iaX-2101

A system for optical reading of lateral flow assays manufactured by Assaya Ltd.

Report from the evaluation

SKUP/2025/138

organised by SKUP at the request of NordicDx

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1. 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

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.

2. Abbreviations and Acronyms

Ag	Antigen
AUH	Aarhus University Hospital
BLS	Biomedical laboratory scientist
C-NPU	Committee on nomenclature, properties and units
Ct	Cycle threshold
DANAK	Danish Accreditation Fund
DEKS	Danish Institute of External Quality Assurance for Laboratories in the Health Sector
EQA	External quality assessment
Equalis	External quality assessment in laboratory medicine in Sweden
IFU	Instructions for use
LFA	Lateral flow assay
Noklus	Norwegian organization for quality improvement of laboratory examinations
NPA	Negative percent agreement
PHCC	Primary health care centre
POC	Point of care
PPA	Positive percent agreement
QCMD	Quality Control for Molecular Diagnostics
RDT	Rapid Diagnostic Test
RNA	Ribonucleic acid
RSV	Respiratory syncytial virus
RT-PCR	Real-time polymerase chain reaction
SARS-CoV-2	Severe acute respiratory syndrome corona virus 2
SKUP	Scandinavian evaluation of laboratory equipment for point of care testing
SWAC	Sterile wood abrasive collector
VTM	Viral transport medium

3. Introduction

The purpose of Scandinavian evaluation of laboratory equipment for point of care testing (SKUP) is to improve the quality of near patient testing in Scandinavia by providing objective information about analytical performance and user-friendliness of laboratory equipment. This information is generated by organising SKUP evaluations in point of care (POC) settings.

3.1. The concept of SKUP evaluations

SKUP evaluations follow common guidelines and the results from various evaluations are comparable[1]. The evaluation set-up and details are described in an evaluation protocol and agreed upon in advance. The analytical results and user-friendliness are assessed according to pre-set performance specifications. To fully demonstrate the performance of a product, the intended users should be involved in the evaluation. If possible, SKUP evaluations are carried out using three lot numbers of test kits from separate and time-spread productions. Some evaluation codes are followed by an asterisk (*), indicating an evaluation with a more specific objective. The asterisk is explained on the front page of these protocols and reports.

3.2. Background for the evaluation

The iaX-2101 is a system for optical reading of lateral flow assays (LFAs), such as immunochromatographic and immunofluorescence assays. The system is produced by Assaya Ltd. and is supplied by NordicDx AS. The system is intended for health care professionals, both in clinical laboratories and POC settings, as well as trained operators. For this evaluation, the iaX-2101 was evaluated using the ABCR Antigen Test for Flu, COVID-19 and RSV for qualitative detection of Influenza A and B, severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) and respiratory syncytial virus (RSV) antigens (Ags) in nasal specimens. The system was launched into the Scandinavian market in 2022. The SKUP evaluation was carried out during the winter of 2024 at the request of NordicDx in Norway.

3.3. The aim of the evaluation

The aim of the evaluation was to assess the performance of iaX-2101, by comparing optical reading with iaX-2101 to visual interpretation of the ABCR Ag Test, and to assess the user-friendliness of iaX-2101. The intended users for this evaluation were health care professionals both in hospital laboratories and in primary health care centres (PHCCs).

3.4. The model for the evaluation of iaX-2101

This evaluation was carried out by BLSs in a hospital laboratory to assess the performance and the user-friendliness of iaX-2101. The health care professionals at two PHCCs assessed only the user-friendliness of iaX-2101. The evaluation of iaX-2101 included the assessment of agreement between optical reading and visual interpretation of the ABCR Ag Test for the detection of Influenza A/B, SARS-CoV-2 and RSV. The combination of this LFA and the optical reading with the iaX-2101 will hereafter be called the iaX-2101/ABCR system (figure 1).

[1]SKUP evaluations are under continuous development. In some cases, it may be difficult to compare earlier protocols, results and reports with more recent ones.

The evaluation included:

- Examination of the agreement between iaX-2101 optical reading and visual interpretation of the ABCR Ag Test by three biomedical laboratory scientists (BLSs) in a clinical microbiology laboratory. The visual interpretation of the results of the ABCR Ag Test were independently interpreted without being influenced by the iaX-2101 optical reading or other personnel interpretations. In case of discrepancy between optical readings and visual interpretations, agreement between the iaX-2101/ABCR system and real-time polymerase chain reaction (RT-PCR) was assessed.
- Evaluation of the user-friendliness of the iaX-2101 system and its instruction for use (IFU) and quick guide by the intended users.

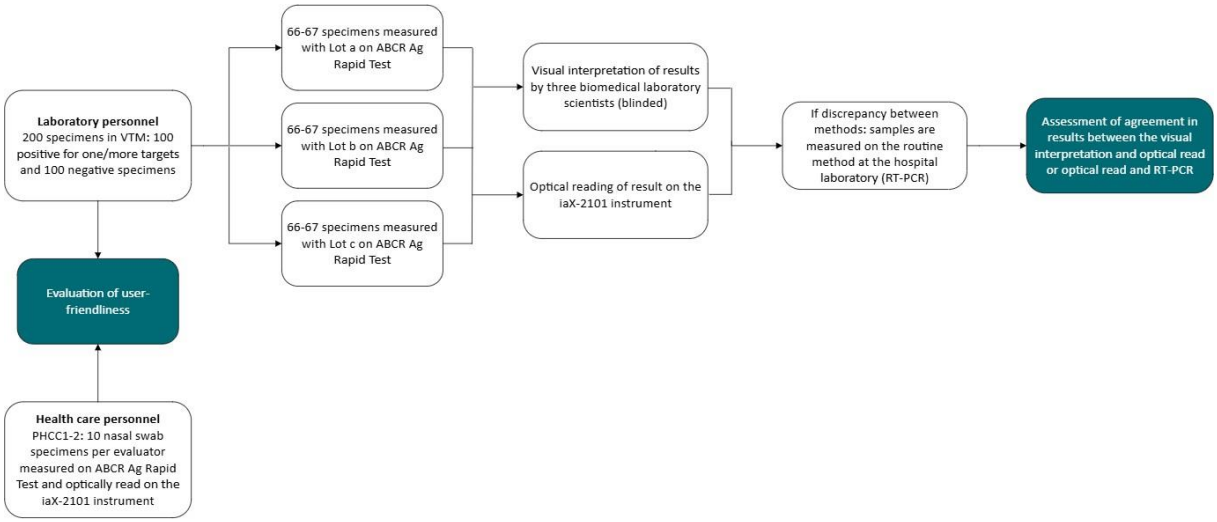

Figure 1. Flowchart illustrating the model for the evaluation of iaX-2101/ABCR system in fresh/frozen nasopharyngeal, oropharyngeal or nasal specimens in viral transport medium (VTM) in the clinical microbiology laboratory, as well as nasal swab specimens collected from the patients' nostrils in PHCCs.

4. Performance specifications

4.1. Analytical performance specifications

There are currently no specific recommendations for performance specifications of LFA reader-based systems. However, evaluations suggest that these reader systems should meet or exceed the performance specifications of the LFAs they interpret. This is based on the assumption that reader systems can provide more consistent and accurate interpretations, especially for results near the visible threshold, compared to visual inspection. For instance, the mobile-based reader system RDTScan achieved a 97,5 % and 96,3 % agreement with visual interpretation when interpreting positive and negative results of LFAs for detecting Influenza A/B and Malaria, respectively [1]. Another study using a different reader for detection of Malaria reported a 98,9 % agreement with visual interpretation, demonstrating better sensitivity than the traditional method [2]. Other reader-based systems for LFAs detecting Influenza A and B, demonstrated better performance compared to LFAs that were not interpreted by a reader in the same study [3].

The ABCR Ag Test to be used in this evaluation has previously demonstrated, in comparison to RT-PCR, 100 % sensitivity and 100 % specificity for Influenza A, 80 % sensitivity and 100 % specificity for Influenza B, 97 % sensitivity and 100 % specificity for SARS-CoV-2, and 80 % sensitivity and 100 % specificity for RSV on specimens with high viral loads (cycle threshold (ct)-values <30) by visual interpretation [4].

Based on the criteria above and to reflect the clinical usefulness of the iaX-2101 system, SKUP has chosen to use a performance specification of ≥90 % agreement for this evaluation. In case of discrepancy between optical reading and visual interpretation of the ABCR Ag Test, agreement between the iaX-2101/ABCR system and RT-PCR was assessed.

4.2. User-friendliness

The evaluation of user-friendliness was carried out by asking the evaluating persons in the hospital laboratory and the PHCCs to fill in a questionnaire, see section 6.4.

Technical errors
SKUP recommends that the fraction of tests wasted due to technical errors should not exceed 2 %.

4.3. SKUP's performance specifications in this evaluation

As agreed upon when the protocol was drawn up, the results from the evaluation of iaX-2101 are assessed against the following performance specifications:

SKUP recommendations:
Agreement with visual interpretation / RT-PCR ..... ≥90 %

Technical errors… ..... ≤2 %

User-friendliness, overall rating… ..... Satisfactory

4.4. Principles for the assessments

4.4.1. Assessment of the analytical performance

The analytical results were assessed according to pre-set performance specifications for the evaluation.

Agreement between methods

The results were presented as agreement in total number of positive and negative results between the optical read on the iaX-2101/ABCR system and visual interpretation of ABCR Ag Test. Three BLSs performed the visual interpretations of the test independently, without knowledge of each other's interpretations and without being influenced by the result from the iaX-2101. The visual assessment is subjective, and the test may be interpretated differently by different BLSs. One of the BLS performed the optical reading on iaX-2101. If there were discrepancy between the methods or a disagreement among the BLSs visual interpretation regarding the test results on the ABCR Ag Test, the results from the iaX-2101/ABCR system were compared to a real time polymerase chain reaction (RT-PCR) method at the clinical laboratory, described in section 5.3.

Accordance between lot numbers

Separate lot-to-lot calculations were not performed. Three lots of test kits were used for the purpose of having an evaluation less sensitive to the risk of a poor batch. If distinct differences between the lots appeared, this was pointed out and discussed.

4.4.2. Assessment of the user-friendliness

The user-friendliness was assessed according to the answers and comments given in the questionnaire (see section 6.4). For each question, the evaluator could choose between three given ratings; satisfactory, intermediate and unsatisfactory, or the evaluator could mark the choice no opinion/not read. The responses from the evaluators were reviewed and summed up. To achieve the overall rating "satisfactory", the tested equipment had to reach a total rating of "satisfactory" in all three subareas of characteristics described in section 6.4.

Technical errors

The evaluating persons register failed measurements on the test and failed readings and technical errors on the instrument during the evaluation. A technical error is defined as an error not caused by external factors and user errors such as during specimen application or handling of the test and before the test is inserted into the instrument. The fraction of tests wasted due to technical errors concerning the iaX-2101 reader was taken into account in connection with the assessment of the user-friendliness.

5. Materials and methods

5.1. Definition of the measurand

For the ABCR Ag Test, which is optically read on the iaX-2101 system and visually interpretated, the sample materials in this evaluation were nasopharyngeal, oropharyngeal and nasal specimens. For the RT-PCR method at the clinical microbiology laboratory the ribonucleic acids (RNA) from Influenza A and B, SARS-CoV-2 and RSV were identified in nasopharyngeal, oropharyngeal or nasal specimens. The results were expressed on an ordinal scale (positive or negative) for both methods. The Committee on Nomenclature, Properties and Units (C-NPU) systematically describes clinical laboratory measurands in a database [5]. The NPU codes related to the ABCR Ag Test are NPU12049, NPU12050, NPU59310 and NPU12048 for the measurands given above, respectively. The NPU codes related to the comparison method are NPU27654, NPU27655, NPU59106 and NPU28217. In this report, the terms Influenza A/B, SARS-CoV-2 and RSV will be used for the measurands.

5.2. The evaluated system iaX-2101

The information in this section derives from the company's information material.

iaX-2101 is a POC instrument for optical reading of LFAs, including immunochromatographic and immunofluorescence membrane assays. The system is intended for professional use. The system supports tests from various manufactures. To date, more than 130 different LFAs are approved to be optically read on the iaX-2101 system [6].

Figure 2. iaX-2101 system

Once the rapid test is ready for interpretation, the test is fully inserted into the instrument and read automatically within seconds, where the exact time depending on the complexity of the assay. The system identifies the test type by reading the barcode or QR code on the test. Results are shown on the instrument using simplified LED indicators: green for negative, yellow for invalid, and red for positive.

Test results and patient data are not stored on the instrument. Instead, they are automatically uploaded to a secure cloud database that can be accessed through a portal by authorised personnel. The instrument requires an internet connection to communicate with the cloud database. Test results in the portal can be shown quantitatively, qualitatively, or semi-quantitatively, depending on the type of test used.

The instrument performs self-checks to validate system components during every powerup. The system is factory calibrated; no further calibration is needed. A functional test cassette is included with the instrument. To ensure the instrument is working properly, the functional test cassette should be inserted at least once every three months or after 10 000 tests.

5.2.1. The measuring system optically read on iaX-2101

The ABCR Ag Test kit that is used with the iaX-2101 system in this evaluation includes:

- 1 Sterile wood abrasive collector (SWAC)
- 1 Extraction buffer vial
- 1 Test strip

The ABCR Ag Test is an immunochromatographic membrane assay intended for professional use for qualitative detection of antigens from Influenza type A and type B viruses, SARS-CoV-2, and RSV in nasal secretion.

Two internal procedural controls are required to confirm correct assay procedure and the activity of the kit components. The first control serves as a procedural control, indicating that the proper volume of specimen has been added, and membrane wicking has occurred. It appears as a coloured line in the control line region of the test strip. The second control serves as a negative control, appearing as a clear white background. If no coloured line appears in the control line region, or if the background colour is not clear white, the test is considered invalid, regardless of whether a coloured line is present in the test line region.

For more information about the iaX-2101 system, and name of the manufacturer and the suppliers in the Scandinavian countries, see attachment 1 and 2. For product specifications in this evaluation, see attachment 3.

5.3. The selected comparison method

In general, a selected comparison method is a fully specified method which, in the absence of a reference method, serves as a common basis for the comparison of the evaluated method.

5.3.1. The selected comparison method in this evaluation

Results from the iaX-2101/ABCR system were compared with visual interpretation of the ABCR Ag Tests. Visual interpretation of the ABCR Ag Test was performed by three BLSs, independently of each other and of the optical reading on iaX-2101. Visual reading of the test was performed as described in the IFU regarding interpretation of positive, negative and invalid test results. If there was a discrepancy between the results of the iaX-2101/ABCR system and the visual interpretation of ABCR Ag Test, the correct results was determined as the measurement result on the routine RT-PCR method for Influenza A/B, SARS-CoV-2 and RSV at the Department of Clinical Microbiology, Aarhus University Hospital (AUH), Denmark, hereafter called “the RT-PCR method”. The clinical microbiology laboratory is accredited according to ISO 15189 (2022) by the Danish Accreditation Fund (DANAK). The division performing the RT-PCR measurements has approximately 19 employees.

Instruments:	Roche Cobas 6800 (Roche)
Reagent:	LDT (laboratory developed test) PCR. Mastermix: Flow + internal control cobas SARS-CoV-2 Qualitative Test
Principle:	RT-PCR detection of the specific gene regions of the Influenza A (H1N1, H3N2, including other subtypes of avian origin), Influenza B and RSV. For SARS-CoV-2, the detection of the E-gene of the Sarbeco Betacorona virus, including SARS-CoV-2

Internal analytical quality control

Kit-independent positive (DNA/RNA virus isolates) and negative (transport medium) controls are included in the extraction step. In addition, an internal control (bacteriophage with RNA) is added to each sample.

External analytical quality control
The clinical microbiology laboratory participates in the Quality Control for Molecular Diagnostics (QCMD, United Kingdom) external quality assessment (EQA) schemes for Influenza A/B, SARS-CoV-2 and RSV with 10 samples each and one or two challenges per year. Additionally, the clinical microbiology laboratory participates in an EQA scheme from Labquality EQAS by Aurevia for Influenza A/B, SARS-CoV-2 and RSV with 3 samples each and four challenges per year.

5.3.2. Verification of the analytical performance of the comparison method

Trueness
The trueness of the RT-PCR method for detection of Influenza A/B, SARS-CoV-2 and RSV was verified with EQA results for a period circumventing the evaluation period.

5.4. The evaluation

5.4.1. Planning of the evaluation

Inquiry about an evaluation
NordicDx via Tommy Selnes, CEO at NordicDx AS, applied to SKUP in November 2023 for an evaluation of iaX-2101.

Protocol, arrangements and contract
In November 2024, the protocol for the evaluation was approved, and NordicDx and SKUP signed a contract for the evaluation. BLSs at Department of Clinical Microbiology, AUH, agreed to participate in the evaluation and were assigned to do the practical work with iaX-2101 at the clinical microbiology laboratory as well as to perform the RT-PCR method. Two PHCCs, Lægerne Preislers Plads and Lægerne Helga Gøtke og Henrik Wibrand from the Central Denmark Region, agreed to participate in the evaluation of the user-friendliness of iaX-2101.

Training
NordicDx AS in Norway was responsible for the necessary training in use of iaX-2101 and ABCR Ag Test in the evaluation. The training in the clinical microbiology laboratory and PHCCs was given in Norwegian or English. The training procedure reflected the training usually given to the end-users. NordicDx AS and Assaya Ltd. were not allowed to contact or supervise the evaluating personnel at the evaluation sites directly.

5.4.2. Evaluation sites and persons involved

The practical work was carried out over eight weeks at the clinical microbiology laboratory and four weeks in the PHCCs, ending in January 2025. The clinical microbiology laboratory is located in the Central Denmark Region and has approximately 21 employees. The RT-PCR method was performed by BLSs according to the local procedures at the clinical microbiology laboratory. At the clinical microbiology laboratory five BLSs were involved in the practical work with the evaluation of iaX-2101.

PHCC1 is a large medical clinic located in Viborg with four physicians and nine healthcare workers. From PHCC1 one physician and one nurse participated in the evaluation. PHCC2 is a small medical clinic with two physicians and two nurses. From PHCC2 one physician and one nurse participated in the evaluation.

5.4.3. The evaluation procedure at the clinical microbiology laboratory

Internal analytical quality control

Internal analytical quality control for iaX-2101 (functional test cassette, Assaya Ltd.), was measured weekly on iaX-2101. Internal analytical quality control sample for the ABCR Ag Test (positive control, Sino Biological) was measured upon opening a new kit box. In addition, internal procedural controls on the test strip were checked during measurement.

Collection of samples and ethical considerations

Left-over fresh and frozen samples from over 200 patients were included in the evaluation. No patient recruitment was necessary, as the specimens were selected from already measured samples from the RT-PCR method. The evaluation was planned to include at least 100 samples positive for one or more of the targets that the ABCR Ag Test can detect and at least 100 samples negative for all four targets when measured on RT-PCR. The selected samples in the evaluation were swab specimens in tubes containing Amies medium (eSwab®, Copan) or tubes with nasal secretion diluted in isotonic sodium chloride solution. The results were reported deidentified to SKUP. An ethical approval was not necessary because the evaluation is considered a quality assurance project.

Handling of the samples and measurements

The ABCR Ag Test kit was kept at room temperature (15 – 30°C) prior to testing. The selected samples were blinded prior to measurement with the ABCR Ag Test, and the measurements were performed as soon as possible. The selected fresh samples were either positive for one or more of the targets or negative for them all. They were stored at room temperature and measured on the same day, if possible. If not, they were refrigerated (4 – 5°C) for up to 48 hours and measured with the ABCR Ag Test after reaching room temperature. Frozen samples stored by the clinical microbiology laboratory at -80°C, that were positive for one or more targets detected by the ABCR Ag Test, were included to get enough positive results. These were thawed and thoroughly mixed before measurement. Note that the ABCR Ag Test is not validated for use with frozen samples, but it had been settled with NordicDx that frozen samples could be used in the evaluation.

Before the evaluation, adjustments in the sample preparation and testing procedure were made in collaboration with NordicDx to accommodate the testing of specimens in Amies medium; the samples were prepared for measurement by mixing 200 µL of the specimen with 200 µL of the extraction buffer into a sterile tube. The tube was mixed briefly and allowed to stand for one minute before the test strip was inserted into the sterile tube containing the extracted specimen. After 12 minutes, the results on the test strip were visually interpreted individually by three BLSs and then inserted into iaX-2101.

If the time between inserting the test strip into the extracted specimen and placing it into the instrument exceeded the 20-minute reading limit, the test was repeated with a new test strip. In case of failed measurements, the test was repeated until a result was obtained, if possible. If the

test strip was valid but a technical error or reading failure occurred after inserting it into iaX-2101, the test strip was reinserted. If the result was still not obtained on iaX-2101, the result was registered as a technical error on the instrument. Three lot numbers of ABCR Ag Test kit were used in the clinical microbiology laboratory, alternating between the lot numbers.

If there was discrepancy between the results of the iaX-2101/ABCR system and the visually interpreted ABCR Ag Test, or if there was a disagreement among the BLSs regarding the test results on the ABCR Ag Test, the specimen was measured on the RT-PCR method. All samples were treated according to the internal procedures of the clinical microbiology laboratory regarding potential interfering substances.

5.4.4. The evaluation procedure in primary health care

Internal analytical quality control

Internal analytical quality control for iaX-2101 (functional test cassette, Assaya Ltd.), was measured on iaX-2101 a few times for assessment of its user-friendliness. Internal analytical quality control sample for the ABCR Ag Test (positive control, Sino Biological) was measured upon opening a new kit box. In addition, internal procedural controls on the test strip were checked during measurement.

Recruitment of participants

At least 10 participants per healthcare worker participating in the evaluation were included in each of the PHCCs. People, 18 years or older, coming into the PHCCs with symptoms of upper airway infection (sore throat, dry cough etc.) was asked and given written information if they were willing to participate in the evaluation of iaX-2101 by donating one extra sample. Participation was voluntary and verbal informed consent was considered sufficient.

The results obtained in the PHCCs were not used for diagnosis, treatment, or in evaluating the performance of iaX-2101. Specimen collection and measurements were used solely to allow the healthcare personnel to evaluate the user-friendliness of the iaX-2101 system. No personal information of the participants was obtained. Privacy protection of the participants was secured.

Handling of the samples and measurements

The ABCR Ag Test kits were kept at room temperature (15-30°C) prior to testing. Nasal swab specimens, collected from participants, were measured on the ABCR Ag Test as soon as possible.

Nasal swab specimens were collected using the SWAC in accordance with the instructions from the manufacturer and transferred to the vial containing extraction buffer. The SWAC was rotated five times in the extraction buffer and allowed to stand for one minute before test strip was inserted into the vial (with the end marked with droplets placed into the buffer). After 10 minutes, but no longer than 20 minutes, the test strip was inserted into the iaX-2101 system. In case of failed measurements, the test was repeated until a result is obtained, if possible. If technical errors or measurement failures occur with the instrument, the test strip will be reinserted. One lot number of ABCR Ag Test kit was used at both PHCCs, as this was considered sufficient for evaluating user-friendliness of iaX-2101.

6. Results and discussion

Statistical expressions and calculations used by SKUP are shown in attachment 4.

6.1. Number of samples

At the clinical microbiology laboratory, a total of 210 samples were selected and measured, of which 209 were included in the evaluation; Of these 73 had a positive result for one or more of the targets and 136 had a negative result for all four targets when visually interpreted on the ABCR Ag Test. One result was not included due to a technical error when measured on the iaX-2101.

An account of the number of samples not included in the calculations is given below.

Missing results
There was one missing result due to technical error.

Omitted results
There were no omitted results.

Recorded error codes, technical errors and failed measurements
There was one failed reading after the ABCR Ag Test was placed several times in the iaX-2101 (result: BLANK!), despite the ABCR Ag Test being valid. The fraction of tests wasted due to technical error was 0,48 % (1 out of 209). The SKUP recommendation of a fraction of ≤2 % tests wasted due to technical errors was achieved.

6.2. Analytical performance of the selected RT-PCR method

6.2.1. Internal analytical quality control

All results from the internal analytical quality controls (negative, positive) were in the accordance with the assigned values (data not shown).

6.2.2. The trueness of the comparison method

The trueness of the RT-PCR method for detection of Influenza A/B, SARS-CoV-2 and RSV was verified with EQA results for the period circumventing the evaluation period (table 1).

Table 1. EQA controls measured on the RT-PCR method.

Time of measurements	EQA scheme	Assigned target	Assigned value (dPCR Log10 Copies/ml)	Results from the RT-PCR method (ct value)
Dec. 2024	QCMD	Negative	Negative	Negative
		Influenza A	Positive strain H3N2	Positive
		Influenza A	Positive strain H1N1	Positive
		Influenza A	Positive strain H3N2	Positive
		Influenza A	Positive	Positive

			strain H1N1	
		Influenza B	Positive strain Victoria	Positive
		Influenza B	Positive strain Yamagata	Positive
		Influenza B	Positive strain Yamagata	Positive
		Influenza B	Positive strain Victoria	Positive
		Influenza A	Positive strain H3N1	Positive
Oct. 2024	QCMD	SARS-CoV-2	Positive (2,54) Lineage BQ1.1	Positive (31,0)
		Negative	Negative	Negative
		SARS-CoV-2	Positive (4,17) Lineage BQ1.1	Positive (30.0)
		SARS-CoV-2	Positive (3,04) Lineage BQ1.1	Positive (32.0)
		SARS-CoV-2	Positive (3,04) Lineage BQ1.1	Positive (31.0)
Dec 2024	QCMD	RS Virus	Positive type A	Positive
		RS Virus	Positive type B	Positive
		RS Virus	Positive type B	Positive
		RS Virus	Positive type A	Positive
		Negative	Negative	Negative
		RS Virus	Positive type A	Positive
		RS Virus	Positive type A	Positive
		RS Virus	Positive type A	Positive
		RS Virus	Positive type B	Positive
		RS Virus	Positive type B	Positive

Discussion

The trueness of the comparison method was confirmed during the evaluation period by the results from the QCMD EQA scheme for Influenza A/B, SARS-CoV-2 and RSV.

6.3. Performance of iaX-2101

The results in this section reflects the performance of iaX-2101 when used by BLSs at a clinical microbiology laboratory.

6.3.1. Internal analytical quality control

The iaX-2101 includes a functional test cassette as an internal quality control. The functional test cassette was measured on iaX-2101 and approved only once before the evaluation and not weekly as intended in the protocol. The internal quality control (positive control) for the ABCR Ag Test was measured three times, once for each lot number. All four targets for the ABCR Ag Test were positive, although RSV was only weakly positive (data not shown).

6.3.2. The agreement between iaX-2101/ABCR system and visual interpretation

The agreement between iaX-2101/ABCR system and visual interpretation of ABCR Ag Test was calculated as described in attachment 4. In case of discrepancy between the methods, the sample was analysed using the RT-PCR method and those results were used instead of the results from the visual interpretation to calculate the agreement.

The total number of samples included in the evaluation, and the number of samples with discrepancy between iaX-2101/ABCR system and visual interpretation of ABCR Ag Test and number of samples with visual interpretation disagreement is shown in table 2. Raw data is attached to the requesting company only (attachment 5, 6, 7).

Table 2. Overview of the number of samples included in the evaluation, including the number of samples with disagreement between methods and samples with visual interpretation disagreement. Total number and stratified on positive and negative result, based on visual interpretation. Results achieved by intended users in a clinical microbiology laboratory.

	Number of samples included	Number of samples with discrepancy between the methods	Number of samples with visual interpretation disagreement
Total	209	7	2
Positive	73	7	2
Negative	136	0	0

Of a total of 209 samples analyzed, there was reported a discrepancy between the iaX-2101/ABCR system and the visual interpretation for 7 of the samples, where all 7 samples were positive for one or more targets. Two of the samples with a positive result showed a disagreement between the evaluators performing visual interpretations. This gives a total of 9 samples that were compared to the RT-PCR method instead of visual interpretations.

Of the 9 samples compared to the RT-PCR method, 8 were not in agreement with the results from the iaX-2101/ABCR system. For one of the samples with discrepancy between iaX-2101 and visual interpretation and one of the samples with disagreement between visual interpretations, the result from the iaX-2101/ABCR system was in agreement with the result from the RT-PCR method.

The overall agreement, positive and negative percent agreement for the iaX-2101/ABCR system and the combination of visual interpretation and analysis on the PCR-method for samples with disagreement between iaX-2101 and visual interpretation is shown in table 3.

Table 3. Agreement between the iaX-2101/ABCR system and the combination of visual interpretation and analysis on the RT-PCR method for samples with disagreement between iaX-2101 and visual interpretation. Results achieved by intended users in a clinical microbiology laboratory. Overall agreement, positive and negative percent agreement.

	Number of samples included, n	Samples with agreement, n	Samples with discrepancy between the methods, n	Agreement, % (90 % CI)
Overall	209	201	8	96 (93-98)
Positive	73	65	8	89 (81-94)
Negative	136	136	0	100 (99-100)

The agreement between the iaX-2101/ABCR system and the combination of visual interpretation and analysis on the RT-PCR method for samples with disagreement between iaX-2101 and visual interpretation stratified on the different targets are shown in table 4.

Table 4. Agreement between the iaX-2101/ABCR system and the combination of visual interpretation and analysis on the RT-PCR method for samples with disagreement between iaX-2101 and visual interpretation stratified on target, based on visual interpretation and RT-PCR result for samples with disagreement. Results achieved by intended users in a clinical microbiology laboratory.

	Number of results	Samples with agreement, n	Samples with discrepancy between the methods, n	Agreement, % (90 % CI)
Influenza A, total	209	206	3	99 (96-100)
Positive	*15*	*13*	*2*	*87 (66-96)*
Negative	*194*	*193*	*1*	*99 (98-100)*
Influenza B, total	209	206	3	99 (96-100)
Positive	*1*	*1*	*0*	*
Negative	*208*	*205*	*3*	*99 (96-100)*
SARS-CoV-2, total	209	206	3	99 (96-100)
Positive	*16*	*15*	*1*	*94 (75-100)*
Negative	*193*	*191*	*2*	*99 (97-100)*
RSV, total	209	207	2	99 (97-100)
Positive	*40*	*40*	*0*	*100 (95-100)*
Negative	*169*	*167*	*2*	*99 (96-100)*

An account of the number of samples is given in section 6.1.
*Agreement not calculated due to low number of samples.

Eighteen samples measured on the iaX-2101/ABCR system were repeated (once or more), after reviewing the result of the test strip in the portal and finding out that the test strips were placed incorrectly. Of these, three were invalid and thus repeated to obtain a valid result, whereas eight gave false results compared to the interpretation or RT-PCR. Only the three samples with invalid result triggered an error message on the iaX-2101, whereas the remaining repeated samples placed incorrectly were identified by the BLS upon reviewing the results in the portal.

In the evaluation, 162 fresh samples and 47 frozen samples were used. Of the fresh samples, four showed a discrepancy between the methods (2,5 %), whereas four of the frozen samples showed a discrepancy between the methods (8,5 %).

Discussion and conclusion
The overall agreement of the iaX-2101 was 96 % with a 90 % CI of 93-98 % when compared to the results from the visual interpretation/RT-PCR method. The agreement was lower for the positive samples (89 % (CI: 81-94 %)) than for the negative samples (100 % (99-100 %)).

The agreement stratified on target showed good agreement for all targets with results >90 % for all, except for samples positive for influenza A (87 % (CI: 66-96 %)).

Conclusion
When used by biomedical laboratory scientists at a clinical microbiology laboratory the APS for overall agreement (≥90 %) was fulfilled.

6.4. Evaluation of user-friendliness

6.4.1. Questionnaire to the evaluators

The most important response regarding user-friendliness comes from the intended users themselves. At the end of the evaluation period, the intended users filled in a questionnaire about the user-friendliness of the system. SKUP has prepared detailed instructions for this. The user-friendliness included rating of the iaX-2101 system, its user manual (IFU) and quick guide. The intended users of iaX-2101 are experienced laboratory personnel as well as health care professionals in primary care. Therefore, the questionnaire was filled in by the evaluators in both the clinical microbiology laboratory and the PHCCs.

The questionnaire is divided into three subareas:

Table A) Rating of ease of operation. Is the system easy to handle?
Table B) Rating of the information in the IFU / quick guide
Table C) Rating of the portal and training time

The intended users filled in table A, B and C. SKUP filled in topics marked with grey colour in table B and C.

In the tables, the first column shows what is up for consideration. The second column in table A and B shows the rating by the users at the evaluation sites. The rest of the columns show the rating options. The overall ratings from all the evaluating sites are marked in coloured and bold text.

The total rating is an overall assessment by SKUP of the described property, and not necessarily the arithmetic mean of the rating in the rows. Consequently, a single poor rating can justify an overall poor rating if this property seriously influences the user-friendliness of the measuring system.

Unsatisfactory and intermediate ratings are marked with a number and explained below the tables. The intermediate category covers neutral ratings, assessed as neither good nor bad.

An assessment of the user-friendliness is subjective, and the topics in the questionnaire may be emphasised differently by different users. The assessment can therefore vary between different persons and between the evaluation sites. This is discussed and taken into account in the overall assessment of the user-friendliness.

Comment
In this evaluation, the user-friendliness was assessed by:
Clinical microbiology laboratory; Five BLSs.
PHCC 1; one physician and one nurse.
PHCC 2; one physician and one nurse.

Table A. Rating of ease of operation

Topic	Rating	Rating	Rating	Rating	Option
To prepare the instrument	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Number of procedure step	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Instrument design	**U[1], I[1,2], U[1]**	Satisfactory	**Intermediate**	**Unsatisfactory**	No opinion
Readability of the test result, time aspect	**S, I[3], I[3]**	**Satisfactory**	**Intermediate**	Unsatisfactory	No opinion
Readability of the test result on the instrument	**I[4], I[4], S**	**Satisfactory**	**Intermediate**	Unsatisfactory	No opinion
Readability of the functional test cassette	**N, S, N**	**Satisfactory**	Intermediate	Unsatisfactory	**No opinion**
Sources of errors	**I[5], I[6], U[5]**	Satisfactory	**Intermediate**	**Unsatisfactory**	No opinion
Cleaning / Maintenance	**S, S, N[7]**	**Satisfactory**	Intermediate	Unsatisfactory	**No opinion**
Hygiene, when using the procedure	**I[7], I[7], U[8]**	Satisfactory	**Intermediate**	**Unsatisfactory**	No opinion
Size and weight of the instrument	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Noise	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Total rating by SKUP				**Unsatisfactory**	

[1] *Inserting the test strip into the instrument is inconvenient, because you need to touch the wet end of the test strip where the sample material is added, which requires frequent glove changes when testing multiple samples.*
[2] *The area where the test strip is inserted into is too wide, which gives a high risk of misplacing the test strip.*
[3] *Inserting the test exactly 10 minutes later is inconvenient, as we often need to leave the current patient to insert the strip, interrupting consultations.*
[4] *There were several instances where the reading on the iaX-2101 had to be repeated due to incorrect placement of the test strip. This required double-checking in the portal which was time-consuming and inconvenient. The device does not indicate which target is positive or if there are multiple positive targets.*
[5] *The instrument does not indicate if the test strip is inserted correctly.*
[6] *The instrument identifies test results by the test strip barcode number rather than the patient ID. In a larger clinic, where multiple tests may be measured simultaneously, this can create uncertainty about which patient the test results belong to.*
[7] *We have not performed any cleaning or maintenance during the testing period.*
[8] *When reading the test strip, it is necessary to use gloves. The clean end of the test strip enters the instrument, while the end with the sample material needs to be handled.*

Additional positive comments to the ease of operation:
The instrument is simple to operate, and the reading time of the test is short. The instrument requires minimal maintenance. The size of the instrument is small, taking up little space.

Additional negative comments to the ease of operation:
It is unclear from the reading result which target is positive or if the test was misplaced in the iaX-2101. Accessing the portal is required to obtain this information. The test strip is very light and can be easily misplaced without an insert for additional support.

Table B. Rating of the information in the quick guide

Topic	Rating	Rating	Rating	Rating	Option
Descriptions of preparation of the instrument	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	Not read
Description of procedure steps	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	Not read
Description of how to read the test result on the instrument	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	Not read
Description of how to read the result of the functional test cassette	**N, S, N**	**Satisfactory**	Intermediate	Unsatisfactory	**Not read**
Description of the sources of error	**I[1], S, S**	**Satisfactory**	**Intermediate**	Unsatisfactory	Not read
Description of troubleshooting	**N, S, N**	**Satisfactory**	Intermediate	Unsatisfactory	**Not read**
The quick guide ease of use?	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	Not read
Table of contents/index		**Satisfactory**			
Description of measurement principle		**Satisfactory**			
Total rating by SKUP		**Satisfactory**			

[1] *The quick guide does not indicate that the barcode can be misplaced or that test strips with a background can give false positive results.*

Additional positive comments to the quick guide:
Easy to read and easy to understand.

Additional negative comments to the quick guide:
Potential sources of error are not mentioned.

Table C. Rating of ease of use of the portal and training time.

Topic	Rating	Rating	Rating	Rating	Option
Accessibility of the test result in the portal	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	Not read
Readability of the test result in the portal	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	Not read
Usefulness of the information in the portal	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	Not read
Required training time		**<2 hours**			
Total rating by SKUP		**Satisfactory**			

6.4.2. Assessment of the user-friendliness

Assessment of the ease of operation (table A)

The ease of operation was in total assessed as unsatisfactory, as there were several unsatisfactory ratings on vital steps of the handling procedure and sources of errors. The motivation for the negative ratings were mainly related to the fact that test results were not fully displayed on the iaX-2101 for tests that include multiple targets. The users therefore needed to access the portal to check the result. In addition, the results were registered in the portal based on the test strip barcode and not patient ID. This poses a risk of mixing up the test results if there are multiple samples being analysed at the same time and if there are multiple people handling the instrument. It should be noted that there is a barcode reader for patient ID that can be used with the instrument, but this was not included in this evaluation. The evaluating personnel also reported that the test strip was inserted into the iaX-2101 by holding the wet end where the sample was added, this poses a risk of infection and contamination. The instrument was unable to detect if the test was inserted incorrectly into the reader, and accessing the portal was necessary to review and evaluate each test result to avoid false readings.

Assessment of the information in the quick guide (table B)

The quick guide was assessed as satisfactory with positive comments that it was easy to read and understand. However, the quick guide could benefit from including descriptions of potential sources of errors when reading the test.

Assessment of the portal and training time (table C)

The ease of use of the portal and training time were assessed as satisfactory.

Conclusion

The ease of operation of iaX-2101 was rated unsatisfactory, while the information in the user manual and ease of use of the portal and training time was rated satisfactory.
The overall rating of the user-friendliness of iaX-2101 was assessed as unsatisfactory, due to unsatisfactory ratings on vital steps of the handling procedure, risk to patient safety and sources of errors. The performance specification for user-friendliness was not fulfilled.

7. References

1. Park C. *et al.* The design and evaluation of a mobile system for rapid diagnostic test interpretation. Proceedings of the ACM on Interactive, Mobile, Wearable and Ubiquitous Technologies. 2021; **5** (1): 1-26.

2. Oyet C. *et al.* Evaluation of the Deki Reader™, an automated RDT reader and data management device, in a household survey setting in low malaria endemic southwestern Uganda. Malaria journal. 2017; **16**: 1-6.

3. Ryu SW. *et al.* Comparison of three rapid influenza diagnostic tests with digital readout systems and one conventional rapid influenza diagnostic test. Journal of clinical laboratory analysis. 2018; **32** (2): e22234.

4. University of the Witwatersrand, Johannesburg. Multiplex Antigen Assay Laboratory Evaluation Report: Assaya ABCR Flu, COVID-19, and RSV Antigen Rapid Test. Version 1.0 (2024-08-15).

5. The IFCC – IUPAC terminology for properties and units. http://www.ifcc.org/ifcc-scientific-division/sd-committees/c-npu/npusearch/ (accessed 2024-10-14)

6. UTID Specification for Lateral Flow Assay (LFA). http://www.utid.org/ (accessed 2024-10-14)

Attachments

1. Facts about iaX-2101 and ABCR Flu, COVID-19, and RSV Antigen Rapid Test Kit
2. Information about manufacturer, retailers and marketing
3. Product specifications for this evaluation, iaX-2101
4. Statistical expressions and calculations
5. Raw data of Influenza A/B, SARS-CoV-2 and RSV, visual interpreted results, at the clinical microbiology laboratory
6. Raw data Influenza A/B, SARS-CoV-2 and RSV, iaX-2101, at the clinical microbiology laboratory
7. Raw data Influenza A/B, SARS-CoV-2 and RSV, RT-PCR results, at the clinical microbiology laboratory
8. Comments from NordicDx AS

Attachments with raw data are included only in the copy to NordicDx.

Facts about iaX-2101 and ABCR Flu, COVID-19, and RSV Antigen Rapid Test Kit

This form is filled in by NordicDx AS

Table 1. Basic facts iaX-2101

Name of the measurement system	intelligent analyzer eXpress-2101 Rapid Diagnostic Reader (iaX RDR / iaX-2101)
Dimensions and weight	Width: 11.5 mm Depth: 9mm Height: 10 mm Weight: 605 g
Components of the measurement system	LED Camera Lighting Board
Measurand	Relative Intensity (RI) of a test line on an LFA test.
Sample material	Depends on the LFA test to be read on the iaX reader; it varies from bodily fluids to environmental samples. For ABCR nasal swabs are immersed in extraction buffer.
Sample volume	Depends on the LFA test to be read on the iaX reader. For ABCR it is 0.4 mL.
Measuring principle	The iaX reader uses a camera and a complex light source that consists of multiple LEDs with specific wavelengths that are illuminated in a particular sequence specific to each test. LEDs range from infrared, through visible and ultraviolet light.
Traceability	N/A
Calibration	iaX is self-calibrated and does not require any user input or interaction to ensure proper operation.
Measuring range	0 – 100 (RI)
Haematocrit range	N/A
Measurement time	The development time for the test depends on the LFA test. Reading time: a few seconds (depending on the LFA-test)
Operating conditions	Ideal Operating temperature: 18-25 °C Operating temperature: 5-35 °C Humidity: 10-90 %
Electrical power supply	+12VDC 3A (36W)
Recommended regular maintenance	- There are no user-serviceable parts inside. You can only perform cleaning if required (in case of dust or spill) - Insert Functional Test Cassette every 3 months. Green light means it works properly, and red means there is an error.
Package contents	- iaX Reader - Power supply cable - Functional Test Cassette
Necessary equipment not included in the package	None

Table 2. Post analytical traceability of iaX-2101

Is input of patient identification possible?	The results are stored anonymously in a cloud platform and are traceable by unique barcodes.
Is input of operator identification possible?	Yes. Each user has a password-protected unique user account with specific access level.
Can the instrument be connected to a bar-code reader?	Yes. But not required.
Can the instrument be connected to a printer?	No
What can be printed?	N/A
Can the instrument be connected to a PC?	Not directly. It should be connected to the internet (wired or wireless LAN). The software is controlled through a cloud database portal.
Can the instrument communicate with LIS (Laboratory Information System)? If yes, is the communication bidirectional?	The system has an open API. While bidirectional communication is technically possible, we prioritize maintaining it unidirectional to ensure data security.
What is the storage capacity of the instrument and what is stored in the instrument?	eMMC 32GB For temporary storage on the unit for the OS and applications and the data while it's being buffered.
Is it possible to trace/search for measurement results?	The results can be tracked by barcode identifier. To search for a particular test, you can look for the exact date and time when the test was read.

Table 3. Facts about the reagent / test strips / test cassette - ABCR Flu, COVID-19, and RSV Antigen Rapid Test Kit

Name of the test	ABCR Antigen Test for Flu A, Flu B, COVID-19 and RSV
Stability in unopened sealed vial	Storage condition: Room temperature. 24 months
Stability in opened vial	After opening the foil bag, the test should be used as soon as possible.
Package contents	- Sterile Wood Abrasive Collectors (SWACs) - Tubes containing reagent: Sodium Azide (<0.1 %); Sodium Hydroxide (<0.5 %); Albumin Bovine Serum (<1 %) - Test strips Non-kit specific: - Flocked swabs or Micro-pipettes - Positive Control

Table 4. Quality control - ABCR Flu, COVID-19, and RSV Antigen Rapid Test Kit

Electronic self check	N/A
Recommended control materials and volume	400 µL positive control containing a mixture of all 4 antigens are provided (non-kit specific).
Stability in unopened sealed vial	Storage condition: Room temperature. Expiration date is on the package.
Stability in opened vial	Should be used immediately.
Package contents	Positive controls for each antigen.

Information about manufacturer, retailers and marketing

This form is filled in by NordicDx AS

Table 1. Marketing information - iaX-2101

Manufacturer:	Assaya Ltd., formerly Apollo Biotech Co., Ltd.
Retailers in Scandinavia:	Denmark: No retailers Norway: NordicDx AS Sweden: No retailers
In which countries is the system marketed:	Globally ☒ Scandinavia ☐ Europe ☐
Date for start of marketing the system in Scandinavia:	2022
Date for CE-marking:	2020.12.29
In which Scandinavian languages is the manual available:	The full manual is only available in English, but a quick guide is prepared in Norwegian.

Product specifications for this evaluation, iaX-2101 and ABCR Flu, COVID-19, and RSV Antigen Rapid Test Kit

iaX-2101 instruments, REF. iaX-2101

Serial number	Used by
iax-2101-00001105	Hospital laboratory
iax-2101-00001107	PHCC1
iax-2101-00001110	PHCC2

ABCR Flu, COVID-19, and RSV Antigen Rapid Test Kit, REF. AKIT-ABCR-01

Lot no.	Alias	Expiry date	Used by
14SA01-R2401	Lot a	2026-09-12	Hospital laboratory
14SA01-R2403	Lot b	2026-09-26	Hospital laboratory
14SA01-R2404	Lot c	2026-10-03	Hospital laboratory
14SA01-R2402	Lot d	2026-09-19	PHCCs

Positive control ABCR Flu, COVID-19, and RSV Antigen Rapid Test Kit

Control mix	Lot no	Manufacturer	Used by
Flu A Positive Control	B002-2401	SinoBiological	All evaluation sites
Flu B Positive Control	B003-2402	SinoBiological	
RSV Positive Control	B013-2201	SinoBiological	
COVID-19 Positive Control	B075-2001	SinoBiological	

Statistical expressions and calculations

This attachment is valid for evaluations of qualitative methods with results on the ordinal scale.

These calculations are based on the guidelines described in CLSI EP12 [a]. This attachment defines the terms overall agreement, positive percent agreement (PPA) and negative percent agreement (NPA) for use when comparing two binary diagnostic tests. An agreement study is conducted to calculate these statistics when the condition status of the subjects is not determined by diagnostic accuracy criteria.

Statistical calculations

- **Positive percent agreement (PPA)**: *The proportion of positive results from the comparative/reference method in which the test method also returns a positive result.*
- **Negative percent agreement (NPA)**: *The proportion of negative results from the comparative/reference method in which the test method also returns a negative result.*
- **Overall percent agreement**: *The proportion of total results in which the test method and the comparative/reference method agree, regardless of positive or negative results.*

Table 1. Illustration of statistical calculations.

	Truth		
	Positive	**Negative**	
Evaluated test positive	a	b	a+b
Evaluated test negative	c	d	d+c
Total	a+c	b+d	a+b+c+d

Overall percent agreement = $\mathbf{100}\ \% \times (\boldsymbol{a}+\boldsymbol{d})/(\boldsymbol{a}+\boldsymbol{b}+\boldsymbol{c}+\boldsymbol{d})$

Positive percent agreement = $\mathbf{100}\ \% \times \boldsymbol{a}/(\boldsymbol{a}+\boldsymbol{c})$

Negative percent agreement = $\mathbf{100}\ \% \times \boldsymbol{d}/(\boldsymbol{b}+\boldsymbol{d})$

Calculation of confidence intervals

Estimation of CI for fractions/proportions is performed according to Adjusted Walds [b]. The confidence intervals (CIs) are given for information only and are not part of the performance specifications.

a. CLSI. *User Protocol for Evaluation of Qualitative Test Performance; Approved guideline – Second Edition*. CLSI document EP12-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.
b. http://www.measuringu.com/wald.htm

Raw data of Influenza A/B, SARS-CoV-2 and RSV, visual interpreted results, at the clinical microbiology laboratory

Shown to the requesting company only.

Raw data Influenza A/B, SARS-CoV-2 and RSV, iaX-2101, at the clinical microbiology laboratory.

Shown to the requesting company only.

Raw data Influenza A/B, SARS-CoV-2 and RSV, RT-PCR results, at the clinical microbiology laboratory

Shown to the requesting company only.

Comments from NordicDx AS

NordicDx	Page 1 of 5
Supplementary Information for SKUP's iaX-ABCR Assessment (Ref. SKUP/2025/138)	
Issue Date:	**March 31st, 2025**

Dear SKUP Evaluation Committee,

Thank you for your thorough assessment of our iaX-ABCR system (Ref. SKUP/2025/138). We sincerely appreciate SKUP's detailed insights, which have enabled us to implement key improvements to enhance both the performance and user-friendliness of our rapid diagnostic system, iaX- ABCR (intelligent analyzer eXpress for Flu A/B, COVID-19, and RSV).

As stated in the SKUP iaX-ABCR report, the analytical performance of the iaX-2101 demonstrated an overall **agreement of 96%**, well above SKUP's Acceptance Performance Standard (APS ≥90%).

Regarding user-friendliness, the 'Rating of the information in the quick guide' and the 'Rating of ease of use of the portal and training time' were both rated as **satisfactory**, while the 'Ease of operation' was assessed as **unsatisfactory**.

In response to these findings and to improve ease of operation, we have provided the following improvements and clarifications:

- Transitioning from test strips to test cassettes, which significantly reduces user error and improves hygiene standards.
- Making additional equipment more prominent, such as barcode scanning for patient ID registration and an HDMI output for real-time results.
- Implementing a "walk-away mode" with automatic timing through embedded QR codes to ensure precise test reading.
- Strengthening training materials and updating the Instructions for Use (IFU) to provide clearer procedural guidelines and enhance error prevention strategies.

We are confident that these improvements, along with the additional equipment, will ensure that the system meets **satisfactory** user-friendliness standards.

Thank you once again for your valuable evaluation and recommendations. Should you require any further information or clarification, please do not hesitate to contact us.

Sincerely,

Tommy Selnes

Tommy Selnes
CEO
NordicDx AS

1. Introduction

SKUP, on behalf of NordicDx, has assessed the iaX-ABCR system (see full report for details, ref. SKUP/2025/138, hereafter referred to as the SKUP-iaX-ABCR report). To provide further clarity on this assessment, we have prepared this supplementary report.

During the evaluation, several findings were made regarding the performance and user-friendliness of the iaX-ABCR system. In response, we have implemented some clarifications (Table 2) and improvements (section 4), which we believe will enhance both the performance and user-friendliness of the system.

2. Performance of iaX-2101

The performance of iaX-2101, as referenced in SKUP-iaX-ABCR report section 6.3, demonstrated an **overall agreement of 96%**, meeting the Acceptance Performance Standard (APS) of ≥90%.

The assessment identified eight discrepancies when compared to qPCR (SKUP-iaX-ABCR report, Table 3), out of 209 samples analyzed. It is also worth noting that the system is designed for POC settings using fresh samples. If we consider only the fresh samples (n=162), excluding the frozen samples (n=47), only four discrepancies (2.5%) were identified.

Key findings:

- In four instances (SKUP ID no. 7, 55, 59, and 134), test strip misalignment and/or test insertion errors occurred, causing incorrect positioning of the control and test lines, which led to false readings or shifted results across different analysis areas (Figure 1).
- In one result (SKUP ID no. 206), dust in the analysis area gave a false positive (Figure 2). Since iaX measures the relative intensity of the test line, any external particles can affect the reading, and the sample should have been analyzed again using a new test.
- In one result (SKUP ID no. 143), letters from the test name appear in the first two analysis areas, causing all test lines to be misaligned and rendering all results unreliable (Figure 3). This issue was due to user error, as the test was tilted in the insert area instead of being positioned parallel to the camera. It is not related to the performance of the iaX-ABCR system.
- Two instances (SKUP ID no. 35, and 41) are false negatives for Flu B and RSV, respectively.

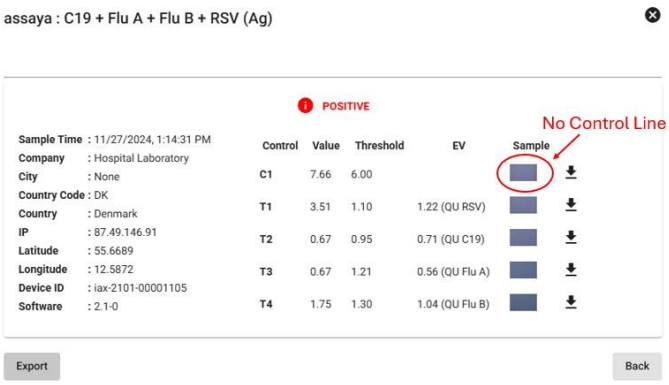

Figure 1. Test strip misalignment, leading to incorrect positioning of control (red circle) and test lines, resulting in false readings and shifted results across all analyzing areas. Picture collected from the iaX portal.

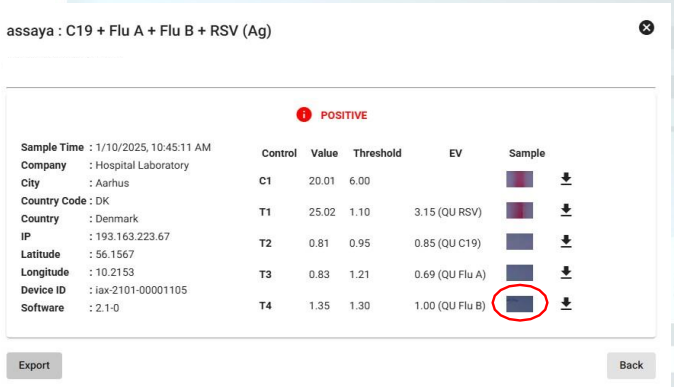

Figure 2. Dust in the analysis area of the test gave a false positive result (red circle). Picture collected from the iaX portal.

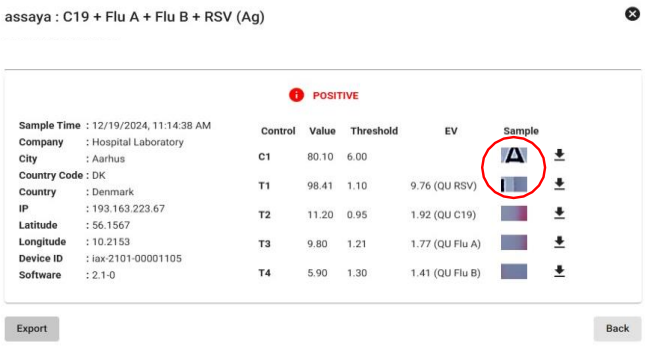

Figure 3. Letters from the test name appear in the first two analysis areas (red circle), causing all test lines to be misaligned and rendering all results unreliable. Picture collected from the iaX portal.

3. Evaluation of user-friendliness

The evaluation of user-friendliness, as outlined in section 6.4 of the SKUP-iaX-ABCR report, identified some issues mainly due to the use of test strips instead of test cassettes, resulting in an **unsatisfactory** rating (SKUP-iaX-ABCR report p. 21, Table A. Rating of Ease of Operation). However, by implementing the suggested improvements and additional equipment (Table 2), we believe the user-friendliness will meet **satisfactory** standards.

The two remaining assessments in the SKUP-iaX-ABCR report "Table B. Rating of the information in the quick guide" and "Table C. Rating of ease of use of the portal and training time" were deemed **satisfactory**.

Additionally, the fraction of tests wasted due to technical error was 0.48% (1 out of 209). The SKUP recommendation of a fraction of ≤2% tests wasted due to technical errors was **achieved**.

Table 2. NordicDx's clarifications and resolutions in response to the SKUP-iaX-ABCR report.

Topic	Unsatisfactory or Intermediate finding	Clarification or Resolution
Hygiene, when using the procedure	Hygiene and use of multiple gloves	The issue is related to using test strips instead of cassettes. Transitioning to cassette-based tests would eliminate these issues. Additionally, the extraction buffer lyses viruses within five minutes, eliminating the infection risk.
Sources of errors	Test strip insertion and misplacement challenges.	
Instrument design	Insertion area width	The LFA insertion area is designed to ensure proper test placement within a predefined tolerance, guaranteeing accurate analysis of all positions within this range (Figure 4). This confirms that the insertion area is appropriately sized.
Sources of errors	Patient ID registration	iaX supports barcode scanning, and patient IDs are stored under the "Specimen ID" column in the "Tests" tab.
Readability of the test result on the instrument	Identification of multiple positive targets	The iaX has an HDMI output that enables users to view positive targets in real-time on a connected monitor.
Readability of the test result, time aspect	Timing of test insertion	With the introduction of the "walk-away mode," users can now insert the test, and the internal timer will activate automatically. This feature ensures the test results are read at the exact time defined by the QR code in the tests.

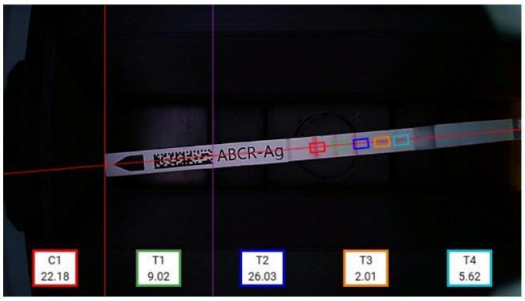

Figure 4. Test strip inserted in the maximum angle in the tray showing that the iaX adjusts the reading area accordingly and analyses the results correctly.

4. **Improvements implemented by NordicDx**
   - For customers and external studies, a test cassette will be used instead of a test strip (Figure 4).
   - Increased acceptance criteria for control line intensity to ensure that the iaX identifies the test as invalid when the control line is not correctly aligned in the analysis area.
   - Strengthened training materials, including Standard Operating Procedures (SOPs) for training to minimize personal errors.
   - Updated the existing Instructions for Use (IFU) to include the following improvements:
     - Accessories: **barcode scanner** for patient ID tracking and **portable screen** to view real-time results on the display, allowing immediate identification of multiple positive markers.
     - Sterilization routine.
     - Sources of errors.

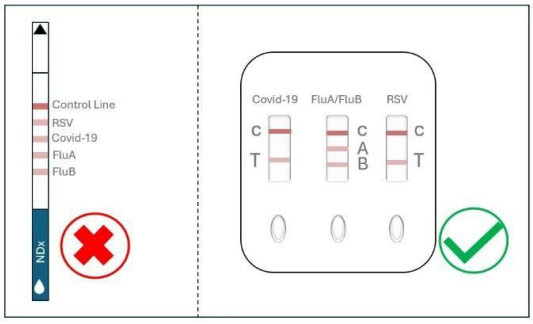

Figure 4. Use of a test cassette instead of test strip for customers and external studies, as it reduces personal errors and is more hygienic.