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Report Summary

POCT-for-Scot Evaluation of the Point-of-Care CE-IVD Dragonfly[™] Respiratory Test Panel for the Rapid Detection of SARS-CoV-2, Flu A, Flu B, RSV, and HRV

POCT-for-Scot Ltd. works with NHS colleagues across Scotland and further afield to build a network and to help create a robust future for point-of-care testing. POCT-for-Scot completed a service evaluation of the Dragonfly Respiratory Test Panel to determine the feasibility of the device for a point-of-care setting, with a focus on accuracy, portability, storage/handling, patient comfort, and ease of adoption.

The Dragonfly Respiratory Test Panel and Point-of-Care Evaluation

The Dragonfly Respiratory Test Panel is a sample-to-result in vitro diagnostic test which employs RT-LAMP technology and colorimetric detection to swiftly deliver accurate results from five pathogens in under 30 minutes. This test is intended for the qualitative extraction and detection of five viral pathogens: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Influenza A Virus (IAV), Influenza B Virus (IBV), Respiratory Syncytial Virus (RSV), and Human Rhinovirus (HRV) from nasopharyngeal, nasal, and throat samples.



Figure 1. The Dragonfly platform includes the tablet based Application, Sample Preparation Kit, Test Panel, and portable Heat Block.

Key findings

- 100% specificity and 98.4% sensitivity with 135 samples vs. RT-PCR
- Enhanced portability
- User-friendly
- Comfortable for the patient
- Easy to adopt in point-of-care settings

Results of the Evaluation

Viral Targets	Sensitivity PPA	Specificity NPA
SARS-CoV-2	96%	100%
Flu A	100%	100%
Flu B	100%	100%
RSV	100%	100%
HRV	90%	100%
Overall	98.4%	100%

Figure 2. The Dragonfly Respiratory Test Panel demonstrated an impressive 100% specificity and 98.4% sensitivity when compared to 135 sample with RT-PCR results.

Enhanced Portability

The Dragonfly Respiratory Test Panel boasts a compact design with its streamlined components, including a sample preparation kit, test panel, heater, power cables, and an optional tablet, occupying minimal space, such as a small table.

This portability enables the device to be used easily in outpatient areas, community centres, general practices, and even on-the-go scenarios. Its compact form even allows it to be conveniently carried in a backpack, empowering clinics, care homes, community nurses, and ambulances with the ability to swiftly detect and manage respiratory infections.



Figure 3. Dragonfly can easily be transported in a backpack to remote locations for on-demand testing.



Figure 4. The tablet app user interface provides two user-friendly modes, one with step-by-step instructions for new users, and a second more streamlined interface for experienced users.

Simple and Efficient Sample Preparation

One of the hallmarks of the Dragonfly Respiratory Test Panel is its user-friendly sample preparation procedure. Taking only 3.5 minutes, this pre-analytical step harnesses silica-coated magnetic beads and proprietary SmartLid technology, which is power-free and requires minimal pipetting.

The result is a streamlined process that ensures the isolation of viral nucleic acids with highly accurate results. The procedure's simplicity, combined with the app's guidance, allows professionals to execute the sample preparation with ease.

User-Friendly Interface and Traceability

The Dragonfly Respiratory Test Panel is accompanied by an application that guides users through stepby-step instructions. It also facilitates full recordkeeping, including unique bar code tracking, result documentation, and custom note recording.

Designed for users of varying learning styles, the application uses visual and written instructions to make it accessible to a diverse user base. This level of traceability paves the way for inclusion within the ISO 15189:2022 UKAS accredited point-of-care service, further underscoring its commitment to accuracy and quality.



Figure 5. With only 3.5 minutes of hands on time, Dragonfly is easy to use in a variety of locations.

Storage and Handling

The consumables are also designed for versatility and a wide temperature range for the storage. Both the sample preparation kit and Respiratory Test Panel can be stored and shipped at ambient temperatures ranging from 2°C to 25°C and -20°C to 25°C respectively. This adaptability accommodates diverse point-of-care settings, where intermittent or seasonal use is common. The consumables' compact footprint with single-use packaging further simplifies storage and handling.



Figure 6. The Sample Preparation Kit and Respiratory Test Panel may be shipped and stored at ambient temperature, simplifying storage and providing flexibility-of-use in point-of-care settings.

Enhancing Patient Comfort

One key challenge in diagnostic testing is patient comfort. The Dragonfly Respiratory Test Panel addresses this concern by being able to test for multiple respiratory pathogens, reducing the need for repetitive swabbing. Patients benefit from a less invasive and more comfortable testing experience, which can lead to increased test acceptance rates.

Ease of Adoption of Dragonfly

Easily adoptable in point-of-care settings, Dragonfly's portability, three types of in-built quality controls, user-friendliness, and compact design make it a seamless choice. It can also be effortlessly integrated with Electronic Patient Records and export results as CSV files, aligning smoothly with POCT guidelines.

Conclusion

The Dragonfly Respiratory Test Panel, evaluated and endorsed by POCT-for-Scot, represents a shift in point-of-care diagnostics. Its exemplary 100% specificity eliminates the spectre of false positives, reinforcing confidence in diagnostic accuracy.

With rapid, accurate results, and user-friendly features, this testing device is poised to redefine respiratory pathogen detection in diverse healthcare settings.



Scan to view the full report, or visit: <u>https://www.poct-for-scot.com/</u> <u>protondx-dragonfly-evaluation</u>

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