EC DECLARATION OF CONFORMITY

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SRN: CN-MF-000038774

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SRN: ES-AR000000293

No.	Cat. No.	Product Name	Classification	EMDN Code	GMDN Code	Intended Purpose
1	C011-3002	Procalcitonin (PCT) Rapid Test (Serum/Plasma)	Other	W0102 069013	58305	The Procalcitonin (PCT) Rapid Test (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Procalcitonin in serum or plasma.
2	C011-4002	Procalcitonin (PCT) Rapid Test (Whole Blood/Serum/Plasma)	Other	W0102 069013	58305	The Procalcitonin (PCT) Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Procalcitonin in whole blood, serum or plasma.
3	COV-N001	SARS-CoV-2 Antigen Test	Other	W0105 090501	64787	The SARS-CoV-2 Antigen Test is a lateral flow immunoassay that allows for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasopharyngeal swab specimens
4	COV-N002	SARS-CoV-2 Antigen Test	Other	W0105 090501	64787	The SARS-CoV-2 Antigen Test is a lateral flow immunoassay that allows for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab specimens.
5	COV-NH002	Coronavirus (SARS-CoV-2) Ag Self Test	Other	W0105 090501	65454	Coronavirus (SARS-CoV-2) Ag Self Test is a lateral flow immunoassay that allows for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in self-collected nasal swab specimen from symptomatic individuals who are suspected of being infected with SARS-CoV-2. For self-testing in vitro diagnostic use.
6	COV-S001	SARS-CoV-2 Antigen Test-Saliva	Other	W0105 090501	64787	The SARS-CoV-2 Antigen Test-Saliva is a lateral flow immunoassay that allows for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human saliva specimens.
7	I013-6002	Giardia Lamblia Rapid Test	Other	W0105	52249	The Giardia Lamblia Rapid Test (Feces) is a

				050208		rapid chromatographic immunoassay for the qualitative detection of Giardia Lamblia antigen in human feces specimen.
8	I014-6002	Cryptosporidium Rapid Test	Other	W0105 050207	52163	The Cryptosporidium Rapid Test (Feces) is a rapid chromatographic immunoassay for the qualitative detection of Cryptosporidium Antigens in human feces.
9	I015-6025	Cryptosporidiumand Giardia LambliaCombo Rapid Test	Other	W0105 050299	47358	The Cryptosporidium and Giardia Lamblia Combo Rapid Test (Feces) is a rapid chromatographic immunoassay for the qualitative detection of Cryptosporidium Antigens and/or Giardia Lamblia in human feces.
10	I018-6002	Clostridium difficile GDH Rapid Test	Other	W0105 011801	50831	The Clostridium difficile GDH Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Clostridium difficile GDH antigen in the human feces specimen.
11	I019-6025B	Clostridium difficile Toxin A+Toxin B Combo Rapid Test	Other	W0105 011802	50831	The Clostridium difficile Toxin A+Toxin B Combo Rapid Test (Feces) is a rapid chromatographic immunoassay for the qualitative detection of Clostridium difficile Toxin A and Toxin B antigens in the human feces specimen.
12	I020-6035B	Clostridium difficile GDH+Toxin A+Toxin B Combo Rapid Test	Other	W0105 011803	50831	The Clostridium difficile GDH+Toxin A+Toxin B Combo Rapid Test (Feces) is a rapid chromatographic immunoassay for the qualitative detection of Clostridium difficile GDH, Toxin A and Toxin B antigens in the human feces specimen.
13	I021-3002	H. pylori Antibody Rapid Test (Serum/Plasma)	Other	W0105 090102	66872	The H. pylori Antibody Rapid Test (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Antibody to H. pylori in serum or plasma.
14	I021-4001	H. pylori Antibody Rapid Test (Whole Blood/Serum/Plasma)	Other	W0105 090102	66872	The H. pylori Antibody Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to H. pylori in whole blood, serum, or plasma to aid in the diagnosis of H. pylori infection.
15	I021-4002	H. pylori Antibody Rapid Test (Whole Blood/Serum/Plasma)	Other	W0105 090102	66872	The H. pylori Antibody Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to H. pylori in human whole blood, serum, or plasma to aid in the diagnosis of H. pylori infection.
16	I021-6001	H. pylori Antigen Rapid Test	Other	W0105 090102	30825	The H.pylori Antigen Rapid Test (Feces) is a rapid chromatographic immunoassay for the qualitative detection of H.pylori antigens in human feces specimens to aid in the diagnosis of H.pylori infection.
17	I021-6002	H. pylori Antigen Rapid Test	Other	W0105 090102	30825	The H. pylori Antigen Rapid Test (Feces) is a rapid chromatographic immunoassay for the qualitative detection of H. pylori antigens in

						human feces specimens to aid in the diagnosis of H. pylori infection.
18	I021-6007	H. pylori Antigen Rapid Test Cup	Other	W0105 090102	30825	The H. pyloriAntigenRapidTestCup (Feces) is a rapid chromatographic immunoassay for the qualitative detection of H. pyloriantigenshuman fecesto aid in the diagnosis of H. pyloriinfection.
19	I038-4002	Leptospira IgG/IgM Rapid Test	Other	W0105 011704	63726	The Leptospira IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Leptospira interrogans in human's whole blood, serum or plasma.
20	I047-1002	Streptococcus pneumoniae Antigen Rapid Test	Other	W0105 090109	51770	The Streptococcus pneumoniae Antigen Rapid Test (Urine) is a rapid chromatographic immunoassay for the qualitative detection of Streptococcus pneumoniae antigens in human urine specimen.
21	I048-4025	Mycoplasma Pneumoniae IgG/IgM Combo Rapid Test	Other	W0105 010802	65221	The Mycoplasma pneumoniae IgG/IgM Combo Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Mycoplasma pneumoniae in whole blood, serum, or plasma to aid in the diagnosis of Mycoplasma pneumoniae infection.
22	I048-5002	Mycoplasma pneumoniae Antigen Rapid Test	Other	W0105 010801	51221	Mycoplasma pneumoniae Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Mycoplasma pneumoniae (M. pneumoniae) antigens in human throat swabs. It is intended to aid in the rapid differential diagnosis of Mycoplasma pneumoniae infections.
23	I050-5002	Adenovirus pneumoniae Antigen Rapid Test	Other	W0105 040601	49856	The Adenovirus pneumoniae Antigen Rapid Test (Swab) is a rapid chromatographic immunoassay for the qualitative detection of Adenovirus antigen in eye conjunctive swab, throat swab and nasopharyngeal swab as an aid in the diagnosis of adenovirus infections.
24	I051-5001	Influenza A+B Rapid Test	Other	W0105 099004	49119	The Influenza A+B Rapid Test (Swab/Nasal Aspirate) is a rapid chromatographic immunoassay for the qualitative detection of influenza A and B antigens in nasopharyngeal swab, throat swab or nasal aspirate specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.
25	I051-5002	Influenza A+B Rapid Test	Other	W0105 099004	49119	The Influenza A+B Rapid Test (Swab/Nasal Aspirate) is a rapid chromatographic immunoassay for the qualitative detection of influenza A and B antigens in nasopharyngeal swab, throat swab or nasal aspirate

						specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.
26	I052-5001	Influenza A Rapid Test	Other	W0105 099004	49119	The Influenza A Rapid Test is an in vitro diagnostic test for the qualitative detection of influenza type A nucleoprotein antigens in nasopharyngeal swab, throat swab or nasal aspirate samples, using the rapid immunochromatographic method.
27	I052-5002	Influenza A Rapid Test	Other	W0105 099004	49119	The Influenza A Rapid Test is an in vitro diagnostic test for the qualitative detection of influenza type A nucleoprotein antigens in nasopharyngeal swab, throat swab or nasal aspirate samples, using the rapid immunochromatographic method.
28	I073-1002	Legionella pneumophila Rapid Test	Other	W0105 090108	51054	Legionella pneumophila Rapid Test (Urine) is an in vitro diagnostic test based on immunochromatographic assay. It is designed for detection of soluble antigen from Legionella pneumophila serogroup 1 in human urine specimen.
29	I074-4002	Mycoplasma Pneumoniae IgM Rapid Test	Other	W0105 010802	65851	The Mycoplasma pneumoniae IgM Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgM antibody to Mycoplasma pneumoniae in whole blood, serum, or plasma to aid in the diagnosis of Mycoplasma pneumoniae infection.
30	I080-4002	Cryptococcus Antigen Rapid Test	Other	W0105 060303	65815	The Cryptococcus Antigen Rapid Test (Whole Blood/Serum/Plasma/Cerebral Spinal Fluid (CSF)) is a rapid chromatographic immunoassay for the qualitative detection of the capsular polysaccharide antigen of Cryptococcus species complex (Cryptococcus neoformans and Cryptococcus gattii) in whole blood, serum, plasma or cerebral spinal fluid (CSF) to aid in the diagnosis of cryptococcosis.
31	I091-4001	HBsAg Rapid Test	List A	W0105 090201	48322	The HBsAgRapid Test is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Surface Antigen in whole blood, serum or plasma.
32	I091-4002	HBsAg Rapid Test	List A	W0105 090201	48322	The HBsAg Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Surface Antigen in whole blood, serum or plasma.
33	I092-4001	HBsAb Rapid Test	List A	W0105 020203	48317	The HBsAb Rapid Test(Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Antibody to Hepatitis B Surface Antigen in whole blood, serum or plasma.
34	I092-4002	HBsAb Rapid Test	List A	W0105 020203	48317	The HBsAb Rapid Test (Whole Blood/Serum/Plasma) is a rapid

						chromatographic immunoassay for the qualitative detection of Antibody to Hepatitis B Surface Antigen in whole blood, serum or plasma.
35	I097-4001	HCV Rapid Test	List A	W0105 090202	30829	The HCV Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus in whole blood, serum or plasma.
36	I097-4002	HCV Rapid Test	List A	W0105 090202	30829	The HCV Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus in whole blood, serum or plasma.

Standards applied:

EN ISO 13485, 2016, EN 13612:2002/AC:2002, EN 13641: 2002, EN 13975: 2003, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO18113-1:2011, EN ISO18113-2:2011, EN ISO 23640:2015; EN ISO 17511:2003.

Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We, HANGZHOU TONGZHOU BIOTECHNOLOGY CO., LTD., herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above-mentioned product meet the corresponding national laws and Standards. All supporting documentations are retained at the premises on the manufacturer.

Authorised Signatory: Steve Shao

Name: Steve Shao

Position: General Manager

Date: 2022.5.24

Streptococcus pneumoniae Antigen Rapid Test (Urine)
For professional use

CE IVD REF I047-1002

A rapid test for the qualitative detection of S. pneumoniae Antigens in human urine specimen.
For professional in vitro diagnostic use only.

INTENDED USE

The *Streptococcus pneumoniae* Antigen Rapid Test (Urine) is a rapid chromatographic immunoassay for the qualitative detection of *Streptococcus pneumoniae* antigens in human urine specimen.

SUMMARY

Streptococcus pneumoniae, or pneumococcus, is a Gram-positive, alpha-hemolytic (under aerobic conditions) or beta-hemolytic (under anaerobic conditions), facultative anaerobic member of the genus Streptococcus,[1] As a significant human pathogenic bacterium *S. pneumoniae* was recognized as a major cause of pneumonia in the late 19th century, and is the subject of many humoral immunity studies. *S. pneumoniae* resides asymptomatically in healthy carriers typically colonizing the respiratory tract, sinuses, and nasal cavity. However, in susceptible individuals with weaker immune systems, such as the elderly and young children, the bacterium may become pathogenic and spread to other locations to cause disease. It spreads by direct person-to-person contact via respiratory droplets and by autoinoculation in persons carrying the bacteria in their upper respiratory tract.[2] It can be a cause of neonatal infections.[3] *S. pneumoniae* is the main cause of community acquired pneumonia and meningitis in children and the elderly,[4] and of septicemia in those infected with HIV. The organism also causes many types of pneumococcal infections other than pneumonia. These invasive pneumococcal diseases include bronchitis, rhinitis, otitis media, conjunctivitis, meningitis, sepsis, osteomyelitis, septic arthritis, endocarditis, peritonitis, pericarditis, cellulitis, and brain abscess.[5]

PRINCIPLES

The *Streptococcus pneumoniae* Antigen Rapid Test (Urine) is a qualitative, membrane based immunoassay for the detection of *Streptococcus pneumoniae* in urine specimen. During testing, *Streptococcus pneumoniae (S. pneumoniae)* antigens, if present in the specimen react with *S. pneumoniae* antibody-conjugate in the reagent area. The conjugate-antigens complex thus formed will will bind with Anti- *S. pneumoniae* antibodies coated on the membrane in case of a positive result. This would result in a dark red colored line in T line region in case of a positive result. In case of negative result, no conjugates would bind at Anti-*S. pneumoniae* coated in T line region and no line would form in T line region of the test membrane. The intensity of the lines will vary depending upon the amount of antigen present in the sample. A line in Control region should appear in all correctly performed cases. Absence of C line indicates an invalid test result.

MATERIALS

Materials provided

• Test cassette • Droppers • Package insert

Materials required but not provided

• Timer • Specimen collection containers

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. The used test should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.
7. Caution must be taken at the time of specimen collection. Inadequate volume of specimen may lead to lower sensitivity.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

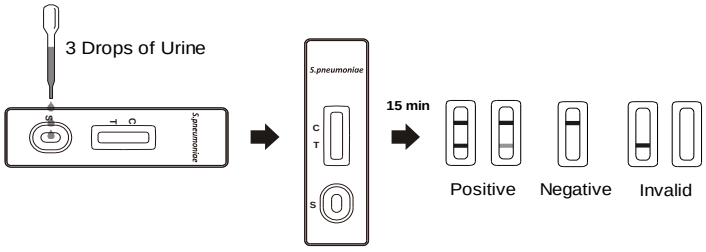
SPECIMEN COLLECTION AND PREPARATION

The *Streptococcus pneumoniae* Antigen Rapid Test (Urine) can be performed using urine. Urine specimens should be collected in standard containers. The sample can be stored at room temperature (15-30 °C) if assayed within 24 hours of collection. Alternatively, specimens may be stored at 2-8 °C for up to 14 days or at -10 °C to -20 °C for longer periods before testing. When necessary, urine specimens should be shipped in leak-proof containers at 2-8 °C or frozen. Allow all specimens to equilibrate to room temperature before testing.

DIRECTIONS FOR USE

Allow the test, specimen and/or controls to reach room temperature (15-30 °C) prior to testing.

1. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the cassette on a clean and level surface.
3. Absorb the urine specimen with a dropper, add **3 full drops** (approx.120 µL) specimen into the sample well of test cassette vertically.
4. Wait for the colored line(s) to appear. **Read results at 15 minutes**. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: * Two colored lines appear. One colored line should be in the control line region (C) and the other colored line should be in the test line region (T). A positive result indicates that *S.pneumoniae* antigens are present in the specimen.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of *S.pneumoniae* antigens present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that *S.pneumoniae* antigen is not present in the specimen, or is present below the detectable level of the test.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The *Streptococcus pneumoniae* Antigen Rapid Test is for *in vitro diagnostic* use only. The test should be used for the detection of *S.pneumoniae* antigens in urine specimens only. Neither the quantitative value nor the rate of increase in *S.pneumoniae* antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of *S.pneumoniae* antigens in the specimen from both viable and non-viable *S.pneumoniae* bacteria.
3. A negative result should be confirmed by culture. A negative result may be obtained, if the concentration of the *S.pneumoniae* antigens present in the urine is not adequate or is below the detectable level of the test.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The performance of the *Streptococcus pneumoniae* Antigen Rapid Test (Urine) has been evaluated with 103 clinical specimens collected from the patient symptomatic and asymptomatic in comparison with other rapid test method. The results show that the relative sensitivity of the *Streptococcus pneumoniae* Antigen Rapid Test (Urine) is 90.0% and the relative specificity is 98.9%.

***Streptococcus pneumoniae* Antigen Rapid Test vs. Other Rapid Test**

Method		Other Rapid Test		Total Results
***Streptococcus pneumoniae* Antigen Rapid Test (Urine)**	**Results**	Positive	Negative	
	Positive	9	1	10
	Negative	1	92	93
Total Results		10	93	103

Relative Sensitivity: 90.0% (95%CI*: 55.5%~99.7%);
Relative Specificity: 98.9% (95%CI*: 94.2%~>99.9%);
Overall Accuracy: 98.1% (95%CI*: 93.2%~99.8%).
*Confidence Intervals

Analytical Sensitivity (Detection Limit)

Streptococcus pneumoniae Antigen Rapid Test (Urine) can detect *S. pneumoniae* antigen as low as 0.25 ng/mL CWPS (Cell Wall Polysaccharides).

Cross-reactivity

Cross-reactivity to urines spiked with the following 1.0 x 10^7 pathogens was tested and found to be negative.

Legionella pneumophila	*Candida albicans*	*Chlamydia*
Helicobacter pylori	*Neisseria gonococcus*	*Clostridium difficile*

Precision

Intra-Assay

Within-run precision has been determined by using 3 replicates of these specimens: negative, 0.25 ng/mL, 1 ng/mL and 5 ng/mL positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same specimens: negative, 0.25 ng/mL, 1 ng/mL and 5 ng/mL positive specimens. Three different lots of the *Streptococcus pneumoniae* Rapid Test (Urine) have been tested using these specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

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INDEX OF SYMBOLS

	Consult instructions for use	Σ	Contains sufficient for <n> tests
IVD	*In vitro* diagnostic medical device		Use-by date
	Temperature limit	LOT	Batch code
	Do not use if package is damaged		Manufacturer
EC REP	Authorized representative in the european community		Do not re-use
REF	Catalogue number		

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EC REP
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Number: M150020600B
Revision date: 2023-08-02

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 120095 0001 Rev. 00

Holder of Certificate: **Hangzhou Tongzhou Biotechnology Co., Ltd.**
Room 102, Building 4, No. 191, Xintian Road, Yunhe Street
Linping District
311103 Hangzhou, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents, Control Material and Instruments for Clinical Chemistry, Immunochemistry (Immunology) and Infectious Diseases, including Professional Laboratory Use, Near Patient and Self Testing**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 120095 0001 Rev. 00

Report No.: SH23211001

Valid from: 2023-07-20
Valid until: 2026-07-19

Date, 2023-07-21

Christoph Dicks
Head of Certification/Notified Body

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 120095 0001 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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See Scope of Certificate

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