoulos CD, Dimopoulou D, et al. Performance of point-of care molecular and antigen-based tests for SARS-CoV-2: a living systematic review and meta-analysis. <i>Clin Microbiol Infect.</i> 2023 Mar;29(3):291-301. PubMed: PM36336237	Various settings; Various countries (1 study*)	92% (73% to 99%)	98% (96% to 100%)
Rebbapragada A, Cariazo L, Elchuk D, et al. Performance of the Cue COVID-19 point-of-care molecular test: insights from a multi-site clinic service model. <i>Microbiol Spectr.</i> 2023 Sep 20:e0406422. PubMed: PM37728337	Family health clinics; Ontario, Canada (N = 3,037)	100% (NR)	99.4%(NR)
QIAstat-Dx			
Fragkou PC, Moschopoulos CD, Dimopoulou D, et al. Performance of point-of care molecular and antigen-based tests for SARS-CoV-2: a living systematic review and meta-analysis. <i>Clin Microbiol Infect.</i> 2023 Mar;29(3):291-301. PubMed: PM36336237	Various settings; Various countries (1 study*)	100% (91% to 100%)	93% (77% to 99%)
Al-Hail H, Mirza F, Al Hashemi A, et al. Evaluation of automated molecular tests for the detection of SARS-CoV-2 in pooled nasopharyngeal and saliva specimens. <i>J Clin Lab Anal.</i> 2021 Aug;35(8):e23876. PubMed: PM34132419	Tertiary care hospital; Qatar	77.0% (46.9% to 95%) ^a	100% (96.1% to 100%) ^a

Study	Setting, country (N)	Accuracy (95% CI)	
		Sensitivity or PPA	Specificity or NPA
Brendish NJ, Poole S, Naidu VV, et al. Clinical impact of molecular point-of-care testing for suspected COVID-19 in hospital (COV-19POC): a prospective, interventional, nonrandomized, controlled study. <i>Lancet Respir Med</i> . 2020 12;8(12):1192-1200. PubMed: PM33038974	ED; UK (N = 500)	85.9% (79.9% to 90.7%)	99.0% (97% to 99.8%)
The BD Veritor			
Fragkou PC, Moschopoulos CD, Dimopoulou D, et al. Performance of point-of care molecular and antigen-based tests for SARS-CoV-2: a living systematic review and meta-analysis. <i>Clin Microbiol Infect</i> . 2023 Mar;29(3):291 to 301. PubMed: PM36336237	Various settings; Various countries (1 study*)	87% (75% to 94%)	100% (98% to 100%)
Brummer LE, Katzenschlager S, McGrath S, et al. Accuracy of rapid point-of-care antigen-based diagnostics for SARS-CoV-2: An updated systematic review and meta-analysis with meta-regression analyzing influencing factors. <i>PLoS Med</i> . 2022 05;19(5):e1004011. PubMed: PM35617375	Various settings; Various countries (N = 5721)	71.2% (56.8% to 82.3%)	99.2% (98.6% to 99/6%)
Dinnes J, Sharma P, Berhane S, et al. Rapid, point-of-care antigen tests for diagnosis of SARS-CoV-2 infection. <i>Cochrane Database Syst Rev</i> . 2022 07 22;7:CD013705. PubMed: PM35866452	Various settings; Various countries (N = 5,196)	68% (51% to 81.3%)	99.4% (99.1% to 99.6%)
Koga P, Maluf M, Nunes F, et al. Comparison of the SARS-CoV-2 BD Veritor Nasal Antigen Test with Nasopharyngeal Reverse Transcription-PCR in Symptomatic Patients. <i>Microbiol Spectr</i> . 2022 10 26;10(5):e0019022. PubMed: PM36036635	NR; NR (N = 148)	84.3 (NR)	NR
Parikh A, Cooper L, Frogel D, Le Benger K, Cooper CK, Parvu V. Large-Scale SARS-CoV-2 Antigen Testing With Real-World Specimens. <i>Front Public Health</i> . 2022;10:836328. PubMed: PM35450121	Urgent care walk-in clinics; US (N = 1,952,931)	77.2% (NR)	97.6% (NR)
STANDARD Q COVID-19 Ag Test			
Fragkou PC, Moschopoulos CD, Dimopoulou D, et al. Performance of point-of care molecular and antigen-based tests for SARS-CoV-2: a living systematic review and meta-analysis. <i>Clin Microbiol Infect</i> . 2023 Mar;29(3):291-301. PubMed: PM36336237	Various countries (1 studies*)	78% (69% to 85%)	99% (98% to 99%)
Kim SW, Park Y, Kim D, Jeong SH. A single-center experience on long-term clinical performance of a rapid SARS-CoV-2 Antigen Detection Test, STANDARD Q COVID-19 Ag Test. <i>Sci Rep</i> . 2023 11 27;13(1):20777. PubMed: PM38012319	NR; Korea (N = 14,194)	0.577 (0.539% to 0.614%)	0.991 (0.989% to 0.993%)
Brummer LE, Katzenschlager S, McGrath S, et al. Accuracy of rapid point-of-care antigen-based diagnostics for SARS-CoV-2: An updated systematic review and meta-analysis with meta-regression analyzing influencing factors. <i>PLoS Med</i> . 2022 05;19(5):e1004011. PubMed: PM35617375	Various settings; Various countries (N = 9,739)	70.9%(65.9% to 75.5%)	98.8% (98.2% to 99.2%)
Dedeic-Ljubovic A, ulic EJ, Husic E, Halkovic J, Gacanovic D, Salimovic-Besic I. Performance Characteristics and Utility of the Standard Q COVID-19 Antigen Test for Emergency Admissions to Health care Facilities. <i>Acta Medica (Hradec Kralove)</i> . 2022;65(4):139-143. PubMed: PM36942704	Emergency admissions; Bosnia and Herzegovina (N = 120)	92.98% (NR)	88.89%(NR)

Study	Setting, country (N)	Accuracy (95% CI)	
		Sensitivity or PPA	Specificity or NPA
Dinnes J, Sharma P, Berhane S, et al. Rapid, point-of-care antigen tests for diagnosis of SARS-CoV-2 infection. <i>Cochrane Database Syst Rev.</i> 2022 07 22;7:CD013705. PubMed: PM35866452	Various settings; Various countries (N = 25,193)	68.1% (56.1% to 78.2%)	98.1% (97% to 98.7%)
Konstantinus I, Chiwara D, Ndevaetela EE, et al. Laboratory and field evaluation of the STANDARD Q and Panbio™ SARS-CoV-2 antigen rapid test in Namibia using nasopharyngeal samples. <i>PLoS One.</i> 2022;17(9):e0269329. PubMed: PM36166414	Health facilities; Namibia (N = 160)	88% (79% to 93%)	99% (95% CI, 93% to 99%)
Pandey S, Poudel A, Karki D, Thapa J. Diagnostic accuracy of antigen-detection rapid diagnostic tests for diagnosis of COVID-19 in low-and middle-income countries: A systematic review and meta-analysis. <i>PLOS Glob Public Health.</i> 2022;2(4):e0000358. PubMed: PM36962195	Various settings; Various countries (2 studies)	79.4% (NR)	99.1% (NR)
Shin H, Lee S, Widyasari K, Yi J, Bae E, Kim S. Performance evaluation of STANDARD Q COVID-19 Ag home test for the diagnosis of COVID-19 during early symptom onset. <i>J Clin Lab Anal.</i> 2022 Jun;36(6):e24410. PubMed: PM35441745	Hospitals or institutes; South Korea (N = 296)	94.94% (87.54% to 98.60%)	100% (98.31%–100%)
Sitoe N, Sambo J, Nguenha N, et al. Performance Evaluation of the STANDARD™ Q COVID-19 and Panbio™ COVID-19 Antigen Tests in Detecting SARS-CoV-2 during High Transmission Period in Mozambique. <i>Diagnostics (Basel).</i> 2022 Feb 12;12(2):12. PubMed: PM35204566	Health facilities; Mozambique (N = 1,277)	45.0% (39.9% to 50.2%)	97.6% (95.3% to 99.0%)
Hayer J, Kasapic D, Zemmrich C. Real-world clinical performance of commercial SARS-CoV-2 rapid antigen tests in suspected COVID-19: A systematic meta-analysis of available data as of November 20, 2020. <i>Int J Infect Dis.</i> 2021 Jul;108:592-602. PubMed: PM34015523	Various settings; Various countries (19 studies)	82.4% (74.2% to 88.4%)	≥ 97 (NR)
Oh SM, Jeong H, Chang E, et al. Clinical Application of the Standard Q COVID-19 Ag Test for the Detection of SARS-CoV-2 Infection. <i>J Korean Med Sci.</i> 2021 Apr 12;36(14):e101. PubMed: PM33847084	ED; Korea (N = 98)	17.5% (8.8% to 32%)	100% (95.3% to 100.0%),
Lucira COVID-19 and Flu Test			
Simms E, McCracken GR, Hatchette TF, et al. Real-world evaluation of the Lucira Check-It COVID-19 loop-mediated amplification (LAMP) test. <i>Microbiol Spectr.</i> 2023 Dec 12;11(6):e0277223. PubMed: PM37962351	Preoperative setting, ED, and community testing sites; Nova Scotia, Canada	93% (83% to 98.1%)	98.3% (96.3% to 99.4%)
PCL COVID19 Ag Gold			
Dinnes J, Sharma P, Berhane S, et al. Rapid, point-of-care antigen tests for diagnosis of SARS-CoV-2 infection. <i>Cochrane Database Syst Rev.</i> 2022 07 22;7:CD013705. PubMed: PM35866452	Various settings; Various countries (N = 132)	88.7% (78.1% to 95.3%)	98.6% (92.3% to 100%)

ED = emergency department; NPA = negative percent agreement; NR = not reported; PPA = positive percent agreement.

*Studies included in the systematic review for the specific device.

^aPooled testing.

^bIncludes Respiratory Syncytial Virus, Influenza, and SARS-CoV-2 samples.

Table 6: Studies with DTA or Accuracy Outcomes for Influenza by Device

Study	Setting; country (n)	Accuracy (95% CI)			
		Influenza A		Influenza B	
		Sensitivity or PPA	Specificity or NPA	Sensitivity or PPA	Specificity or NPA
EasyNAT Rapid Flu Assay					
Deng J, Zhu H, An S, et al. Accurate detection of influenza A virus by use of a novel cross-priming isothermal amplification-based point-of-care assay. <i>Microbiol Spectr</i> . 2024 Feb 13:e0307423. PubMed: PM38349165	Outpatient settings and ED; China (n = 119)	97.7%(87.9% to 99.6%)	98.6%(92.4% to 99.8%)	NA	NA
ID Now					
Mitamura K, Yamazaki M, Ichikawa M, et al. Clinical usefulness of a rapid molecular assay, ID NOW™ influenza A and B 2, in adults. <i>J Infect Chemother</i> . 2021 Mar;27(3):450-454. PubMed: PM33218876	Medical institutions; Japan (n = 254)	100% (89.1% to 100%)	98.7% (92.8% to 100%)	100% (74.1% to 100%)	97.8% (92.3% to 99.7%)
Mitamura K, Shimizu H, Yamazaki M, et al. Clinical evaluation of ID NOW influenza A and B 2, a rapid influenza virus detection kit using isothermal nucleic acid amplification technology - A comparison with currently available tests. <i>J Infect Chemother</i> . 2020 Feb;26(2):216-221. PubMed: PM31558351	Internal medicine facilities; Japan (n = 238)	95.9% (89.9% to 98.9%)	100% (98.1% to 100%)	100% (90.2% to 100%)	100% (98.7% to 100%)
Kanwar N, Michael J, Doran K, Montgomery E, Selvarangan R. Comparison of the ID Now Influenza A and B 2, Cobas Influenza A/B, and Xpert Xpress Flu Point-of-Care Nucleic Acid Amplification Tests for Influenza A/B Virus Detection in Children. <i>J Clin Microbiol</i> . 2020 02 24;58(3):24. PubMed: PM31941689	Hospital and clinics; US (n = 201)	93.2% (84.1% to 97.5%)	99.2% (95.1% to 100%)	97.2% (83.8% to 99.9%)	98.8% (95.2% to 99.8%)
Cobas Liat					
Park K, Sung H, Kim MN. Evaluation of the cobas Liat detection test for SARS-CoV-2 and influenza viruses following the emergence of the SARS-CoV-2 Omicron variant. <i>Diagn Microbiol Infect Dis</i> . 2023 Apr;105(4):115891. PubMed: PM36738537	Tertiary hospital; Korea (n = 1,147)	99.6%(NR) ^a	100% (NR)	99.6%(NR) ^a	100% (NR)

Study	Setting; country (n)	Accuracy (95% CI)			
		Influenza A		Influenza B	
		Sensitivity or PPA	Specificity or NPA	Sensitivity or PPA	Specificity or NPA
Youngs J, Iqbal Y, Glass S, et al. Implementation of the cobas Liat influenza point-of-care test into an emergency department during a high-incidence season: a retrospective evaluation following real-world implementation. <i>J Hosp Infect.</i> 2019 Mar;101(3):285-288. PubMed: PM30562558	ED; UK (n = 1,074)	86.3% (73.7% to 94.3%)	99.1% (97.8% to 99.8%)	84.6% (69.5% to 94.1%)	98.9% (97.7% to 99.6%)
Gosert R, Naegele K, Hirsch HH. Comparing the Cobas Liat Influenza A/B and respiratory syncytial virus assay with multiplex nucleic acid testing. <i>J Med Virol.</i> 2019 04;91(4):582-587. PubMed: PM30345524	NR: Switzerland (n = 194)	100% (81.5% to 100%)	100% (97.9% to 100%)	100% (73.5 to 100%)	99.5% (97% to 100%)
Akashi Y, Suzuki H, Ueda A, et al. Analytical and clinical evaluation of a point-of-care molecular diagnostic system and its influenza A/B assay for rapid molecular detection of the influenza virus. <i>J Infect Chemother.</i> 2019 Aug;25(8):578-583. PubMed: PM30905631	Hospital; Japan (n = 159)	61.1% (43.3% to 76.9%)	100% (95.6% to 100%)	53.7%(37.4% to 69.3%)	100% (95.6% to 100%)
Kanwar N, Michael J, Doran K, Montgomery E, Selvarangan R. Comparison of the ID Now Influenza A and B 2, Cobas Influenza A/B, and Xpert Xpress Flu Point-of-Care Nucleic Acid Amplification Tests for Influenza A/B Virus Detection in Children. <i>J Clin Microbiol.</i> 2020 02 24;58(3):24. PubMed: PM31941689	Hospital and clinics; US (n = 201)	100% (93.8 to 100%)	99.2% (95.1% to 100.0%)	94.4% (80% to 99%)	97.6% (93.5% to 99.2%)
Xpert Xpress					
Liu YL, Xie TA, Lin GL, et al. Diagnostic Accuracy of Xpert Xpress Flu/RSV for the Detection of Influenza and Respiratory Syncytial Viruses. <i>Jpn J Infect Dis.</i> 2022 Mar 24;75(2):183-191. PubMed: PM34053954	Various settings; Various countries (10 studies)	97% (95% to 98%)	97% (96% to 97%)	98% (96% to 99%)	100% (99% to 100%)
Shihabuddin BS, Faron ML, Relich RF, et al. Cepheid Xpert Xpress Flu/RSV evaluation performed by minimally trained non-laboratory operators in a CLIA-waived environment. <i>Diagn Microbiol Infect</i>	Various health care settings; US (n = 3,265)	98.9% (96.2% to 99.7%)	97.5% (96.6% to 98.2%)	98.4% (91.7% to 99.7%)	99.3% (98.7% to 99.6%)

Study	Setting; country (n)	Accuracy (95% CI)			
		Influenza A		Influenza B	
		Sensitivity or PPA	Specificity or NPA	Sensitivity or PPA	Specificity or NPA
<i>Dis.</i> 2022 Oct;104(2):115764. PubMed: PM35917666					
Morris TC, Bird PW, Horvath-Papp E, Dhillon JK, May S, Tang JW. Xpert Xpress Flu/RSV: Validation and impact evaluation at a large UK hospital trust. <i>J Med Virol.</i> 2021 08;93(8):5146-5151. PubMed: PM33559907	University hospitals; UK (n = 642)	96.6% (92.8% to 98.8%)	98.1% (96.4% to 99.1%)	85.7% (42.1% to 99.6%)	100% (99.4% to 100.0%)
Morris TC, Bird PW, Horvath-Papp E, Dhillon JK, May S, Tang JW. Xpert Xpress Flu/RSV: Validation and impact evaluation at a large UK hospital trust. <i>J Med Virol.</i> 2021 08;93(8):5146-5151. PubMed: PM33559907	Various settings; US (n = 166)	98.7%(NR) ^b	100%(NR) ^b	98.7%(NR) ^b	100%(NR) ^b
Zou X, Chang K, Wang Y, et al. Comparison of the Cepheid Xpert Xpress Flu/RSV assay and commercial real-time PCR for the detection of influenza A and influenza B in a prospective cohort from China. <i>Int J Infect Dis.</i> 2019 Mar;80:92-97. PubMed: PM30634045	Hospital; China (n = 621)	100% (97.5% to 100)	98.6% (97.2% to 99.4%)	100% (97.2%–100%)	99.2% (98.1% to 99.8%)
Kanwar N, Michael J, Doran K, Montgomery E, Selvarangan R. Comparison of the ID Now Influenza A and B 2, Cobas Influenza A/B, and Xpert Xpress Flu Point-of-Care Nucleic Acid Amplification Tests for Influenza A/B Virus Detection in Children. <i>J Clin Microbiol.</i> 2020 02 24;58(3):24. PubMed: PM31941689	Hospital and clinics; US (n = 201)	100% (93.8% to 100%)	97.7% (92.8% to 99.4%)	91.7% (76.4% to 97.8%)	98.2% (94.4% to 99.5%)
The Sofia SARS Antigen FIA					
Lee J, Song JU, Kim YH. Diagnostic Accuracy of the Quidel Sofia Rapid Influenza Fluorescent Immunoassay in Patients with Influenza-like Illness: A Systematic Review and Meta-analysis. <i>Tuberc Respir Dis (Seoul).</i> 2021 Jul;84(3):226-236. PubMed: PM33979987	Various settings; Various countries (17 studies*)	78% (71% to 83%)	99% (98% to 99%)	72% (60% to 82%)	Specificity = 98% (96% to 99%)
The BD Veritor					
Cantais A, Mory O, Plat A, Giraud A, Pozzetto B, Pillet S. Analytical performances of the BD Veritor TM	Pediatric ED; France (n = 694)	100% (NR)	98.7% (NR)	96.6% (NR)	98.8% (NR)

Study	Setting; country (n)	Accuracy (95% CI)			
		Influenza A		Influenza B	
		Sensitivity or PPA	Specificity or NPA	Sensitivity or PPA	Specificity or NPA
System for the detection of respiratory syncytial virus and influenzaviruses A and B when used at bedside in the pediatric emergency department. <i>J Virol Methods</i> . 2019 08;270:66-69. PubMed: PM31047969					
Kanwar N, Michael J, Doran K, Montgomery E, Selvarangan R. Comparison of the ID Now Influenza A and B 2, Cobas Influenza A/B, and Xpert Xpress Flu Point-of-Care Nucleic Acid Amplification Tests for Influenza A/B Virus Detection in Children. <i>J Clin Microbiol</i> . 2020 02 24;58(3):24. PubMed: PM31941689	Hospital and clinics; US (n = 201)	79.5% (68.1% to 87.7%)	99.2% (95.0% to 99.9%)	66.7% (48.9% to 80.9%)	99.4% (96.1% to 99.9%)

ED = emergency department; NA = not applicable; NPA = negative percent agreement; NR = not reported; PPA = positive percent agreement.

*Studies included in the systematic review for the specific device.

^aincludes Influenza A and B.

^bincludes Respiratory Syncytial Virus, Influenza, and SARS-CoV-2 samples.

ISSN: 2563-6596

Disclaimer: The information in this document is intended to help Canadian health care decision-makers, health care professionals, health systems leaders, and policy-makers make well-informed decisions and thereby improve the quality of health care services. While patients and others may access this document, the document is made available for informational purposes only and no representations or warranties are made with respect to its fitness for any particular purpose. The information in this document should not be used as a substitute for professional medical advice or as a substitute for the application of clinical judgment in respect of the care of a particular patient or other professional judgment in any decision-making process. The Canadian Agency for Drugs and Technologies in Health (CADTH) does not endorse any information, drugs, therapies, treatments, products, processes, or services.

While care has been taken to ensure that the information prepared by CADTH in this document is accurate, complete, and up-to-date as at the applicable date the material was first published by CADTH, CADTH does not make any guarantees to that effect. CADTH does not guarantee and is not responsible for the quality, currency, propriety, accuracy, or reasonableness of any statements, information, or conclusions contained in any third-party materials used in preparing this document. The views and opinions of third parties published in this document do not necessarily state or reflect those of CADTH.

CADTH is not responsible for any errors, omissions, injury, loss, or damage arising from or relating to the use (or misuse) of any information, statements, or conclusions contained in or implied by the contents of this document or any of the source materials.

This document may contain links to third-party websites. CADTH does not have control over the content of such sites. Use of third-party sites is governed by the third-party website owners' own terms and conditions set out for such sites. CADTH does not make any guarantee with respect to any information contained on such third-party sites and CADTH is not responsible for any injury, loss, or damage suffered as a result of using such third-party sites. CADTH has no responsibility for the collection, use, and disclosure of personal information by third-party sites.

Subject to the aforementioned limitations, the views expressed herein are those of CADTH and do not necessarily represent the views of Canada's federal, provincial, or territorial governments or any third-party supplier of information.

This document is prepared and intended for use in the context of the Canadian health care system. The use of this document outside of Canada is done so at the user's own risk.

This disclaimer and any questions or matters of any nature arising from or relating to the content or use (or misuse) of this document will be governed by and interpreted in accordance with the laws of the Province of Ontario and the laws of Canada applicable therein, and all proceedings shall be subject to the exclusive jurisdiction of the courts of the Province of Ontario, Canada.

The copyright and other intellectual property rights in this document are owned by CADTH and its licensors. These rights are protected by the Canadian *Copyright Act* and other national and international laws and agreements. Users are permitted to make copies of this document for noncommercial purposes only, provided it is not modified when reproduced and appropriate credit is given to CADTH and its licensors.

About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Questions or requests for information about this report can be directed to Requests@CADTH.ca



Canada's Drug and
Health Technology Agency

cadth.ca