

Formularz dla podmiotów / Form for organizations

A. Identyfikacja właściwego organu / Identification of the Competent Authority	
1.001 Kod / Code PL/CA01	
1.002 Nazwa w języku miejscowym - po polsku / Name in local language - in Polish Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych	
1.003 Nazwa po angielsku / Name in English The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	
1.004 Kod kraju / Country code PL	1.005 Kod pocztowy i miasto / Postal code and city
1.006 Ulica, nr / Street, no.	1.007 Telefon / Phone +48 22 4921100

Proszę wypełniać tylko pola z białym tłem / Please fill in fields with a white background only

B. Identyfikacja zgłoszenia lub powiadomienia / Identification of notification	
1.008 Data wpływu / Date of notification	1.009 Numer referencyjny / Reference number
1.010 Rodzaj zgłoszenia lub powiadomienia / Notification type	
<input checked="" type="checkbox"/> 1. Pierwsze dla wyrobu / First for device <input type="checkbox"/> 2. Zmiana danych podmiotu / Change of entity details <input type="checkbox"/> 3. Zmiana danych wyrobu / Change of device details	
1.011 W przypadku zmiany dotyczącej podmiotu proszę wskazać dane ulegające zmianie In case of change of entity details please indicate the data being changed	
1.012 Status podmiotu dokonującego niniejszego zgłoszenia lub powiadomienia / Status of the organization making this notification	
<input type="checkbox"/> W - Wytwórcza (Producent) / Manufacturer <input type="checkbox"/> A - Autoryzowany przedstawiciel (Upoważniony przedstawiciel) / Authorized representative <input type="checkbox"/> I - Importer / Importer <input checked="" type="checkbox"/> D - Dystrybutor / Distributor <input type="checkbox"/> Z - Podmiot zestawiający system lub zestaw zabiegowy / Organization assembling system or procedure pack <input type="checkbox"/> S - Podmiot sterylizujący wyrob medyczny, system lub zestaw zabiegowy / Organization sterilizing medical device, system or procedure pack <input type="checkbox"/> O - Świadczeniodawca wykonujący ocenę działania (badanie działania) / Organization carrying out performance evaluation <input type="checkbox"/> L - Laboratorium wytwarzające na swój użytek wyrob IVD / Laboratory produced in home IVD device <input type="checkbox"/> DL - Podmiot wykonujący działalność leczniczą / Entity performing medical activity <input type="checkbox"/> IZ - Instytucja zdrowia publicznego / Health institution <input type="checkbox"/> P - Podmiot, który używa wyrobów do działalności gospodarczej lub zawodowej / Entity that uses products for business or professional activity	

C. Identyfikacja wytwórcy (producenta) / Identification of the manufacturer

1.013 Numer referencyjny / Reference number GA Generic Assays GmbH	1.014 Kod kraju / Country code DE
1.015 Nazwa wytwórcy (producenta), pełna / Name of the manufacturer, in full GA Generic Assays Gm	
1.016 Nazwa wytwórcy (producenta), skrócona / Name of the manufacturer, abbreviated GA Generic Assays Gm	
1.017 Miasto / City Dahlewitz	1.018 Kod pocztowy / Postal code 15827
1.019 Ulica, nr / Street, no. Ludwig - Erhard - Ring 3	1.020 Skrytka pocztowa / PO Box 15827 Dahlewitz/Berlin
Osoba do kontaktu / Contact person	
1.021 Imię i nazwisko / Full name Prof. Dr. Dirk Roggenbuck	1.022 Telefon / Phone
1.023 E-mail info@genericassays.com	1.024 Faks / Fax

D. Identyfikacja autoryzowanego przedstawiciela (upoważnionego przedstawiciela) / Identification of the authorized representative

1.025 Numer referencyjny / Reference number	1.026 Kod kraju / Country code
1.027 Nazwa autoryzowanego przedstawiciela (upoważnionego przedstawiciela), pełna / Name of the authorized representative, in full	
1.028 Nazwa autoryzowanego przedstawiciela (upoważnionego przedstawiciela), skrócona / Name of the authorized representative, abbreviated	
1.029 Miasto / City	1.030 Kod pocztowy / Postal code
1.031 Ulica, nr / Street, no.	1.032 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.033 Imię i nazwisko / Full name	1.034 Telefon / Phone
1.035 E-mail	1.036 Faks / Fax

E. Identyfikacja ... / Identification of the ...

1.037 I - ... importera / ... importer
 D - ... dystrybutora / ... distributor

1.038 Numer referencyjny / Reference number	1.039 Kod kraju / Country code PL
1.040 Nazwa importera lub dystrybutora, pełna / Name of the importer or distributor, in full PBC PHARMA - B.PABIAN, K.BUZGAN, R.CIECIORKO SPÓŁKA JAWNA	
1.041 Nazwa importera lub dystrybutora, skrócona / Name of the importer or distributor, abbreviated PBC PHARMA	
1.042 Miasto / City Zielona Góra	1.043 Kod pocztowy / Postal code 65-068
1.044 Ulica, nr / Street, no. Pod Filarami 1/2	1.045 Skrytka pocztowa / PO Box
Osoba do kontaktu / Contact person	
1.046 Imię i nazwisko / Full name Bartosz Pabian	1.047 Telefon / Phone 663617229
1.048 E-mail pabus00@gmail.com	1.049 Faks / Fax

F. Identyfikacja ... / Identification of the organization ...

- | |
|---|
| <input type="checkbox"/> Z - ... podmiotu zestawiającego system lub zestaw zabiegowy / ... assembling system or procedure pack |
| <input type="checkbox"/> S - ... podmiotu sterylizującego wyrób medyczny, system lub zestaw zabiegowy / ... sterilizing medical device, system or procedure pack |
| <input type="checkbox"/> O - ... świadczeniodawcy wykonującego ocenę działania (badanie działania) / ... carrying out performance evaluation |
| 1.050 <input type="checkbox"/> L - ... laboratorium wytwarzające na swój użytek wyrób IVD / Laboratory produced in home IVD device |
| <input type="checkbox"/> DL - ... podmiot wykonujący działalność leczniczą / Entity performing medical activity |
| <input type="checkbox"/> IZ - ... instytucja zdrowia publicznego / Health institution |
| <input type="checkbox"/> P - ... podmiot, który używa wyrobów do działalności gospodarczej lub zawodowej / Entity that uses products for business or professional |

1.051 Numer referencyjny / Reference number	1.052 Kod kraju / Country code
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1.053 Nazwa podmiotu, pełna / Name of the organization, in full
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1.054 Nazwa podmiotu, skrócona / Name of the organization, abbreviated

1.055 Miasto / City	1.056 Kod pocztowy / Postal code
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1.057 Ulica, nr / Street, no.	1.058 Skrytka pocztowa / PO Box
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Osoba do kontaktu / Contact person

1.059 Imię i nazwisko / Full name	1.060 Telefon / Phone
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1.061 E-mail	1.062 Faks / Fax
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G. Identyfikacja pełnomocnika działającego w imieniu podmiotu dokonującego zgłoszenia lub powiadomienia

Identification of the person acting as proxy for the organization making this notification

Wypełnia pełnomocnik ustanowiony na mocy art. 33 KPA lub art. 38 ust. 1 ustawy o CEIDG i Punkcie Informacji dla Przedsiębiorcy
To be filled in by person acting as proxy in accordance with art. 33 of the Polish Code of Administrative Procedure or art. 45 par. 1 of CEIDG Act

1.063 Imię i nazwisko / Full name
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Radosław Cieciorko

1.064 Miasto / City	1.065 Kod pocztowy / Postal code
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Szczecin	70 - 100
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1.066 Ulica, nr / Street, no.	1.067 Skrytka pocztowa / PO Box
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J.H.Dąbrowskiego 4/20

1.068 Telefon / Phone	1.069 Faks / Fax
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662044562

H. Liczba wyrobów objętych tym zgłoszeniem lub powiadomieniem / Number of devices covered by this notification

Proszę podać właściwe liczby lub zero, jeśli nie dołączono danego typu formularza
Please provide proper numbers or zero if there are no attached forms of given type

1.070 Liczba dołączonych Załączników nr 2 / Number of attached forms no. 2	0
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1.071 Liczba dołączonych Załączników nr 3 / Number of attached forms no. 3	0
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1.072 Liczba wyrobów wymienionych w dołączonych Załącznikach nr 4 / Number of devices listed in attached forms no. 4	1
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Potwierdzam, że powyższe informacje są poprawne według mojej najlepszej wiedzy.

I affirm that the information given above is correct to the best of my knowledge.

Miasto / City

Szczecin

Data / Date

2021-03-17

Nazwisko / Name

Cieciorko

Podpis / Signature

RADCA PRAWNY
Radosław Cieciorko

Wykaz wyrobów objętych powiadomieniem

List of devices covered by this notification

Proszę wypełnić tylko pola z białym tłem / Please fill in fields with a white background only

A. Identyfikacja powiadomienia / Identification of notification			
4.001 Numer kolejny Załącznika nr 4 w obrębie tego powiadomienia 1	4.002 Numer referencyjny Załącznika nr 1 / Reference number of form no. 1 Ordinal number of form no. 4 within this notification		
B. Wykaz wyrobów / List of devices			
4.003 Nr referencyjny / Ref. no	4.004 Nazwa handlowa wyrobu / Trade name of device 1, 2)	4.005 Kod Basic UDI-DI, jeżeli został nadany / Basic UDI-DI code, if applicable	4.006 Nazwa rodzajowa wyrobu1 / Generic device name 3)
	GA - CoV - 2 Antigen Rapid Test		



INSTRUCTION MANUAL

REF 3985

January 08, 2021

GA CoV-2 Antigen Rapid Test

- 20 determinations -



IVD In-vitro diagnostic device

Rapid immunochromatographic test for the detection of SARS-CoV-2 (COVID-19) Antigen in human nasopharynx specimen

REF	Catalogue number	LOT	Batch code
	Consult accompanying documents		Manufactured by
	Temperature limitation		Use by
	Consult operating instruction		Biological risk
	Number of tests		Do not reuse



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Fax: +49 (0) 33708 – 9286-50

www.genericassays.com

INTENDED USE

GA CoV-2 Antigen Rapid Test is used for the qualitative determination of SARS-CoV-2 (COVID-19) Antigen in human nasopharynx specimen. The test is intended for use by trained clinical laboratory personnel.

Severe acute respiratory syndrome (SARS) is caused by novel coronavirus 2 (SARS-CoV-2, formerly "2019-nCoV"). SARS-CoV-2 is a zoonotic single-stranded RNA virus with positive polarity that belongs to the coronavirus family. It is classified in the beta-coronavirus genus, which also includes SARS-CoV (2003) and MERS-CoV (2012). Of the coronavirus structural proteins envelope, membrane, spike and nucleocapsid, the latter two are the most important immunogens.

Infection with SARS-CoV-2 can lead to a respiratory disease called COVID-19 (Coronavirus Disease 2019). It occurred in humans since late 2019 in Hubei Province, China, and spread rapidly with pandemic proportions around the world.

Patients infected with SARS-CoV-2 may remain asymptomatic or develop only mild upper respiratory symptoms similar to those of a cold or flu. Others develop pneumonia and ARDS requiring intensive care intubation, and may suffer complications that can be fatal. It can take up to 14 days after exposure to SARS-CoV-2 for symptoms to appear. Infected individuals can pass on the infection regardless of clinical symptoms. In addition to testing the genetic material of the virus using the polymerase chain reaction (PCR), the virus can also be detected directly immunologically. A rapid test provides a result after 15 minutes.

The results are used to detect SARS-CoV-2 antigens, which are generally detectable in upper respiratory tract samples during the acute phase of infection. Although positive results indicate the presence of viral antigens, clinical correlation with patient history and other diagnostic information is required to determine infection status. The pathogen detected may not be the definitive cause of current illness for the patient, as positive results with COVID-19 Antigen Rapid Test do not rule out bacterial infection or co-infection with other viruses. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19. Therefore, negative results should be treated as suspected and confirmed with a molecular assay if necessary for patient management.

Zhu N. et al. A Novel Coronavirus from Patients with Pneumonia in China, 2019. *N Engl J Med.* 2020; doi:10.1056/NEJMoa2001017 (2020).

Coman V.M. et al. Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. *Euro Surveill.* https://doi.org/10.2807/1560-7917.ES.2020.25.3.2000045 (2020). WHO pandemic statement, <http://www.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news-room/2020/3/who-announces-covid-19-outbreak-apandemic>. Visited on April 8th, 2020.

Zhang J. et al. Evolving epidemiology and transmission dynamics of coronavirus disease 2019 outside Hubei province, China: a descriptive and modelling study. *The Lancet, Infectious Diseases* DOI:https://doi.org/10.1016/S1473-3099(20)30230-9 (2020)

PRINCIPLE OF THE TEST

The GA CoV-2 Antigen Rapid Test is a rapid immunochromatographic test for the qualitative determination of SARS-CoV-2 antigen.

The SARS-CoV-2 antibody is coated in the area of the test line T. During the test, the sample reacts with the particles coated with SARS-CoV-2 antibodies. This complex migrates through the membrane by capillary action and reacts with the SARS-CoV-2 antibody in the test line region. If the sample contains SARS-CoV-2 antigens, a coloured line appears in the test line region as a result. If the sample contains no antigens against SARS-CoV-2, no coloured line appears in the test line region, indicating a negative result. A second coloured line in the control line region C is used as a procedural control, which appears when the sample volume is applied correctly and the membrane is sufficiently moistened.

TEST COMPONENTS for 20 determinations

Test cassettes, coated with antibodies to SARS-CoV-2 Nucleocapsid (conjugated to microparticles and immobilized at the membrane)	20
Specimen Collection Tubes Filled with extraction buffer	20
Sterile swabs	20

Materials required but not provided

- timer

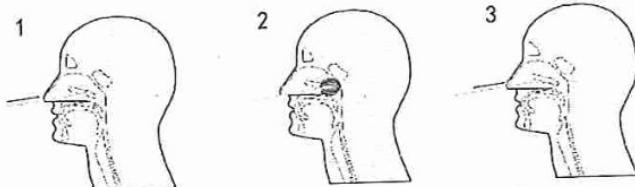
Shelf life and storage

The expiry date of the tests is indicated on the label. Do not use the test after the expiry date.

Until use, store the test at 2-30°C in the sealed packages.

SAMPLE COLLECTION

1. insert a sterile swab into the patient's nostril up to the surface of the posterior nasopharynx.
2. swab over the surface of the posterior nasopharynx.
3. withdraw the sterile swab from the nasal cavity.

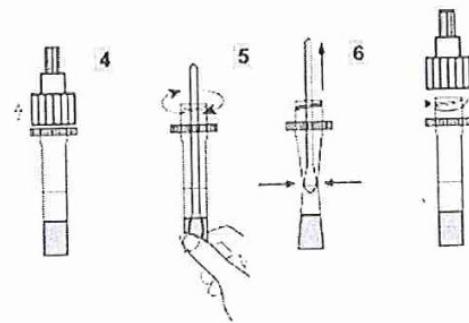


Test swab samples as soon as possible after collection!

If the swabs are not processed immediately, they should be placed in a dry, sterile and tightly closed plastic tube for storage. Based on data generated by the influenza virus, the swab sample was stable up to 8 hours at room temperature and 24 hours at 2-8°C.

SAMPLE PREPARATION

4. unscrew the cap of the sampling tube.
5. insert the swab specimen into the specimen collection tube. Press against the inner wall of the tube and agitate the swab for approximately 10 times while pressing the swab head against the inner wall of the tube to release the antigens in the collection tube.
6. remove the swab while squeezing the sides of the tube to extract the liquid from the swab

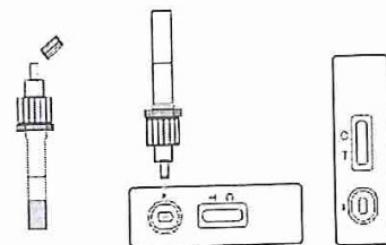


After extraction the samples are stable for 1 h at room temperature or 24 hours at 2-8°C.

ASSAY PROCEDURE

If stored in a cool place, bring the test cassette to room temperature (15-30°C) before performing the test.

1. Remove the test device from the sealed pouch and use it within one hour. For best results, perform the test immediately after opening the pouch.
2. invert the sample collection tube and add 2 drops of the extracted sample into the sample well (S) and then start the timer.
3. wait until the coloured line(s) appear(s). Read the result after 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

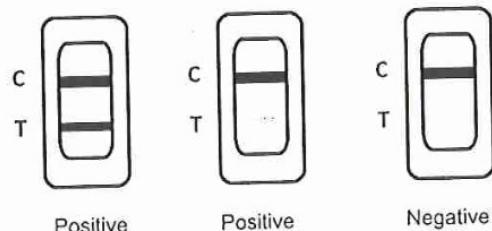
In the result window, a colour band appears as a control line at position C if the test has run correctly. A colour band appears at position T if the viral antigen is detected.

Positive:

2 visible lines appear in the result window. The line in the region T indicates the presence of the CoV-2 antigen in the sample. The colour intensity in the test line region (T) varies depending on the amount of antigen present in the sample. Therefore, any shade of colour in the test line region (T) should be considered positive.

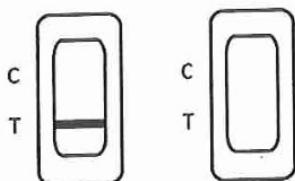
Negative:

Only one coloured line appears in the control region C. There is no coloured line in the test line region T.



Invalid result

The colour line in region C does not appear. Insufficient sample volume or incorrect test performance are possible causes for the control line not appearing. Check the procedure and repeat the test with a new cassette.



Internal Quality control

A coloured line that appears in the control region (C) is an internal positive procedural control. It confirms sufficient sample volume and correct process engineering. A clear background is an internal negative procedural control. If the test works properly, the background in the result area should be white to light pink and should not affect the readability of the test result.

External Quality control

Control materials are not included in this kit. However, in accordance with Good Laboratory Practice (GLP), positive/negative controls are recommended.

Limitations of Method

1. The test procedure and the interpretation of the test result must be carried out exactly according to the test instructions. Proper specimen collection is critical for optimal test performance. Failure to follow the procedure can lead to inaccurate results.
2. The performance of the GA CoV-2 Antigen Rapid Test has been evaluated using only the procedures described in this package insert. Changes to these procedures may alter the performance of the test. The result may be affected by Viral Transport Media (VTM). Extracted specimens for PCR testing cannot be used for testing.
3. The GA CoV-2 Antigen Rapid Test is intended for in vitro diagnostic use only. This test should be used to detect SARS-CoV-2 antigens in human nasopharyngeal specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with the clinical presentation and results of other laboratory tests. This qualitative test cannot determine the quantitative value or rate of increase of SARS-CoV-2 antigen concentration.
4. The GA CoV-2 Antigen Rapid Test only indicates the presence of SARS-CoV-2 antigens in the specimen and should not be used as the sole criterion for the diagnosis of SARS-CoV-2 infection.
5. Results obtained with the test should be considered in conjunction with other clinical findings from other laboratory tests and evaluations.
6. If the test result is negative or non-reactive and clinical symptoms persist, it is recommended that the patient be re-sampled and re-tested a few days later or checked with a molecular diagnostic test to rule out infection in these individuals.
7. The test will show negative results under the following conditions: The titre of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
8. Negative results do not exclude infection with SARS-CoV-2, especially in persons who have been in contact with the virus. Follow-up testing with molecular diagnostics should be considered to rule out infection in these individuals.
9. Blood or excess mucus on the swab sample may interfere with the test performance and lead to a false positive result.
10. The accuracy of the test depends on the quality of the swab sample. False negative results may result from improper specimen collection or storage.
11. Positive results of COVID-19 may be due to infection with non-SARS CoV-2 coronavirus strains or other interference factors.

ASSAY PERFORMANCE

Detection limit

The limit of detection (LOD) of the GA CoV-2 Antigen Rapid Test is 100 pg/mL recombinant SARS-CoV-2 nucleocapsid protein.

Comparison with Reference method

The GA CoV-2 Antigen Rapid Test was compared with results of the RT-PCR reference method using nasal swab samples from patients. The samples were considered positive if RT-PCR showed a positive result. Samples were considered negative if RT-PCR showed a negative result.

	RT-PCR		Total
	Positive	Negative	
GA CoV-2 Antigen Rapid	Positive	99	4
	Negative	3	496
Total		102	500
		602	

Days after onset of symptoms	No. of samples	PCR positive	GA CoV-2 Rapid positive
≤3	20	20	19/20 = 95.0%
4 - 7	43	43	42/43 = 97.7%
8 - 14	25	25	24/25 = 96.0%
> 14	14	14	14/14 = 100.0%
Total	102	102	99/102=97.1%
			95% CI: (91.64% ~ 99.39%)

Relative Sensitivity	97.059%; 95% CI: (91.645% - 99.389%)
Relative Specificity	99.200%; 95%CI: (97.964% - 99.782%)
Agreement	0.981; 95%CI: (0.967 - 0.991)

The cycle threshold value (Ct) in PCR describes the number of cycles performed after which a positive signal is detected. The later the positive signal is detected (i.e. the larger the Ct value), the less viral RNA was contained in the sample. The following table shows the positive agreement of the GA CoV-2 Antigen Rapid Test with the PCR as a function of the Ct value.

GA CoV-2 Antigen Rapid	RT-PCR positive	
	Ct < 35	Ct ≥ 35
Positive	70	29
Negative	0	3
Total	70	32

Cross reactivity

The following organisms were tested and all were found negative using the GA CoV-2 Antigen Rapid Test:

Human coronavirus 229E	Human Metapneumovirus
Human coronavirus HKU1	Human RSV
Human coronavirus OC43	Human Enterovirus
Human coronavirus NL63	Human Rhinovirus
MERS-CoV	Adenovirus
Influenza A H1N1 (2009) virus	Avian influenza virus H7N9
Influenza A H3N2 virus	Staphylococcus aureus
Seasonal Influenza A H1N1	Mycoplasma pneumoniae
Influenza B virus (Victoria line)	Neisseria meningitidis
Influenza B virus (Yamagata series)	Streptococcus pneumoniae
Parainfluenza virus	

Interfering substances

The following substances were tested with the GA CoV-2 Antigen Rapid and no interference was observed.

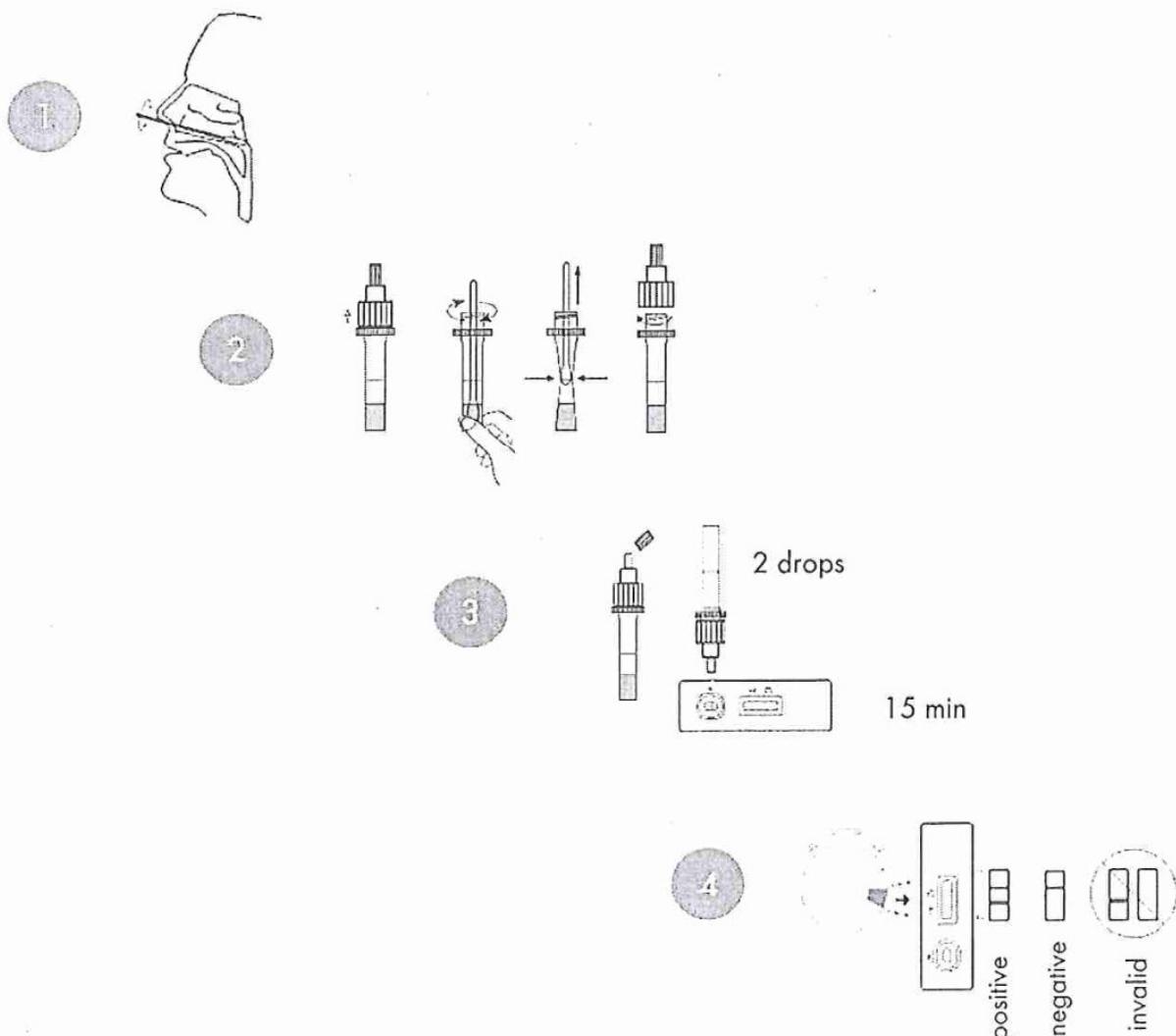
Substance	Concentration
Aspirin	300 µg/l
Ascorbic Acid	200 mg/l
Ibuprofen	2 mg/l
Bilirubin	600 mg/l
Chloramphenicol	30 µg/l

SAFETY PRECAUTIONS

- This reagent kit is for in vitro use only and must be performed by trained laboratory personnel. The working instructions must be strictly followed.
- The test kit should only be used within the specified shelf life.
- Samples and contaminated material must be treated as potentially infectious and disposed of accordingly.
- Since the kit contains potentially hazardous materials, the following precautions should be observed:
 - Do not smoke, eat or drink while handling kit material,
 - Always use protective gloves,
 - Never pipette material by mouth,
 - Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.

GA CoV-2 Antigen Rapid Test

TEST PROCEDURE





**Declaration of Conformity -
Assays
(according DIN EN ISO/IEC 17050-1)**

Document:	LI-4.2.3-3
Version:	09
Valid from:	15.01.2021
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Wir; **GA Generic Assays GmbH, Ludwig-Erhard-Ring 3, 15827 Dahlewitz, Deutschland;** erklären in alleiniger Verantwortung, dass das Medizinprodukt für die In-vitro Diagnostik

GA CoV-2 Antigen Rapid Test (REF: 3985); EDMA: 15-04-80-90-00

allen Anforderungen der Richtlinie 98/79/EG entsprechen. Das Konformitätsbewertungsverfahren wurde nach Annex III Absatz 2 durchgeführt. Die folgenden wichtigsten normativen Anforderungen sind, soweit anwendbar, implementiert.

We; **GA Generic Assays GmbH, Ludwig-Erhard-Ring 3, 15827 Dahlewitz, Germany;** declare under our sole responsibility that the medical device for in vitro diagnostics

GA CoV-2 Antigen Rapid Test (REF: 3985); EDMA: 15-04-80-90-00

comply with all requirements of Directive 98/79/EC. The conformity assessment procedure was carried out according to Annex III, paragraph 2. The following main normative requirements are implemented where applicable.

Anwendbare Normen Applicable Standards Normes applicables Normas vigentes Norme vigenti Применимые стандарты	Titel Title Título Título Titolo титул
DIN EN ISO 13485:2016	Medizinprodukte – Qualitätsmanagementsysteme – Anforderungen für regulatorische Zwecke Medical devices - Quality management systems – Requirements for regulatory purposes
DIN EN 13612:2002	Leistungsbewertung von In-vitro-Diagnostika Performance evaluation of in vitro diagnostic medical devices
DIN EN ISO 14971:2019	Medizinprodukte – Anwendung des Risikomanagements auf Medizinprodukte Medical devices – Application of risk management to medical devices
DIN EN ISO 15223-1:2017	Medizinprodukte – Bei Aufschriften von Medizinprodukten zu verwendende Symbole, Kennzeichnung und zu liefernde Informationen – Teil 1: Allgemeine Anforderungen Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
DIN EN ISO 17511:2003	In-vitro Diagnostika – Messung von Größen in Proben biologischen Ursprungs – Metrologische Rückführbarkeit von Werten, die Kalibriermaterialien und Kontrollmaterialien zugeordnet sind In vitro diagnostic medical devices - Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control materials
DIN EN ISO 18113-1:2013	In-vitro-Diagnostika – Bereitstellung von Informationen durch den Hersteller – Teil 1: Begriffe und allgemeine Anforderungen In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements



**Declaration of Conformity -
Assays
(according DIN EN ISO/IEC 17050-1)**

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DIN EN ISO 18113-2:2013	In-vitro-Diagnostika – Bereitstellung von Informationen durch den Hersteller – Teil 2: In-vitro-diagnostische Reagenzien für den Gebrauch durch Fachpersonal In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
DIN EN ISO 18113-3:2013	In-vitro-Diagnostika – Bereitstellung von Informationen durch den Hersteller – Teil 3: Geräte für in-vitro-diagnostische Untersuchungen zum Gebrauch durch Fachpersonal In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use
DIN EN ISO 23640	In-vitro-Diagnostika – Haltbarkeitsprüfung von Reagenzien für in-vitro-diagnostische Untersuchungen In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
DIN EN 62366:2008	Medizinprodukte: Anwendung der Gebrauchstauglichkeit auf Medizinprodukte Medical devices: Application of usability engineering to medical devices

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Erstellt von: Abdullah Nasser

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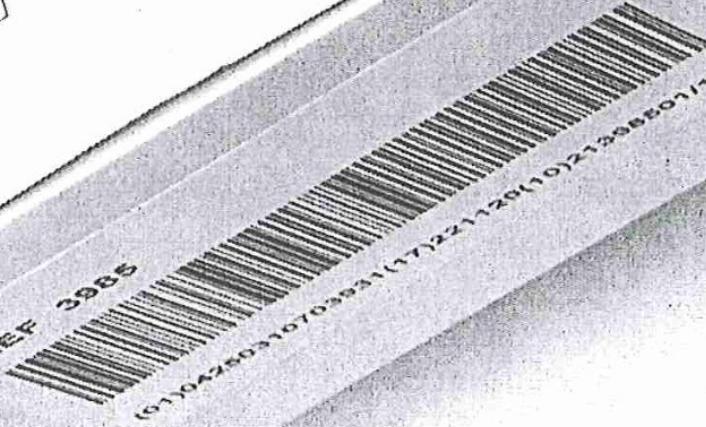
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ppa. Kai Reiser
GA Generic Assays GmbH

2

• 2 Antigen Rapid Test

REF 3985



GA CoV-2 Antigen Rapid Test

Kit	Lot	21 3985 01/1	Σ 20.11.2022
cassette	20x	270908	Σ 20.11.2022
Buffer	0.35 ml	20x 21010757	Σ 31.01.2023
Sterile swabs	20x		
workstation	1x		
Dropper tip	20x		
Specimen collection tube	20x		
		2°	30°C
IVD	CE	EN	CE



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