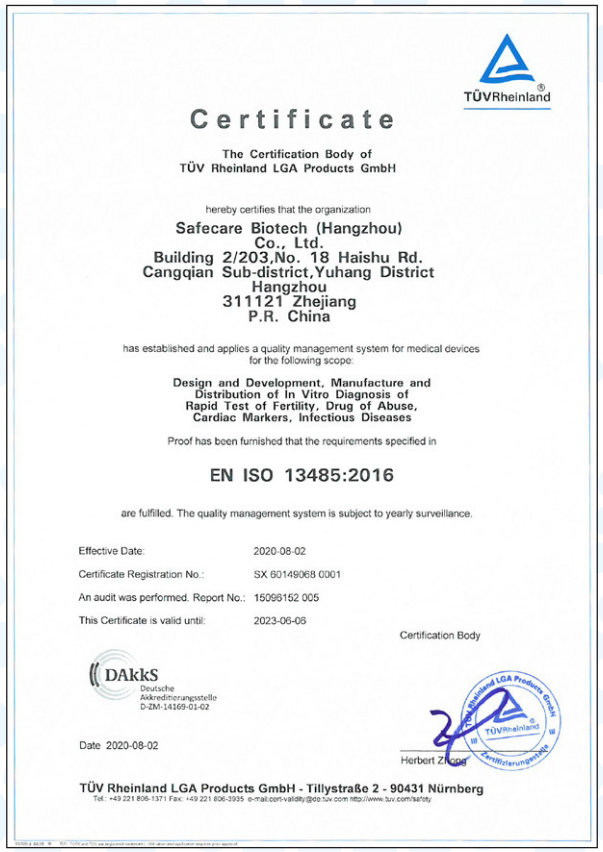
Dokumente & Zertifikate

TÜV Rheinland Zertifikat



TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Safecare Biotech (Hangzhou) Co., Ltd.
Building 2/203,No. 18 Haishu Rd.
Cangqian Sub-district,Yuhang District
Hangzhou
311121 Zhejiang
P.R. China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of In Vitro Diagnosis of Rapid Test of Fertility, Drug of Abuse, Cardiac Markers, Infectious Diseases

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-08-02
Certificate Registration No.: SX 60149068 0001
An audit was performed. Report No.: 15096152 005
This Certificate is valid until: 2023-06-06

Certification Body

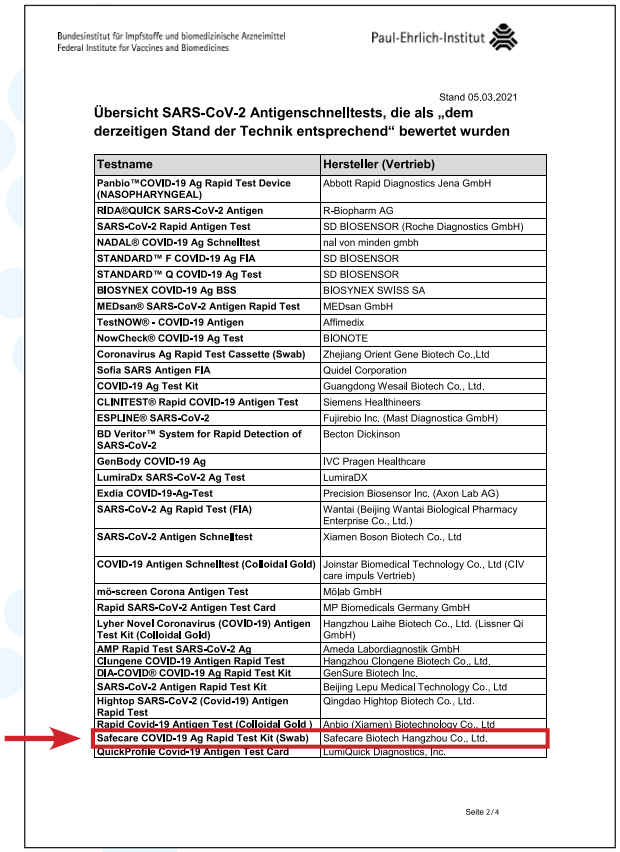
DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Date 2020-08-02

Herbert Zinser

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

Übersichts-Liste Paul-Ehrlich Institut



Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Stand 05.03.2021

Übersicht SARS-CoV-2 Antigenschnelltests, die als „dem derzeitigen Stand der Technik entsprechend“ bewertet wurden

Testname	Hersteller (Vertrieb)
Panbio™COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	Abbott Rapid Diagnostics Jena GmbH
RIDA®QUICK SARS-CoV-2 Antigen	R-Biopharm AG
SARS-CoV-2 Rapid Antigen Test	SD BIOSENSOR (Roche Diagnostics GmbH)
NADAL® COVID-19 Ag Schnelltest	nal von minden gmbh
STANDARD™ F COVID-19 Ag FIA	SD BIOSENSOR
STANDARD™ Q COVID-19 Ag Test	SD BIOSENSOR
BIOSYNEX COVID-19 Ag BSS	BIOSYNEX SWISS SA
MEDsan® SARS-CoV-2 Antigen Rapid Test	MEDsan GmbH
TestNOW® - COVID-19 Antigen	Affimedix
NowCheck® COVID-19 Ag Test	BIONOTE
Coronavirus Ag Rapid Test Cassette (Swab)	Zhejiang Orient Gene Biotech Co.,Ltd
Sofia SARS Antigen FIA	Quidel Corporation
COVID-19 Ag Test Kit	Guangdong Wesail Biotech Co., Ltd.
CLINITEST® Rapid COVID-19 Antigen Test	Siemens Healthineers
ESPLINE® SARS-CoV-2	Fujirebio Inc. (Mast Diagnostica GmbH)
BD Veritor™ System for Rapid Detection of SARS-CoV-2	Becton Dickinson
GenBody COVID-19 Ag	IVC Pragen Healthcare
LumiraDx SARS-CoV-2 Ag Test	LumiraDX
Exdia COVID-19-Ag-Test	Precision Biosensor Inc. (Axon Lab AG)
SARS-CoV-2 Ag Rapid Test (FIA)	Wantai (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.)
SARS-CoV-2 Antigen Schnelltest	Xiamen Boson Biotech Co., Ltd
COVID-19 Antigen Schnelltest (Colloidal Gold)	Joinstar Biomedical Technology Co., Ltd (CIV care impuls Vertrieb)
mö-screen Corona Antigen Test	Mölab GmbH
Rapid SARS-CoV-2 Antigen Test Card	MP Biomedicals Germany GmbH
Lyher Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Hangzhou Laihe Biotech Co., Ltd. (Lissner Qi GmbH)
AMP Rapid Test SARS-CoV-2 Ag	Ameda Labordiagnostik GmbH
Clungene COVID-19 Antigen Rapid Test	Hangzhou Clongene Biotech Co., Ltd.
DIA-COVID® COVID-19 Ag Rapid Test Kit	GenSure Biotech Inc.
SARS-CoV-2 Antigen Rapid Test Kit	Beijing Lepu Medical Technology Co., Ltd
Hightop SARS-CoV-2 (Covid-19) Antigen Rapid Test	Qingdao Hightop Biotech Co., Ltd.
Rapid Covid-19 Antigen Test (Colloidal Gold)	Anbio (Xiamen) Biotechnology Co., Ltd
Safecare COVID-19 Ag Rapid Test Kit (Swab)	Safecare Biotech Hangzhou Co., Ltd.
QuickProfile Covid-19 Antigen Test Card	LumiQuick Diagnostics, Inc.

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EU-Konformitätserklärung

CE CE

EC Declaration of Conformity

according to the Directive 98/79/EC
(applicable to IVD Devices of NOT Annex II and NOT self-test)

Manufacturer: Safecare Biotech (Hangzhou) Co., Ltd.
Address: Building 2/203, No.18 Haishu Rd.Cangqian Sub-district, Yuhang District, Hangzhou, Zhejiang China 311121
EC Representative: NIC GmbH Erlenweg 13,49076 Osnabrück,Germany

We, the manufacturer, declare under our sole responsibility that

the medical device(s) Product Name: COVID-19 Antigen Rapid Test Kit(Swab)
Type/model, identification of product allowing traceability (Where applicable): Cassette(COV Ag-6012)
of Category: **Common/Others IVD**
(Devices of **NOT Annex II** and **NOT self-test**)

is/are in conformity with the relevant provisions and requirements of Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Applied harmonised standards, national standards or other normative documents: EN ISO23640:2015, EN 13612:2002, EN 13641:2002, EN ISO 14971:2019, ISO13485:2016, EN ISO 18113-1:2011, ISO 18113-2: 2009, EN1041- 2008, EN ISO15223-1:2016

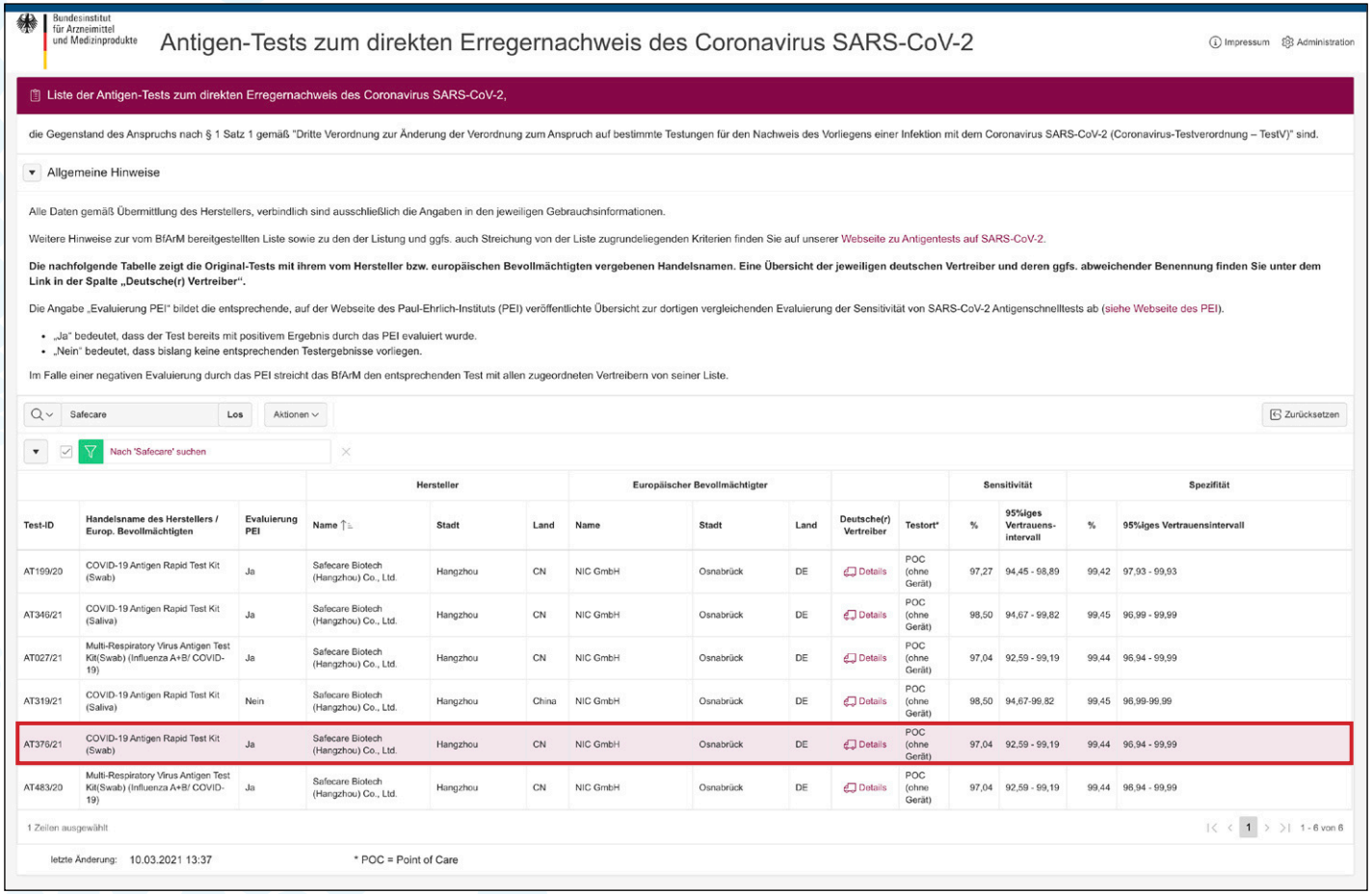
Conformity assessment procedure: Module A (EC Declaration of Conformity) (Annex III, except point 6)
Notified Body (name & number) Certificate & number: **NOT applicable**

Signed on 28th Sep.,2020 Place: Hangzhou, Zhejiang, China

Signature (on behalf of the manufacturer): Kebin Qiu 2020.9.28

Name of authorized signatory: Kebin Qiu
Position held in the company: General Manager
Seal/Stamp

Antigen-Test Liste des Bundesinstitut für Arzneimittel und Medizinprodukte



Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

Impressum | Administration

Liste der Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2,

die Gegenstand des Anspruchs nach § 1 Satz 1 gemäß "Dritte Verordnung zur Änderung der Verordnung zum Anspruch auf bestimmte Testungen für den Nachweis des Vorliegens einer Infektion mit dem Coronavirus SARS-CoV-2 (Coronavirus-Testverordnung – TestV)" sind.

Allgemeine Hinweise

Alle Daten gemäß Übermittlung des Herstellers, verbindlich sind ausschließlich die Angaben in den jeweiligen Gebrauchsinformationen.

Weitere Hinweise zur vom BfArM bereitgestellten Liste sowie zu den der Listung und ggfs. auch Streichung von der Liste zugrundeliegenden Kriterien finden Sie auf unserer Webseite zu Antigentests auf SARS-CoV-2.

Die nachfolgende Tabelle zeigt die Original-Tests mit ihrem vom Hersteller bzw. europäischen Bevollmächtigten vergebenen Handelsnamen. Eine Übersicht der jeweiligen deutschen Vertreiber und deren ggfs. abweichender Benennung finden Sie unter dem Link in der Spalte „Deutsche(r) Vertreiber".

Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden Test mit allen zugeordneten Vertreibern von seiner Liste.

Safecare | Los | Aktionen | Zurücksetzen

Nach 'Safecare' suchen

			Hersteller			Europäischer Bevollmächtigter					Sensitivität		Spezifität	
Test-ID	Handelsname des Herstellers / Europ. Bevollmächtigten	Evaluierung PEI	Name	Stadt	Land	Name	Stadt	Land	Deutsche(r) Vertreiber	Testort*	%	95%iges Vertrauens-intervall	%	95%iges Vertrauensintervall
AT199/20	COVID-19 Antigen Rapid Test Kit (Swab)	Ja	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	CN	NIC GmbH	Osnabrück	DE	Details	POC (ohne Gerät)	97,27	94,45 - 98,89	99,42	97,93 - 99,93
AT346/21	COVID-19 Antigen Rapid Test Kit (Saliva)	Ja	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	CN	NIC GmbH	Osnabrück	DE	Details	POC (ohne Gerät)	98,50	94,67 - 99,82	99,45	96,99 - 99,99
AT027/21	Multi-Respiratory Virus Antigen Test Kit(Swab) (Influenza A+B/ COVID-19)	Ja	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	CN	NIC GmbH	Osnabrück	DE	Details	POC (ohne Gerät)	97,04	92,59 - 99,19	99,44	96,94 - 99,99
AT319/21	COVID-19 Antigen Rapid Test Kit (Saliva)	Nein	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	China	NIC GmbH	Osnabrück	DE	Details	POC (ohne Gerät)	98,50	94,67-99,82	99,45	96,99-99,99
AT376/21	COVID-19 Antigen Rapid Test Kit (Swab)	Ja	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	CN	NIC GmbH	Osnabrück	DE	Details	POC (ohne Gerät)	97,04	92,59 - 99,19	99,44	96,94 - 99,99
AT483/20	Multi-Respiratory Virus Antigen Test Kit(Swab) (Influenza A+B/ COVID-19)	Ja	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	CN	NIC GmbH	Osnabrück	DE	Details	POC (ohne Gerät)	97,04	92,59 - 99,19	99,44	96,94 - 99,99

1 Zeilen ausgewählt | 1 | 1 - 6 von 6

letzte Änderung: 10.03.2021 13:37 | * POC = Point of Care

https://antigentest.bfarm.de/ords/f?p=101:100:9507865114131::::&tz=1:00

Klinische Test-Studie

Clinical Evaluation Report

1. Purpose:
In order to verify the clinical performance of the improved test

2. Material:
Fresh negative COVID-19 samples were collected from the hospital and validated by PCR.
Fresh positive COVID-19 samples were collected from CDC and validated by PCR.
Product used: COV20082701

3. Protocol:
3.1 Sample Size:
Positive Sample: >100
Negative Sample:>150

3.2 Sample's collection:
Nasal swab specimen or nasopaharygeal swab specimen can be used by Safecare COVID-19 Antigen Rapid Test Kit(Swab) to detect the presence of SARS-CoV-2 antigen in the specimen. Internal validation studies based on Matrix Equivalency were performed on both nasal swab specimens and nasopaharygeal swab specimen, no statistic difference was observed among those specimens. All swabs were randomly blinded and assigned to testing with PCR assay as the comparator method for this study.

3.3 Sample Entry criteria:
The samples from hospital outpatient screening cases and COVID-19 Patients who presented within 7 days of symptom onset;
Samples of people that gender and age are not limited.

3.4 Sample Exclusion criteria:
Samples without PCR test results;
Samples that the quantity is not enough to complete the test;
Samples with failed test results (C-line has not appeared);
Freeze samples repeatedly.

3.5 Comparator method
All samples was confirmed by PCR.
PCR tests used from Sansure Biotech Inc. and performed on ABI7500.

4. Operator and site:
Site 1:
Study Site Info: ZHEJIANG PROVINCIAL CENTER FOR DISEASE CONTROL AND PREVENTION
Researcher: Dr. ZHANG LEI
Lab Name (or Hospital or Doctor's office)：Immunology Laboratory
Address: 3399 Binsheng Road, Binjiang District, Hangzhou City, Zhejiang Province
Site 2:
Study Site Info: THE FIRST AFFILIATED HOSPITAL ZHEJIANG UNIVERSITY SCHOOL OF MEDICINE
Researcher: Dr.Xuwei
Lab Name (or Hospital or Doctor's office):Immunology Laboratory
Address: No. No. 366, Wutong Road, Xihu District, Hangzhou, Zhejiang

5. Statistical methods:
5.1 Statistical of test result

		Referencing reagent Test		Total
		Positive	Negative	
Research Reagent	Positive	A	B	A+B
	Negative	C	D	C+D
Total		A+C	B+D	A+B+C+D

Percent Positive Agreement=A/(A+C)*100%
Negative Percent Agreement=D/(B+D)*100%
Overall Agreement=(A+D)/(A+B+C+D)*100%

5.2 Statistical of Specimens correlation
Record and statistics the correlation of antigen-positive/PCR-positive and antigen-negative/PCR-positive samples with the Ct values of the PCR to determine the mean Ct value of antigen-positive samples

6. Evaluation indicators:
The total PPA should be no less than 80%.
The total NPA should be no less than 90%.

7. Statistical results of the clinical evaluation
7.1 Test result

		Referencing Method (RT-PCR)		Total
		Positive	Negative	
Test-strip	Positive	131	1	132
	Negative	4	179	183
Total		135	180	315

7.2 Statistical results

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity-PPA （%）	131/135	97.04% (92.59%～99.19%)
Relative Specificity-NPA （%）	179/180	99.44% (96.94%～99.99%)
Overall Agreement （%）	310/315	98.41% (96.33%～99.48%)

7.3 Kappa consistency test
Calculate the Kappa value and standard error; test hypothesis is established for Kappa: H0: k = 0, Kappa value comes from 0 population, H1: k > 0, Kappa value comes from non-0 population, α = 0.05.

Project	Value
Kappa Value	0.9675, Good consistency.
Standard Error Se(K)	0.0144
95% Confidence Interval	0.9392～0.9958
Standard Error Se0(K)	0.056
Test Value Z	Z=17.1747 Probability value P=0.0000
Test Result	P<0.05,refuse H0, Kappa values come from populations other than 0.

7.4 Specimens correlation

The performance of Safecare COVID-19 Antigen Rapid TestKit(Swab) with positive results stratified by the comparator method (Ct) counts were collected and assessed to determine the correlation of assay performance to the Ct.

Safecare COVID-19 Antigen Rapid Test	Comparator Method (POS by Ct ≤ 40)	
	Ct<28	Ct ≥ 28
Positive	130	1
Negative	0	4
Total	130	5
Positive Agreement(95% CI)	100.00% (97.20%～100.00%)	20.00% (0.51%～71.64%)

Based on above table, the positive agreement of the Safecare COVID-19 Antigen Rapid TestKit(Swab) is higher with samples of a Ct count <28.

8. Conclusion

A side-by-side comparison was conducted using the research reagent and referencing reagent. Compare with RT-PCR:
The Relative Sensitivity is 97.04%, the Relative Specificity is 99.44%, the Overall Agreement is 98.41%.
In summary, The study showed that there is a high coincidence rate between the test-strip and RT-PCR, and have the equivalence on the clinical usage.

Reporter: Wei Lihua Date: 2020.12.16