Panther Fusion® SARS-CoV-2/Flu A/B/RSV and New Flu A Subtyping Assay

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Abstract

This work describes the verification of Hologic's FDA-cleared Panther Fusion® SARS-CoV-2/Flu A/B/RSV multiplex assay and validation of a laboratory-developed Influenza A subtyping PCR assay on the Panther Fusion® System, which differentiates H1pdm09 (pdmA and pdmH1 targets), H3, H5a, and potential novel variants. The Flu A subtyping test uses the same primer and probe sequences as the current Centers for Disease Control and Prevention (CDC) real-time PCR method traditionally performed on the Applied Biosystems 7500 Fast platform.

Why SHL Switched to the Panther Fusion ®

Continuous Loading & Time to First Result
2.4 hrs[1] VS. 4 hrs

High Throughput Testing
Minimal Hands-on time

Fully Automated Sample to Results
No more 96-well plate bingo

Bi-directional Interfacing with LIMS
No manual transcription errors

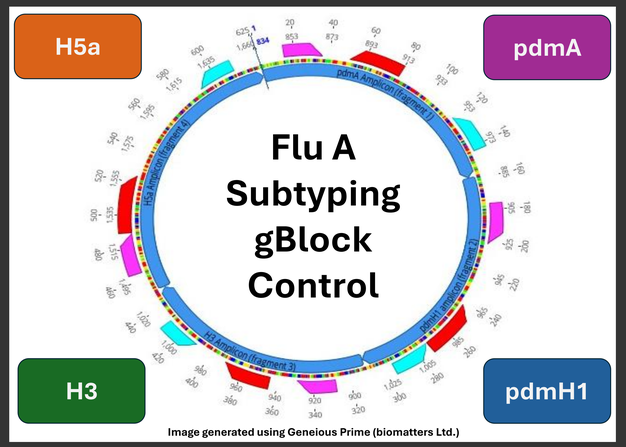


Image generated using Geneious Prime (biomatters Ltd.)

Assay Performance Metrics

	H3	pdmA	pdmH1	H5a
Accuracy	100%	98.4%	96.9%	100%
Precision	100%	96.5%	99%	100%
LOD	4.5 copies/uL	15 copies/uL	4.5 copies/uL	15 copies/uL
PCR Efficiency	101.2%	101.9%	96.5%	93.4%

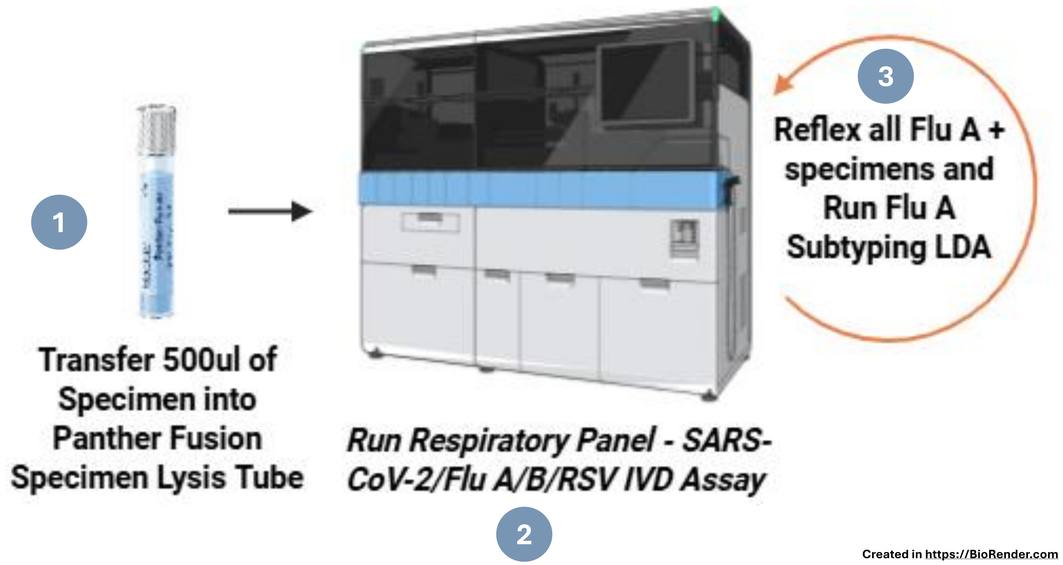
HOLOGIC The Science of Sure

IOWA State Hygienic Laboratory

APHL

New Influenza A Subtyping Assay

High-Throughput, Fully Automated & Bi-Directional Interfacing with LIMS



Created in https://BioRender.com

Scan QR code for further detail related to my study and for additional information (including full abstract, locked protocol, Validation Plan, and SOP contact information and more)

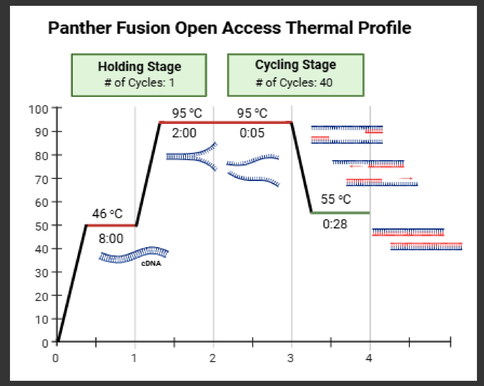
Conclusions

- Strengthen respiratory surveillance capacity
- Enhance emergency preparedness
- Support timely public health response with limited staff.

PPM Components	Stock Concentration	Units	Final Concentration
Nuclease-Free Water			
MgCl-2	1000	mM	2
KCl	1000	mM	50
Tris	1000	mM	10
FWD Primer	40	uM	0.8
REV Primer	40	uM	0.8
Probe	10	uM	0.2
IC-X Primers	37.5	uM	0.6
IC-X Probe	25	uM	0.6

Used the CDCs Flu A Subtyping Primers and Probes (pdmA, pdmH1, H3, H5a) sequences

Use Panther Fusion® Specimen Lysis Tubes– need 500uL of specimen.
Note: each tube can be run twice without additional set up



Sample Tube	Panther Fusion Specimen Lysis Tube with Pierceable Cap
Extraction Volume	360uL
Elution Buffer Volume	50uL
Template Volume	5uL
Reagent Kit	FCR-S/FER-S
Template	RNA or DNA

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References

1. Hologic, Inc.. (2020). *Panther Fusion® information sheet (EUR EN).*
2. Biomatters Ltd. (n.d.). *Geneious Prime* (Version 2026.0.2) [Computer software]. https://www.geneious.com
3. BioRender. (n.d.). *Created with BioRender.com*. https://biorender.com/
4. CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (CDC Flu rRT-PCR Dx Panel) Influenza A Subtyping Kit (Ver 4); Instructions for Use; Package Insert.