銳偵 家用新冠肺炎抗原快速檢測試劑 使用說明書 (型號：G69RHSD1)

防疫專案核准輸入第1106608063號

本說明書適用於 BIOCREDIT COVID -19 Ag Home Test Nasal ，使用此檢測之前，請詳細閱讀使用說明。

BIOCREDIT
COVID-19 Ag Home Test Nasal | Rapigen

■ 使用範圍與用途

本產品為家用型檢驗試劑，利用側向流動原理，定性檢測疑似感染 COVID-19 患者自行採集之人類鼻腔檢體中存在的 SARS-CoV-2 核殼蛋白抗原。陽性結果並不能排除細菌感染或與其他病毒共同感染；陰性結果不能排除 SARS-CoV-2 感染。本檢測僅提供初步篩選結果。不應單以本產品檢驗結果作為病患管理之唯一依據。

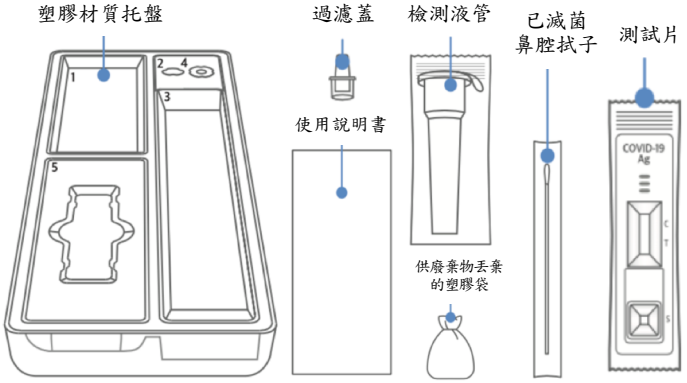
■ 注意事項

1. 本產品僅供體外檢測使用，不應單憑檢測結果作為感染與否的依據，須配合專業醫師諮詢來做判定。專業醫師的診斷將對本檢測結果做最終判定。
2. 檢測結果如為陽性，請立即前往鄰近的社區採檢院所檢測，並依據中央疫情指揮中心規定執行相關防疫措施。
3. 本產品僅評估 19 歲以上人員自行採檢結果，建議應由 19 歲以上人員使用。

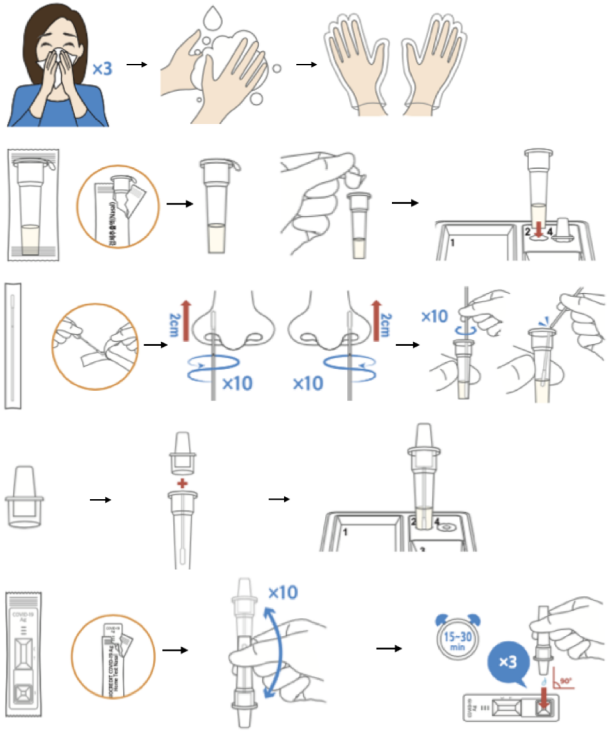
一、 使用前注意事項：清潔雙手，並確認產品內容物。



使用洗手乳或肥皂
將雙手清洗乾淨並擦乾



二、 操作步驟：



步驟一、檢測前的準備
> 用紙巾輕輕擤鼻子 3 次，以去除鼻中異物。
> 用肥皂或洗手液，徹底洗手並擦乾。
> 戴上手套，同時可準備計時器。

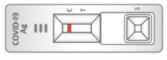
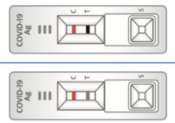
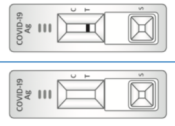
步驟二、準備檢測液管
> 小心撕開鋁箔外包裝，取出檢測液管。
> 緩緩撕掉檢測液管上的鋁箔封膜，避免液體漏出。
> 將檢測液管置放到管固定孔 (2) 中。

步驟三、用鼻腔拭子採樣
> 小心撕開已滅菌鼻腔拭子的外包裝，避免觸碰到拭子尖端。
> 將棉棒輕輕插入鼻孔中約 2 公分，對著鼻壁旋轉約 10 次，慢慢取出棉棒，對另一側鼻孔重複相同步驟。
> 將鼻腔拭子插入檢測液管中，輕輕旋轉約 10 次，在棉棒標示的斷點處折斷棉棒。

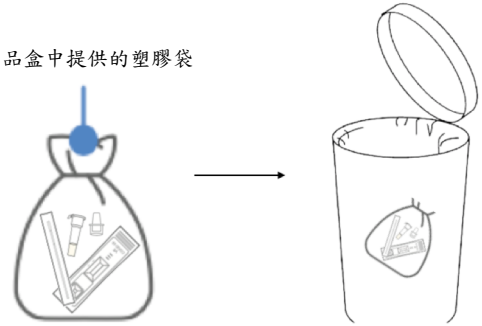
步驟四、蓋上過濾蓋
> 將拭子尖端保留於管內，用過濾蓋蓋緊，勿將已組合的過濾蓋與檢測液管分開。
> 將已組合的過濾蓋與檢測液管置放到管固定孔 (2) 中。

步驟五、測試片執行檢測
> 小心撕開測試片的鋁箔外包裝，取出測試片。
> 將採樣後的檢測液管輕輕反轉混合 10 次。
> 將 3 滴採樣後的檢測液滴入樣品孔 (S) 中，靜待約 15 到 30 分鐘後，即可判讀結果。

三、 結果判讀：

結果	圖示	判讀
陰性		結果視框中僅出現一條**紅色**的控制組線 "C"。 [**陰性結果**，表示未在您的樣本中找到 COVID-19 的病毒。但若出現 COVID-19 症狀，請撥打 1922 或聯繫當地衛生局，依指示儘速就醫。]
陽性		兩條線；結果視框中同時出現一條**黑色**測試組線 "T" 以及一條**紅色**的控制組線 "C"。 [**陽性結果**，表示您很可能感染 COVID-19，請立即前往鄰近的社區採檢院所檢測，並依據中央疫情指揮中心規定執行相關防疫措施。] *** 即使測試線 (T) 是微弱的，也應判讀為陽性結果。**
無效		結果視框中沒有出現控制組線 "C"，建議將此樣本重新進行檢測。 [**無效結果**，表示可能操作過程有錯誤或產品出現問題，導致結果無效，請立即檢查關於試劑盒的使用方法是否有誤，若有問題請務必聯繫購買處。]

四、 廢棄物處理：將使用過的所有產品內容物集中至提供的塑膠袋中，依據檢測結果做不同處置。



若檢測結果為**陰性**，
請將檢體及檢測裝置妥善密封放在塑膠處理袋中密封，並將所有測試包材料丟棄在垃圾桶內。

若檢測結果為**陽性**，
需前往鄰近的社區採檢院所進行第二次檢測，並將本次自行檢測的檢體及檢測裝置妥善密封，交付篩檢站進行醫療廢棄物處理。

(使用說明影片連結)

製造商名稱：Rapigen, Inc.
製造商地址：3-4F, 16, LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do 14119, Republic of Korea
進口商名稱：弘朗生物科技有限公司
進口商地址：屏東縣潮州鎮南華路24號
弘朗生物科技有限公司
HomeRun BioTech Inc.

REF G69RHSD1

Rapigen

BIOCREDIT
COVID-19 Ag Home Test Nasal

ENGLISH

■ Intended Use

BIOCREDIT COVID -19 Ag Home Test Nasal is a rapid chromatographic immunoassay intended for the qualitative detection of nucleocapsid (N) protein antigen from SARS-CoV-2 in individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection. This test is authorized for home use with self-collected direct nasal (nares) swab samples from individuals collected nasal swab.

■ Principle of Test

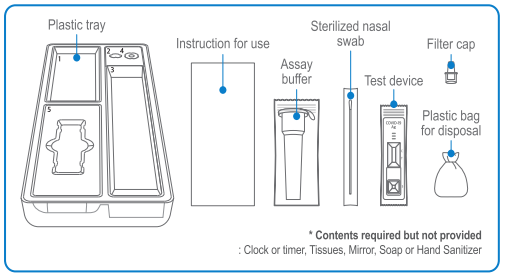
BIOCREDIT COVID-19 Ag Home Test Nasal is a lateral flow immunochromatographic assay that adopted dual color system. The test contains colloid gold conjugate pad and a membrane strip pre-coated with antibodies specific to SARS-CoV-2 antigen on the test line (T). If SARS-CoV-2 antigen is present in the specimen, a visible black band appears on the test line (T) as antibody-antigen-antibody gold conjugate complex forms. The control line (C) is used for procedural control and should always appear if the test is performed correctly.

■ Test preparation

1. Prepare a flat and dry surface such as a desk. Clean the prepared area.
2. Wash your hands with soap or hand sanitizer for 30 seconds, then dry them off.
3. If you use more than one test, you will need to clean the table and wash your hands after each test.
4. Make sure you have all the components required to use this kit. If there is any missing or damaged part, do not use the kit.

[Components provided]

Plastic tray, Sterilized nasal swab, Filter cap, Assay diluent, Test device, Instruction for use, Plastic bag for disposal.



[Components required but not provided]

Clock or timer, Tissues, mirror, soap or hand sanitizer.

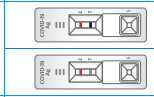
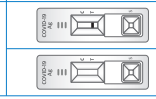
■ Specimen collection using Nasal swab

1. Gently blow your nose into a tissue 3 times to remove foreign substances.
2. Wash hands clean with soap or hand sanitizer, wear gloves (not included) and prepare timer (not included).
3. Take out the assay buffer tube from the aluminum pouch located at (1) and remove the lid. That contains a colorless liquid.
4. Install the assay buffer tube into the tube fixing hole (2).
5. Take out the swab in (3). Open the closed wrapper and take out the swab by holding the handle. Don't touch the soft, fabric tip of the swab with your hands. 6. Gently insert the swab into the nostril. Collect sample from nasal wall by rotating the swab in a circular path 10 times against the nasal wall. Slowly remove the swab.
7. Repeat above procedure to the opposite nostril.
8. Take out the tube placed in (2), insert the swab into tube and immerse the entire tip of swab into the assay buffer. Rotate the swab about 10 times with the head in contact with the bottom and wall of the tube.
9. After collecting the specimen, place the swab inside the tube and break the swab stick at the break point, and the tip of the swab is inserted into the tube. Throw the broken plastic handle away in a plastic bag for disposal.
10. Take out the filter cap of (4) and press the cap tightly on to the tube to avoid any leaks (Do not separate the combined filter cap from the assay diluent tube.).
11. Place the assay buffer tube in the tube fixing hole (2).

■ Test Procedure

1. Take the test device out of the aluminum pouch located in (5) and lay it on the fixing frame (5).
2. Take out the tube from the tube fixing hole (2) and mix by gently invert 10 times.
3. Hold the tube vertically and apply 3 drops of assay buffer into the sample well (S).
4. Check the results after 15 to 30 minutes.

■ Interpretation

Result	Representation	Interpretation
Negative		One red control line "C" in results window
Positive		Two stripes; black test line "T" and a red control line "C" in the window results.
Invalid		There is no control line in the results window "C". It is recommended that the sample retested

* Even if the test line is faint should be interpreted as a positive result.

1. Look at the results window of the test device and check if there is a red line next to control line C or a black line next to test line T.
2. Negative result: The appearance of only the red line in control line C indicates negative result.
   [A negative test result means that the SARS-CoV-2 antigen that causes COVID-19 was not found in your specimen. This does not mean that you are not infected with COVID-19, so if symptoms develop, persist or become more severe, consult your healthcare professional.]
3. Positive result: The appearance of the control line C and test line T indicates positive result.
   [An antigen of the COVID-19 virus has been found in your specimen, which means that you are very likely infected with COVID-19. It is very unlikely that this test can give a positive result that is wrong (false positive result). You should self-isolate to avoid spreading the virus to others, and consult a healthcare professional as soon as possible.]
4. Invalid result: If the control line C does not appear or only test line T is appeared, the results are invalid.
   [Check if there are any problems with the usage method, and contact the place of purchase if you have any questions.]

■ Disposal

1. After completing the test, throw all used parts of the kit into the plastic bag for disposal.
2. Dispose of all samples and materials used to perform the test in accordance with all local, state, and national regulations.

■ Clinical Performance

The clinical trial of 'BIOCREDIT COVID-19 Ag Home Test Nasal', developed as a personal COVID-19 corona test kit, was conducted prospectively for men and women between the ages of 19 and 74 in South Korea. The individual used the test medical device to read the result and compared it with the result of the confirmed molecular diagnostic conducted by the expert.
As a result of the performance evaluation, the sensitivity and specificity of ' BIOCREDIT COVID-19 Ag Home Test Nasal' were analyzed as 93.15% (95% CI: 84.76% ~ 97.74%) and 100% (95% CI: 98.30% ~ 100%). There were no cases of Invalid in the entire test.

[Clinical sensitivity and specificity]

		Reference Test		
		Positive	Negative	Total
BIOCREDIT COVID-19 Ag Home Test Nasal	Positive	68	0	68
	Negative	5	215	220
	Total	73	215	288
Sensitivity		93.15% (68/73) [95% CI: 84.76% ~ 97.74%]		
Specificity		100% (215/215) [95% CI: 98.30% ~ 100%]		
Positive predictive value		100% (68/68) [95% CI: 97.81% ~ 100%]		
Negative predictive value		97.73% (215/220) [95% CI: 94.86% ~ 99.01%]		

[Sensitivity for symptom]

Symptom	Positive	Negative	Sensitivity
Symptomatic	47	1	97.92%(47/48)[95% CI: 87.53%-99.89%]
Asymptomatic	21	4	84.00%(21/25)[95% CI: 63.08%-94.74%]
Total	68	5	93.15%(68/73)[95% CI: 84.76%-97.74%]

[Sensitivity for symptom onset days]

Post onset symptoms	Positive	Negative	Sensitivity
0~3	12	0	100%(12/12)[95% CI: 69.87%-100%]
4~7	35	1	97.22%(35/36)[95% CI: 83.79%-99.85%]
Total	47	1	97.92%(47/48)[95% CI: 87.53%-99.89%]

■ Precautions when reading results

1. Be sure to read and understand the Instruction for use.
2. All kit components must be brought to room temperature (15~25 °C) for a minimum of 30 minutes prior to performing the test.
3. Do not store the test kit in direct sunlight and freezer. If you have children, keep them out of reach.
4. One kit is used by one person and it must not be reused. Also, do not use on animals.
5. Do not eat or drink for 30 minutes before you use the kit. If you have a nosebleed, you should use the product after 24 hours.
6. If you have any piercings on your nose, remove them all before testing.
7. Keep a sufficient distance from other people and conduct the test in a well-ventilated area and in a bright place.

■ Precautions during test

1. Do not dip the swab into the assay diluent or other liquid before inserting the swab into the nose.
2. When opening the enclosed swab, do not touch the head.
3. After collecting specimens using the nasal swab, put it into the assay diluent tube immediately.
4. Open the aluminum pouch containing the test kit before use and use immediately.
5. Dropping less than 3 drops or more of the sample may affect the results, please hold the sample extract containing the sample extract vertically and drip it slowly.

■ General precautions

1. For in vitro diagnostic use only.
2. The test kit is a screening test, it is recommended to conduct the test periodically.
3. Do not re-use the test kit and other components.
4. The test device is sensitive to humidity as well as heat. The test device must remain sealed in the foil pouch until use. Do not use the test kit if the foil pouch is damaged or the seal is broken.
5. Dispose of the used sample and all components in a plastic bag for disposal.
6. Wear protective gloves (not provided), and wash your hands before and after testing.
7. The assay buffer contains less than 0.1% of sodium azide. In case of dermal or eye exposure, wash out thoroughly with running water and seek medical attention if necessary.
8. Do not use the kit beyond the expiration date.
9. Be sure to test with the components in the product packaged together.
10. Keep out of reach from children.
11. Do not use a sterilized nasal swab to collect specimens from any part other than the nostril.
12. Do not use any other swabs other than the provided sterilized nasal swab.
13. Do not use with any liquid other than the provided assay diluent.
14. Be careful not to let children swallow the desiccant added to the device packaging. If swallowed, let it spit out and see if necessary for treatment.
15. Be careful not to swallow the filter cap by children. If swallowed, let it spit out and see if necessary for treatment.
16. The user should not draw any conclusions on the health impact of the results obtained, without first consulting those results with your doctor.
17. People who have difficulty distinguishing colors or have low vision may find it difficult to see results.
18. For older users, read the results with the help of a guardian.

■ Precautions for results

1. The test result of this product is not possible to diagnose for COVID-19 infection, and cannot be used for the purpose of confirming negative for COVID-19. It must be confirmed by an approved molecular diagnostic method and followed by a doctor's decision.
2. This product has not been evaluated for those under the age of 19. If you are under the age of 19, please use it under the guidance of a guardian.
3. The clinical performance test of this product was evaluated in patients within 7 days of onset of COVID-19 symptoms and in asymptomatic patients.
4. Very rarely, false positives or false negatives results can occur.
5. This product cannot distinguish between SARS-CoV and SARS-CoV-2 antigens.

■ Storage condition

1. Store kit between 2~30 °C and keep away from direct sunlight.
2. Do not freeze the product.

EN ENGLISH | FR FRANÇAIS | DE DEUTSCH | ES ESPAÑOL | IT ITALIANO | PT PORTUGUÊS

BIOCREDIT
COVID-19 Ag Home Test Nasal

Rapigen

EN Quick guide / ES Guía rápida | FR Guide rapide / I T Guida veloce | DE Kurzanleitung / PT Guia rápido

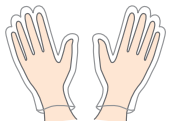
1
EN Preparation before test | ES Preparación antes de la prueba
FR Préparation avant test | I T Preparazione prima del test
DE Vorbereitung vor dem Test | PT Preparação antes do teste



1
EN Blow nose | ES Sonarse la nariz
FR Se moucher | I T Soffiare il naso
DE Schlag Nase | PT Assoar o nariz

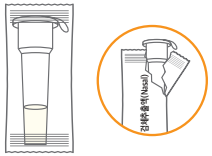


2
EN Washing hands | ES Lavándose las manos
FR Lavage des mains | I T Lavarsi le mani
DE Hände waschen | PT Lavar as mãos



3
EN Wear gloves | ES Usar guantes
FR Porter des gants | I T Indossare i guanti
DE Trag Handschuhe | PT Use luvas

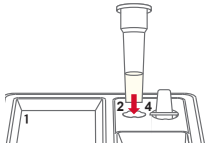
2
EN Assay diluent solution | ES Solución diluyente de ensayo
FR Solution de dilution de dosage | I T Soluzione diluente del saggio
DE Assay-Verdünnungslösung | PT Solução de diluente de ensaio



1
EN Take out the assay diluent tube | ES Saque el tubo de diluyente del ensayo
FR Sortez le tube de diluant de dosage | I T Estrarre il tubo del diluente del dosaggio
DE Nehmen Sie das Testverdünnerröhrchen heraus | PT Retire o tubo de diluente de ensaio

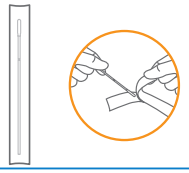


2
EN Seal removal | ES Remoción del sello
FR Retrait du sceau | I T Rimozione del sigillo
DE Entfernen der Dichtung | PT Remoção do selo

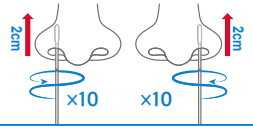


3
EN Mounted on a fixed hole | ES Montado en un agujero fijo
FR Monté sur un trou fixe | I T Montato su un foro fisso
DE An einem festen Loch montiert | PT Montado em um orifício fixo

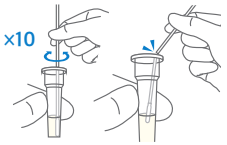
3
EN Swab / ES Torunda | FR Écouvillon / I T Tampone | DE Tupfer / PT Cotonete



1
EN Take out swab | ES Sacar hisopo
FR Sortir l'écouvillon | I T Tira fuori il tampone
DE Tupfer herausnehmen | PT Tirar cotonete



2
EN Specimen collection from both nasal | ES Colección de muestras de ambos nasales
FR Prélèvement d'échantillons à la fois nasale | I T Prelievo di campioni sia da nasale
DE Probenentnahme aus beiden Nasen | PT Coleta de espécime de ambos nasais

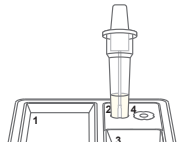


3
EN Dilute and break | ES Diluir y romper
FR Diluer et casser | I T Diluire e rompere
DE Verdünnen und brechen | PT Diluir e quebrar

4
EN Filter cap / ES Tapa de filtro | FR Bouchon de filtre / I T Tappo del filtro | DE Filterkappe / PT Tampa do filtro

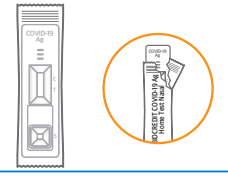


1
EN Insert the filter cap | ES Inserte la tapa del filtro
FR Insérez le bouchon du filtre | I T Inserire il tappo del filtro
DE Setzen Sie die Filterkappe ein | PT Insira a tampa do filtro

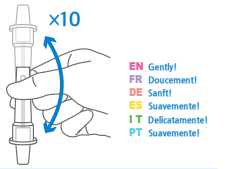


2
EN Mounted on a fixed hole | ES Montado en un agujero fijo
FR Monté sur un trou fixe | I T Montato su un foro fisso
DE An einem festen Loch montiert | PT Montado em um orifício fixo

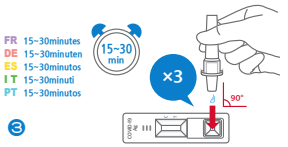
5
EN Device / ES Dispositivo | FR Dispositif / I T Dispositivo | DE Gerät / PT Dispositivo



1
EN Take out the device | ES Saca el dispositivo
FR Sortir l'appareil | I T Estrarre il dispositivo the
DE Nimm das gerät raus | PT Tire o dispositivo

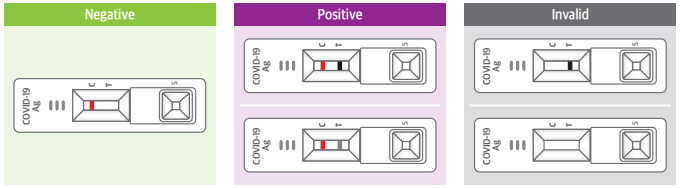


2
EN Specimen mixing | ES Mezcla de muestras
FR Mélange d'échantillons | I T Miscelazione del campione
DE Probenmischung | PT Mistura de espécimes



3
EN Dispense | ES Dispensar
FR Dispenser | I T Dispensare
DE Dosieren | PT Dispensar

EN Interpretation / ES Interpretación | FR Interprétation / I T Interpretazione | DE Interpretation / PT Interpretaçãow



Negative
FR Négative | DE Negativ | ES Negativo
I T Negativo | PT Negativo

Positive
FR Positive | DE Positiv | ES Positivo
I T Positivo | PT Positivo

Invalid
FR Invalide | DE Ungültig | ES Inválido
I T Non valido | PT Inválido

EN Band intensity / ES Intensidad de la banda | FR Intensité de la bande / I T Intensità della banda | DE Bandintensität / PT Intensidade da banda



Negative
EN Negativ
FR Négative
DE Negativ
ES Negativo
I T Negativo
PT Negativo

Wick positive
FR Mèche positive
DE Docht positiv
ES Mecha positiva
I T Atoppino positivo
PT Pavio positivo

Moderate positive
FR Modérément positif
DE Moderat positiv
ES Moderado positivo
I T Moderatamente positivo
PT Moderado positivo

Strong positive
FR Fort positif
DE Stark positiv
ES Fuerte positivo
I T Forte positivo
PT Forte positivo

Negative
EN Negativ
FR Négative
DE Negativ
ES Negativo
I T Negativo
PT Negativo

*EN **Positivity!** Contact the nearest screening clinic *FR **Positivité!** Contactez la clinique de dépistage la plus proche *DE **Positivität!** Kontaktieren Sie die nächste Screening-Klinik *ES **Positividad!** Comuníquese con la clínica de detección más cercana
*I T **Positività!** Contatta la clinica di screening più vicina *PT **Positividade!** Contate a clínica de triagem mais próxima

Manufactured by
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