LABORATORY DIAGNOSTICS: Molecular Diagnostics
FTD IVD Respiratory Assays - Influenza

Siemens Healthcare Diagnostics Inc.

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Dear Valued Customer,

A recent publication from Jørgensen *et al*.[1] in the *Journal of pathology, microbiology, and immunology (the APMIS)*, has shown specific mutations in the matrix gene of newly circulating influenza A H3N2 strain caused a genetic drift in the matrix gene which could lead to suboptimal performance of PCR-based assays.

Siemens Healthineers assessed by *in silico* analysis the performance of the influenza A assay included in the FTD SARS-CoV-2/FluA/FluB/HRSV Assay*, FTD Respiratory pathogens 21 Assay*, and FTD FLU/HRSV Assay* to detect this new H3N2 strain exhibiting those genetic drifts.[2]
The following sequences, described in Jørgensen *et al*., were aligned with the FTD influenza A primers and probes:

- A/Denmark/87/2022 - EPI_ISL_10803052
- A/Denmark/88/2022 - EPI_ISL_10803082
- A/Denmark/89/2022 - EPI_ISL_10802906
- A/Denmark/90/2022 - EPI_ISL_10803038
- A/Denmark/92/2022 - EPI_ISL_10803071
- A/Denmark/97/2022 - EPI_ISL_10803256
- A/Denmark/100/2022 - EPI_ISL_10803069

The *in silico* analysis showed that the genetic drifts mentioned in Jørgensen *et al.* are located outside of FTD assay's targeted region. No mismatch was observed between the mutated strain sequences and the assay primer and probe sequences, indicating that the performance of FTD tests (Table 1) for the detection of the above influenza A H3N2 strains will **not** be affected by those genetic drifts.

Table 1. Product information:

Product Description	**Siemens Material Number (SMN)**
FTD SARS-CoV-2/FluA/FluB/HRSV Assay (CE marked IVD; 48 reactions)*	10731383
FTD Respiratory pathogens 21 Assay (CE marked IVD; 32 reactions)*	10921702
FTD Respiratory pathogens 21 Assay (CE marked IVD; 64 reactions)*	10921703
FTD FLU/HRSV Assay (CE marked IVD; 32 reactions)*	10921784
FTD FLU/HRSV Assay (CE marked IVD; 64 reactions)*	10921785

*CE marked IVD for diagnostic use in the EU.

Should you have any questions or need any further information, please contact your Siemens Healthineers Customer Care Center or local Siemens Healthineers support representative. We appreciate your business and thank you for choosing Siemens Healthineers as your partner.

Sincerely yours,

Corey Bouwman
Global Franchise Head Molecular Diagnostics
Siemens Healthineers, Molecular Diagnostics

References:

1) Emergence of circulating influenza A H3N2 viruses with genetic drift in the matrix gene: be alert of false-negative test results. Rikke Lind Jørgensen, Christian Johann Lerche, Martin Schou Pedersen, Nikolai Soren Kirkby, Amanda Bolt Botnen, Ramona Trebbien, Stephen Nilsson-Møller, Mette Pinholt, Alex Christian Yde Nielsen, Henrik Westh, Jan Gorm Lisby, Uffe Vest Schneider.
APMIS 130: 612–617 2022 - DOI 10.1111/apm.13262.

2) Data on file at Fast Track Diagnostics Luxembourg S.à r.l., a Siemens Healthineers Company. Data is current as of date 30th November 2022.