Validation

Sars-CoV-2 Antigen Test

with

COVID-19 Antigen Detection Kit (Newgene(Hangzhou) Bioengineering)

Department of microbiology LMZ Dr Risch Pregassona

Validation interval:01/21 – 02/21

Summary

1 Executive Summary

Following the SOP «standard operating procedure to validate SARS-CoV-2 antigen Tests, V.2;04.12.2020" published by the SGM-SSM a novel Antigen test from Newgene (TA1) will be validate comparing it to PCR and to the standard Ag-test of Roche. Following point will be addressed:

1) Technical validation: in the first step of the validation 100 PCR positive sample will be analyzed in parallel with 200 negative samples from patients
2) The step 2 of the validation is aimed to determine the limit of detection

Conclusion: the validation revealed that the TAG1 is comparable to the analytical performance of Roche and is, therefore, suitable for the use in the swiss settings.

2 Aim

Starting point
In order to offer an effective defense against the SARS-CoV-2 pandemic, the FOPH evaluates new rapid test in order to test an optimal patient number within a short-time frame

Objective
To evaluate a new rapid kit TAG1 comparing it with the Roche-standard and the PCR

3 Feasibility

Responsibility

Rolle	Person(en)	Funktion
Initiator der Prüfung	Mauro Imperiali	Head of microbiology department (Pregassona)
Eigner der Prüfung	Mauro Imperiali	Head of microbiology department (Pregassona)
Definition der Prüfung	BAG/SSM	
Prüfung	Margherita Pezzoli	Cand. Pharm, Basel
Berichtswesen	Mauro Imperiali	Head of microbiology department (Pregassona)
Freigabe	Mauro Imperiali	Head of microbiology department (Pregassona)

Ressourcen
Roche (ref9901-NCOV-01G): SARS-CoV-2 rapid antigen test, LOT (Extraction buffer: STEB1020408; Rapid antigen Test: QC0390016A)

Newgene Bioegineering: COVID-19 Antigen Detection Kit LOT (Number: 20201115)

4 Verification

Validation-plan

1) Fresh patient sample (<72h): 95 PCR positive➔ left-over material from the lab
2) Fresh patient sample (<72h): 150 PCR negative➔ left-over material from the lab
3) Standardized positive sample: 5 diluted positive samples obtained from Basel
4) Negative samples: 37 respiratory samples from Basel with viral pathogens other than SARS-CoV-2
    a. Other coronavirus n=12
    b. Parainfluenza n=12
    c. Rinho/entero n=5
    d. RSV n=6
    e. HMPV n=3
    f. Influenza A n=6
    g. Influenza B n=6
5) Cell culture-derived supernatant
6) Serial dilution of a very highly positive clinical sample

Results

1 Fresh patient Sample: PCR positive

97 positive sample were processed using the 2 Antigen Assay. Results can be summarized as follow:

	Roche	TA1
TP	46	52
FN	51	45
Total	97	97

1 Fresh patient Sample: PCR negative

158 negative samples (Ct=45) were tested. Sample nr 57 gave a false positive result in both Roche Ag assay and TAG1. Sample 118 gave a false positive result only in the TAG1.

Results can be summarized as follow.

	Roche	TA1
TN	157	156
FP	1	2
Total	**158**	**158**

3 Positive standardized Samples

Standarized positive samples		
CT value	Roche	TA1
21	positive	positive
23	positive	positive
24	positive	positive
25	positive	positive
26	positive	positive

4 Negative Samples

Negative samples		
	Roche	TA1
CoV 229	negative	negative
CoV 229	negative	negative
CoV HKU1	negative	negative
CoV HKU1	negative	negative
CoV HKU1	negative	negative
CoV OC43	negative	negative
CoV OC43	negative	negative
CoV OC43	negative	negative
CoV NL63	negative	negative
CoV NL63	negative	negative
CoV NL63	negative	negative
Parainfluenza 1	negative	negative
Parainfluenza 1	negative	negative
Parainfluenza 1	negative	negative
Parainfluenza 2	negative	negative
Parainfluenza 2	negative	negative
Parainfluenza 2	negative	negative
Parainfluenza 3	negative	negative
Parainfluenza 3	negative	negative
Parainfluenza 3	negative	negative
Parainfluenza 4	negative	negative
Parainfluenza 4	negative	negative
Parainfluenza 4	negative	negative
Rhino/Enterovirus	negative	negative
Rhino/Enterovirus	negative	negative
Rhino/Enterovirus	negative	negative
Rhino/Enterovirus	negative	negative
Rhino/Enterovirus	negative	negative
Influenza A	negative	negative
Influenza A	negative	negative
Influenza A	negative	negative
Influenza A	negative	negative
Influenza A	negative	negative
Influenza A	negative	negative
Influenza B	negative	negative
Influenza B	negative	negative
Influenza B	negative	negative
Influenza B	negative	negative
Influenza B	negative	negative
Influenza B	negative	negative
RSV	negative	negative
RSV	negative	negative
RSV	negative	negative
RSV	negative	negative
RSV	negative	negative
RSV	negative	negative
Metapneumovirus	negative	negative
Metapneumovirus	negative	negative
Metapneumovirus	negative	negative

5 Cell culture-derived supernatant

	RV. Nr	Material	Ct Wert	Roche (aliquot 48)	TA1 (aliquot 49)
B106	RV-K-1	SARS-CoV-2 Zellkultur-Überstand	21	positive	positive
B107	RV-K-2		22	positive	positive
B108	RV-K-3		23	positive	positive
B109	RV-K-4		24	negative	positive
B110	RV-K-5		25	negative	positive
B111	RV-K-6		26	negative	negative
B112	RV-K-7		27	negative	negative

6 Serial dilution of a very highly positive clinical sample

	RV. Nr	Material	Ct Wert		
B113	RV-P-1	Patienten-Probe	21	positive	positive
B114	RV-P-2		22	positive	positive
B115	RV-P-3		23	positive	positive
B116	RV-P-4		24	positive	positive
B117	RV-P-5		25	positive	positive
B118	RV-P-6		26	negative	positive
B119	RV-P-7		27	negative	negative

5 Conclusions

The comparable results with the Roche Test makes the newgene test suitable to be introduced in Switzerland. It important to note the better sensitivity of that assay in comparison to Roche

Date: 08.02.2021

Visum:

Mauro Imperiali