

**WHO Prequalification of In Vitro Diagnostics
PUBLIC ASSESSMENT REPORT**

**Product: Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)
WHO reference number: PQDx 12343-021-00**

The Flowflex SARS - CoV - 2 Antigen Rapid Test (Self - Testing), with product codes L031-13025, L031-13035, L031-13045, L031-13055, L031-13065, L031-13075, L031-13085, and L031-13095, manufactured by ACON Biotech (Hangzhou) Co., Ltd., Rest-of-World regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 15 December 2025.

**Summary of the WHO Prequalification Assessment for the Flowflex
SARS-CoV-2 Antigen Rapid Test (Self-Testing)**

	Date	Outcome
Prequalification listing	15 December 2025	listed
Dossier assessment	4 July 2025	MR
Product performance evaluation	6 May 2024	MR

MR: Meets Requirements

Intended use

According to the intended use claim from ACON Biotech (Hangzhou) Co., Ltd., *“The SARS-CoV-2 Antigen Rapid Test is a lateral flow test for the qualitative detection of the nucleocapsid antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals suspected of COVID-19 within the first seven days of the onset of symptoms. The test can also test specimens from individuals without symptoms. The test may produce a false-positive result if you are infected with SARS-CoV.*

SARS-CoV-2 Antigen Rapid Test is intended to be used for self-testing by untrained lay users in a private setting to aid in the diagnosis of SARS-CoV-2 infection. Children under 14 years should be supervised by an adult.”

Test kit contents

Materials Provided	L031-13025	L031-13035	L031-13045	L031-13055	L031-13065	L031-13075	L031-13085	L031-13095
Test cassette	x 1	x 2	x 3	x 5	x 7	x 10	x 20	x 25
Extraction Buffer Tube	x 1	x 2	x 3	x 5	x 7	x 10	x 20	x 25
Disposable swab (sterile)	x 1	x 2	x 3	x 5	x 7	x 10	x 20	x 25
Waste Bag	x 1	x 2	x 3	x 5	x 7	x 10	x 20	x 25
Tube holder	On the kit box						x 1	x 1
Package Insert	x 1	x 2	x 3	x 5	x 7	x 10	x 1	x 1

Item required but not provided

- Timer

Storage Temperature and Stability

Parameter	Condition
Storage Temperature	2 to 30 °C
Shelf Life (from manufacture) ¹	24 months

Dossier review

The manufacturer submitted a product dossier as per the “Instructions for compilation of a product dossier” (PQDx_018). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The manufacturer's responses to the discrepancies found during dossier screening and assessment findings were accepted on 4 July 2025.

¹ The assigned device shelf-life is based on stability data generated from the date of manufacture. The finished goods shelf-life, calculated from the date of packaging completion, may be shorter depending on the time elapsed between manufacture and final packaging of the device.

Based on the product dossier screening and assessment findings, the product dossier for the Flowflex SARS - CoV - 2 Antigen Rapid Test (Self - Testing) meets WHO prequalification requirements.

Manufacturing site inspection

The inspection of the manufacturing site(s) was conducted to assess whether the manufacturer’s quality management system (QMS) and manufacturing practices are in alignment with:

- (i) applicable international standards, such as ISO 13485 (Medical devices – Quality management systems – Requirements for regulatory purposes);
- (ii) the manufacturer’s own documented procedures and quality requirements; and
- (iii) other relevant international standards and guidelines applicable to in vitro diagnostic (IVD) medical devices. The WHO’s Public Inspection Reports are accessible at:

<https://extranet.who.int/pqweb/vitro-diagnostics/who-public-inspection-reports>

Product performance evaluation

Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing) was evaluated by the National Serology Reference Laboratory (NRL), Australia, on behalf of WHO in the first quarter of 2025, according to protocol IVD/PR/4/P27, version 1.1.

Analytical performance evaluation

Analytical performance characteristics	
Limit of detection	Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing) detected 20 of 20 specimens at concentration 667 IU/mL. The LoD claimed by the manufacturer (667 IU/mL) was verified.
Variants of concern	All variants of concerns tested (Wild-type (beta lineage), Delta VOC (B.1.617.2), Omicron VOC (BA.2.75), Omicron VOC (XBB)) were detected.
Lot-to-lot variation	Among the 105 specimens tested on each lot, 55 were detected on lot A and 57 were detected on lot B. No significant lot-to-lot variation was detected.
Invalid tests	0/211 (0%).

	One specimen had red background obscuring the test lines, rendering the test uninterpretable and the specimen was retested.
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Operational characteristics and ease of use

This test does not require laboratory equipment and can be performed in laboratories with limited facilities or in non-laboratory settings.

The test was found easy to use by the operators performing the evaluation. However, red background was reported on 17 test devices (8.1%), rendering one of them uninterpretable.

Key operational characteristics	
Validated specimen type(s) and volume	Human anterior nasal swab specimen Specimen volume is not specified
Number of steps*	4 steps in total for self-testing 0 steps with precision pipetting for self-testing
Time to result	15 minutes
Endpoint stability (interval)	15 minutes (The IFU states to read at 15 minutes and no later than 30 minutes)
Internal QC	Yes – reagent addition control

** Definition: each action required to obtain a result (excluding specimen collection, device preparation – opening the pouch), e.g. for RDTs: add specimen, add buffer (2 steps).*

Based on these results, the performance evaluation for Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing) meets the WHO prequalification requirements.

Labelling review

The labelling submitted for Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing) was reviewed by WHO staff and external technical experts appointed by WHO. The review evaluated the labelling for clarity and consistency with the information submitted in the product dossier, alignment with international guidance and standards, and suitability for the intended users and settings in WHO Member States, including low- and middle-income countries.

The table below provides traceability of the labelling documents reviewed during the assessment, including document titles, version numbers, approval dates, and control identifiers.

Controlled Labelling References

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Outer box artwork	Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-1T (L031-13025)	Version 02	2026-01-23	1130592802
	Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-2T (L031-13035)	Version 02	2026-01-23	1130592902
	Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-3T (L031-13045)	Version 02	2026-01-23	1130593002
	Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-5T (L031-13055)	Version 02	2026-01-23	1130593102
	Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-7T (L031-13065)	Version 02	2026-01-23	1130593202
	Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-10T (L031-13075)	Version 02	2026-01-23	1130593302
	Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-20T (L031-13085)	Version 02	2026-01-23	1130593402
	Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-25T (L031-13095)	Version 02	2026-01-23	1130593502
Pouch / Device label	Flowflex SARS-CoV-2 Ag Self-Testing Cassette Pouch (WPQ)	Version 02	2023-04-14	1120116802

Reagent bottle labels	Extraction Buffer Tube bag ink-printing-Bio	Version 01	2023-04-28	PCA11277-01
Accessory labels	Nasal swab CF-075-P3B	Version 06	2025-11-13	1030068206
	Nasal swab G-015	Version 01	2021-08-04	1030070101
	Waste bag	Version 01	2021-03-26	1200006901
Instructions for Use (IFU)	Flowflex SARS-CoV-2 Ag Self-Testing Package Insert (WPQ, En)	Version 02	2026-01-23	1151445102

Labels

Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-1T (L031-13025), Rev. A

COVID-19 Test
A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specimens.
Only for use outside the body (for in vitro diagnostic use only). For self-testing.

SARS-CoV-2 Antigen Rapid Test
(Self-Testing)



1130592802

1 Test

FlowflexTM

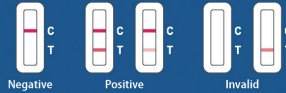


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INSTRUCTION VIDEO

Results Interpretation:



SARS-CoV-2 Antigen Rapid Test (Self-Testing)

- Contents:
- 1 Test Cassette
 - 1 Extraction Buffer Tube
 - 1 Disposable Swab
 - 1 Waste Bag
 - Package Insert



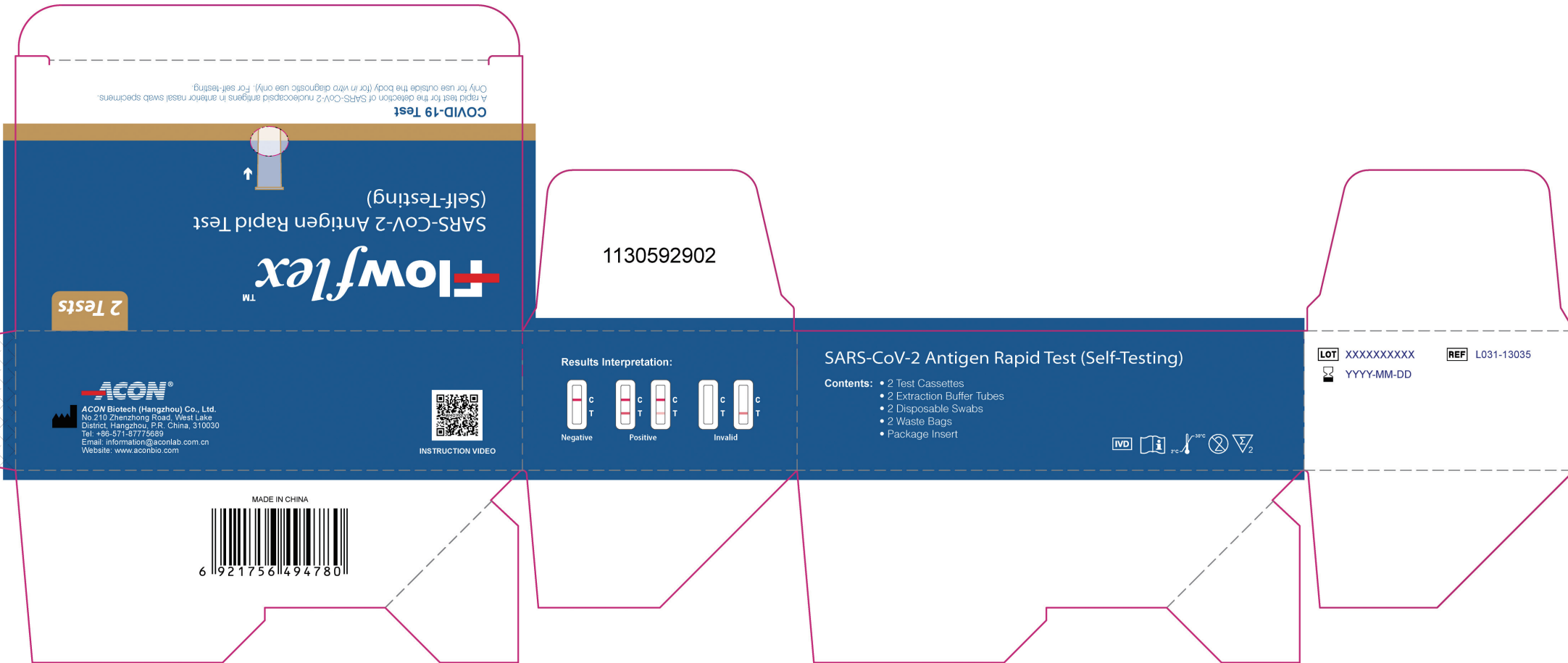
LOT XXXXXXXXX
YYYY-MM-DD

REF L031-13025

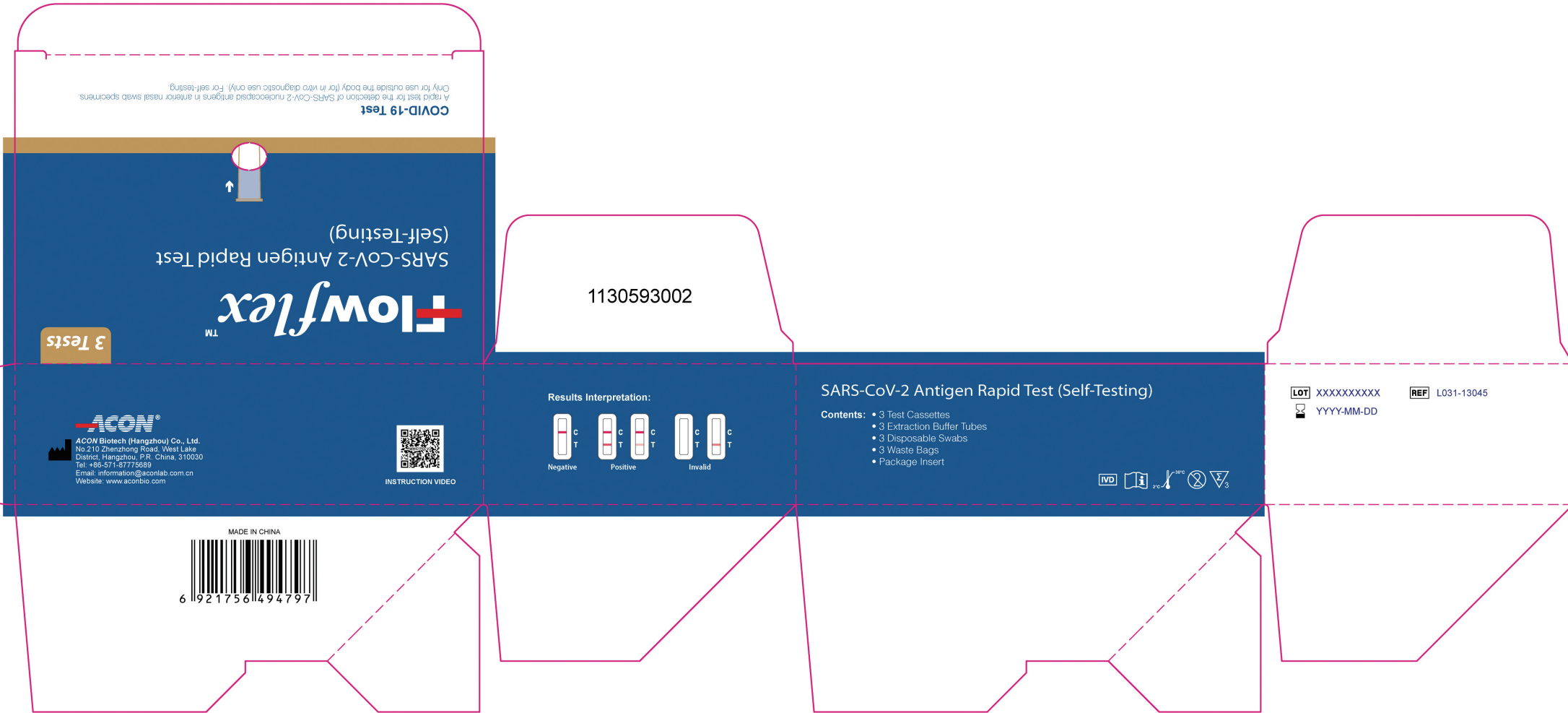
MADE IN CHINA



Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-2T (L031-13035), Rev. A



Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-3T (L031-13045), Rev. A



Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-5T (L031-13055), Rev. A

COVID-19 Test
 A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal specimens.
 Only for use outside the body (for in vitro diagnostic use only). For self-testing.

SARS-CoV-2 Antigen Rapid Test (Self-Testing)

FlowflexTM

5 Tests

1130593102

FlowflexTM SARS-CoV-2 Antigen Rapid Test (Self-Testing)

FlowflexTM SARS-CoV-2 Antigen Rapid Test (Self-Testing)

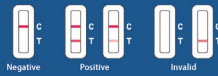
LOT XXXXXXXXXX REF L031-13055
 YYYY-MM-DD

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 Website: www.aconbio.com



INSTRUCTION VIDEO

Results Interpretation:



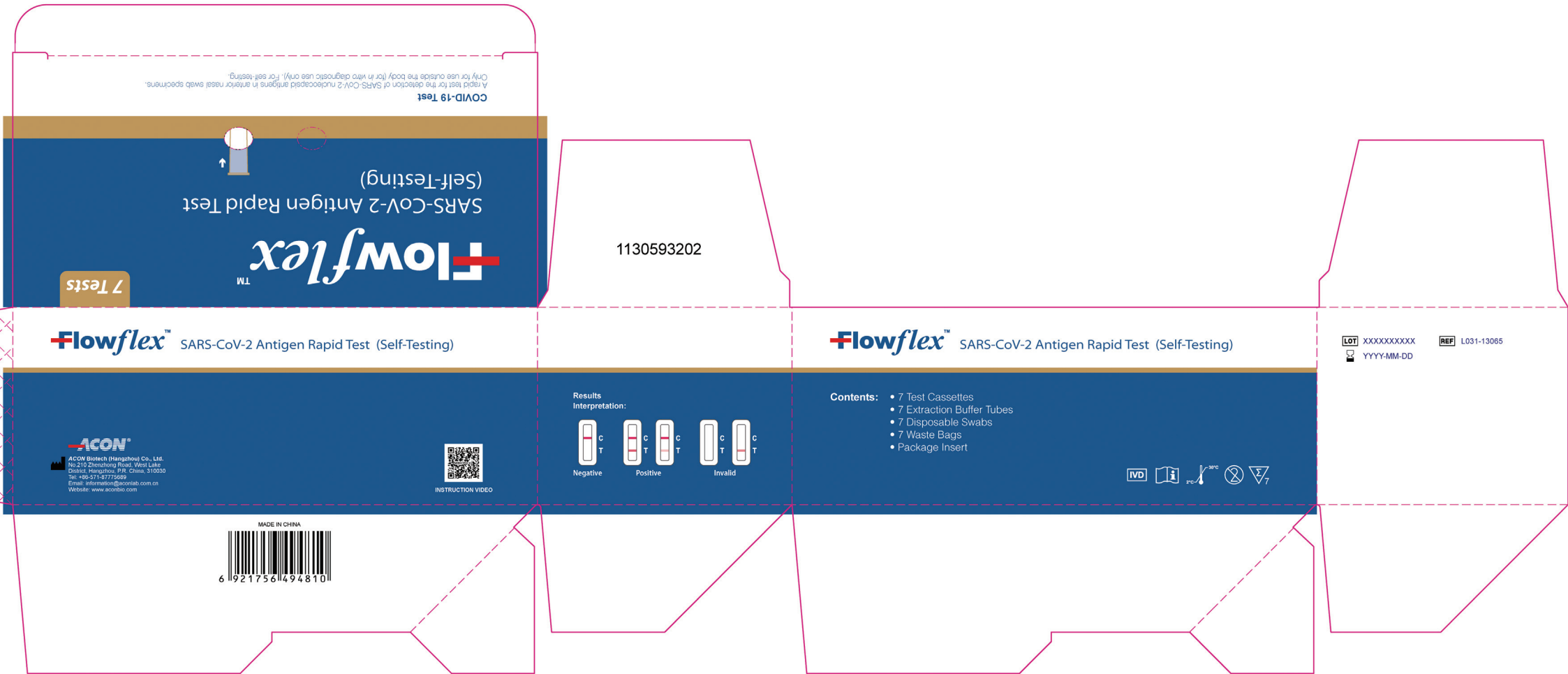
- Contents:
- 5 Test Cassettes
 - 5 Extraction Buffer Tubes
 - 5 Disposable Swabs
 - 5 Waste Bags
 - Package Insert



MADE IN CHINA



Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-7T (L031-13065), Rev. A



COVID-19 Test
A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specimens.
Only for use outside the body (for in vitro diagnostic use only). For self-testing.

7 Tests
FlowflexTM
SARS-CoV-2 Antigen Rapid Test (Self-Testing)

1130593202

FlowflexTM SARS-CoV-2 Antigen Rapid Test (Self-Testing)

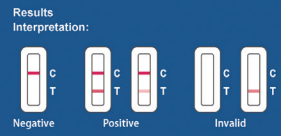
FlowflexTM SARS-CoV-2 Antigen Rapid Test (Self-Testing)

LOT XXXXXXXXX REF L031-13065
YYYY-MM-DD

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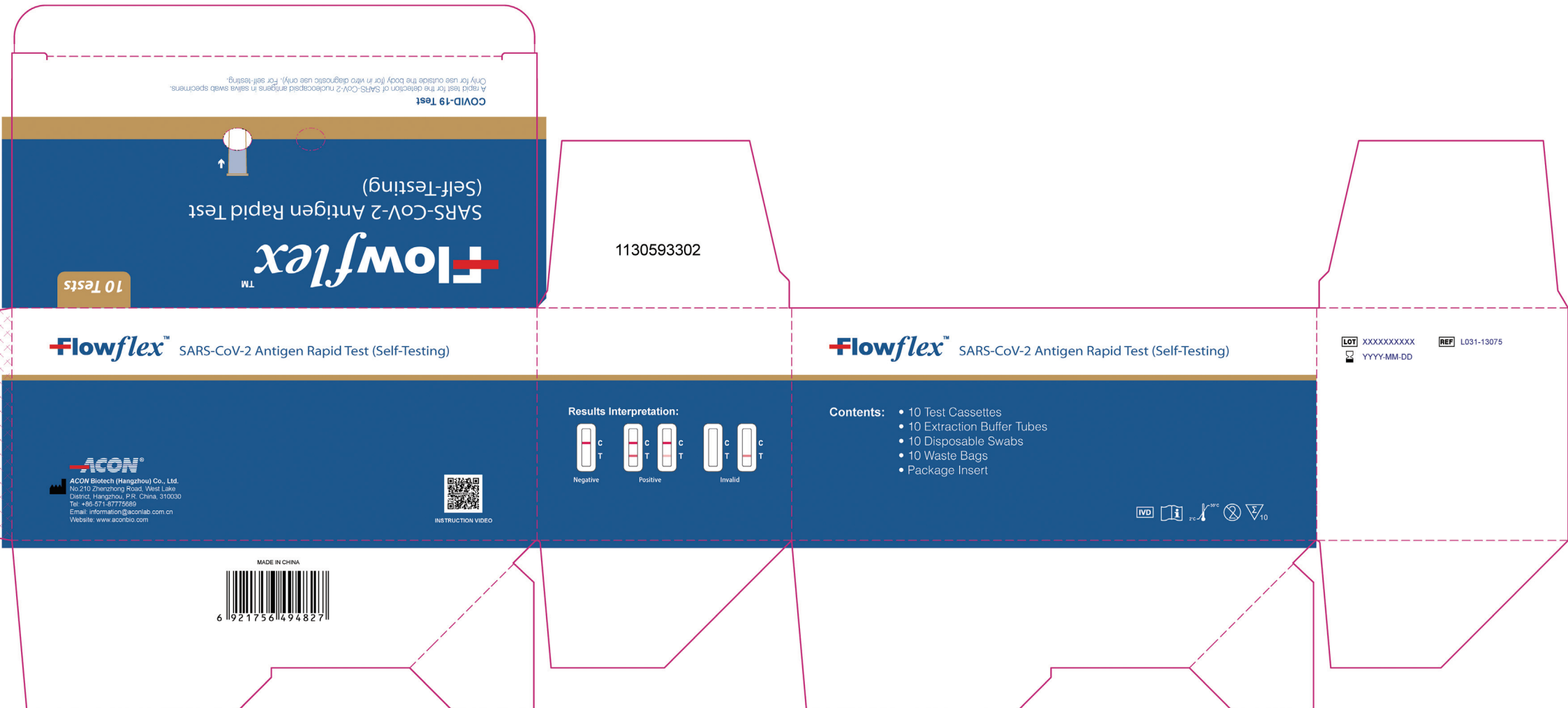
INSTRUCTION VIDEO



- Contents:
- 7 Test Cassettes
 - 7 Extraction Buffer Tubes
 - 7 Disposable Swabs
 - 7 Waste Bags
 - Package Insert



Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-10T (L031-13075), Rev. A



COVID-19 Test
A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in saliva swab specimens.
Only for use outside the body (for in vitro diagnostic use only). For self-testing.

SARS-CoV-2 Antigen Rapid Test (Self-Testing)

FlowflexTM

10 Tests

1130593302

FlowflexTM SARS-CoV-2 Antigen Rapid Test (Self-Testing)

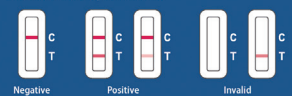
FlowflexTM SARS-CoV-2 Antigen Rapid Test (Self-Testing)

LOT XXXXXXXXXX REF L031-13075
YYYY-MM-DD

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Results Interpretation:

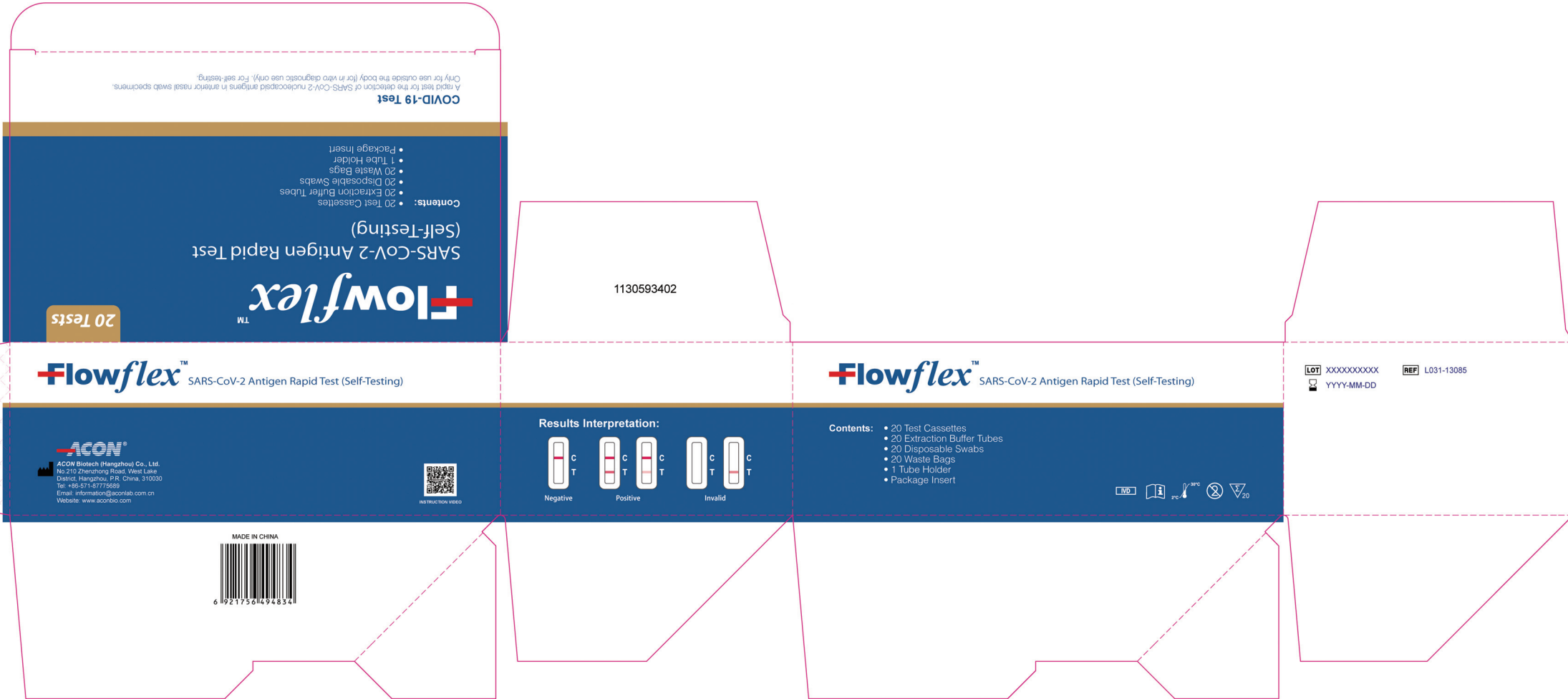


- Contents:
- 10 Test Cassettes
 - 10 Extraction Buffer Tubes
 - 10 Disposable Swabs
 - 10 Waste Bags
 - Package Insert



MADE IN CHINA
6 921756 149482 7

Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-20T (L031-13085), Rev. A



Flowflex SARS-CoV-2 Ag Self-Testing kit box (WPQ)-25T (L031-13095), Rev. A

A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specimens. Only for use outside the body (for in vitro diagnostic use only). For self-testing.

COVID-19 Test

- Contents:**
- 25 Test Cassettes
 - 25 Extraction Buffer Tubes
 - 25 Disposable Swabs
 - 25 Waste Bags
 - 1 Tube Holder
 - Package Insert

SARS-CoV-2 Antigen Rapid Test (Self-Testing)

Flowflex™

25 Tests

1130593502

Flowflex™

SARS-CoV-2 Antigen Rapid Test (Self-Testing)

Flowflex™

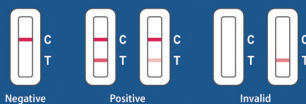
SARS-CoV-2 Antigen Rapid Test (Self-Testing)

LOT XXXXXXXXXX REF L031-13095
 YYMM-DD

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 Website: www.aconbio.com



Results Interpretation:



- Contents:**
- 25 Test Cassettes
 - 25 Extraction Buffer Tubes
 - 25 Disposable Swabs
 - 25 Waste Bags
 - 1 Tube Holder
 - Package Insert

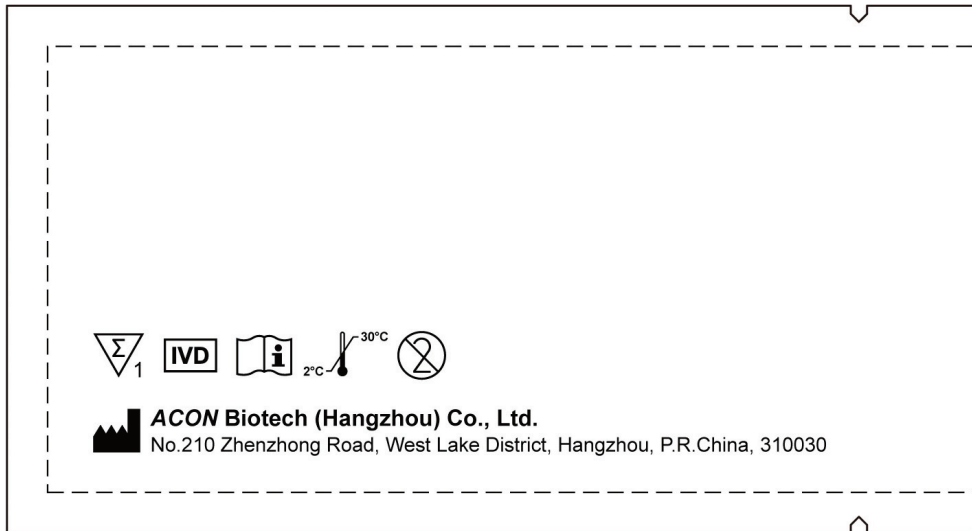


MADE IN CHINA



6 921756 494841

Flowflex SARS-CoV-2 Ag Self-Testing Cassette Pouch (WPQ)



Document No.: 1120116802



Extraction Buffer Tube bag ink-printing-Bio

Extraction Buffer Tubes



LOT XXXXXXXXXX  YYYY-MM-DD

ACON Biotech (Hangzhou) Co., Ltd.

PCA11277-01

PEEL HERE

Disposable swabs

CF 075-P 3 B

STERILE

EO

Nasal Swab



MD



- 1. Single use only.
- 2. There is a risk of cross-infection if re-use
- 3. Do not use if package is damaged

EU REP

Name: Lins Service & Consulting GmbH
 Add: Hemigstrasse 26, 67059
 Ludwigshafen, Germany
 E-mail: info@lins-service.com

CE 0197

UDI



(01)XXXXXXXXXXXXXXXXXXXX
 (11)XXXXXXXX
 (17)XXXXXXXX
 (10)XXXXXXXXXXXXXXXXXXXX

LOT

XXXXXXXXXXXX



XXXXXXXXXXXX



XXXXXXXXXXXX



Jiangsu Changfeng Medical
 Industry Co., Ltd.
 Touqiao Town, Guangling
 District, Yangzhou,
 Jiangsu 225109 China








← OPEN

Disposable sampling swab (Nasal Swab)

Jiangsu HanHeng Medical Technology Co., Ltd.
 #118 Xinyuan 3rd Road, Xinbei District,
 Changzhou, 213031 Jiangsu P.R. China

IPC

EC REP Luxus Lebenswelt GmbH
 Kochstr.1, 47877, Willich, Germany

STERILE EO

1. Disposable product, do not reuse.
 2. Please read the IFU carefully before use.
 3. Don't use if the pouch or the product is damaged.

CE 0197

Type: G-015

LOT XXXXXXXX

YYYYMMDD

YYYYMMDD

Waste bag

Document No.: 1200006901



Instructions for Use²

² English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

Flowflex™ SARS-CoV-2 Antigen Rapid Test (Self-Testing) Package Insert

REF L031-13025	REF L031-13035	REF L031-13045	REF L031-13055	English
REF L031-13065	REF L031-13075	REF L031-13085	REF L031-13095	

Only for use outside the body (for *in vitro* diagnostic use only). For self-testing. Carefully read the instructions before performing the test.

Materials Provided	Test Kit Configuration							
	L031-13025	L031-13035	L031-13045	L031-13055	L031-13065	L031-13075	L031-13085	L031-13095
Test Cassette	x 1	x 2	x 3	x 5	x 7	x 10	x 20	x 25
Extraction Buffer Tube	x 1	x 2	x 3	x 5	x 7	x 10	x 20	x 25
Disposable Swab (sterile)	x 1	x 2	x 3	x 5	x 7	x 10	x 20	x 25
Waste Bag	x 1	x 2	x 3	x 5	x 7	x 10	x 20	x 25
Tube Holder	on the kit box						x 1	x 1
Package Insert	x 1	x 1	x 1	x 1	x 1	x 1	x 1	x 1

KIT CONTENTS

Test Cassette with a desiccant in a pouch (Desiccant is to prevent the effects of humidity.)

Extraction Buffer Tube **DO NOT DRINK!**

Disposable Swab

Tube Holder (Only for 20 or 25 tests kit)

Waste Bag

Package Insert

YOU NEED TO PREPARE

Timer
It is needed but not provided in the kit.

INSTRUCTION VIDEO

Scan to learn how to test

PREPARATION (Allow the test cassette and extraction buffer tube to reach room temperature (15-30 °C) prior to testing.)

1. Wash or sanitize your hands. Make sure they are dry before starting the test.
2. Read the instructions before performing the test.
3. Check the expiration date printed on the test cassette pouch, extraction buffer tube and disposable swab bags.
4. Open the test cassette pouch. Place the test cassette on a flat and clean surface. Identify the result window and specimen well on the cassette.

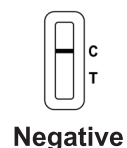
SPECIMEN COLLECTION

A nasal swab specimen can be self-collected by an individual aged 14+ years. Children under 14 years should be supervised by an adult.

TEST PROCEDURE

1. Carefully remove the aluminum foil from the top of extraction buffer tube, avoid spilling.
2. Insert the tube into the hole on the kit box. (Or place the tube in the tube holder.)
3. Open the swab packaging at stick end. **Caution:** Do not touch the absorbent tip of the swab with your hands.
4. Insert the entire absorbent tip of the swab into one nostril. Using gentle rotation, push the swab from the edge of the nostril until resistance is felt (about 2.5 cm). With children, the depth of insertion may be less than 2.5cm.
5. Rotate the swab 5 times brushing against the inside of the nostril.
6. Remove the swab and insert it into the other nostril. Repeat step 4-5. Remove the swab from the nostril.
7. Insert the swab into the tube and swirl for 30 seconds.
8. Rotate the swab 5 times while squeezing the side of the tube.
9. Remove the swab while squeezing the tube.
10. Attach the dropper tip firmly onto the extraction buffer tube. Mix thoroughly by swirling or flicking the bottom of the tube.
11. Gently squeeze the tube and dispense 4 drops of solution into the specimen well.
12. Start the timer. Read the result when the timer reaches 15 minutes. Do not read after 30 minutes.

RESULT INTERPRETATION AND NEXT STEPS

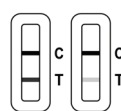


Negative

If the red control line (C) is visible, but the test line (T) is not visible, the test is negative. This means that no SARS-CoV-2 antigen was detected.

WHAT IF I HAVE A NEGATIVE TEST RESULT?

If you have symptoms like COVID-19 but test negative, you probably do not have COVID-19. If you suspect an infection, repeat the test within 1-2 days. If your COVID-19-like symptoms last or get worse, you should contact your doctor or local health authority for advice on confirmatory testing or medical evaluation.



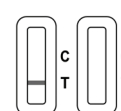
Positive

If the red control line (C) and test line (T) are visible, the test is positive. This means that SARS-CoV-2 antigen was detected.

NOTE: Any faint line (light pink to red) in the test line region (T) should be considered positive.

WHAT IF I HAVE A POSITIVE TEST RESULT?

A positive test result means it is very likely you currently have COVID-19. You should self-isolate from others and contact your doctor or local health authority for advice on confirmatory testing or medical evaluation.



Invalid

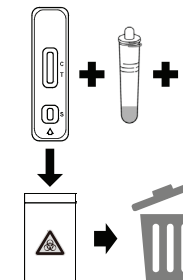
If the red control line (C) is not visible, the test is not valid.

WHAT IF THE TEST RESULT IS INVALID?

Review the instructions again and perform a new test. If the test results remain invalid, contact your doctor or e-mail us at: information@aconlab.com.cn

SAFELY DISPOSE

Once your test is complete, put the used swab, extraction buffer tube and test cassette in the waste bag provided in your kit, and dispose of them in your household waste.



SUMMARY AND EXPLANATION

Coronavirus disease (COVID-19) is an acute respiratory infectious disease, which is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. The main symptoms include fever, chills and sore throat. Fatigue, new and persistent cough, nasal congestion, runny nose, myalgia and diarrhea are found in a few cases.¹ SARS-coronavirus (SARS-CoV) is a virus that causes a viral respiratory disease of Severe Acute Respiratory Syndrome (SARS)². People infected with SARS-CoV may also get a positive result.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test is a lateral flow test for the qualitative detection of the nucleocapsid antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals suspected of COVID-19 within the first seven days of the onset of symptoms. The test can also test specimens from individuals without symptoms. The test may produce a false-positive result if you are infected with SARS-CoV. SARS-CoV-2 Antigen Rapid Test is intended to be used for self-testing by untrained lay users in a private setting to aid in the diagnosis of SARS-CoV-2 infection. Children under 14 years should be supervised by an adult.

PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test is a lateral flow immunochromatographic test for the detection of the nucleocapsid antigen from SARS-CoV-2 in human anterior nasal swab specimens. When a processed specimen is added to the test cassette, SARS-CoV-2 antigens, if present in the specimen, will bind to the specific antibodies on the test cassette, forming a visible light pink to red line in the test line region (T). To serve as a procedural control, a red line will always appear in the control line region indicating that sufficient specimen volume was added and membrane absorption has occurred. Test results are read visually at 15-30 minutes based on the presence or absence of red lines.

REAGENTS

The test cassette contains specific antibodies to nucleocapsid antigen from SARS-CoV-2.

PRECAUTIONS

- Read the SARS-CoV-2 Antigen Rapid Test Package Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results.
- Do not use the test after the expiration date shown on the test cassette pouch.
- Do not eat, drink, or smoke before and during the test.
- Do not use the test if the pouch is damaged.
- A desiccant is included in the test cassette pouch to prevent the effects of humidity. Do not eat it.
- The test cassette, disposable swab and extraction buffer tube can only be used once. Put the used swab, extraction buffer tube and test cassette in the waste bag provided and dispose of them with your household waste.
- Humidity and temperature can adversely affect results. Remove the test cassette from the pouch and use it as soon as possible (in 1 hours with humidity \leq 80% at 15-30 °C).
- The test line for a high viral load specimen may become visible within 15 minutes, or as soon as the specimen passes the test line region.
- The test line for a low viral load specimen may become visible within 30 minutes.
- Do not collect the nasal swab specimen when nosebleed happens.
- Wash hands thoroughly after use.

- If the extraction buffer contacts the skin or eyes accidentally, flush with large amounts of water. Seek medical advice if irritation persists.
- Keep the test kit away from children and animals.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal swab specimen.
- Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored in the extraction buffer tube at room temperature (15-30°C).
- Use only the disposable swabs and extraction buffer tubes supplied in your test kit. Do not mix and match components from other test kits.

STORAGE AND STABILITY

- The kit can be stored at temperatures between 2 - 30 °C. DO NOT FREEZE.
- The test is stable until the expiration date printed on the sealed test cassette pouch. Do not use after the expiration date.
- The test must remain in the sealed test cassette pouch until use.

QUALITY CONTROL

The internal procedural control is included in the test. A red line appearing in the control line region (C) is an internal procedural control. It confirms that enough specimen volume was added, and the correct procedure was carried out.

LIMITATIONS

- The SARS-CoV-2 Antigen Rapid Test is for self-testing use only. The test should only be used for the detection of SARS-CoV-2 antigens in nasal swab specimens. The intensity of the test line does not necessarily relate to the SARS-CoV-2 viral load in the specimen.
- A false-negative test may occur if the level of antigen in a specimen is below the detection limit of the test or if the specimen was collected incorrectly.
- Test results should be looked at with other clinical data available to the doctor.
- A positive test result cannot necessarily determine whether you are infected.
- A positive test result does not rule out co-infections with other pathogens.
- A false-positive result may occur if you are infected with SARS-CoV.
- A negative test result does not rule out other viral or bacterial infections.
- A negative result, from an individual having symptoms beyond seven days, should be treated as likely negative and confirmed with a molecular assay, if necessary.
- The test is less reliable in the later phase of infection and in asymptomatic individuals.
- There is a higher chance of false-negative results with this self test than with laboratory-based molecular tests.
- Recommend repeat testing (e.g., within 1-2 days) if ongoing suspicion of infection, high-risk setting or occupational or other requirements.
- Test one individual at a time.
- Failure to follow the instructions for use may lead to inaccurate test result.

PERFORMANCE CHARACTERISTICS

The clinical performance of the test was established with 605 nasal swabs collected from individuals who were suspected of COVID-19. The results show that the clinical sensitivity from SARS-CoV-2 positive specimen is 97.1% (165/170) and clinical specificity from SARS-CoV-2 negative specimen is 99.5% (433/435). As SARS-CoV-2 virus has changed over time. These new forms of the virus are called variants. The test can detect the major variants of SARS-CoV-2.

It was confirmed that other medical conditions (the substances that naturally present in respiratory specimens, the medical conditions that may be artificially introduced into the nasal cavity or the related pathogens and microorganisms that are likely to be present in the nasal cavity) do not affect the performance of the SARS-CoV-2 Antigen Rapid Test with exception of the SARS-CoV.

TROUBLESHOOTING

Follow these instructions if you have trouble in the test. If the issue persists, contact your supplier or e-mail us at: information@aconlab.com.cn

Issue	Causes	Recommended actions
No control line	The cassette does not work	Perform a new test.
Unclear control line	More than 4 drops of processed specimen were dispensed	Review the instructions again and perform a new test.
Insufficient specimen	Less than 4 drops of processed specimen were dispensed	Review the instructions again and perform a new test.
Buffer spillage or empty	The buffer tube is not sealed well	Discard the tube and perform a new test.
Incorrect timing	Read the results before 15 minutes or after 30 minutes.	Review the instructions again and perform a new test.

BIBLIOGRAPHY

- World Health Organization (WHO). Fact Sheets for Coronavirus Disease (COVID-19). [https://www.who.int/news-room/fact-sheets/detail/coronavirus-disease-\(covid-19\)](https://www.who.int/news-room/fact-sheets/detail/coronavirus-disease-(covid-19)) Accessed 9 August 2023.
- Caldaria A, Conforti C, Di Meo N, Dianzani C, Jafferany M, Lotti T, Zalaudek I, Giuffrida R. COVID-19 and SARS: Differences and similarities. *Dermatol Ther.* 2020 Jul;33(4): e13395. doi: 10.1111/dth.13395.

Index of Symbols

	Manufacturer		Contains sufficient for <n> tests		Temperature limit
	In vitro diagnostic medical device		Use-by date		Do not reuse
	Consult instructions for use		Batch code		Catalogue number
	Date of manufacture		Biological risks		

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Extraction Buffer Tubes	Extraction Buffer Tubes
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