Summary, iaX-2101

A system for optical reading of lateral flow assays

Manufacturer	Assaya Ltd.
Supplier in Denmark	No suppliers
Supplier in Sweden	No suppliers
Supplier in Norway	NordicDx AS
Launched in Scandinavia	2022

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Aim

To assess the performance of iaX-2101, by comparing optical reading and visual interpretation of the ABCR Ag Test when performed by biomedical laboratory scientists (BLSs) at a clinical microbiology laboratory, and to assess the user-friendliness of iaX-2101 when used by the intended users, represented by BLSs at a clinical microbiology laboratory and health care professionals at two primary health care centres.

Recommended performance specifications	Results	Conclusions
Overall agreement SKUPs performance specification ≥90 % agreement in relation to visual interpretation or, for results with disagreement between iaX-2101 and visual interpretation, agreement to PCR-results.	Overall agreement: 96 % (90 % CI: 93-98 %)	Fulfilled
User-friendliness A total rating of "Satisfactory"	The user-friendliness was rated unsatisfactory. Vital steps of the handling procedure and sources of errors were rated unsatisfactory.	Not fulfilled

Additional information

Samples	210 samples, nasopharyngeal, oropharyngeal or nasal specimen were included in the evaluation. 136 samples were negative, and 73 samples were positive on the ABCR Antigen Test.
Evaluated method	iaX-2101, a system for optical reading of lateral flow assays, using the ABCR Antigen Test for Flu, COVID-19 and RSV.
Comparison method	Visual interpretation of the ABCR Antigen Test for Flu, COVID-19 and RSV by three BLSs. Samples with discrepancy between optical reading on iaX-2101 and visual interpretation were compared to a real time polymerase chain reaction (RT-PCR) method.
Agreement stratified on positive and negative samples	Positive percent agreement: 89 %: (90 % CI: 81-94 %) Negative percent agreement: 100 %: (90 % CI: 99-100 %)
Comments to the rating of user-friendliness	The user-friendliness was rated unsatisfactory due to the risk of result mix-ups since barcode-based registration of patient ID could not be entered, potential contamination when handling test strips, and the lack of an instrument warning for incorrect test insertion. Notably, the evaluation was conducted without a barcode reader for patient ID.
Technical errors	0,48 %. The SKUP recommendation of ≤2 % was achieved.

A letter with comments from NordicDx AS is attached to the report.

Further information about the evaluation and the organisation of SKUP can be found on www.skup.org.
This summary is also published in Danish, Norwegian and Swedish at www.skup.org.