Evaluation of the new STARlet-AIOS system using the Allplex SARS-CoV-2 assay in comparison with three different assays

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Background

- In epidemic or pandemic situations, fully-automated systems with minimum hands-on time are crucial to ensure rapid bulk diagnostics
- The STARlet-AIOS (Seegene, figure 1) is a new fully automated, sample-to-result molecular platform suitable for bulk testing

Objective

To evaluate performance and ease of use of the STARlet-AIOS in comparison with three different methods, all testing for SARS-CoV-2

Methods

Prospective evaluation

- All naso-/oropharyngeal specimens tested for SARS-CoV-2 in routine diagnostics were included
  - Specimens were tested using either the Cepheid GeneXpert, Hologic Panther or a lab-developed test (LDT)
  - Inclusion during a 3-week study period

Retrospective evaluation

- A cohort of 40 SARS-CoV-2 PCR-positive specimens was tested
  - Different variants were included (table 1)

Discrepancy analysis

- Discrepant results were re-tested with either the GeneXpert assay or the LDT
  - Two identical results were considered the reference

Performance of the system

- Hands-on-time (HOT) and turn-around-time (TAT) of the different systems were monitored and compared
- The number of technical issues of the new system was registered



Characteristics of the STARlet-AIOS

- Batch-based testing only
- Universal nucleic acid extraction for all kind of specimens
- Maximum of 94 samples / extraction
- PCR using established Allplex® assays
- Runs on two CFX-96 cyclers, providing 188 test results per run
- Time to first result: 5.6 hrs maximum
- Max. throughput per day: 376 results

Figure 1 : STARlet-AIOS system and its main performance characteristics

SARS-CoV-2 Variant	N
Wildtype	9
Alpha (B.1.1.7)	11
Delta (B.1.61722)	8
Omicron (BA.1/BA.2)	6
Omicron (BA.4/BA.5)	6

Table 1: variants of SARS-CoV-2 in the retrospective evaluation

	HOT[1]	TAT[2]
STARlet-AIOS	<1	4
GeneXpert	<1	0.5
Panther	<1	4
Lab-developed test	4	4

Table 2: comparison of the HOT and TAT calculated per specimen
1: Hands-on-time in minutes
2: Turn-around-time in hours

Results

Prospective evaluation

- Sensitivities and specificities after discrepancy analysis appeared to be comparable amongst the different assays, all being 96,4% or higher (table 3)

Retrospective evaluation

- An agreement of 100% was obtained when testing the retrospectively collected specimens including different variants of the virus

Performance of the system

- Comparison of the HOT and TAT is presented in table 2
- Technical issues: no critical errors occurred
  - Incidentally, incorrect initialization of the PCR-plate handling robotic arm occurred
  - A software update resolved this issue

	Inclusions		Performance Allplex SARS-CoV-2			Performance Allplex SARS-CoV-2 after discrepancy testing		
	N	Positive	Agreement	Sensitivity	Specificity	Agreement	Sensitivity	Specificity
Xpert ® Xpress SARS-CoV-2 plus	336	84 (25.0%)	95.2%	83.3%	99.2%	98.8%	96.4%	99.6%
AptimaTM SARS-CoV-2 assay	250	55 (22.0%)	91.6%	100%	89.2%	98.8%	100%	98.3%
Lab-developed test	152	59 (38.8%)	94.1%	94.9%	93.5%	97.4%	98.3%	96.8%
Total	738	198 (26.8%)	93.8%	91.4%	94.6%	98.5%	98.1%	98.7%

Table 3: Results of the prospective evaluation

Conclusions

- The STARlet-AIOS proved to be a robust sample-to-result system, with low HOT and moderate TAT
- Results of this study showed reliable detection of SARS-CoV-2 in comparison to other well-established assays