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Author	Approver
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Date Sign	Date Sign
Nov 23 2020	Nov 23 2020

Quality statement SARS-CoV-2 assay

CONTENT

1 Introduction

1.1 Scope

This report (REP) describes an overview, intended for public release, of quality assessments conducted for the SARS-CoV-2 detection assay deployed at A23 Lab AB. Internally the product is denoted C19.

1.2 Authority and responsibility

The Quality Assurance Manager (QA) is the owner of this document and is responsible for the implementation, upkeep and availability of this REP to all affected entities.

2 Conducted quality tests

2.1 A23 Lab procedures

In brief, A23 Lab runs the following methods for determining trace of SARS-CoV-2:

RNA extraction reagents are sourced from the Belgian task-force. The extraction is deployed on a Thermo Fisher Kingfisher 96 instrument.

PCR is run essentially according to the US FDA/CDC protocol as singleplex assays. The PCR is deployed on a Thermo Fisher QuantStudio 12K, in 384 well mode.

A23 Lab use a large number of controls in each assay, in particular during early implementation of a new product such as C19. This to make it possible to detect any aberration almost instantaneously. About 20% of the tested samples in each run are controls with known properties.

2.2 Comparison to lab A

Lab A is major laboratory provider located in the western portion of Sweden. In April 2020, A23 received 96+72 samples as RNA extracts from two different RNA extraction platforms. All samples were tested in a blind manner, i.e. the lab staff at A23 had no information on which samples, if any, were positive. There were 27+20 positive samples according to lab A. A23 found all those and 5 additional ones. The PCR method at A23 is consistently better than the one used at lab A, and the 5 additional positives should in theory not be visible in their assay.

A23 also received 50 raw samples. These were unfortunately deteriorated before the RNA extraction was fully implemented at A23.

2.3 Comparison to lab B

Lab B is a governmental agency in Sweden. In April 2020, A23 received 8+91 samples from lab B. We clearly disagree on the outcome of one sample (positive at lab B, negative at A23).

2.4 Comparison to lab C

Lab C is a laboratory in a Nordic country (not Sweden). In April 2020, A23 received 70 samples that were tested, at the same time, in lab C. When results were available from both laboratories, A23 and the lab C were shown to be in perfect agreement; The same four positive tests were reported from both labs.

2.5 Results from quality program (Equalis)

A23 is participating in a SARS-CoV-2 quality program as arranged by Equalis. In the recent (first) round of testing, A23 reported all six samples in agreement with expected outcome.

EQUALIS

Resultatrapport:
557. SARS-CoV-2

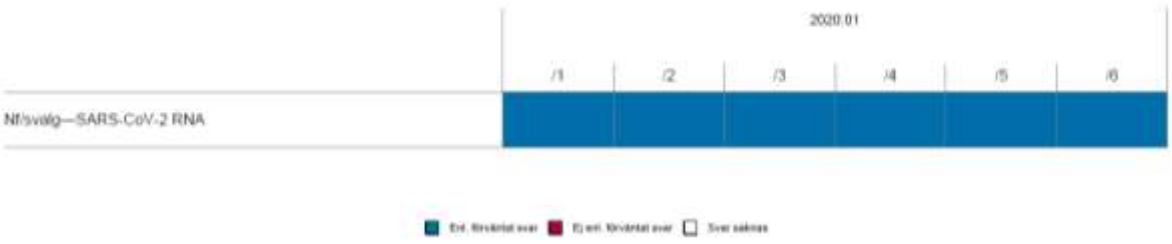
Analysomgång: 2020:01 Sida: 1 (2) 5478-1 | A23 Lab AB, UPPSALA

Översikt

Färg egel svar: Svart = Enl förv. svar/Förv. svar saknas/Numeriskt/Fritextsvar; Röd = Ej enl. förväntat svar

Prov	Komponent	n	Andel med förväntat svar (%)	Förväntat svar	Eget svar
/1	Nt/svalg—SARS-CoV-2 RNA	33	100	Påvisat	Påvisat
	Ct-värde (SARS-CoV-2)	33			30,247
/2	Nt/svalg—SARS-CoV-2 RNA	33	100	Påvisat	Påvisat
	Ct-värde (SARS-CoV-2)	33			29,068
/3	Nt/svalg—SARS-CoV-2 RNA	33	97	Påvisat	Påvisat
	Ct-värde (SARS-CoV-2)	32			34,716
/4	Nt/svalg—SARS-CoV-2 RNA	33	100	Påvisat	Påvisat
	Ct-värde (SARS-CoV-2)	33			29,794
/5	Nt/svalg—SARS-CoV-2 RNA	33	100	Påvisat	Påvisat
	Ct-värde (SARS-CoV-2)	33			36,332
/6	Nt/svalg—SARS-CoV-2 RNA	33	97	Ej påvisat	Ej påvisat
	Ct-värde (SARS-CoV-2)	9			

Historik



2.6 Comparison with lab A, reverse version

In July 2020, Lab A (above) asked A23 for a set of samples to confirm the compatibility of the specimens from the at-home type sampling method used among A23 customers (but not yet among lab A customers). A23 shared 13 samples (8 positives, 5 negatives) with results from the A23 C19 product with lab A. The results obtained at lab A were in perfect agreement with results obtained at A23.

2.7 Comparison to lab B, reverse version

In July 2020, A23 shipped 188 samples to lab B. We agree on results for 13 positive samples and 173 negative samples. A23 measured one weak positive for which Lab B obtained a negative result. Lab B measured one weak positive for which A23 obtained a negative result. This test was blinded, i.e. Lab B did not have access to A23 results when conducting the measurements.

2.8 Comparison to lab D

As part of verifying a sampling method (July 2020) in a public hospital in Sweden, 50 samples were analyzed at both the local microbiology lab and at A23. For A23, this was a blinded test. Results were in complete agreement.

2.9 Comparison to lab C, reverse version

In November 2020, A23 sent a backlog of sample from one particular customer to lab C for analysis, so as to temporarily relieve the Swedish healthcare. Along with the backlog of about 2000 samples to be measured, 10 controls were added. These were samples with known content as measured by A23, and results were blind to lab C. Results from lab C and A23 were in complete agreement.

3 Conclusions

A23 has crosschecked assay performance to different external laboratories. The performance of the A23 Lab C19 product is comparable to other suppliers.

4 Revisions and updates

This document is revised and updated by its owner when deemed necessary.

4.1 Document history

Revised by	Date	Version	Description
Christina Atterby	2020-04-27	1	New document
Christina Atterby	2020-04-28	2	Update, additional data from lab B
Christina Atterby	2020-06-03	3	Update, Equalis results
Christina Atterby	2020-07-08	4	Update, new test with lab A
Christina Atterby	2020-07-15	5	Update, new test with lab B
Christina Atterby	2020-11-23	6	Update, new test with lab D & lab C

Audit Trail

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