衡昱集克家用快篩檢測試劑盒

目錄

2022-05-24-第 5.0 版

美國、歐盟、香港、新加坡、台灣核可

✓美國食品藥品管理署核可字號:EUA210259
✓歐盟CE-IVD（體外診斷醫療器材）認證(標準):IVDD98/79/EC Annex III.

全球最被信賴的居家自檢快篩劑

衡昱集克快篩

衛生福利部食藥署核准
防疫專案核准輸入 第1110710592號

美國FDA核准 快速判讀
舒適/簡單/安全/快速/準確

深入鼻孔2公分

10分鐘快速判讀

2入 *獨立使用包裝

衡昱集克快篩　COVID-19　防疫自檢專用

- ✓ 輕鬆採集鼻內樣本進行檢測
- ✓ 極高準確度：敏感性(陽性準確率)97.0%，特異性(陰性準確率)99.0%
- ✓ 可用於公共測試場所、實驗室或聚會論壇等場合
- ✓ 可直接讀取檢驗結果，無需設備
- ✓ 非韓國製造、非大陸製造

感謝以下單位合作使用

台灣塑膠工業股份有限公司｜中興保全股份有限公司｜台灣東洋藥品工業股份有限公司｜杏國新藥股份有限公司｜
財團法人農業科技研究院｜益邦製藥股份有限公司｜健喬信元醫藥生技股份有限公司｜兆豐國際商業銀行｜財團法人中華民國衛生保健基金會

客服專線

台北電話 02-2795-1313　傳真 02-2793-6565　台北市內湖區金莊路100號11樓
台中電話 04-2206-0689　分機 117/121/168/209/715/724　傳真 04-2206-0739　台中市北區太原路二段66號7樓

衡昱電商　穆拉德國際集團 Murad Interantional Group

使用說明書

REF P0038, P0039, P0040, P0041

集克家用新冠病毒抗原快速檢測試劑盒

Indicaid® covid-19 rapid antigen at-home test

防疫專案核准輸入第1110710592號

測試前，請仔細閱讀使用說明。如未有按照說明使用，則可能會令測試結果不準確。

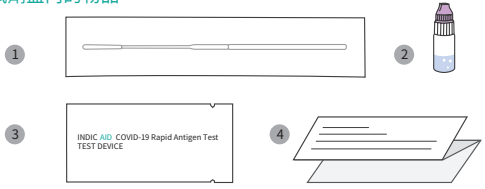
核准之使用範圍與用途:本產品為家用檢驗試劑，使用橫向流動免疫分析法檢測鼻腔檢體中SARS-CoV-2核殼蛋白抗原。適用於2歲以上人士(2至13歲兒童須由成年人協助)自行採檢，於COVID-19的病徵出現後的6天內、無病徵或懷疑感染新冠病毒的其他流行病學原因下，當在3天內進行2次檢測，2次檢測之間最少相隔24小時(但不超過48小時)。陽性結果並不能排除細菌感染或與其他病毒共同感染；陰性結果不能排除SARS-CoV-2感染。本檢測僅提供初步測試結果。不應單以本產品檢驗結果作為病患管理之唯一依據。

注意:

· 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。檢測結果仍須經由專業醫師診斷作 為最終判定。

· 檢測結果如為陽性，請立即前往社區採檢院所篩檢，並依據中央疫情指揮中 心規定執行相關防疫措施。

試劑盒內的物品



1. 獨立包裝採樣棒
2. 測試溶液瓶
3. 獨立包裝測試棒
4. 快速參考指南(見背頁)
5. 使用說明書(本文件)

註：本產品提供2件、4件、12件或24件裝，不同件裝提供的物品數量不同。如要進行測試，請自行準備一個計時器。（試劑盒內並沒有提供）測試最少需25分鐘，假如時間不足，請勿啟動測試。開始測試前，請先洗手最少20秒，並將雙手擦乾。請在室內及室溫環境下，並於乾淨及平坦的表面上進行測試。

注意事項及安全資訊

· 測試前測試棒應保持密封。測試棒一經打開，須在2小時內使用。

· 請勿觸摸採樣棒末端。

· 須按照說明書使用，以確保測試結果正確。

· 只可使用試劑盒中提供的物品進行測試。

· 所有測試部件為一次性使用，不可重複使用。

· 請勿使用過期試劑盒。

· 請勿使用任何包裝出現損壞或已被打開的測試部件。

· 請讓兒童和寵物於使用前後遠離試劑盒及檢測部件。請避免皮膚、眼睛、鼻子或口部接觸試劑盒及檢測部件。請勿吞服任何檢測部件。試劑溶液含有有害化學物質，一旦溶液與身體接觸，請使用大量清水沖洗。如刺激感持續，請尋求醫護人員協助。

· 請勿為不足2 歲兒童進行本測試。

· 2 至13 歲的兒童須由成年人協助測試。

· 為兒童或其他人士採集樣本時，請佩戴口罩或面罩。

· 如樣本採集或處理不當，可能會出現假陰性測試結果。

· 測試期間，請將其他物件和家用清潔產品放置在遠離測試的地方。如接觸其他物件和家用清潔產品（例如1% 漂白劑），可能會令測試結果不正確。

連續測試資訊及限制

假如你在過去6天內出現COVID-19的病徵，你可以進行單次測試。

為無病徵人士進行的測試，應在3天內進行最少2次，每次測試之間最少相隔24小時，但不超過48小時。你可能需要購買額外的試劑盒來進行連續（重複）測試。

在連續測試下，如你的第1個測試結果為陰性，應在24至48小時內使用新的試劑盒再次測試。

當你沒有任何病徵時，連續測試（即每天或隔天測試）檢測到新冠病毒的機會更高。

如你在第1次或第2次測試中的結果為陽性，則表示在你的樣本中檢測出能引發COVID-19的病毒蛋白，以及你可能已感染了新冠病毒。

如你在第1次及第2次測試中的結果均為陰性，則表示你可能沒有感染新冠病毒，但假如你處於感染新冠病毒高風險的環境，則應該與醫護人員安排進一步醫療協助。

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儲存及穩定性

使用前請將集克家用新冠病毒抗原快速檢測試劑存2-30°C(36-86°F)的環境中。請確保所有試劑盒部件在使用前均放置在室溫環境。在外層包裝上所印刷的有效日期前，試劑盒內的物品均為穩定。請勿使用過期的試劑盒。

支援

如有任何疑問或需回報問題，請致電02-2299-3513，或電郵至cs@indic-aid.com或瀏覽indicaid.com。你和醫護人員亦可以瀏覽indicaid.com 以了解更多資訊。本用戶說明書、快速參考指南、供醫護人員閱讀的資料表，以及醫護人員使用說明書，亦可在indicaid.com 上取得。集克家用新冠病毒抗原快速檢測試劑盒的授權書、授權資料表及授權標籤，均可在FDA 網站及indicaid.com 上獲取。

符號說明

IVD 體外診斷試劑	保持乾燥
請查閱使用說明書	不可重覆使用
警告	REF 目錄編號
溫度限制	LOT 批號
避免陽光直射	使用期限
含量足夠測試<N>次	製造商

PHASE SCIENTIFIC

製造業者名稱：Phase Scientific International Limited
製造業者地址：32 & 33F, Gravity, 29 Hing Yip Street, Kwun Tong, Kowloon, Hong Kong

醫療器材商名稱：達正生技醫學股份有限公司
醫療器材商地址：新北市五股區五工路119號4樓

INDICAID 集克 OTC

操作影片

快參考指南

集克家用新冠病毒抗原快速檢測試劑盒

Indicaid® covid-19 rapid antigen at-home test

REF P0038, P0039, P0040, P0041

IVD

適合2歲以上人士使用

使用者必須年滿14 歲方能在無人監督的情況下使用測試套裝

測試前需知

- 本測試有助臨床診斷COVID-19，但不應被用作疾病管理的唯一指標。若你的徵狀持續或惡化，請向醫護人員查詢。
- 本測試套裝僅用於測試現時的感染情況，且無法判斷你過去曾否感染過COVID-19。
- 進行測試前，請仔細閱讀使用說明書並按照說明進行測試以得到準確的結果。
- 若你出現COVID-19的感染徵狀，可進行單次測試。
- 若你沒有出現COVID-19的感染徵狀，你將需要至少進行2次測試。
- 請確保你有足夠的時間完成整個測試程序。完成整個過程大約需要25分鐘。
- 本測試套裝不適用於不足2 歲的兒童。2 - 13 歲兒童的鼻拭子樣本必須由成人(18 歲以上) 協助採樣及測試。
- 為其他人(無論是兒童還是成人) 採集鼻拭子樣本時，請時刻佩戴防護口罩或面罩。

⚠ 於鼻孔採集拭子樣本對能否得到準確的結果十分重要。若你沒有於鼻孔採樣，測試將產生假陰性結果。

進行測試

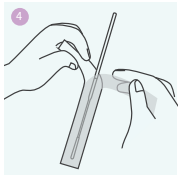
預備你的用具

- 檢查產品包裝盒上的有效日期。
- 取出1 支採樣棒、1 支測試棒和1 個測試溶液瓶。
- 請準備一個可計算20 分鐘的計時器。(試劑盒內並沒有提供)

在進進行測試前和測試後，請徹底洗手最少20秒

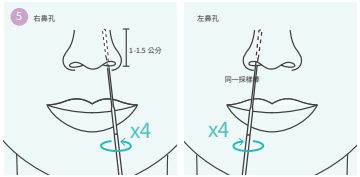
扭開測試溶液瓶的整個瓶蓋

- 將測試溶液瓶的整個瓶蓋(紫色和白色的部分)扭開。
- 將測試溶液瓶和瓶蓋放在平坦的表面上。



打開包裝取出採樣棒

- 為保持採樣棒潔淨，請避免讓採樣棒接觸任何表面，並在進行測試前，方從包裝中取出採樣棒。

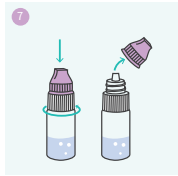


使用同一的採樣棒從兩側鼻孔採集鼻拭子樣本

- 將採樣棒伸進一側鼻孔 (不超過1至1.5公分)；不需過度深入。請參閱圖示
- 採樣棒緊貼鼻孔內壁，輕力按壓並慢慢旋轉最少4 個圈，以採集鼻腔上所有分泌物，這個過程需時約15 秒。
- 使用同一的採樣棒在另一側鼻孔重複同樣的步驟。
- 為兒童採集樣本時，伸進鼻孔的最大深度應少於1公分。同時，你亦可能需要在伸入採樣棒採樣時，由另一人穩定兒童的頭部。

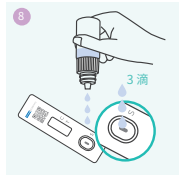
將樣本放進測試溶液瓶

- 請立即將採樣棒放入測試溶液瓶中。傾斜瓶子以確保採樣棒頂端(軟端) 完全浸泡在溶液中。
- 將採樣棒在測試溶液中來回轉動20 次。
- 在取出前，將採樣棒頂端壓向瓶子的內壁並轉動，以除去過多的溶液。
- 請將用過的採樣棒妥善地丟棄在垃圾桶內。



扭上瓶蓋，並露出滴頭

- 扭緊瓶蓋。
- 扭開蓋子的紫色部分，露出滴頭。
- 手指避免觸摸到滴頭。



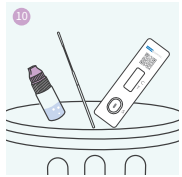
將測試溶液滴到測試棒上

- 打開測試棒的包裝，將測試棒放在平坦的表面上。
- 在測試棒上找出橢圓形開口。
- 慢慢擠出 3 滴溶液到橢圓形開口。
- 滴出少於3 滴溶液於橢圓形開口可能會出現假陰性結果。

將測試棒置於靜止狀態20分鐘，並讀取測試結果

- 啟動計時器，並倒數20 分鐘。
- 將測試棒放在桌上或平面上，直至計時器響起。
- 20 分鐘後，立即檢視你的測試結果。

⚠ 請勿在20分鐘內或多於25分鐘讀取結果，否則測試會出現不準確的結果。



妥善棄置用過的測試套裝

- 判讀完成後，請將本產品所有物品放入提供之塑膠袋中，封緊後依照以下方式處理：
  - 如檢驗結果為陽性，請前往鄰近的社區採檢院所進行檢測，並將密封好之試劑交付採檢院所進行醫療廢棄物處理。
  - 如檢驗結果為陰性，將密封後之塑膠袋依家庭垃圾處理。
- 請勿將測試液傾倒至馬桶或排水管中。

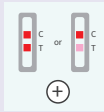
⚠ 採樣後請立即測試樣本。須於採樣後5分鐘內放入提取測試溶液，或在放入提取測試溶液後最多2小時內測試樣本 (存放於室溫下)。

結果解讀

- 尋找測試棒上 (C) (對照)和 (T) (測試)區域旁邊的顯示線。請使用下表解讀所看到的結果

陽性測試結果

陽性測試結果表示從你的樣本中檢測出能引發COVID-19的病毒，你很可能已感染了COVID-19並且具有傳染性。



如同時看到對照線(C)和測試線(T)，則測試結果為陽性。任何帶有對照線(C)和微弱可見的紅色測試線(T)，均應被視為陽性。

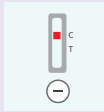
⚠ 請細心留意！“T”區域的顏色深淺度可能會有差異。然而，在“T”字旁出現的任何微弱線均都應被視為陽性結果。

請採取這些後續步驟

如您的測試結果為陽性，請前往醫療院所做進一步的醫療檢查，並依照中央流行疫情指揮中心規定處理。

陰性測試結果

陰性測試結果表示未有在你的樣本中檢測出能引發COVID-19的病毒之抗原。陰性測試結果並不能排除感染COVID-19的可能性。與以實驗室為基礎的分子檢測相比，抗原測試出現假陰性結果的機會較高。因此當你感染新冠病毒時，你在抗原測試中得到陰性結果的機會比分子檢測為高。如果你的檢測結果呈陰性，但持續出現與COVID-19類似的病徵（如發燒、咳嗽及/或呼吸急促），你應向醫護人員尋求醫療協助。



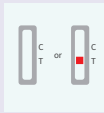
若能見到對照線(C)，但並未見到測試線(T)，測試結果則為陰性

後續步驟

若你出現COVID-19徵狀或徵狀變得嚴重，請立即求醫。若你並沒有任何徵狀，或此次是連續測試計劃中的第一次測試，則必須在第一次測試後的24至48小時之間進行第二次測試。

無效測試結果

若在“C”旁沒有出現任何紅色線，表示測試無效。



⚠ 若“C”旁邊沒有紅線，則無論“T”旁是否有紅線，結果均屬無效。

後續步驟

請用新的集克家用新冠病毒抗原快速檢測試劑盒重新採樣及測試。若你出現COVID-19徵狀或徵狀變得嚴重，請立即求醫。

INDICAID 集克 OTC

操作影片

衡昱集克快篩－外盒中文標籤

集克家用新冠病毒抗原快速檢測試劑盒
INDICAID Covid-19 Rapid Antigen At-Home Test
核准字號：防疫專案核准輸入第 1110710592 號
製造廠名稱：PHASE Scientific International Limited
製造廠地址：32 & 33F, Gravity, 29 Hing Yip Street, Kwun Tong, Kowloon, Hong Kong
醫療器材商名稱：達正生技醫學股份有限公司
醫療器材商地址：新北市五股區五工路 119 號 4 樓
製造批號/保存期限：如包裝所示

《衡昱集克快篩包裝資訊》

！！2 支裝！！

一箱是 126 kit，252 test

一層是 252 x 4 箱 = 1,008 test

一板是 1,008 test x 6 層 = 6,048 支

一紙箱尺寸：57 x 43 x 22 公分

產地：香港 （註：非中國製）

Product Packaging Information

Logistics

PHASE SCIENTIFIC 相達生物科技

Item Details

Item Code	Description	Quantity no of tests	Quantity no of kits	UoM
P0038	INDICAID COVID-19 Rapid Antigen Home Test - 2s - United States OTC	48,384	24,192	PACK

for this enquiry

Shipping Information

Item Code	HTS Code / Tariff Code	FDA/CE Information details
P0038	3822.19.0030	Please check with Phase Operation

Carton details

Item Code	Dimension per carton: Length x Width x Height (cm)	Vol (cbm)	Weight per carton: Gross	Chargeable	TTL Shipping Unit: carton	Vol (cbm)	Chareable Wt.	Sales Unit per carton: Kits	tests
P0038	57 x 43 x 22 cm	0.054 cbm	7.14 Kgs	9.00 Kgs	192.0	10.350 cbm	1,728.45 Kgs	126 kits	252 tests

Pallet details

Item Code	Dimension per pallet: Length x Width x Height (cm)	Vol (cbm)	Weight per full pallet: Gross	Chargeable	TTL Shipping Unit: pallet	Vol (cbm)	Chareable Wt.	Sales Unit per pallet: Kits	tests
P0038	102 x 102 x 148 cm	1.540 cbm	177 Kgs	257 Kgs	8.0	12.320 cbm	2,057.44 Kgs	3,024 kits	6,048 tests

standard packing

Shipping Information

Item Code	HTS Code / Tariff Code	FDA/CE Information details
P0038	3822.19.0030	Please check with Phase Operation

Carton details

Item Code	Dimension per carton: Length x Width x Height (cm)	Vol (cbm)	Weight per carton: Gross	Chargeable	TTL Shipping Unit: carton	Vol (cbm)	Chareable Wt.	Sales Unit per carton: Kits	tests
P0038	57 x 43 x 22 cm	0.054 cbm	7.14 Kgs	9.00 Kgs	1.0	0.050 cbm	8.35 Kgs	126 kits	252 tests

Pallet details

Item Code	Dimension per pallet: Length x Width x Height (cm)	Vol (cbm)	Weight per full pallet: Gross	Chargeable	TTL Shipping Unit: pallet	Vol (cbm)	Chareable Wt.	Sales Unit per pallet: Kits	tests
P0038	102 x 102 x 148 cm	1.540 cbm	177 Kgs	257 Kgs	1.0	1.540 cbm	257.18 Kgs	3,024 kits	6,048 tests

Cartons per Pallet

No of Layers	Cartons per Layer	No of Cartons
6.0	4.0	24.0

抄本

檔　　號：
保存年限：

衛生福利部　函

地址：115204 臺北市南港區忠孝東路六段488號
聯絡人：陳柏任
聯絡電話：2787-8087
傳真：
電子郵件：pjchen53@fda.gov.tw

受文者：如正、副本行文單位

發文日期：中華民國111年5月13日
發文字號：衛授食字第1110710592號
速別：普通件
密等及解密條件或保密期限：
附件：專案輸入醫療器材名稱數量一覽表

主旨：有關貴公司因嚴重特殊傳染性肺炎防疫需求，申請專案輸入「集克家用新冠病毒抗原快速檢測試劑盒 /Indicaid covid-19 rapid antigen at-home test」醫療器材供國內緊急公共衛生使用一案，本部原則同意，復請查照。

說明：

一、復貴公司111年4月28日及111年5月9日特定醫療器材專案核准製造或輸入申請書。

二、本部同意貴公司專案輸入醫療器材1批（簽審文件編號:DHS00001164702）如附件，共4項次。

三、核准之使用範圍與用途：本產品為家用檢驗試劑，使用橫向流動免疫分析法檢測鼻腔檢體中SARS-CoV-2核殼蛋白抗原。適用於2歲以上人士(2至13歲兒童須由成年人協助)自行採檢，於COVID-19的病徵出現後的6天內、無病徵或懷疑感染新冠病毒的其他流行病學原因下，當在3天內進行2次檢測，

2次檢測之間最少相隔24小時(但不超過48小時)。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。本檢測僅提供初步測試結果。不應單以本產品檢驗結果作為病患管理之唯一依據。

四、本同意函限量多用，有效期間：自發文日起至中央流行疫情指揮中心解散日止。

五、本案核准產品之販售流通，應符合醫療器材管理法規定，且作為嚴重特殊傳染性肺炎防治使用，其使用及處置，不得逾越或違反核准之目的、限制、方式、期限或其他相關內容。

六、法律依據及理由

(一)醫療器材管理法第35條第1項第2款規定略以:「中央主管機關得因應緊急公共衛生情事之需要，專案核准特定醫療器材之輸入。」。

(二)行政程序法第93條第1項及第2項規定略以:「(第1項)行政機關作成行政處分有裁量權時，得為附款。」，「(第2項)前項所稱之附款如下:…三、負擔。四、保留行政處分之廢止權。…」。

(三)查本產品已完成基本之分析性能測試，及具備適當之品質風險控管，基於現實防疫需求，考量預期利益超過可能風險，爰予旨揭同意。惟為使公益之維護更為周全，爰予附加附款。

七、本同意處分有以下之負擔，貴公司應予遵行：

(一)產品包裝上應依醫療器材管理法第32條及第33條標示，其中許可證字號事項，請刊載「防疫專案核准輸入第1110710592號」字樣。

(二)以書面建立生產日期、批號與各批號生產數量，及販售對象名稱、販售日期、販售批號與各批號數量之紀錄，並請貴公司每月定期向本部提報產品流向及使用情形。

(三)每月應評估產品檢測新出現的突變和變異株性能，及加強本產品使用情形之監視相關資料應留廠備查(必要時須提供本部審查)，如有發現評估檢測低於臨床性能規格要求及知有檢測結果不一致情事者，立即通報本部食品藥物管理署。

(四)本產品係因緊急公共衛生情事，專案核准使用，不得有醫療器材廣告行為。違者，依醫療器材管理法相關規定處辦。

八、本同意處分，除得依醫療器材管理法第36條第1項第2款或第3款規定辦理外，中央主管機關亦得依行政程序法第93條第2項第4款、同法第123條第4款或第5款規定，隨時就最新科學發展、檢測結果、疫情變化，及其他檢驗試劑、治療藥品或疫苗之供應狀態，為利益風險之衡量後，廢止本同意處分，並令申請者限期處理未使用之醫療器材，並得公告回收。

九、受處分人如對本處分不服，得依訴願法第14條第1項、第58條第1項規定，自處分書送達之次日30日內，遞送訴願書至本部，由本部層轉訴願管轄機關行政院提起訴願。

十、副本抄送財政部關務署、本部疾病管制署、本部中央健康保險署及新北市政府衛生局。

正本：達正生技醫學股份有限公司
副本：財政部關務署、衛生福利部疾病管制署、衛生福利部中央健康保險署、新北市政府衛生局(均含附件)

專案輸入醫療器材名稱數量一覽表

公文文號：衛授食字第1110710592號

製造廠：Phase Scientific International Limited

製造廠地址：32 & 33F, Gravity, 29 Hing Yip Street, Kwun Tong, Kowloon, Hong Kong

項次	貨名、規格、廠牌及製造廠名稱	數量	單位	生產國別	製造廠
1	集克家用新冠病毒抗原快速檢測試劑盒 Indicaid covid-19 rapid antigen at-home test (P0038)(2 Tests/Kit)	400萬	Kit	香港	Phase Scientific International Limited
2	集克家用新冠病毒抗原快速檢測試劑盒 Indicaid covid-19 rapid antigen at-home test (P0039)(4 Tests/Kit)	26萬	Kit	香港	Phase Scientific International Limited
3	集克家用新冠病毒抗原快速檢測試劑盒 Indicaid covid-19 rapid antigen at-home test (P0040)(12 Tests/Kit)	4萬	Kit	香港	Phase Scientific International Limited
4	集克家用新冠病毒抗原快速檢測試劑盒 Indicaid covid-19 rapid antigen at-home test (P0041)(24 Tests/Kit)	2萬	Kit	香港	Phase Scientific International Limited
	共計	432萬 Kits (1000萬 Tests)			

達正生技醫學股份有限公司
TOUCH BIO MEDICAL CORPORATION
新北市五股區五工路119號4樓
TEL：02-22984119

總經銷證明書

茲證明

衡昱電商股份有限公司

於

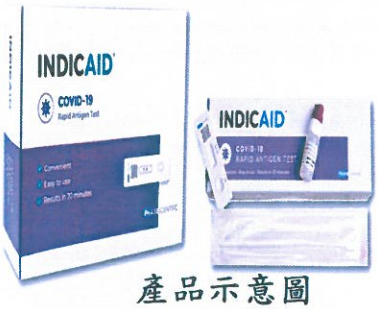
2022年05月11日起至2024年05月10日

為衡昱集克快篩

新型冠狀病毒抗原自我檢測(鼻腔)

INDICAID SARS-CoV-2 Antigen self Test Nasal

在台灣地區的唯一總經銷商



產品示意圖

達正生技醫學股份有限公司
董事長　歐　正　義

297 | HKG | 82005770

CYTS-91853

Shipper's Name and Address | **Shipper's Account Number**

PHASE SCIENTIFIC INTERNATIONAL LIMITED
32 & 33F, GRAVITY, 29 HING YIP STREET,
KWUN TONG KOWLOON, HONG KONG

NOT NEGOTIABLE

Air Waybill

Issued by

CYTS-SPIRIT LOGISTICS LIMITED
6/F, EVER GAIN CENTRE,
43-57 WANG WO TSAI STREET, TSUEN WAN
N.T, HONG KONG TEL:85239020500 CTC:ANDY CHAN
SHP-TRADE REGISTER NUMBER39897545

Copies 1, 2 and 3 of this Air Waybill are originals and have the same validity.

Consignee's Name and Address | **Consignee's Account Number**

TOUCH BIO MEDICAL CORPORATION
4 F., NO. 119, WUGONG RD., WUGU DIST.,
NEW TAIPEI CITY 24886,
TAIWAN(R.O.C.)
TEL: +886222993513

Issuing Carrier's Agent Name and City

CYTS-SPIRIT LOGISTICS LIMITED

Accounting Information FREIGHT COLLECT

UBC LOGISTICS CO., LTD
4/F, NO.66, SEC-2, JIANGUO N ROAD,
TAIPEI 104, TAIWAN
TEL:886-2-2507-1118
FAX:886-2-2507-0898

Agent's IATA Code: 1330951 | **Account No.**:

Airport of Departure (Addr. of First Carrier) and Requested Routing: HONG KONG

Reference Number | **Optional Shipping Information**

To	By First Carrier	Routing and Destination to	by	to	by
TPE	CI				

Currency	CHGS Code	WT/VAL PPD	WT/VAL COLL	Other PPD	Other COLL	Declared Value for Carriage	Declared Value for Customs
HKD	CC		CC		CC	N.V.D.	AS PER INVOICE

Airport of Destination	Flight/Date		Amount of Insurance	INSURANCE - If Carrier offers insurance, and such insurance is requested in accordance with the conditions thereof, indicate amount to be insured in figures in box marked "Amount of Insurance."
TAIPEI	CI5836	17MAY2022	NIL	

Handling Information

TOTAL: TWENTY-FIVE (25) PALLET(S) ONLY

COMMERCIAL INVOICE & PACKING LIST ATTACHED.

SCI

No of Pieces RCP	Gross Weight	Kg lb	Rate Class Commodity Item No.	Chargeable Weight	Rate / Charge	Total	Nature and Quantity of Goods (incl. Dimensions or Volume)
25	4228.0-K	K	Q	6676.0-K	AS ARRANGED DIM: 102x102x154cm/25.		INDICAID COVID-19 RAPID ANTIGEN AT-HOME TEST P0038 (2 TESTS/KIT) "FREIGHT COLLECT"

Prepaid	Weight Charge	Collect	Other Charges
	AS ARRANGED		

Valuation Charge

Tax

Total other Charges Due Agent

Total other Charges Due Carrier

Total Prepaid	Total Collect
	AS ARRANGED

Currency Conversion Rates	CC Charges in Dest. Currency

For Carrier's Use only at Destination | Charges at Destination | Total Collect Charges

Shipper certifies that the particulars on the face hereof are correct and that insofar as any part of the consignment contains dangerous goods, such part is properly described by name and is in proper condition for carriage by air according to the applicable Dangerous Goods Regulations.

Job No: AE22050170
CYTS-SPIRIT LOGISTICS LIMITED

Signature of Shipper or his Agent

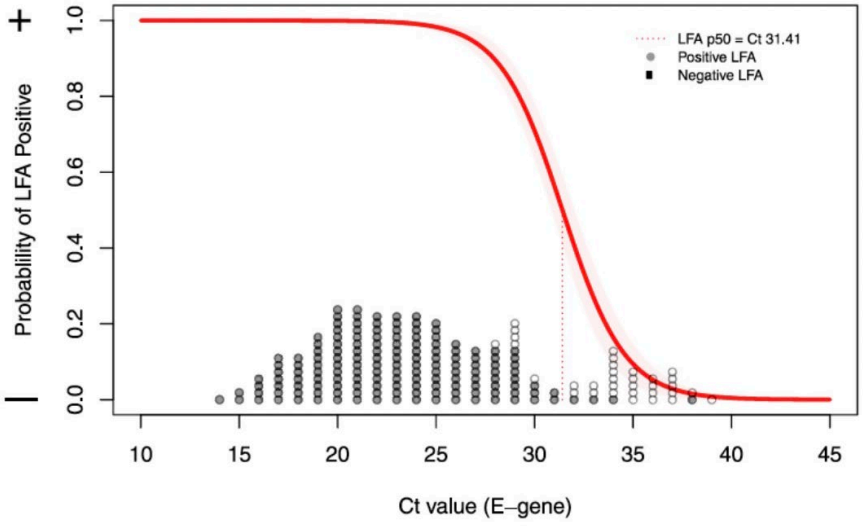
17May2022 HONG KONG AIROPS4

Executed on (date) at(place) Signature of Issuing Carrier or its Agent

CYTS-91853

衡昱集克快篩 比對 亞培 Panbio 快篩 之精確度對比

美國亞培"Panbio"快篩



美國CDC警告說亞培產品，

有近60%無症狀感染者是抓不到的

PHASESCIENTIFIC

Table 1.Positive and negative percent agreement between INDICAID and the comparator method for all tested patients.

INDICAID® COVID-19 Rapid Antigen Test	Comparator Method (RT-PCR ONCO-PHASE)		
	Positive	Negative	Total
Positive	14	5	19
Negative	1	9,114	9,115
Total	15	9,119	9,143
PPA	93.33%		
NPA	99.95%		

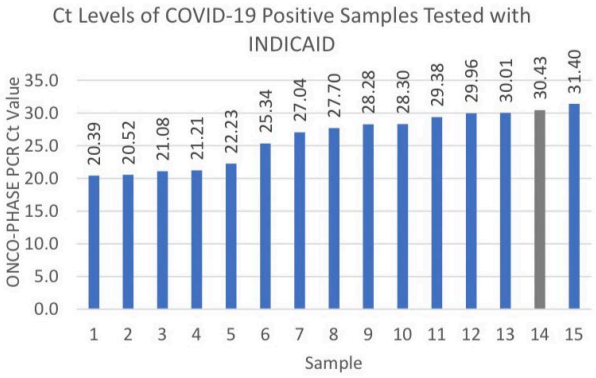


Figure 1. Ct values of the 15 positive patient samples that were detected by RT-PCR during the dual-track testing are shown. The INDICAID COVID-19 Rapid Antigen Test correctly detected 14 of the 15 positive samples (blue bars), while one positive sample was not detected by INDICAID (grey bar).

衡昱集克快篩 CT 30.43，精確度優於 亞培 Panbio 快篩 CT 28.

Protocol: EXT-00027 Clinical Evaluation of Phase Scientific's INDICAID™ COVID-19 Rapid Antigen Home Test in Nasal Swab Samples

1. Purpose

The objective of this study is to evaluate the clinical performance of the Phase Scientific INDICAID COVID-19 Rapid Antigen At-Home Test in anterior nasal swab samples from symptomatic and asymptomatic individuals, both with or without reason to suspect COVID-19 by a healthcare provider. The clinical performance of the INDICAID COVID-19 Rapid Antigen At-Home Test was evaluated in the hands of the intended user at four (4) clinical study sites that were representative of OTC/home-use test settings. Subject visits took place in exam rooms set up to simulate home environments with basic necessities such as a sink, garbage can, table space, adequate lighting, etc.

2. Study Design

Study Population:

Subjects enrolled into the study included individuals with or without symptoms or other epidemiological reasons to suspect COVID-19. Subjects were from different socioeconomic and educational backgrounds, as well as spanned across all ages (2 – 65+ years old).

A total of 356 subjects were prospectively enrolled across four (4) sites in the United States (US), including 33 children between the ages of 2 and 13 to ensure that the proposed sample collection techniques can be conducted by parents or guardians in a home use setting. The study prospectively enrolled subjects until at least 30 positive samples and 30 negative samples were obtained. An interim analysis was conducted, and the study data from 82 positive subjects will be used to support an Emergency Use Authorization (EUA) submission for the INDICAID Rapid Antigen At-Home Test. Simultaneously, study sites continued to enroll subjects until at least 20 positive samples from asymptomatic individuals were acquired. Subjects had to meet all inclusion and exclusion criteria to be enrolled in the study.

Inclusion Criteria	Subjects eligible to participate in the study were required to meet the following criteria: 1. Willing and able to provide written, signed informed consent, or in the case of patients <18 years, provide written assent (if required) and written informed consent by a legally authorized representative after the study has been explained and prior to any study specific procedures. 2. Stated willingness and ability to comply with the study procedures including nasal swab collection. 3. Exhibiting at least one symptom of COVID-19; or presenting no symptoms or reasons to suspect COVID-19 within 14 days of study enrolment.

Exclusion Criteria	Subjects who met any of the following criteria were not enrolled in the study: 1. Subject is < 2 years of age 2. Previously enrolled in the study 3. Knows infected status (positive or negative) based on a predecessor COVID-19 test resulted in 14 days prior to enrolment 4. Prior medical or laboratory training 5. Regularly uses a home diagnostic test

Sample Collection Method:

Each consented subject aged 14 and over self-collected and self-tested a nasal swab sample using the INDICAID COVID-19 Rapid Antigen At-Home Test, per the instructions detailed in the IFU (user instructions/quick reference guide). For pediatric subjects aged two (2) to 13 years, a parent or legal guardian collected the sample, conducted the test, and interpreted and documented the result for the enrolled subject.

At least 15 minutes after the subject self-collected their nasal swab sample, a health care provider (HCP) also collected another nasal swab from the subject for testing at the central laboratory with an EUA RT-PCR assay – Hologic Panther Fusion® SARS-CoV-2 Assay. Samples were processed per the Panther Fusion® SARS-CoV-2 Assay Instructions For Use.

Results Interpretation:

After the test was completed, each subject interpreted the test result and documented their observation, followed by an independent result interpretation of their test by the HCP. Results were interpreted using a blinded version of,the IFU, which listed the possible test outcomes and the corresponding pictures labeled as Option 1, Option 2, and Option 3. Both the subject and the HCP interpreted the results no earlier than 20 minutes and no later than 25 minutes from when the sample was added to the test device.

Comparator Method:

The Hologic Panther Fusion SARS-CoV Assay was used for a comparator test. Anterior nasal (nares) swab specimens were collected using Copan Diagnostics Single Nasal UTM Specimen Collection Kit (SKU #3C064N) for the comparator test. Specimens were collected in viral transport medium (VTM).

Acceptance Criteria:

- Negative percent agreement (NPA) > 98%
- Positive percent agreement (PPA) > 80% with a lower bound of the two-sided 95% confidence interval > 70%

3. Results

Data collected from patients with symptom onset within six (6) days are the basis for the performance claims, as this is the optimized time interval that supports the intended use of the INDICAID COVID-19 Rapid Antigen At-Home Test for patients presenting with symptoms. Data collected from patients presenting with symptoms greater than six (6) days or without symptoms are not included in the analyses.

The INDICAID COVID-19 Rapid Antigen At-Home Test results were compared against the results of the Hologic Panther Fusion SARS-CoV-2 Assay to calculate the positive percent agreement (PPA), negative percent agreement (NPA), and overall percent agreement (OPA). When conducted by a lay-user, the INDICAID COVID-19 Rapid Antigen At-Home Test identified 81.7% (95% CI: 72.0% - 88.6%) of the subjects that were identified as SARS-CoV-2 positive by the comparator assay. Additionally, INDICAID COVID-19 Rapid Antigen At-Home Test correctly identified 99.4% (95% CI: 96.5% - 99.9%) of SARS-CoV-2 negative subjects.

INDICAID COVID-19 Rapid Antigen At-Home Test Performance Against Hologic Panther Fusion Comparator Method (Within 6 Days Symptom Onset):

INDICAID® COVID-19 Rapid Antigen At-Home Test	Comparator Method		
	Positive	Negative	Total
Positive	67	1	68
Negative	15	159	174
Total	82	160	242
PPA	81.7% (95% CI: 72.0% - 88.6%)		
NPA	99.4% (95% CI: 96.5% - 99.9%)		
OPA	93.4% (95% CI: 89.5% - 95.9%)		

INDICAID COVID-19 Rapid Antigen At-Home Test Performance Against Hologic Panther Fusion Comparator Method, Ct < 35 (Within 6 Days Symptom Onset):

INDICAID® COVID-19 Rapid Antigen At-Home Test	Comparator Method		
	Positive	Negative	Total
Positive	67	1	68
Negative	10	159	169
Total	77	160	237
PPA	87.0% (95% CI: 77.7% - 92.8%)		
NPA	99.4% (95% CI: 96.5% - 99.9%)		
OPA	95.4% (95% CI: 91.9% - 97.4%)		

Positive results by age (years) of patient:

Age, years	Total	Comparator Positive	Prevalence	INDICAID Positive
2 to 13	23	6	26.1%	4
14 to 24	34	14	41.2%	14
25 to 64	150	54	36.0%	45
65+	34	8	23.5%	4

Positive results by days since symptom onset:

Days Since Symptom Onset	Cumulative Comparator Positive	Cumulative INDICAID Positive	PPA
1	13	10	76.9%
2	35	30	82.9%
3	52	43	80.8%
4	63	52	81.0%
5	74	61	81.1%
6	82	68	81.7%

Separate analysis excluding samples due to protocol deviation:

A protocol deviation was reported for a subset of 12 subjects enrolled in the study. The deviation that occurred was for the interpretation of test results at 20 minutes (and no later than 25 minutes) as specified in the INDICAID COVID-19 Rapid Antigen At-Home Test IFU. Eleven subjects read the test result between 1 and 4 minutes before the 20-minute read time and one subject read the test result 10 minutes after the 20-minute mark.

A sub-analysis with these subjects removed is presented and demonstrates that the procedural deviation has negligible impact on the clinical performance of the test (81.7% vs. 82.1% PPA). Furthermore, our analytical flex studies evaluating the effect of read time variation on test result interpretation demonstrated that interpreting the result up to 10 minutes before and 90 minutes after the recommended 20-minute read time still produces the expected result.

INDICAID® COVID-19 Rapid Antigen At-Home Test	Comparator Method		
	Positive	Negative	Total
Positive	64	1	65
Negative	14	151	165
Total	78	152	230
PPA	82.1% (95% CI: 72.1% - 89.0%)		
NPA	99.3% (95% CI: 96.4% - 99.9%)		
OPA	93.5% (95% CI: 89.5% - 96.0%)		

4. Raw Data

Subject ID	Currently symptomatic?	Days since symptom onset	INDICAID - Subject Reported Result	INDICAID - HCP Reported Result	PCR Ct Value	Has a deviation from the protocol occurred?
648000	Yes	4	Negative	Negative	Not Detected	No
648001	Yes	3	Negative	Negative	Not Detected	No
648002	Yes	0	Negative	Negative	Not Detected	No
648003	Yes	3	Negative	Negative	Not Detected	No
648005	Yes	2	Negative	Negative	Not Detected	No
648006	Yes	3	Negative	Negative	Not Detected	No
648007	Yes	3	Negative	Negative	Not Detected	No
648008	Yes	2	Negative	Negative	Not Detected	No
648009	Yes	5	Negative	Negative	Not Detected	No
648010	Yes	4	Negative	Negative	Not Detected	No
648011	Yes	3	Negative	Negative	Not Detected	No
648013	Yes	3	Negative	Negative	Not Detected	No
648014	Yes	6	Positive	Positive	28.6	No
648015	Yes	5	Negative	Negative	Not Detected	No
648016	Yes	2	Negative	Negative	Not Detected	No
648017	Yes	2	Negative	Negative	Not Detected	No
648018	Yes	0	Negative	Negative	Not Detected	No
648020	Yes	3	Negative	Negative	Not Detected	No
648022	Yes	4	Negative	Negative	Not Detected	No
648025	Yes	2	Negative	Negative	Not Detected	No
648030	Yes	4	Negative	Negative	Not Detected	No
648023	Yes	1	Positive	Positive	24.6	No
648024	Yes	2	Negative	Negative	Not Detected	No
648026	Yes	2	Negative	Negative	Not Detected	No
648029	Yes	1	Negative	Negative	38	No
648031	Yes	2	Negative	Negative	Not Detected	No
648032	Yes	1	Positive	Positive	21.8	No
648034	Yes	1	Negative	Negative	Not Detected	No
648027	Yes	3	Negative	Negative	Not Detected	No
648028	Yes	2	Negative	Negative	Not Detected	No
648033	Yes	3	Negative	Negative	Not Detected	No
648035	Yes	3	Positive	Positive	27.6	No
648036	Yes	2	Positive	Positive	17.7	No
648037	Yes	4	Negative	Negative	Not Detected	No
648038	Yes	4	Negative	Negative	Not Detected	No
648039	Yes	1	Negative	Negative	Not Detected	Yes - HCP & subject result read out of 20-25 min window
648040	Yes	2	Negative	Negative	Not Detected	No

Subject ID	Currently symptomatic?	Days since symptom onset	INDICAID - Subject Reported Result	INDICAID - HCP Reported Result	PCR Ct Value	Has a deviation from the protocol occurred?
648088	Yes	3	Positive	Positive	15.8	No
648089	Yes	3	Positive	Positive	20.6	No
648090	Yes	2	Positive	Positive	21.2	No
648091	Yes	1	Negative	Negative	28.3	No
648092	Yes	4	Negative	Negative	Not Detected	No
648093	Yes	2	Negative	Negative	Not Detected	No
648094	Yes	5	Negative	Negative	32.5	No
648095	Yes	4	Positive	Positive	25.9	No
648096	Yes	1	Negative	Negative	Not Detected	No
648085	Yes	3	Negative	Negative	Not Detected	No
648211	Yes	5	Negative	Negative	Not Detected	No
648212	Yes	2	Negative	Negative	Not Detected	No
648213	Yes	1	Negative	Negative	Not Detected	No
648214	Yes	3	Negative	Negative	Not Detected	No
648215	Yes	1	Negative	Negative	Not Detected	No
648216	Yes	2	Negative	Negative	Not Detected	No
648217	Yes	6	Negative	Negative	Not Detected	No
648218	Yes	4	Negative	Negative	Not Detected	No
648219	Yes	2	Negative	Negative	Not Detected	No
648220	Yes	4	Negative	Negative	Not Detected	No
648221	Yes	5	Negative	Negative	Not Detected	No
648222	Yes	4	Negative	Negative	Not Detected	No
648223	Yes	4	Negative	Negative	Not Detected	No
648224	Yes	5	Negative	Negative	Not Detected	No
648225	Yes	3	Negative	Negative	Not Detected	No
648227	Yes	2	Negative	Negative	Not Detected	No
648228	Yes	1	Negative	Negative	Not Detected	No
648229	Yes	6	Negative	Negative	Not Detected	No
648230	Yes	6	Negative	Negative	Not Detected	No
648231	Yes	2	Negative	Negative	Not Detected	No
648232	Yes	6	Negative	Negative	Not Detected	No
648233	Yes	3	Negative	Negative	Not Detected	No
648235	Yes	2	Negative	Negative	Not Detected	No
648236	Yes	1	Negative	Negative	Not Detected	No
648238	Yes	3	Negative	Negative	Not Detected	No
648239	Yes	4	Negative	Negative	Not Detected	No
648241	Yes	6	Negative	Negative	Not Detected	No
648243	Yes	6	Negative	Negative	Not Detected	No
648242	Yes	3	Negative	Negative	Not Detected	No
648244	Yes	2	Negative	Negative	Not Detected	No

Subject ID	Currently symptomatic?	Days since symptom onset	INDICAID - Subject Reported Result	INDICAID - HCP Reported Result	PCR Ct Value	Has a deviation from the protocol occurred?
648246	Yes	4	Negative	Negative	Not Detected	No
648247	Yes	2	Negative	Negative	Not Detected	No
648248	Yes	3	Negative	Negative	Not Detected	No
648249	Yes	3	Negative	Negative	Not Detected	No
648250	Yes	3	Negative	Negative	Not Detected	No
648251	Yes	1	Negative	Negative	Not Detected	No
648252	Yes	3	Negative	Negative	Not Detected	No
648253	Yes	6	Negative	Negative	Not Detected	No
648042	Yes	1	Negative	Negative	Not Detected	No
648045	Yes	2	Negative	Negative	Not Detected	No
648044	Yes	1	Positive	Positive	23	No
648043	Yes	3	Negative	Negative	Not Detected	No
648046	Yes	3	Negative	Negative	Not Detected	No
648047	Yes	1	Positive	Positive	26.7	No
648048	Yes	3	Positive	Positive	30.7	No
648049	Yes	2	Negative	Negative	Not Detected	No
648086	Yes	2	Positive	Positive	19.5	No
648087	Yes	3	Negative	Negative	Not Detected	No
648097	Yes	2	Negative	Negative	30.9	No
648098	Yes	3	Negative	Negative	Not Detected	No
648099	Yes	2	Negative	Negative	25.5	No
648100	Yes	3	Positive	Positive	26.5	No
648101	Yes	3	Negative	Negative	Not Detected	No
648102	Yes	2	Negative	Negative	Not Detected	No
648103	Yes	3	Negative	Negative	Not Detected	No
648104	Yes	3	Positive	Positive	27.2	No
648105	Yes	2	Positive	Positive	22.1	No
648106	Yes	2	Positive	Positive	33	No
648107	Yes	4	Positive	Positive	28	No
648108	Yes	3	Negative	Negative	Not Detected	No
648109	Yes	1	Negative	Negative	Not Detected	No
648110	Yes	2	Negative	Negative	Not Detected	No
648111	Yes	1	Positive	Positive	23.8	No
648112	Yes	2	Negative	Negative	Not Detected	No
648113	Yes	3	Negative	Negative	Not Detected	No
648114	Yes	3	Negative	Negative	Not Detected	No
648115	Yes	1	Negative	Negative	Not Detected	No
648116	Yes	3	Positive	Positive	28.2	No
648118	Yes	3	Negative	Negative	Not Detected	No
648119	Yes	3	Negative	Negative	Not Detected	No

Subject ID	Currently symptomatic?	Days since symptom onset	INDICAID - Subject Reported Result	INDICAID - HCP Reported Result	PCR Ct Value	Has a deviation from the protocol occurred?
648120	Yes	3	Negative	Negative	36.7	No
648121	Yes	3	Positive	Positive	23.2	No
648122	Yes	3	Negative	Negative	Not Detected	No
648123	Yes	3	Negative	Negative	28.7	No
648129	Yes	3	Negative	Negative	Not Detected	No
648130	Yes	3	Positive	Positive	22.2	No
648131	Yes	4	Positive	Positive	24.3	No
648136	Yes	2	Positive	Positive	19.3	No
648138	Yes	5	Positive	Positive	19.4	No
648139	Yes	3	Positive	Positive	32.3	No
648254	Yes	2	Negative	Negative	Not Detected	Yes - HCP & subject result read out of 20-25 min window
648255	Yes	5	Negative	Negative	Not Detected	No
648256	Yes	5	Negative	Negative	Not Detected	No
648257	Yes	3	Negative	Negative	Not Detected	No
648258	Yes	3	Negative	Negative	Not Detected	No
648259	Yes	4	Negative	Negative	Not Detected	No
648260	Yes	1	Negative	Negative	Not Detected	No
648117	Yes	4	Negative	Negative	Not Detected	No
648124	Yes	5	Positive	Positive	30.4	No
648125	Yes	4	Negative	Negative	Not Detected	No
648126	Yes	2	Positive	Positive	22	No
648127	Yes	2	Positive	Positive	Not Detected	No
648128	Yes	2	Positive	Positive	26.5	No
648137	Yes	3	Negative	Negative	Not Detected	No
648140	Yes	1	Negative	Negative	Not Detected	No
648141	Yes	4	Negative	Negative	Not Detected	No
648142	Yes	6	Positive	Positive	30.7	No
648143	Yes	4	Positive	Positive	25	No
648146	Yes	4	Positive	Positive	22.7	No
648147	Yes	4	Negative	Negative	Not Detected	No
648148	Yes	1	Negative	Negative	36.1	No
648149	Yes	5	Negative	Negative	27.4	No
648151	Yes	4	Negative	Negative	29.7	No
648152	Yes	5	Positive	Positive	22	No
648153	Yes	1	Negative	Negative	Not Detected	No
648154	Yes	5	Positive	Positive	19.2	No
648155	Yes	2	Positive	Positive	19.3	No
648156	Yes	6	Positive	Positive	23.6	No

Subject ID	Currently symptomatic?	Days since symptom onset	INDICAID - Subject Reported Result	INDICAID - HCP Reported Result	PCR Ct Value	Has a deviation from the protocol occurred?
648157	Yes	2	Negative	Negative	Not Detected	No
648158	Yes	1	Negative	Negative	Not Detected	No
648159	Yes	4	Negative	Negative	Not Detected	No
648161	Yes	4	Negative	Negative	Not Detected	No
648162	Yes	4	Negative	Negative	Not Detected	No
648163	Yes	1	Positive	Positive	26	No
648164	Yes	6	Positive	Positive	31.6	No
648168	Yes	1	Negative	Negative	Not Detected	No
648167	Yes	3	Positive	Positive	19.8	No
648133	Yes	2	Positive	Positive	21.4	Yes - HCP & subject result read out of 20-25 min window
648134	Yes	2	Positive	Positive	30.2	No
648175	Yes	3	Negative	Negative	Not Detected	No
648177	Yes	4	Negative	Negative	Not Detected	No
648178	Yes	1	Negative	Negative	Not Detected	No
648264	Yes	1	Positive	Positive	26.3	No
648267	Yes	3	Negative	Negative	Not Detected	Yes - HCP & subject result read out of 20-25 min window
648275	Yes	5	Negative	Negative	Not Detected	Yes - HCP & subject result read out of 20-25 min window
648276	Yes	2	Negative	Negative	Not Detected	Yes - HCP & subject result read out of 20-25 min window
648279	Yes	4	Negative	Negative	Not Detected	Yes - HCP & subject result read out of 20-25 min window
648282	Yes	2	Positive	Positive	22.9	Yes - HCP & subject result read out of 20-25 min window
648286	Yes	6	Positive	Positive	22.9	Yes - HCP & subject result read out of 20-25 min window
648411	Yes	2	Negative	Negative	Not Detected	No
648413	Yes	1	Negative	Negative	Not Detected	No
648414	Yes	5	Negative	Negative	Not Detected	No
648415	Yes	2	Negative	Negative	Not Detected	No
648416	Yes	2	Negative	Negative	Not Detected	No
648417	Yes	5	Positive	Positive	20.5	No
648418	Yes	1	Negative	Negative	Not Detected	No
648419	Yes	2	Negative	Negative	Not Detected	No
648420	Yes	5	Negative	Negative	Not Detected	No

Subject ID	Currently symptomatic?	Days since symptom onset	INDICAID - Subject Reported Result	INDICAID - HCP Reported Result	PCR Ct Value	Has a deviation from the protocol occurred?
648421	Yes	5	Negative	Negative	Not Detected	No
648422	Yes	3	Negative	Negative	Not Detected	No
648423	Yes	6	Negative	Negative	Not Detected	No
648424	Yes	1	Positive	Positive	21.2	No
648425	Yes	1	Positive	Positive	28.3	No
648426	Yes	2	Positive	Positive	21.3	No
648427	Yes	3	Negative	Negative	Not Detected	No
648428	Yes	5	Positive	Positive	17.2	No
648429	Yes	3	Negative	Negative	Not Detected	No
648430	Yes	6	Positive	Positive	24.4	No
648431	Yes	6	Negative	Negative	Not Detected	No
648432	Yes	4	Positive	Positive	26.4	No
648433	Yes	3	Negative	Negative	34	No
648435	Yes	2	Negative	Negative	35.5	No
648434	Yes	2	Negative	Negative	Not Detected	No
648436	Yes	3	Positive	Positive	19.9	No
648437	Yes	6	Negative	Negative	27.7	No
648438	Yes	4	Positive	Positive	18.1	No
648439	Yes	2	Positive	Positive	20.1	No
648442	Yes	3	Negative	Negative	Not Detected	No
648444	Yes	5	Negative	Negative	Not Detected	No
648445	Yes	2	Negative	Negative	Not Detected	No
648446	Yes	4	Positive	Positive	26.1	No
648447	Yes	4	Negative	Negative	Not Detected	No
648448	Yes	2	Positive	Positive	18.3	No
648449	Yes	2	Negative	Negative	Not Detected	No
648450	Yes	1	Negative	Negative	Not Detected	No
648451	Yes	1	Positive	Positive	18.3	No
648452	Yes	3	Negative	Negative	Not Detected	No
648453	Yes	5	Positive	Positive	26.7	No
648454	Yes	2	Positive	Positive	32.8	No
648455	Yes	3	Negative	Negative	38.1	No
648456	Yes	2	Negative	Negative	Not Detected	No
647035	Yes	4	Positive	Positive	17.5	No
647036	Yes	6	Positive	Positive	33.2	No
647039	Yes	1	Negative	Negative	Not Detected	No
647040	Yes	3	Negative	Negative	Not Detected	No
647045	Yes	1	Negative	Negative	Not Detected	No
648179	Yes	5	Positive	Positive	17.3	No

Subject ID	Currently symptomatic?	Days since symptom onset	INDICAID - Subject Reported Result	INDICAID - HCP Reported Result	PCR Ct Value	Has a deviation from the protocol occurred?
648301	Yes	5	Negative	Negative	Not Detected	HCP & subject result read out of 20-25 min window
648443	Yes	5	Positive	Positive	25.2	No
648457	Yes	3	Negative	Negative	Not Detected	No
648459	Yes	5	Negative	Negative	Not Detected	No
648460	Yes	5	Negative	Negative	Not Detected	No
648176	Yes	3	Negative	Negative	Not Detected	No
648289	Yes	2	Negative	Negative	Not Detected	No
648291	Yes	3	Positive	Positive	21.6	No
647050	Yes	3	Negative	Negative	Not Detected	No
647051	Yes	1	Negative	Negative	Not Detected	No
648290	Yes	2	Positive	Positive	19.8	No
648292	Yes	4	Negative	Negative	Not Detected	Yes - HCP & subject result read out of 20-25 min window
648145	Yes	3	Negative	Negative	Not Detected	No
648144	Yes	3	Negative	Negative	Not Detected	No
648280	Yes	2	Positive	Positive	20.1	No
648166	Yes	4	Negative	Negative	Not Detected	No
648307	Yes	4	Negative	Negative	30.2	Yes - HCP & subject result read out of 20-25 min window
648297	Yes	2	Positive	Positive	25.2	No

5. Conclusion

In patients presenting symptoms within 6 days, the INDICAID COVID-19 Rapid Antigen At-Home Test demonstrated a PPA, NPA and OPA of 81.7% (95% CI: 72.0% - 88.6%), 99.4% (95% CI: 96.5% - 99.9%) and 93.4% (95% CI: 89.5% - 95.9%), respectively, against the comparator method. Of the 82 positive samples, 17 (20.7%) had a Ct value > 30. PHASE believes these performance specifications meet the FDA EUA requirements listed in the Antigen Template for Test Developers of a minimum PPA of ≥ 80% against a high sensitivity comparator method with a minimum of 10-20% samples with Ct >30.

Further, PHASE asserts that these performance specifications meet the FDA EUA requirements for OTC/at-home use in all patient populations, including individuals with or without symptoms or other epidemiological reasons to suspect COVID-19, with additional mitigations such as serial screening. In subjects age 2-65+ years (with > 30 pediatric subjects aged 2-13 years enrolled between the usability and clinical evaluations), the INDICAID COVID-19 Rapid Antigen At-Home Test's clinical performance satisfies the requirements of ≥ 80% PPA, with a lower bound (LB) of the two-sided 95% confidence interval (CI) ≥70%.

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SAFETY DATA SHEET

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND COMPANY IDENTIFICATION

1.1 Product identifier

Product name: INDICAID® COVID-19 Rapid Antigen At-Home Test
Product form: Mixture

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses: In vitro diagnostic test for self-use

1.3 Details of the supplier of the safety data sheet

Manufacturer: Phase Scientific International Limited
32 & 33F, Gravity, 29 Hing Yip Street,
Kowloon, Hong Kong
www.phasescientific.com

1.4 Emergency telephone number

Emergency Number: +852 9135 2570 [Hong Kong]
+1 (657) 296-6106 [US]

Section 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

When used under normal operating condition according to the product's instructions for use, this product is anticipated to pose no significant health effects. Repeated use or prolonged exposure is not known to aggravate any medical conditions.

Product is not a hazardous substance or mixture according to Regulation (EC) No 1272/2008. Product is not classified under GHS US classification.

2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.
GHS US labelling: Not applicable.

2.3 Other hazards

Sample Extraction Buffer:

Eye contact :	Irritation
Skin contact :	Irritation
Ingestion:	Potentially harmful if swallow
Inhalation:	None known.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

Composition of Extraction Buffer

Chemical Name	CAS#	Concentration (%)	Hazard Statement
ProClin 300	26172-55-4; 2682-20-4	≤ 0.3	Non-hazardous at this concentration
Triton X-100	9002-93-1	≤ 0.1	Non-hazardous at this concentration

Section 4: FIRST AID MEASURES

4.1 Description of first aid measures

In case of skin contact

Immediately wash thoroughly with running water for at least 15 min

In case of eye contact

Rinse thoroughly with plenty of water, also under the eyelids for at least 15 minutes.

If swallowed

Does not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with plenty of water and seek immediate medical attention.

If symptoms persist, seek medical attention or poison control centre at https://www.poison.org/contact-us or 1-800-222-1222.

Section 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

This material is non-flammable and non-reactive under normal condition of use, storage and transport.

5.3 Advice for firefighters

This product does not contain combustible materials.

Special Exposure Hazards: None known.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Take proper precautions to minimize exposure by using personal protective equipment. For personal protection see section 8.

6.2 Environmental precautions

Do not flush Extraction Buffer in drains

6.3 Methods and materials for containment and cleaning up

Soak up spills with inert absorbent material and dispose used devices as hazardous waste. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

Section 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Wear personal protective equipment.

7.2 Conditions for safe storage, including any incompatibilities

Avoid direct sunlight. Store at 2- 30°C in original sealed package.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls

Ensure good ventilation of the workstation. Wash hands after working with substance. Minimize any anticipated skin and eye contact.

Personal Protection Equipment

Eye/face protection

Safety glasses recommended

Respiratory protection

Not normally required.

Hands and other skin protection

Recommended to handle with gloves.

Body Protection
Not normally required.

Control of environmental exposure
Do not let product enter drains.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

	Cassette Device	**Extraction Buffer**	**Swab**
Appearance	Individually sealed foil pouch with a silica gel desiccant and aplastic cartridge containing a white, narrow nitrocellulose membrane test strip.	Odourless, clear liquid	Flocked swab with ABS plastic shaft and nylon fibre head, individually packed and sealed
pH	Not applicable	7.2 ± 0.2	Not applicable
Melting point	No information available		
Boiling point	No information available		
Specific Gravity (H_2O = 1)	No information available		
Vapor Pressure (mmHg & temp)	No information available		
Percent Volatile (%)	No information available		
Vapor Density	No information available		
Evaporation (Butyl Acetate = I)	No information available		
Solubility in Water	Insoluble	soluble	Insoluble
Solubility in Fat	No information available		Insoluble
Flash Point (method used)	200˚C Lower limit: Not available Upper limit: Not available	No information available	
Auto-flammability	No information available		
Explosive Properties	None		
Oxidizing Properties	None		No information available
Partition Coefficient	No information available		

Over time, nitrocellulose membrane will polymerize and become brown. Polymerization reduces the flash point.

Section 10: STABILITY AND REACTIVITY

10.1 Stability Stable under normal conditions of use
10.2 Conditions to avoid Excessive heat, direct sunlight
10.3 Hazardous decomposition products Not established.
10.4 Incompatibility Strong acids or alkalise

Section 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity	No information available
Eyes	No information available
Skin	No information available
Inhalation	No information available
Ingestion	No information available
Specific Effects	No information available
Chronic Toxicity (Target Organ Effects)	No information available
Carcinogenic effects	No information available
Mutagenic effects	No information available
Reproductive toxicity	No information available
Sensitization	No information available
Target Organ Effects	No information available

Section 12: ECOLOGICAL INFORMATION

12.1 Ecotoxicity effects No information available
12.2 Mobility No information available
12.3 Biodegradation No information available
12.4 Bioaccumulation No information available

Section 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose in accordance with all applicable local and national regulations

Section 14: TRANSPORT INFORMATION

14.1 UN number

ADR/RID:	-
IMGD:	-
IATA:	-

14.2 UN proper shipping name

ADR/RID:	Not regulated
IMGD:	Not regulated
IATA:	Not regulated

14.3 Transport hazard class(es)

ADR/RID:	-
IMGD:	-
IATA:	-

14.4 Packaging group

ADR/RID:	-
IMGD:	-
IATA:	-

14.5 Environmental hazards

ADR/RID:	None
IMGD:	None
IATA:	None

According to the 63rd edition (2022) of IATA Dangerous Goods Regulations, the products are not dangerous, poisonous, harmful, corrosive, flammable or explosive. They are not spiritual medicines, not aesthetic or narcotic, and cannot be used to make bio-chemical weapons.

Section 15: REGULATORY INFORMATION

Regulation (EC) No 1272/2008 – classification, labelling and packaging of substances and mixtures (CLP)
Regulation (EC) No. 1907/2006- Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
GHS HazCom 2012
Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

Section 16: OTHER INFORMATION

Further information
This information is based on our present knowledge. The information given is designed only as a guidance for safe handling and is not to be considered a warranty or quality specification. All materials and mixtures may present unknown hazards and should be used with caution.

INDICAID™ COVID-19 Antigen Quality Controls

For use with the INDICAID™ COVID-19 Rapid Antigen Test

Intended use

The INDICAID™ COVID-19 Antigen Quality Controls are intended for quality control testing performed on the INDICAID™ COVID-19 Rapid Antigen Test. The Quality Controls provide users with assurance that the device is performing within specification.

Summary and explanation of the test

The INDICAID™ COVID-19 Antigen Quality Controls are external liquid quality controls. The controls are specifically formulated and manufactured to ensure that the test's reagents and materials are working and that the test procedure is correctly performed. The Quality Controls consist of positive and negative control samples that should be run once with every new lot, shipment, and each new user, using the test procedure provided.

It is the responsibility of each laboratory or healthcare setting using the INDICAID™ COVID-19 Rapid Antigen Test to establish an adequate quality assurance program to ensure the performance of the test kit under its specific locations and conditions of use. Quality control requirements should be followed in conformance with local, state, and federal regulations or accreditation requirements and the user laboratory's standard quality control procedures.

Warnings and precautions

- For in vitro diagnostic use only.
- Quality Control Vials are for one-time use only. Do not reuse vials.
- Exercise the normal precautions required for handling all laboratory reagents.
- Do not swallow or inhale.
- Avoid contact with your eyes. If contact occurs, flush with copious amounts of water immediately.

Storage and Stability

- Store controls between 2°C and 8°C (36 – 46°F).
- Unopened controls that are stored between 2°C and 8°C (36 – 46°F) can be used until the expiration date. Do not use Quality Controls beyond the expiration date given on the label.
- Quality Control Vials should remain sealed until ready for use
- Open a Quality Control Vial only when you are planning to perform a quality control test.

Materials Provided in Kit

REF 2110420	$50	• 5 x 250 µL single-use COVID-19 Antigen Positive Control Vials (non-infectious recombinant SARS-CoV-2 antigen in buffered solution with preservatives) • 5 x 250 µL single-use COVID-19 Antigen Negative Control Vials (buffered solution with preservatives)

Materials Required But Not Provided

1. INDICAID™ COVID-19 Rapid Antigen Test Device
2. INDICAID™ COVID-19 Rapid Antigen Test Buffer Solution Vial
3. INDICAID™ COVID-19 Rapid Antigen Test Individually Wrapped Swab
4. Timer

Preparing the quality controls

The liquid controls are supplied ready to use. Each Quality Control Vial is single-use only.

Test Procedure

Wear appropriate personal protective equipment and gloves when handling patient samples and running the test.

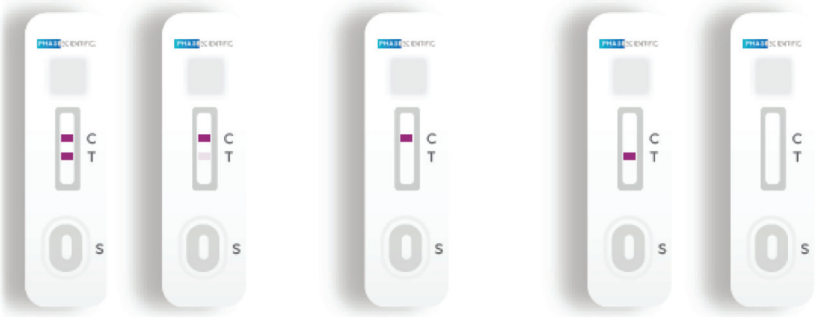
1. Remove a new Swab and Test Device from their packaging. Place the Test Device on a horizontal (flat) surface for running the test.
2. Hold a new INDICAID™ COVID-19 Antigen Positive Control Vial vertically and open the cap.
3. Dip the new Swab into the Positive Control Vial, making sure that the Swab head is fully wetted by the solution. Remove the Swab from the Vial.
4. Test the Swab immediately performing the same steps as described in section "Test Procedure for Patient Swabs" of the INDICAID™ COVID-19 Rapid Antigen Test Instructions For Use (Package Insert).
5. Repeat all the above steps to test the external negative control in the INDICAID™ COVID-19 Antigen Negative Control Vial.

Expected Results

Consult the INDICAID™ COVID-19 Rapid Antigen Test Instructions for Use or Quick Reference Guide for instructions on how to interpret a test result using the Quality Control.

The Test Devices are working properly and all handling has been done correctly when the following expected test results are obtained:

- The INDICAID™ COVID-19 Antigen Positive Control should provide a positive result.
- The INDICAID™ COVID-19 Antigen Negative Control should provide a negative result.



Positive Result | Negative Result | Invalid Result

If the external controls do not produce the expected results, do not use the test for patient testing or report patient results. Please contact PHASE Scientific Technical Support during normal business hours before using the test with patient specimens.

Manufactured By

PHASE Diagnostics, Inc.
10527 Garden Grove Boulevard.
Garden Grove, CA 92843, USA

This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

For more information, questions, or support, please visit www.phasescientificusa.com, or email us at:

Email: ussales@phasesci.com

Symbols

In vitro diagnostic medical device

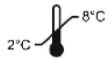

Do not reuse


Consult Instructions for Use

Catalog number


Caution—consult accompanying documents

Batch code



Temperature limitation


Use by


Keep away from sunlight


Manufacturer


Sufficient for use


Keep away from moisture

PI-2110410EUA; Rev.A; December 2021

March 16, 2022

Jo-Ann Gonzales, RAC
Precision for Medicine
Representing: PHASE Scientific International, Ltd.
10527 Garden Grove Blvd.
Garden Grove, CA 92943

Device:	INDICAID COVID-19 Rapid Antigen At-Home Test
EUA Number:	EUA220152
Company:	PHASE Scientific International, Ltd.
Indication:	Non-prescription home use for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 with: Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first six days of symptom onset. Adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first six days of symptom onset. Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

Dear Jo-Ann Gonzales:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.

[1] For ease of reference, this letter will use the term "you" and related terms to refer to PHASE Scientific International, Ltd.
[2] For ease of reference, this letter will use the term "your product" to refer to the INDICAID COVID-19 Rapid Antigen At-Home Test, used for the indication identified above.

Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the "INDICAID COVID-19 Rapid Antigen At-Home Test Healthcare Provider Instructions for Use" identified below.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a rapid lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first six days of symptom onset. This test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first six

[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).
[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

days of symptom onset.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. Your product does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease. Individuals who test positive with your product should self-isolate and seek follow up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. 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, including infection control 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.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by Centers for Disease Control (CDC).

Your product is performed using anterior nasal (nares) swab samples from individuals aged 2 years or older. When using your product, the individual performing the test must follow the instructions provided in the "User Instructions INDICAID COVID-19 Rapid Antigen At-Home Test" when collecting the specimen, running the test procedure and interpreting the results.

The INDICAID COVID-19 Rapid Antigen At-Home Test includes the materials, or other authorized materials (as may be requested under Condition L. and M. below), required to collect the anterior nasal (nares) swab sample and perform the test procedure, as described in the "User Instructions INDICAID COVID-19 Rapid Antigen At-Home Test" and the "INDICAID COVID-19 Rapid Antigen At-Home Test Healthcare Provider Instructions for Use."

Your product includes an internal control test line ("C") that must generate the expected result for a test to be considered valid, as outlined in the "User Instructions INDICAID COVID-19 Rapid Antigen At-Home Test" and the "INDICAID COVID-19 Rapid Antigen At-Home Test Healthcare Provider Instructions for Use."

The labeling entitled "User Instructions INDICAID COVID-19 Rapid Antigen At-Home Test," the "INDICAID COVID-19 Rapid Antigen At-Home Test Healthcare Provider Instructions for Use," and the "INDICAID COVID-19 Rapid Antigen At-Home Test" box labels[5] (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), and the following fact sheet pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Professionals[6]: PHASE Scientific International, Ltd. - INDICAID COVID-19 Rapid Antigen At-Home Test

The above described product, when accompanied by the authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter

[5] "INDICAID COVID-19 Rapid Antigen At-Home Test" box labels include boxes for 2, 4, 12 and 24 test kits and "INDICAID COVID-19 Rapid Antigen At-Home Test" box labels for additional test kits numbers/options as may be requested, and for which you receive appropriate authorization, in accordance with Condition M. below. INDICAID COVID-19 Rapid Antigen At-Home Test kits numbers/options are described in the "User Instructions INDICAID COVID-19 Rapid Antigen At-Home Test" and the "INDICAID COVID-19 Rapid Antigen At-Home Test Healthcare Provider Instructions for Use."

[6] Note that the information typically found in a Fact Sheet for Individuals is contained in the authorized "User Instructions INDICAID COVID-19 Rapid Antigen At-Home Test" that will be available to end users as set forth in the Conditions of Authorization (Section IV).

(Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

PHASE Scientific International, Ltd. (You) and Authorized Distributor(s)[7]

A. Your product must comply with the following labeling requirements: the intended use statement in 21 CFR 809.10(a)(2), (b)(2); adequate directions for use in 21 U.S.C. 352(f) and 21 CFR 809.10(b)(5), (7), and (8); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make available the "User Instructions INDICAID COVID-19 Rapid Antigen At-Home Test" for your product in the shipped kit using the applicable "INDICAID COVID-19 Rapid Antigen At-Home Test" box label (see Footnote 5) and electronically on your website(s).

[7] "Authorized Distributor(s)" are identified by you, PHASE Scientific International, Ltd., in your EUA submission as an entity allowed to distribute the INDICAID COVID-19 Rapid Antigen At-Home Test.

C. You and authorized distributor(s) must maintain records of customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.

D. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or the authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor's offices, etc.) to which your product is distributed and the number of tests distributed to each location.

F. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You and authorized distributor(s) using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

PHASE Scientific International, Ltd. (You)

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.

K. You must make the authorized "INDICAID COVID-19 Rapid Antigen At-Home Test Healthcare Provider Instructions for Use" and the Fact Sheet for Healthcare Professionals electronically available on your website. Additionally, you must provide the opportunity to request a copy of the "INDICAID COVID-19 Rapid Antigen At-Home Test Healthcare Provider Instructions for Use" and Fact Sheet for Healthcare Professionals in

paper form, and after such request, promptly provide the requested labeling at no additional cost.

L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You may request new box labels to allow additional test kits numbers/options for your product. Such additional labeling requests to this EUA should be submitted to and require concurrence of DMD/OHT7-OIR/OPEQ/CDRH prior to implementation.

N. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

O. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the product released for distribution meet the clinical and analytical performance claimed in the authorized labeling.

P. If requested by FDA, you must submit your lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide them within 48 hours of the request.

Q. You must evaluate the analytical limit of detection and assess traceability[8] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You must evaluate the clinical performance of your product to support the serial screening claim in an FDA agreed upon post authorization clinical evaluation study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

S. You must develop a mobile phone application or website to further facilitate results

[8] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

reporting by the individual using your product and submit to FDA such application or website within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission of the mobile phone application or website to, and review of and concurrence with the developed mobile phone application or website by FDA, you must update the authorized labeling. Such labeling updates will be made in consultation with, and require concurrence of, FDA.

T. You must submit to FDA a summary report within 90 calendar days of product launch summarizing the results of any testing performed using your product during that timeframe, including how many products were distributed, the positivity rate for specimens tested with your product, and how many individuals reported results to their healthcare provider as encouraged by the "User Instructions INDICAID COVID-19 Rapid Antigen At-Home Test," along with any proposed corrective action, as necessary.

U. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling to reflect the additional testing if requested by FDA. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

V. You must submit your product for any FDA-recommended independent evaluation to confirm the performance characteristics of your product, if requested by FDA. After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

W. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

X. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Conditions Related to Printed Materials, Advertising and Promotion

Y. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

Z. No descriptive printed matter, advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

AA. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____
Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure

EC Declaration of Conformity

Manufacturer: PHASE Scientific International Limited
Name: Kent Cheng, Ph.D.
Address: 32F, Gravity, 29 Hing Yip St., Kwun Tong, KLN, HK
Tel: +852 3892 7200
E-Mail: info@phasesci.com

Authorized Representative:
Name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com

We, the manufacturer, here with declare that the product(s)

Product Name	**INDICAID® COVID-19 Rapid Antigen Test**	**Specification**	IVD
Intended Use	The INDICAD® COVID-19 Rapid Antigen Test is a lateral flow immunoassay designed for the qualitative detection of SARS-CoV-2 antigens in direct nasal swab samples.		
Classification	Others		

Conformity Assessment Route： IVDD98/79/EC Annex III.

Applicable Standards:

ISO 13485:2016
ISO 14971:2019
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN 13641:2002
ISO 15223-1:2016
EN 13612:2002
ISO 23640:2015
EN 62366-1:2015

CE

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We agree to develop,implement and maintain a documented post-production monitoring process.

Name of Product Director	Kent Cheng, Ph.D.
Signature	
Date	20 October 2020
Place	Hong Kong, China.
Seal (Manufacturer)	

(A1 帳戶)

戶名：	衡昱電商股份有限公司
帳號：	187 018 0005516 7
統編：	91099570
銀行別：	永豐銀行(807)
分行：	員林分行
產品:	衡昱集克快篩

衡昱電商-現場取貨須知

1. 請取貨人攜帶訂購單進行取貨。
2. 請取貨人攜帶身分證以便核實。
3. 請取貨人攜帶公司發票章簽收，或取貨人親簽並加蓋手印。
4. 請取貨人於領取時清點數量是否正確無誤。
5. 取貨人請於現場清點完畢後，確認產品包裝皆完整無誤，因自身需求將說明書與相關標籤取下，請加簽切結書作為確認。

前往取貨前請聯繫：蘇靖雯 0966-384-205 / 王元媛董事 0913-277-377

衡昱電商交通指引

衡昱電商股份有限公司
地址:台北市內湖區金莊路 100 號 11 樓
電話:+886-2-2795-1313
傳真:+886-2-2793-6565

★開車來訪

南下

●國道一號，自 17A-內湖出口下交流道,往南京東路六段方向行駛約 8 分鐘即可抵達金莊路

北上

●國道一號，自 17-內湖出口下交流道,往金豐街方向行駛約 5 分鐘即可抵達金莊路

◎停車指引

本公司大樓停車場入口處位於行善路 383 巷上,
貴賓車位位於 B3 層,車位編號:86 號、87 號、100 號、116 號

★大眾交通運輸

高鐵

●距高鐵台北站車程約 20 分鐘
●距高鐵南港站車程約 10 分鐘

市公車

●藍 50-石潭路口下車步行約 5 分鐘
●0 東、214、278、286、521、617、630、645、652、903、市民小巴 10、藍 27、紅 29、紅 32(民權幹線)-內湖行政大樓站下車步行約 15 分鐘