ZH 新型冠狀病毒（SARS-CoV-2）/肺炎支原體(MP)/呼吸道合胞病毒(RSV)/腺病毒(ADV)/甲型流感病毒（Influenza A）/乙型流感病毒（Influenza B）抗原聯合檢測試劑盒（膠體金法）使用說明書

產品編號 CG128001，CG128005，CG128025

1. 預期用途

本產品爲使用側向免疫層析法的快速檢測，用于體外定性檢測和區分疑似有呼吸道感染症狀患者的鼻、鼻咽或口咽（咽喉）拭子中的新型冠狀病毒（SARS-CoV-2）、肺炎支原體（MP）、呼吸道合胞病毒（RSV）、腺病毒（ADV）以及甲型（Influenza A）、乙型流感病毒（Influenza B）的抗原。

結果用于同時鑒定新型冠狀病毒、肺炎支原體、RSV、ADV 及甲型和乙型流感病毒的抗原，但不能區分 SARS 和新型冠狀病毒，也無法檢出丙型流感病毒抗原。這些抗原通常在感染急性期的上呼吸道標本中可檢測到。陽性結果表明存在病原的抗原，但感染的診斷需結合患者病史和其他診斷信息。陽性結果不排除細菌感染或與其他病毒/細菌共同感染的可能性。檢測到的病原體可能不是疾病的確切原因。

陰性結果應被視爲推定，不排除新型冠狀病毒、肺炎支原體，RSV、ADV 或甲乙型流感病毒感染的可能，也不應作爲治療或患者管理決策（包括感染控制決策）的唯一依據。必要時，建議通過其他檢測手段確認陰性結果，以便對患者進行管理。

僅供專業人員使用。

2. 檢測原理

本試劑使用膠體金免疫層析法。該測試是新型冠狀病毒抗原檢測、肺炎支原體抗原檢測、RSV 抗原檢測、ADV 抗原檢測以及甲、乙型流感病毒抗原檢測的組合。當樣品中的新型冠狀病毒、肺炎支原體、RSV 抗原、ADV 抗原或甲、乙型流感病毒抗原與偶合物墊上的膠體金（標記物）標記的抗新型冠狀病毒/抗肺炎支原體/抗 RSV/抗 ADV/抗甲、乙型流感病毒抗體結合形成免疫複合物。當複合物遷移到檢測綫（包被有抗新型冠狀病毒、抗肺炎支原體、抗 RSV、抗 ADV、抗甲、乙型流感病毒抗體）時，含有新型冠狀病毒或肺炎支原體或 RSV 或 ADV 或甲、乙型流感病毒抗原的複合物將被捕獲。同時，膠體金標記的小鼠抗體將被對照綫上的山羊抗小鼠 IgG 捕獲。被捕獲的含有新型冠狀病毒或肺炎支原體或 RSV 或 ADV 或甲、乙型流感病毒抗原的複合物會在相應的檢測綫區域產生一條帶顏色的條帶，表明樣本爲對相應的抗原呈陽性。類似地，在每個質控綫區域也會產生一條顯色條帶，表明加入了足够量的樣本且層析正常。

3. 試劑盒組成

組分	1T CG128001	5T CG128005	25T CG128025
檢測卡	1	5	25
拭子	1	5	25
提取管	1	5	25
樣本架	/	/	1
說明書	1	1	1

4. 需自備的材料

4.1 計時器

4.2 必要的個人防護設備

5. 儲存條件及有效期

未開封的產品需要 2-30℃，避光且乾燥的環境中。請勿冷凍。生產日期及失效日期：見產品標簽。建議在即將使用前再打開檢測卡的包裝。檢測卡包裝打開後，應于 60 分鐘內完成測試。

6. 樣本要求和采集

6.1 本產品適用于鼻，鼻咽和口咽（咽喉）拭子標本的測試。

6.2 **正確的采集和處理樣本對于獲得正確結果至關重要**。采樣時，請使用本試劑盒件中提供的拭子。處理拭子樣本時，請勿觸摸拭子頭部。

(a). 采集鼻拭子標本：將拭子通過緩慢旋轉的方式插入一個鼻孔。插入後，拭子頭應處在距鼻孔邊緣 1-2 厘米（2 至 14 歲兒童爲 1 厘米）的地方。在鼻腔內將拭子輕輕旋轉 10 次。取出幷插入另一個鼻孔，用同一根拭子重複此過程。

(b). 采集鼻咽拭子標本：通過鼻腔輕輕將拭子以垂直鼻子（面部）方向插入鼻孔，有觸壁感，直至手指觸及鼻子，使拭子在鼻內停留 15—30 秒，然後輕輕旋轉 3 次後取出。

(c). 采集口咽（咽喉）拭子樣本：將拭子伸入後咽扁桃體區域，用拭子擦拭扁桃體和雍垂（腭垂及小舌），儘量避免接觸舌頭、牙齒和牙齦。

6.3 樣品采集後應立即進行檢測。如不能立即檢測，則需在乾燥無菌的容器中低溫保存。樣本在 2-8° C 下可保存 8 小時，在-20° C 可保存 7 天。

7. 檢驗方法

7.1 測試前讓試劑盒恢復至室溫（15 - 30° C）。

7.2 取出檢測卡，將其放在乾燥，平整，乾淨的檯面。將對應的病人 ID 標記在檢測卡上。

7.3 揭去提取管上的密封膜。

7.4 將拭子樣本插入到提取管中，使拭子頭充分浸沒在提取液中。在用力捏住提取管的同時，旋轉其中的拭子 10 次。

7.5 將拭子留在提取液中靜置 1 分鐘。

7.6 輕輕攪動拭子混勻。然後，在捏住提取液管的同時取出拭子。

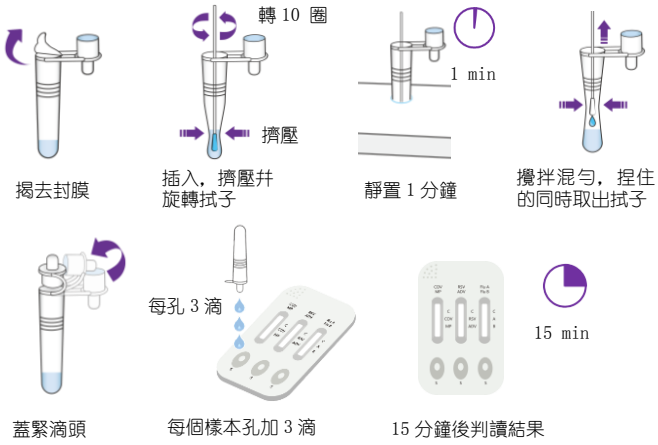
7.7 蓋上幷按緊提取管的滴頭。輕搖或輕彈提取管底部，混勻樣本。

7.8 倒置提取管，將其中液體滴 **3 滴（約 75μL）** 到檢測卡的每個樣本孔中。

7.9 啓動計時器，室溫下靜置 **15 分鐘**。

7.10 15 分鐘後，判讀結果。20 分鐘後判讀無效（從加樣後算起）。

注意：確保在判讀結果時光綫充足。加樣後 15 分鐘前或 30 分鐘後請勿判讀結果，結果可能是假陰性、假陽性或無效。



8. 檢驗結果的解釋

對于三條檢測帶的每一條，無論檢測綫是否出現，只有質控 C 綫顯色時，才可算作有效測試。如未能觀察到質控綫，則表明結果不可信。此時，請仔細檢查測試步驟，然後重新采集樣本，幷使用新檢測卡重測。如果問題仍存在，請聯繫當地的授權代表。

(1) 陽性結果

如果出現對照（C）綫和 COV 或 MP 或 RSV 或 ADV 或 FluA 或 FluB 中任何一種的檢測綫，則相應病原體的檢測結果即 COV（新型冠狀病毒），MP（肺炎支原體），RSV，ADV， FluA（甲型流感病毒），FluB（乙型流感病毒），呈陽性。

注意：

- 檢測綫（A、B 或 T 綫區域）的强度可能因檢測到的抗原量而异。任何可見的（即使是淺的或微弱的）檢測綫都應被判爲陽性。
- 同時感染兩種或以上病原的情況很少見。如果結果對兩種或兩種以上的抗原均（如甲、乙流或新冠同時陽性）呈陽性，建議采集新樣本重新檢測。

(2) 陰性結果

如果對照 (C)綫都出現，但沒有檢測綫（COV、MP、RSV、ADV、FluA、FluB）出現，則檢測結果爲陰性。。

注意：

- 陰性結果應被視爲推定。陰性結果不排除新型冠狀病毒、肺炎支原體、RSV、ADV、或甲、乙型流感病毒感染，不應作爲治療或患者管理決策的唯一依據。

(3) 無效結果

如果對照（C）綫不可見，則檢測無效。

注意：

- 樣本量不足或操作不正確是最有可能導致無效結果的原因。請重新查閱測試步驟，重新采集樣本，幷使用新檢測卡重測。

9. 檢驗方法的局限性

9.1 本産品僅用于定性檢測新型冠狀病毒，肺炎支原體，RSV，ADV，甲型和乙型流感病毒的抗原。

9.2. 該測試即可檢測存活和非存活的新型冠狀病毒，肺炎支原體，RSV，ADV，甲型和乙型流感病毒。測試性能取决于樣本中抗原的量，結果與對同一樣本進行的培養或分子檢測結果，不一定具有相關性。

9.3 當樣本中的抗原水平低于測試的檢測限，樣品收集或處理不當，或者病原在抗體識別的目標表位區域發生氨基酸變化，則可能會出現陰性檢測結果。
9.4 未按照說明書操作可能會對測試性能產生不利影響或使測試結果無效。
9.5 測試結果必須與患者的臨床病史、其他檢測結果和流行病學數據等結合使用。
9.6 陽性檢測結果不能排除與其他病原體的混合感染，不區分 SARS 和新冠感染，也不能確定具體的流感亞型。
9.7 陰性結果應視爲推定，不排除新型冠狀病毒、肺炎支原體、RSV、ADV、或甲、乙型流感病毒感染的可能性，不應作爲治療或患者管理決策（包括感染控制決策）的唯一依據。陰性結果必須與臨床觀察、患者病史和流行病學信息相結合，必要時用分子檢測確認，以便對患者進行管理。

10. 注意事項

10.1 僅供體外診斷使用。
10.2 如果包裝已損壞，標簽不清晰，或試劑盒過期，請勿使用。
10.3 在開始測試前請仔細閱讀說明。爲了獲得準確的結果，請務必按照本說明書進行測試。
10.4 不同批次試劑的提取液不可混用。混用不同批次的提取液可能會導致結果不準確。
10.5 檢測卡適用于一次性使用，請勿重複使用。請勿使用過期的檢測卡。
10.6 乾燥劑不可食用。
10.7 避免皮膚、眼睛、嘴巴、粘膜接觸提取液。如果發生接觸，請用大量水沖洗。
10.8 建議在取樣和檢測過程中佩戴手套。
10.9 本產品涉及的樣本應視爲具有傳染性，采樣和實驗室所有操作應符合國家和地區的相應法規。

11. 標識的解釋

查閱使用說明	LOT 批號	不得二次使用
有效期	IVD 體外診斷醫療器械	溫度極限 2 - 30℃
製造商	每盒測試數	避光
生產日期	REF 產品編號	EC REP 歐盟授權代表
CE 該產品符合歐洲指令 98/79/EC 的要求		

深圳市國賽生物技術有限公司
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國賽科技大厦 1 號樓 1001
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EC REP **CMC MEDICAL DEVICES & DRUGS, S.L.**
C/ Horacio Lengo No 18, CP 29006, Málaga-Spain

IFU4542002, V1, 05/2024

EN SARS-CoV-2 & MP & RSV & ADV & Flu A/B Antigen Kit (Colloidal Gold)

Catalog No.	CG128001, CG128005, CG128025

1. Intended Use

This SARS-CoV-2 & MP & RSV & ADV & Flu A/B Antigen Kit (Colloidal Gold) is a lateral flow rapid chromatographic immunoassay intended for the in vitro qualitative detection and differentiation of antigens from SARS-CoV-2, Mycoplasma Pneumoniae (MP), Respiratory Syncytial Virus (RSV), Adenovirus (ADV) and influenza A (Flu A) and influenza B (Flu B) in nasal, nasopharyngeal, and oropharyngeal (throat) swab specimens from individuals suspected of respiratory infections.

Results are for the identification of antigens of SARS-CoV-2, MP, RSV, ADV, influenza A and influenza B, but does not differentiate between SARS-CoV and SARS-CoV-2 viruses and is not intended to detect influenza C antigens. These antigens are generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral or bacterial antigens, but correlation with patient history and other diagnostic information is necessary to determine the infection status. Positive results do not rule out infection or co-infection with other bacteria or viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive, do not rule out SARS-CoV-2, MP, RSV, ADV or influenza A/B infection, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. It's recommended to confirm negative results with other assays, if necessary, for patient management.

For professional use only.

2. Test Principle

Colloidal gold based immunochromatography is applied. The test is a combination of SARS-CoV-2 antigen test, MP antigen test, RSV antigen test, ADV antigen test, and influenza A/B antigen test. Briefly, the SARS-CoV-2, MP, RSV, ADV or Flu A/B antigens in the sample bind with the colloidal gold (detector) labeled anti-SARS-CoV-2 / anti-MP / anti-RSV / anti-ADV / Flu A/B antibodies on the conjugate pad to form the immunocomplexes. When the complexes migrate to the test line (coated with anti-SARS-CoV-2 or anti-MP or anti-RSV, anti-ADV, anti-Flu A/B antibodies), the complexes that contain the SARS-CoV-2 or MP or RSV or ADV or Flu A/B antigens will be captured. Similarly, the colloidal gold labeled mouse antibody will be captured in the control lines (coated with goat anti-mouse IgG). The complexes containing SARS-CoV-2 or MP or RSV or ADV or Flu A/B antigen will produce a colored line in the specific test line region, indicating the sample is positive for the respective antigen. Similarly, a colored line will also appear in each of the control line region indicating the adequate volume of specimen has been added and the membrane wicking has occurred.

3. Materials Provided

Component	1T CG128001	5T CG128005	25T CG128025
Test Cartridge	1	5	25
Sampling Swab	1	5	25
Extraction Tube	1	5	25
Tube Holder	/	/	1
Instructions For Use	1	1	1

4. Material Required but Not Supplied

4.1 Timer

4.2 Any necessary personal protective equipment

5. Storage and Stability

Store the kit at 2 – 30°C in a dry place and avoid direct sunlight. Do not freeze. The unopened cartridges are stable until the expiry date printed on the labels. It's recommended to open the test cartridge pouch just before use. Once the pouch is opened, the test should be started within 60 minutes.

6. Sample Collection

6.1 Nasal, nasopharyngeal, and oropharyngeal (throat) swab samples are acceptable for testing with this kit.

6.2 **Proper sample collection and handling is critical to the performance of the kit**. When collecting the swab sample, use the swab supplied in the kit. Do NOT touch the swab tip when handling the swab sample.

(a). Nasal swab collection: while gently rotating, insert the swab into one nostril. The swab tip should be inserted up to 1 to 2 cm (or 1 cm for children aged 2-14 years) from the edge of the nostril. Rotate the swab 10 times against the nasal wall. Remove and repeat the sampling process using the same swab for the other nostril.

(b). Nasopharyngeal swab collection: insert swab through the nares perpendicular to the nose (face) until resistance is encountered and the fingers touch the nose. Leave the swab in place for 15 – 30 seconds. Rotate the swab 3 times and remove it from the nasopharynx.

(c). Oropharyngeal (throat) swab collection: insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

6.3 After collection, the sample is recommended to be tested immediately. If this is not possible, the sample should be stored in a dry and sterilized container. The swab sample can be stored at 2-8°C for up to 8 hours or at -20°C for up to 7 days.

7. Test Procedure

7.1 Allow the kit to come to room temperature (15 – 30°C) before testing.

7.2 Remove the Test Cartridge from its package. Place the cartridge on a clean, flat and dry surface. Label the cartridge with patient ID.

7.3 Remove the foil from the top of the Extraction Tube.

7.4 Place and soak the patient swab into the Extraction Tube. Rotate the swab 10 times while squeezing the sides of the tube.

7.5 Leave the swab in the tube for 1 minute.

7.6 Stir to mix the contents well. Remove the swab while squeezing the sides of the tube.

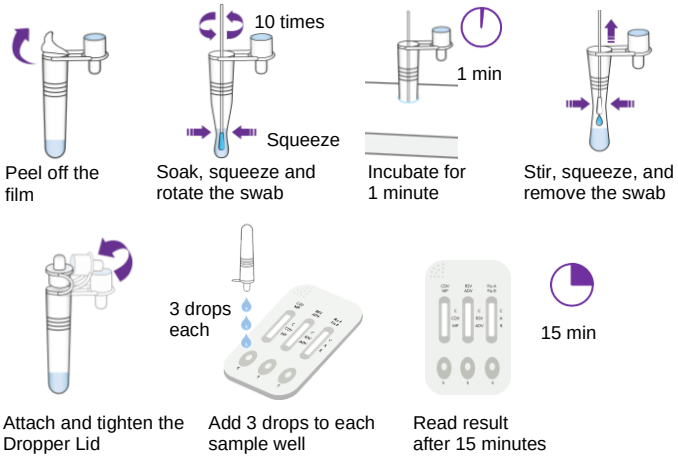
7.7 Attach and tighten the dropper tip to the top of the tube. Swirl or tap the tube bottom to mix the contents well.

7.8 Invert the Extraction Tube, and then vertically add **3 drops** (around 75 µL) into each sample well of the cartridge.

7.9 Start the timer: leave the cartridge at room temperature for **15 minutes**.

7.10 After the 15-minute incubation, read the results. Do not read the results after 30 minutes (from addition of the sample).

Note: Make sure there is sufficient light when reading and interpreting the results. Results read before 15 minutes or after 30 minutes may be false negative, false positive, or invalid.



8. Interpretation of Results

For each of the 3 test lane, the Control (C) line must appear for the test to be valid regardless of the appearance of the test line(s). Failure to observe the control line indicates the results are not reliable. When this

occurs, check the operation procedure carefully, and test again with a new sample. If the problem recurs, contact your local distributor.

(1) Positive Result

If the Control (C) line and the test line(s) for any of COV or MP or RSV or ADV or FluA or FluB appear, the test is positive for the corresponding pathogen, i.e., COV, SARS-CoV-2; MP, Mycoplasma Pneumoniae, RSV, Respiratory Syncytial Virus; ADV, Adenovirus; FluA, Influenza A; FluB, Influenza B.

Note:

- The test lines (A, B or T line region) may vary in intensity depending on the amount of antigen detected. Any visible (even light or faint) T line(s) should be interpreted as positive.
- Co-infection with more than one pathogen is rare. If the results are positive for more than one antigen, e.g., influenza A, B or SARS-CoV-2, it's recommended to retest with a new sample.

(2) Negative Result

If the Control (C) lines are visible, but none of the test lines (COV, MP, RSV, ADV, FluA, FluB) appear, the test is negative.

Note:

- Negative results should be treated as presumptive. Negative results do not rule out infection with SARS-CoV-2, MP, RSV, ADV, Flu A or Flu B, and should not be used as the sole basis for treatment or patient management decisions.

(3) Invalid Result

If the Control (C) line is not visible, the test is invalid.

Insufficient sample volume or incorrect operation are the most likely reasons for invalid results. Review the procedure and repeat the test with a new sample.

9. Limitations

9.1 The test is only for qualitative detection of SARS-CoV-2, MP, RSV, ADV, Flu A and Flu B antigens.

9.2. This test detects both viable and non-viable SARS-CoV-2, MP, RSV, ADV, Flu A and Flu B. Test performance depends on the amount of antigen in the sample and may or may not correlate with pathogen culture or molecular assay performed on the same sample.

9.3 A negative test result may occur if the level of antigen in a sample is below the detection limit of the test, if the sample was collected or handled improperly or if the pathogen has amino acid changes in the target epitope region recognized by the antibodies utilized in the test.

9.4 Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.

9.5 Test results obtained with the test must be used in conjunction with other clinical history, findings, and epidemiological data, etc.

9.6 Positive test results do not rule out co-infections with other pathogens, differentiate between SARS-CoV and SARS-CoV-2 or identify specific influenza subtypes.

9.7 Negative results do not rule out infection with SARS-CoV-2, MP, RSV, ADV, Flu A or Flu B, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results must be combined with clinical observations, patient history and epidemiological information, and confirmed with a molecular assay, if necessary, for patient management.

10. Warnings and Precautions

10.1 For in vitro diagnostic use only.

10.2 If the package has been damaged, the label cannot be seen clearly or if the kit has expired, do not use the kit.

10.3 Read the instructions carefully before starting the test. To obtain accurate results, the instructions must be followed.

10.4 Extraction Buffer of different lots are not interchangeable. The results may not be reliable if reagents from different lots are mixed or used together.

10.5 The test cartridge is for single test and cannot be reused. Do not use expired cartridges.

10.6 Do not eat the desiccant.

10.7 Avoid exposure of the skin, eyes, mouth, mucous membranes to the Extraction Buffer. If the contact occurs, flush with large amounts of water.

10.8 Use of gloves during sampling and testing is recommended.

10.9 The samples, used reagents and consumables are potentially infectious waste and should be disposed of in accordance with national and local regulations.

11. Symbols

	Consult instructions for use	LOT	Lot number		Do not reuse
	Use-by date	IVD	In vitro diagnostic medical device		Temperature limit 2 - 30℃
	Manufacturer	Σ	Tests per kit		Avoid sunshine
	Date of manufacture	REF	Catalog number	EC REP	Authorized representative in the European Community
CE	This product complies with the requirements of the European Directive 98/79/EC				

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