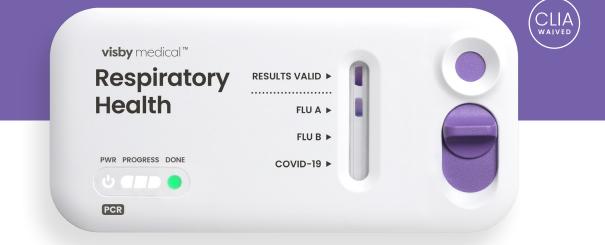
We're Implementing a New Test for COVID-19, Flu A, and Flu B

As simple as lateral flow, but with PCR performance



We have selected the Visby Medical Respiratory Health Test for rapid PCR testing at the point of care.

CDC recommends molecular tests such as PCR over rapid antigen tests for their higher sensitivity.¹²

The Visby Medical Respiratory Health Test is the world's easiest PCR test, with minimal workflow disruption.

- Similar procedure to antigen lateral flow
- True RT-PCR sensitivity/specificity
- Serial repeat testing not required on negatives
- ✓ Results in 30 minutes at the point of care
- ✓ 1 swab sample, 3 results: Flu A, Flu B, COVID-19
- Allows fast decisions while antivirals are most effective^{3,4}
- ✓ FDA Cleared & CLIA Waived



The World's Easiest PCR Test



1. Collect Sample

2. Mix Sample

- No change to workflow
- No complicated cartridge assembly
- No special sample prep/extraction



3. Load Sample



- 4. Flip the Switch
- 🖌 No separate reader or instrument
- 🗸 No maintenance
- 🗸 No complicated training

Users should read the complete test procedure before performing the test. Please refer to the quick reference guide and instructions for use for more information.

Specifications

- Time to Result: ~30 Minutes
- Sample type: Nasopharyngeal or anterior nasal swab (patient or provider collected)
- Positive Percent Agreement (PPA) Flu A 96.9%, Flu B 100.0%, Covid-19 97.2%
- Negative Percent Agreement (NPA) Flu A 99.4%, Flu B 99.8%, Covid-19 99.0%

- Storage: 36°F-86°F (2°C-30°C)
- Swab Stability in Visby buffer: Up to 120 minutes (2 hours) at room temperature 59°F-86°F (15°C-30°C) Up to 48 hours at refrigerated temperature 36°F-46°F (2°C-8°C)
- FDA Cleared & CLIA Waived

References

1. CDC Overview of Testing for SARS-CoV-2 Aug 2024. https://www.cdc.gov/covid/hcp/clinical-care/overview-testing-sars-cov-2.html

- 2. Revisions Related to Serial (Repeat) Testing for the EUAs of Antigen IVDs. Nov 2022. https://www.fda.gov/media/162799/download?attachment
- 3. Paxlovid Prescribing Information 11/2024. https://labeling.pfizer.com/ShowLabeling.aspx?id=19599
- 4. CDC Treating Flu with Antiviral Drugs. Sept 11, 2024. https://www.cdc.gov/flu/treatment/antiviral-drugs.html

Visit <u>www.visby.com/start</u> to begin your journey with Visby.

You'll get helpful instructions to prepare to go live, tools to train staff, and links to download important documents.

Scan to access on-demand training resources



Need further help?

Training & Implementation Support: visby.training@visby.com

Customer Support

Hours: Mon-Fri 8:00 am - 4:00 pm PST | Email: <u>support@visby.com</u> | Phone: 1-833-GoVisby (1-833-468-4729)

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