有关我司新冠试剂质量的严正声明

针对近期社会上关于深圳市爱康试剂有限公司（以下简称我司）新冠快速诊断测试试剂盒产品质量相关的网络媒体报道，结合香港用户对此产品殷切需求，我司特此作出严正声明：

我司目前在售的新冠抗原快速检测试剂盒产品名为：COVID-19 Antigen Test Kit Immunochromatography)，所有有效的第三方质量检测报告均应以此名称为唯一正确标识，任何产品名称不相符的检测报告我司不再另作解释。

我司新冠抗原快速检测试剂盒产品（COVID-19 Antigen Test Kit (Immunochromatography)）在 2021 年 7 月份，获得德国 CE 备案（备案编号：DE/CA22/1311-1060-IVD）并进入中国商务部出口白名单。其中，新冠抗原快速检测试剂盒已陆续获哥伦比亚、马来西亚、泰国等国家的注册，并陆续销往世界各国。

在 2021 年 8 月，英国第三方 Randox 实验室对我司新冠抗原快速检测试剂盒进行了准确性评估的报道《QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study》。此次评估中，我司新冠抗原快速检测试剂盒获得了“非常满意”评价，测试结果展现出极佳的产品性能。

我司始终将产品质量放在第一位，重视检测的准确性。我司坚决反对在未经充分、全面、客观的了解事实和科学测试的情况下，发表片面且不负责任的言论和报道，误导公众和舆论，损害我司名誉和品牌形象，我司将保留追究相关当事人法律责任的权利，以维护我司的合法权益！

特此严正声明！

深圳市爱康试剂有限公司

2022 年 2 月 26 日

有關我司新冠試劑品質的嚴正聲明

針對近期社會上關於深圳市愛康試劑有限公司（以下簡稱我司）新冠快速診斷測試試劑盒產品品質相關的網路媒體報導，結合香港使用者對此產品殷切需求，我司特此作出嚴正聲明：

我司目前在售的新冠抗原快速檢測試劑盒產品名為：COVID-19 Antigen Test Kit Immunochromatography) ,所有有效的協力廠商品質檢測報告均應以此名稱為唯一正確標識，任何產品名稱不相符的檢測報告我司不再另作解釋。

我司新冠抗原快速檢測試劑盒產品（COVID-19 Antigen Test Kit (Immunochromatography)）在 2021 年 7 月份，獲得德國 CE 備案（備案編號：DE/CA22/1311-1060-IVD）並進入中國商務部出口白名單。其中，新冠抗原快速檢測試劑盒已陸續獲哥倫比亞、馬來西亞、泰國等國家的註冊，並陸續銷往世界各國。

在 2021 年 8 月 ,英國協力廠商 Randox 實驗室對我司新冠抗原快速檢測試劑盒進行了準確性評估的報導《QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study》。此次評估中，我司新冠抗原快速檢測試劑盒獲得了“非常滿意”評價，測試結果展現出極佳的產品性能。

我司始終將產品品質放在第一位，重視檢測的準確性。我司堅決反對在未經充分、全面、客觀的瞭解事實和科學測試的情況下，發表片面且不負責任的言論和報導，誤導公眾和輿論，損害我司名譽和品牌形象，我司將保留追究相關當事人法律責任的權利，以維護我司的合法權益！

特此嚴正聲明！

深圳市爱康试剂有限公司

2022 年 2 月 26 日

Solemn Statement

—— About the quality of our COVID-19 Antigen Test Kit

Referring to the recent reports on the social media about the quality of COVID-19 Antigen Test Kit of Aikang Diagnostics Co., Ltd (hereinafter referred to as our company), in light of the demand of Hongkong consumers on this product, our company hereby makes a solemn statement:

The product name of the COVID-19 Antigen Test Kit currently being sold by our company is: COVID-19 Antigen Test Kit (Immunochromatography), and all valid third-party quality test reports should be uniquely identified by this name. Our company will not make any further explanation on any product with the name that does not match the one on the test report.

Our COVID-19 Antigen Test Kit (Immunochromatography) in July 2021, have been registered with CE in Germany (Registration number: DE/CA22/1311-1060-IVD) and entered the export whitelist of the Ministry of Commerce of China. Among them, the COVID-19 Antigen Test Kit has been successively registered in Colombia, Malaysia, Thailand and other countries, and has been sold to countries around the world.

In August 2021, the third-party Randox laboratory in the United Kingdom issued the report "QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study" on the accuracy assessment of our company's COVID-19 Antigen Test Kit. In this evaluation, our company's COVID-19 Antigen Test Kit received " highly satisfactory" scores, and the test results showed excellent product performance.

Our company always puts product quality first and attaches great importance to the accuracy of testing. Our company firmly opposes making one-sided and irresponsible remarks and reports without a full, comprehensive and objective understanding of facts and scientific tests, misleading the public and public opinion, and damaging our reputation and brand image. Our company will retain the right to pursue the legal responsibility of the relevant parties to safeguard the legitimate rights and interests of our company!

Aikang Diagnostics Co., Ltd
February 26, 2022

附件：**Randox 的 QCMD 报告** / Enclosure：**QCMD report from Randox**

QCMD
Quality Control for Molecular Diagnostics

This is to certify that

Registration Department
Aikang Diagnostics Co., Ltd

Shenzhen
China

has participated in the

QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study - QAS214224_1A

The certificate is valid from: 28th of October 2021 to 28th of October 2022

QCMD

Prof. dr. Hubert G.M. Niesters
QCMD Executive Coordinator

CRT004/05

Individual Report	QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study					
Catalogue Code: QAS214224	**Ref Code:** SCV2Ag21	**Challenge:** C1A	**Analysis Type:** POC	**Dataset:** 458322	**Report UID:** 12332/1730/3552	**Laboratory** CN047

Dataset Identifier: Aikang Diagnostics -COVID-19 Antigen Test Kit(Immunochromatography)

Intended Results / Panel Composition

Sample Code	Sample Content	Matrix	Reference Value[1]	Detection Frequency[2]	Sample Status[3]	Percentage Correct (All)[4]	
						(%)	*(n)*
SCV2Ag21C1A-01	SARS-CoV-2 Lineage B.1	Stabilisation buffer virusPHIX-P9	6.4 log10 dc/ml	Detected	Educational	66.9	143
SCV2Ag21C1A-02	SARS-CoV-2 Lineage B.1	Stabilisation buffer virusPHIX-P9	7.4 log10 dc/ml	Detected	Core	89.7	143
SCV2Ag21C1A-03	True Negative	Stabilisation buffer virusPHIX-P9		Negative	Core	90.3	143
SCV2Ag21C1A-04	SARS-CoV-2 Lineage B.1	Transport Medium	6.4 log10 dc/ml	Frequently Detected	Core	96.6	143
SCV2Ag21C1A-05	SARS-CoV-2 Lineage B.1	Transport Medium	5.4 log10 dc/ml	Infrequently Detected	Educational	33.8	143

[1] **Reference Value:** Includes dPCR Log10 Copies/ml, the value obtained using a digital droplet PCR assay (modified from Eurosurveillance Jan 2020 Corman et al).
[2] **Detection Frequency:** To aid qualitative analysis each panel member is assigned a frequency of detection. This is based on the peer group consensus of all qualitative results returned from participants within the EQA challenge / distribution.
[3] **Sample Status:** EQA samples are defined as "CORE" or "EDUCATIONAL". Core proficiency samples are reviewed by the QCMD Scientific Expert(s). This is on the basis of scientific information, clinical relevance, current literature and, where appropriate, professional clinical guidelines. Participating laboratories are expected to report core proficiency samples correctly within the EQA challenge / distribution.
[4] **Percentage Correct (All):** Percentage of datasets (%) reporting the correct qualitative result and the total number of datasets (n) reported for each panel member.
For further details please refer to the current participant manual.

Your Summary Results

Your Assessment Group [1]	Lateral Flow Rapid Antigen Test
Core Panel Detection (Qualitative) Score [2]	0

Individual Report	QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study					
Catalogue Code: QAS214224	**Ref Code:** SCV2Ag21	**Challenge:** C1A	**Analysis Type:** POC	**Dataset:** 458322	**Report UID:** 12332/1730/3552	**Laboratory** CN047

Core Panel Members Results

Sample Code	Qualitative Results		
	Percentage Correct (All) [3]	Your Result [4]	Detection Score [5]
SCV2Ag21C1A-02	89.7	Positive	0
SCV2Ag21C1A-03	90.3	Negative	0
SCV2Ag21C1A-04	96.6	Positive	0

[1] **EQA Assessment Group:** To aid data analysis, participant results are grouped according to the method specified for this challenge / distribution. For further details refer to the Additional Information: *Individual Panel Member Analysis* section of this report

[2] **Core Panel Detection (Qualitative) Score:** An overall core panel detection score provided per challenge / distribution.

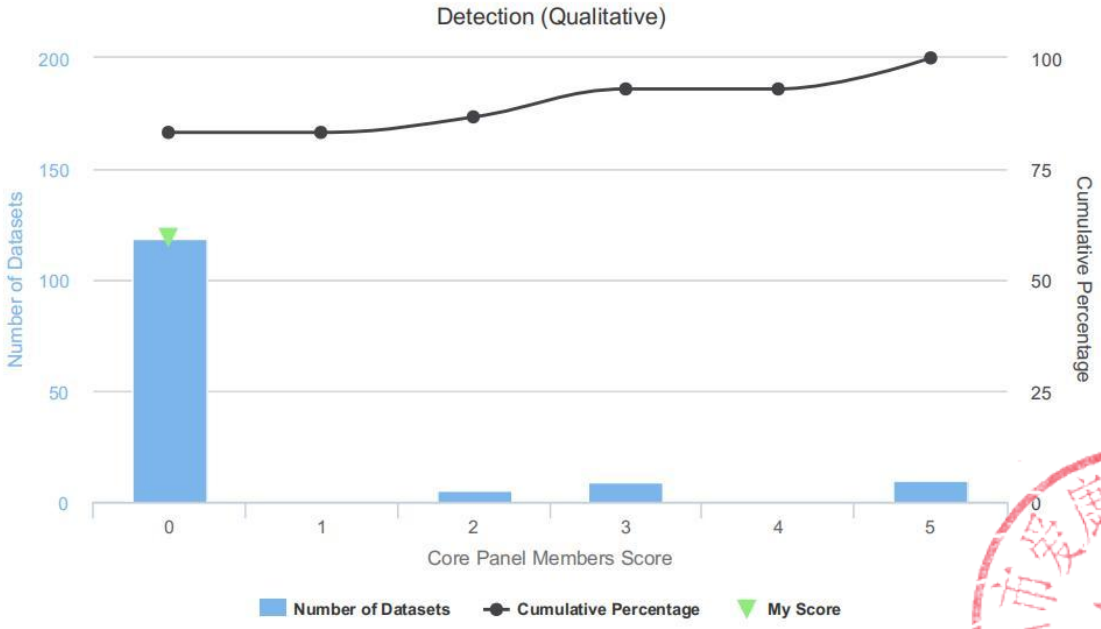
[3] **Percentage Correct (All):** Percentage of datasets (%) reporting the correct qualitative results for each panel member.

[4] **Detection Score:** Your detection (qualitative) scores are based on the assigned detection frequency of each panel members, where 0 (zero) is "highly satisfactory" and 3 (three) is "highly unsatisfactory". Scores are provided for individual panel members.

For further details please refer to the current participant manual.

Individual Report	QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study					
Catalogue Code: QAS214224	**Ref Code:** SCV2Ag21	**Challenge:** C1A	**Analysis Type:** POC	**Dataset:** 458322	**Report UID:** 12332/1730/3552	**Laboratory** CN047

Core Panel Member Score Breakdown



Core Panel Member Score Breakdown - Detection: This figure gives you a breakdown of the qualitative detection scores for all qualitative datasets returned within this EQA challenge / distribution independent of the EQA assessment group. Panel detection scores are generated from only those panel members that are defined as "CORE".
For further details please refer to the current participant manual.

My Test Method

Below you will find details of your assay used.

Type	Lateral Flow Rapid Antigen Test
Method Details	

Individual Report	QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study					
Catalogue Code: QAS214224	**Ref Code:** SCV2Ag21	**Challenge:** C1A	**Analysis Type:** POC	**Dataset:** 458322	**Report UID:** 12332/1730/3552	**Laboratory** CN047

Educational Panel Members Results

Sample Code	Qualitative Results		
	Percentage Correct (All) [3]	Your Result [4]	Detection Score [5]
SCV2Ag21C1A-01	66.9	Positive	0
SCV2Ag21C1A-05	33.8	Positive	0

[1] **EQA Assessment Group:** To aid data analysis, participant results are grouped according to the method specified for this challenge / distribution. For further details refer to the Additional Information: *Individual Panel Member Analysis* section of this report
[2] **Core Panel Detection (Qualitative) Score:** An overall core panel detection score provided per challenge / distribution.
[3] **Percentage Correct (All):** Percentage of datasets (%) reporting the correct qualitative results for each panel member.
[4] **Detection Score:** Your detection (qualitative) scores are based on the assigned detection frequency of each panel members, where 0 (zero) is "highly satisfactory" and 3 (three) is "highly unsatisfactory". Scores are provided for individual panel members.
For further details please refer to the current participant manual.

Further Programme Details

Number of Laboratories	109
Number of Countries	24
Number or Respondents	77
Number of Datasets Submitted	143

Comments

Two results of “not determined” were reported for samples SCV2Ag21C1A-01 and SCV2Ag21C1A-02 where the lab had indicated that the sample had not been tested. Exclusion of these results would change the percentage of correct results to 67.4% for sample 01 and 90.8% for sample 02.

EQA Programme Aims

To assess the proficiency, with respect to sensitivity and overall specificity, of different SARS-CoV-2 antigen tests (Lateral Flow Rapid Ag Tests, Automated PoC Tests, or Laboratory ELISA immunoassays) applied by trained users in different testing settings.

Individual Report	QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study					
Catalogue Code: QAS214224	**Ref Code:** SCV2Ag21	**Challenge:** C1A	**Analysis Type:** POC	**Dataset:** 458322	**Report UID:** 12332/1730/3552	**Laboratory** CN047

Feedback and Enquiries

Participants are encouraged to read the Participants' Manual, which can be downloaded from the QCMD website.
Any enquiries should be submitted through the 'Contact Us' form that you can find in the 'Help' section of your QCMD (ITEMS) Participant Profile Area.

Panel member analysis is separated into CORE samples followed by EDUCATIONAL samples.

Additional Core Samples Information

Individual Panel Member Analysis (Qualitative)

Qualitative analysis for each panel member is provided in relation to your EQA assessment group. EQA assessment groups are established using the assay information reported by all participants within this EQA challenge / distribution.
The principal level of assessment is at the individual method level which is defined based on your reported test method and other laboratories using the same or similar methods.

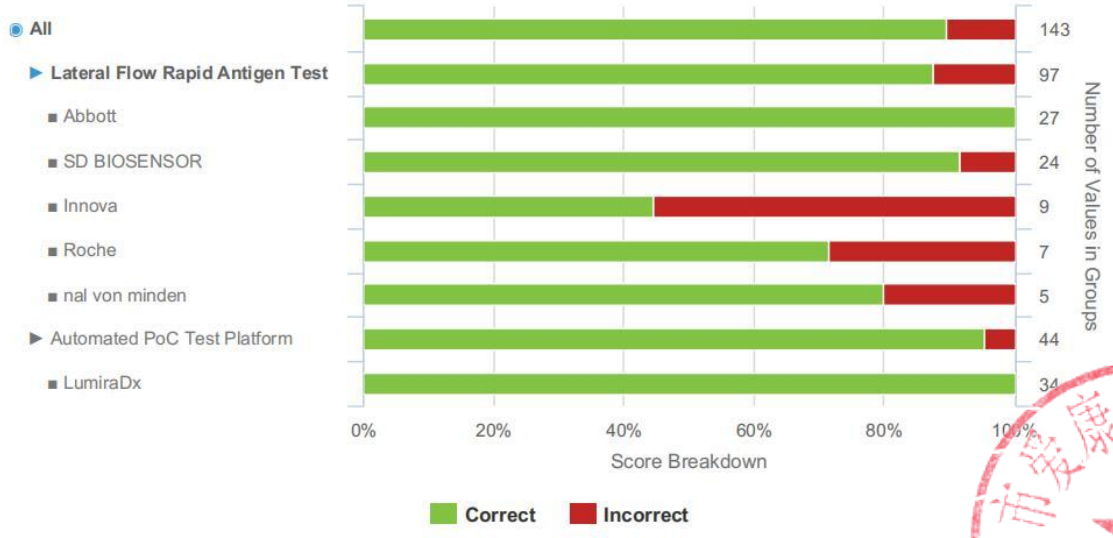
To allow meaningful assessment at the individual method level the EQA assessment group must consist of 5 or more datasets. If there are not sufficient datasets at the individual method level then your results will be included within a higher EQA assessment group based on whether it is a rapid test, POC assay or laboratory based assay. The highest level assessment grouping is "All"participant reported qualitative results.

A breakdown of qualitative results reported by participants on each of the panel members within this EQA challenge / distribution is provided below. You can compare your results to those within your EQA assessment group and those obtained within other EQA assessment groups or to the overall consensus for each sample within this EQA challenge / distribution.

Individual Report	QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study					
Catalogue Code: QAS214224	**Ref Code:** SCV2Ag21	**Challenge:** C1A	**Analysis Type:** POC	**Dataset:** 458322	**Report UID:** 12332/1730/3552	**Laboratory** CN047

SCV2Ag21C1A-02 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Reference Value[1]	Detection Frequency[2]	Sample Status[3]	Percentage Correct (All)[4]	
						(%)	(n)
SCV2Ag21C1A-02	SARS-CoV-2 Lineage B.1	Stabilisation buffer virusPHIX-P9	7.4 log10 dc/ml	Detected	Core	89.7	143



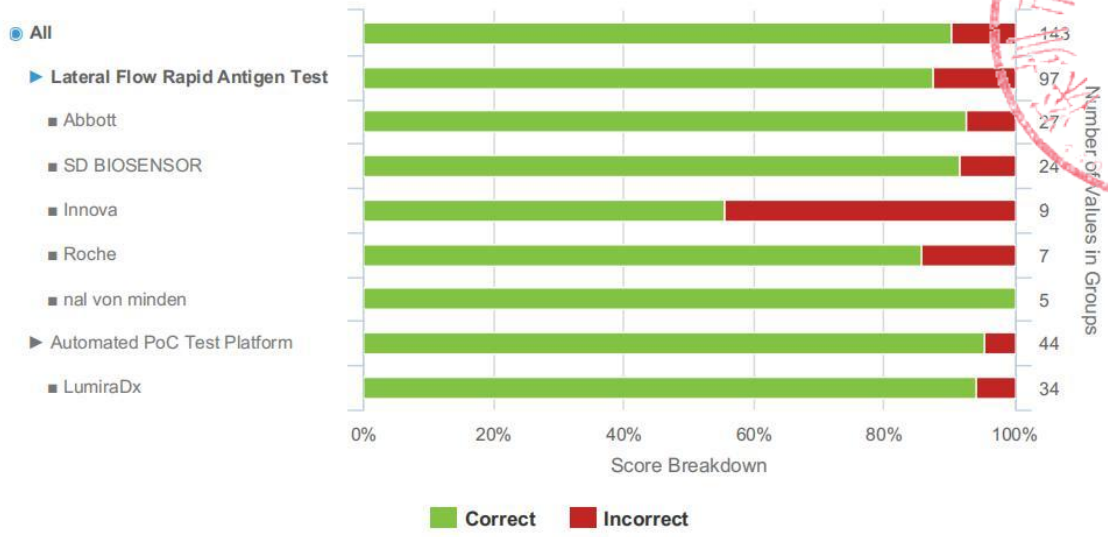
Groups below n=5: Xiamen Boson (n=2),Xiamen Boson - Rapid SARS-CoV-2 Antigen Test (n=2),Not Specified (LF) (n=2),Not Specified (LF) - Lateral Flow Ag Test (manufacturer not specified) (n=2),Siemens (n=2),Siemens - CLINITEST Rapid COVID-19 Antigen Test (n=2),Healgen Scientific (n=2),Healgen Scientific - Coronavirus Ag Rapid Test (n=2),Aikang Diganostics (n=2),Aikang Diganostics - COVID-19 Antigen Test Kit (Immunochromatography) (n=1),Aikang Diganostics - COVID-19 Antigen Rapid Test Kit (Colloidal Gold) (n=1),Wuhan Life Origin Biotech (n=2),Wuhan Life Origin Biotech - COVID-19 Antigen Rapid Test Kit (Saliva) (n=1),Wuhan Life Origin Biotech - SARS-CoV-2 Antigen Assay Kit (Immunochromatography) (n=1),SureScreen Diagnostics (n=2),SureScreen Diagnostics - SureScreen COVID-19 Rapid Antigen Test (n=2),Abbott/Roche/Wondfo (n=1),Abbott/Roche/Wondfo - Multiple Lateral Flow Kits (n=1),Assure Tech. (Hangzhou) (n=1),Assure Tech. (Hangzhou) - COVID-19 Antigen Rapid Test (n=1),BIOMAXIMA (n=1),BIOMAXIMA - SARS-CoV-2 ANTIGEN RAPID TEST (n=1),NG Biotech (n=1),NG Biotech - Ninonasal Antigen (n=1),Medomics (n=1),Medomics - SARS-CoV-2 Antigen Test (n=1),BIOSYNEX (n=1),BIOSYNEX - COVID-19 Ag BSS (n=1),Beijing Lepu (n=1),Beijing Lepu - SARS-CoV-2 Antigen Rapid Test (n=1),UD-Bio (n=1),UD-Bio - SARS-CoV-2 Antigen Test Kit (n=1),MyBio (n=1),MyBio - MyBio COVID-19 Rapid Antigen Test (n=1),INDICAID (n=1),INDICAID - COVID-19 Rapid Antigen Test (n=1),Acon Biotech (n=1),Acon Biotech - Flowflex SARS-CoV-2 Antigen Rapid Test (n=1),Boditech Med Inc (n=3),Boditech Med Inc - Afias 6 (n=3),Diasorin (n=2),Diasorin - LIAISON SARS-CoV-2 Ag (n=2),SD BIOSENSOR POC (n=2),SD BIOSENSOR POC - Standard F COVID-19 Ag FIA (n=2),Quidel (n=1),Quidel - Sofia SARS Antigen FIA (n=1),Becton Dickinson (n=1),Becton Dickinson - BD Veritor System Rapid Detection SARS-CoV-2 (n=1),ArcDia (n=1),ArcDia - mariPOC® COVID-19 test (n=1),Laboratory ELISA / Immunoassay Test (n=2),Not Specified (ELISA) (n=1),Not Specified (ELISA) - Chemiluminescent Microparticle Immunoassays (n=1),Ortho Clinical (n=1),Ortho Clinical - VITROS SARS-CoV-2 Antigen (n=1)

Groups Rolled Up: Abbott - Panbio COVID-19 Ag Rapid (n=27),SD BIOSENSOR - Q COVID-19 Ag Test (n=24),Innova - SARS-CoV-2 Antigen (n=9),Roche - SARS-CoV-2 Rapid Antigen (n=7),nal von minden - NADAL COVID-19 Ag Rapid (n=5),LumiraDx - SARS-CoV-2 Ag Test (n=34)

Individual Report	QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study					
Catalogue Code: QAS214224	**Ref Code:** SCV2Ag21	**Challenge:** C1A	**Analysis Type:** POC	**Dataset:** 458322	**Report UID:** 12332/1730/3552	**Laboratory** CN047

SCV2Ag21C1A-03 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Reference Value[1]	Detection Frequency[2]	Sample Status[3]	Percentage Correct (All)[4]	
						(%)	*(n)*
SCV2Ag21C1A-03	True Negative	Stabilisation buffer virusPHIX-P9		Negative	Core	90.3	143



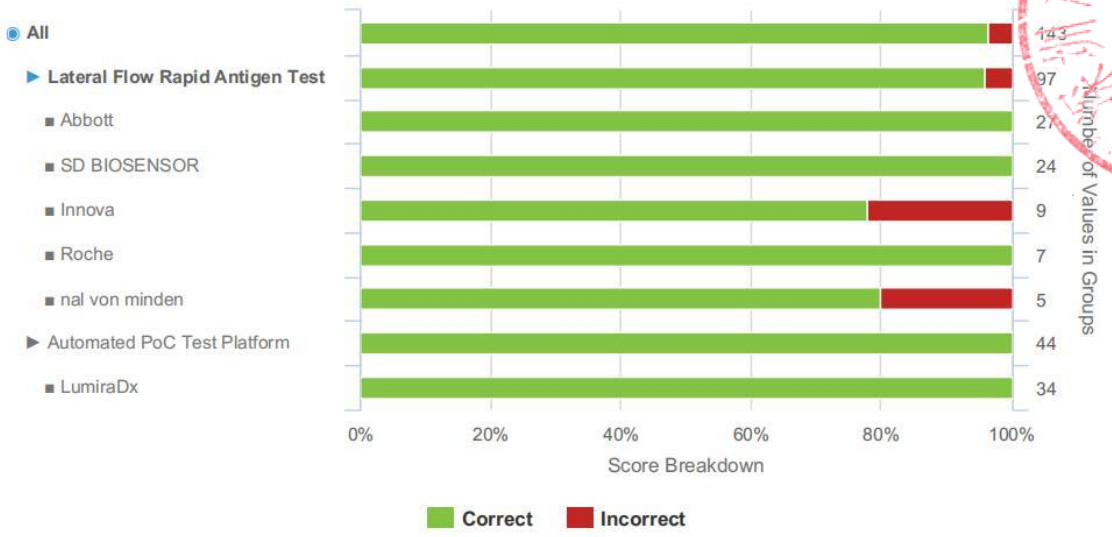
Groups below n=5: Xiamen Boson (n=2),Xiamen Boson - Rapid SARS-CoV-2 Antigen Test (n=2),Not Specified (LF) (n=2),Not Specified (LF) - Lateral Flow Ag Test (manufacturer not specified) (n=2),Siemens (n=2),Siemens - CLINITEST Rapid COVID-19 Antigen Test (n=2),Healgen Scientific (n=2),Healgen Scientific - Coronavirus Ag Rapid Test (n=2),Aikang Diganostics (n=2),Aikang Diganostics - COVID-19 Antigen Test Kit (Immunochromatography) (n=1),Aikang Diganostics - COVID-19 Antigen Rapid Test Kit (Colloidal Gold) (n=1),Wuhan Life Origin Biotech (n=2),Wuhan Life Origin Biotech - COVID-19 Antigen Rapid Test Kit (Saliva) (n=1),Wuhan Life Origin Biotech - SARS-CoV-2 Antigen Assay Kit (Immunochromatography) (n=1),SureScreen Diagnostics (n=2),SureScreen Diagnostics - SureScreen COVID-19 Rapid Antigen Test (n=2),Abbott/Roche/Wondfo (n=1),Abbott/Roche/Wondfo - Multiple Lateral Flow Kits (n=1),Assure Tech. (Hangzhou) (n=1),Assure Tech. (Hangzhou) - COVID-19 Antigen Rapid Test (n=1),BIOMAXIMA (n=1),BIOMAXIMA - SARS-CoV-2 ANTIGEN RAPID TEST (n=1),NG Biotech (n=1),NG Biotech - Ninonasal Antigen (n=1),Medomics (n=1),Medomics - SARS-CoV-2 Antigen Test (n=1),BIOSYNEX (n=1),BIOSYNEX - COVID-19 Ag BSS (n=1),Beijing Lepu (n=1),Beijing Lepu - SARS-CoV-2 Antigen Rapid Test (n=1),UD-Bio (n=1),UD-Bio - SARS-CoV-2 Antigen Test Kit (n=1),MyBio (n=1),MyBio - MyBio COVID-19 Rapid Antigen Test (n=1),INDICAID (n=1),INDICAID - COVID-19 Rapid Antigen Test (n=1),Acon Biotech (n=1),Acon Biotech - Flowflex SARS-CoV-2 Antigen Rapid Test (n=1),Boditech Med Inc (n=3),Boditech Med Inc - Afias 6 (n=3),Diasorin (n=2),Diasorin - LIAISON SARS-CoV-2 Ag (n=2),SD BIOSENSOR POC (n=2),SD BIOSENSOR POC - Standard F COVID-19 Ag FIA (n=2),Quidel (n=1),Quidel - Sofia SARS Antigen FIA (n=1),Becton Dickinson (n=1),Becton Dickinson - BD Veritor System Rapid Detection SARS-CoV-2 (n=1),ArcDia (n=1),ArcDia - mariPOC® COVID-19 test (n=1),Laboratory ELISA / Immunoassay Test (n=2),Not Specified (ELISA) (n=1),Not Specified (ELISA) - Chemiluminescent Microparticle Immunoassays (n=1),Ortho Clinical (n=1),Ortho Clinical - VITROS SARS-CoV-2 Antigen (n=1)

Groups Rolled Up: Abbott - Panbio COVID-19 Ag Rapid (n=27),SD BIOSENSOR - Q COVID-19 Ag Test (n=24),Innova - SARS-CoV-2 Antigen (n=9),Roche - SARS-CoV-2 Rapid Antigen (n=7),nal von minden - NADAL COVID-19 Ag Rapid (n=5),LumiraDx - SARS-CoV-2 Ag Test (n=34)

Individual Report	QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study					
Catalogue Code: QAS214224	**Ref Code:** SCV2Ag21	**Challenge:** C1A	**Analysis Type:** POC	**Dataset:** 458322	**Report UID:** 12332/1730/3552	**Laboratory** CN047

SCV2Ag21C1A-04 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Reference Value[1]	Detection Frequency[2]	Sample Status[3]	Percentage Correct (All)[4]	
						(%)	*(n)*
SCV2Ag21C1A-04	SARS-CoV-2 Lineage B.1	Transport Medium	6.4 log10 dc/ml	Frequently Detected	Core	96.6	143



Groups below n=5: Xiamen Boson (n=2),Xiamen Boson - Rapid SARS-CoV-2 Antigen Test (n=2),Not Specified (LF) (n=2),Not Specified (LF) - Lateral Flow Ag Test (manufacturer not specified) (n=2),Siemens (n=2),Siemens - CLINITEST Rapid COVID-19 Antigen Test (n=2),Healgen Scientific (n=2),Healgen Scientific - Coronavirus Ag Rapid Test (n=2),Aikang Diganostics (n=2),Aikang Diganostics - COVID-19 Antigen Test Kit (Immunochromatography) (n=1),Aikang Diganostics - COVID-19 Antigen Rapid Test Kit (Colloidal Gold) (n=1),Wuhan Life Origin Biotech (n=2),Wuhan Life Origin Biotech - COVID-19 Antigen Rapid Test Kit (Saliva) (n=1),Wuhan Life Origin Biotech - SARS-CoV-2 Antigen Assay Kit (Immunochromatography) (n=1),SureScreen Diagnostics (n=2),SureScreen Diagnostics - SureScreen COVID-19 Rapid Antigen Test (n=2),Abbott/Roche/Wondfo (n=1),Abbott/Roche/Wondfo - Multiple Lateral Flow Kits (n=1),Assure Tech. (Hangzhou) (n=1),Assure Tech. (Hangzhou) - COVID-19 Antigen Rapid Test (n=1),BIOMAXIMA (n=1),BIOMAXIMA - SARS-CoV-2 ANTIGEN RAPID TEST (n=1),NG Biotech (n=1),NG Biotech - Ninonasal Antigen (n=1),Medomics (n=1),Medomics - SARS-CoV-2 Antigen Test (n=1),BIOSYNEX (n=1),BIOSYNEX - COVID-19 Ag BSS (n=1),Beijing Lepu (n=1),Beijing Lepu - SARS-CoV-2 Antigen Rapid Test (n=1),UD-Bio (n=1),UD-Bio - SARS-CoV-2 Antigen Test Kit (n=1),MyBio (n=1),MyBio - MyBio COVID-19 Rapid Antigen Test (n=1),INDICAID (n=1),INDICAID - COVID-19 Rapid Antigen Test (n=1),Acon Biotech (n=1),Acon Biotech - Flowflex SARS-CoV-2 Antigen Rapid Test (n=1),Boditech Med Inc (n=3),Boditech Med Inc - Afias 6 (n=3),Diasorin (n=2),Diasorin - LIAISON SARS-CoV-2 Ag (n=2),SD BIOSENSOR POC (n=2),SD BIOSENSOR POC - Standard F COVID-19 Ag FIA (n=2),Quidel (n=1),Quidel - Sofia SARS Antigen FIA (n=1),Becton Dickinson (n=1),Becton Dickinson - BD Veritor System Rapid Detection SARS-CoV-2 (n=1),ArcDia (n=1),ArcDia - mariPOC® COVID-19 test (n=1),Laboratory ELISA / Immunoassay Test (n=2),Not Specified (ELISA) (n=1),Not Specified (ELISA) - Chemiluminescent Microparticle Immunoassays (n=1),Ortho Clinical (n=1),Ortho Clinical - VITROS SARS-CoV-2 Antigen (n=1)

Groups Rolled Up: Abbott - Panbio COVID-19 Ag Rapid (n=27),SD BIOSENSOR - Q COVID-19 Ag Test (n=24),Innova - SARS-CoV-2 Antigen (n=9),Roche - SARS-CoV-2 Rapid Antigen (n=7),nal von minden - NADAL COVID-19 Ag Rapid (n=5),LumiraDx - SARS-CoV-2 Ag Test (n=34)

Individual Report	QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study					
Catalogue Code: QAS214224	**Ref Code:** SCV2Ag21	**Challenge:** C1A	**Analysis Type:** POC	**Dataset:** 458322	**Report UID:** 12332/1730/3552	**Laboratory** CN047

Additional Educational Samples Information

Individual Panel Member Analysis (Qualitative)

Qualitative analysis for each panel member is provided in relation to your EQA assessment group. EQA assessment groups are established using the assay information reported by all participants within this EQA challenge / distribution.
The principal level of assessment is at the individual method level which is defined based on your reported test method and other laboratories using the same or similar methods.

To allow meaningful assessment at the individual method level the EQA assessment group must consist of 5 or more datasets. If there are not sufficient datasets at the individual method level then your results will be included within a higher EQA assessment group based on whether it is a rapid test, POC assay or laboratory based assay. The highest level assessment grouping is "All"participant reported qualitative results.

A breakdown of qualitative results reported by participants on each of the panel members within this EQA challenge / distribution is provided below. You can compare your results to those within your EQA assessment group and those obtained within other EQA assessment groups or to the overall consensus for each sample within this EQA challenge / distribution.

Individual Report	QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study					
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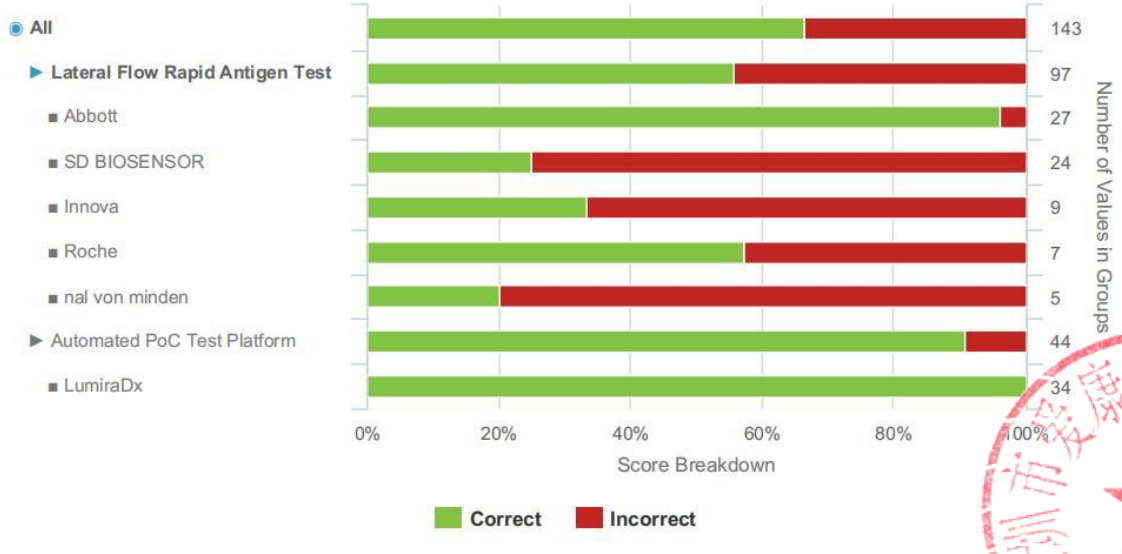
SCV2Ag21C1A-01 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Reference Value[1]	Detection Frequency[2]	Sample Status[3]	Percentage Correct (All)[4]	
						(%)	(n)
SCV2Ag21C1A-01	SARS-CoV-2 Lineage B.1	Stabilisation buffer virusPHIX-P9	6.4 log10 dc/ml	Detected	Educational	66.9	143



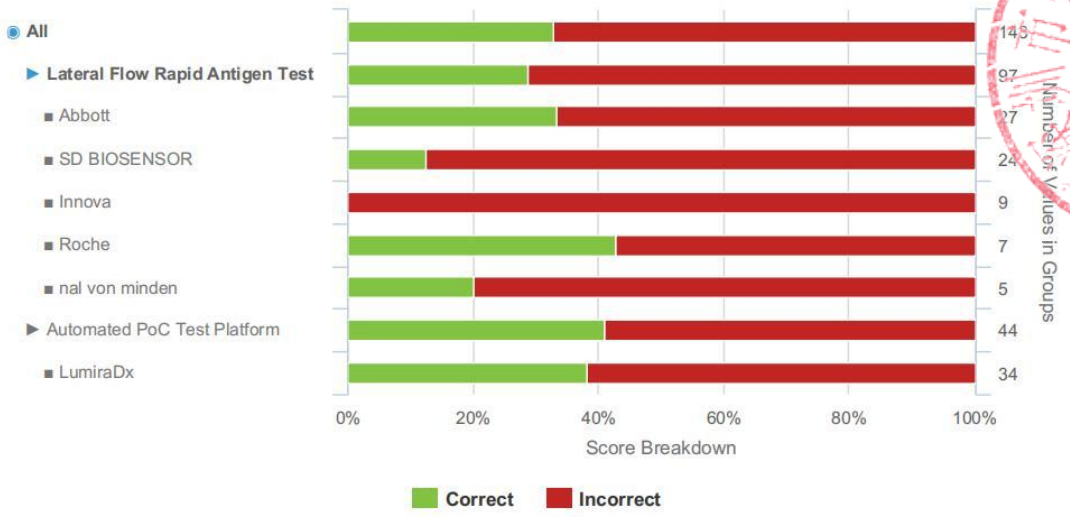
Groups below n=5: Xiamen Boson (n=2),Xiamen Boson - Rapid SARS-CoV-2 Antigen Test (n=2),Not Specified (LF) (n=2),Not Specified (LF) - Lateral Flow Ag Test (manufacturer not specified) (n=2),Siemens (n=2),Siemens - CLINITEST Rapid COVID-19 Antigen Test (n=2),Healgen Scientific (n=2),Healgen Scientific - Coronavirus Ag Rapid Test (n=2),Aikang Diganostics (n=2),Aikang Diganostics - COVID-19 Antigen Test Kit (Immunochromatography) (n=1),Aikang Diganostics - COVID-19 Antigen Rapid Test Kit (Colloidal Gold) (n=1),Wuhan Life Origin Biotech (n=2),Wuhan Life Origin Biotech - COVID-19 Antigen Rapid Test Kit (Saliva) (n=1),Wuhan Life Origin Biotech - SARS-CoV-2 Antigen Assay Kit (Immunochromatography) (n=1),SureScreen Diagnostics (n=2),SureScreen Diagnostics - SureScreen COVID-19 Rapid Antigen Test (n=2),Abbott/Roche/Wondfo (n=1),Abbott/Roche/Wondfo - Multiple Lateral Flow Kits (n=1),Assure Tech. (Hangzhou) (n=1),Assure Tech. (Hangzhou) - COVID-19 Antigen Rapid Test (n=1),BIOMAXIMA (n=1),BIOMAXIMA - SARS-CoV-2 ANTIGEN RAPID TEST (n=1),NG Biotech (n=1),NG Biotech - Ninonasal Antigen (n=1),Medomics (n=1),Medomics - SARS-CoV-2 Antigen Test (n=1),BIOSYNEX (n=1),BIOSYNEX - COVID-19 Ag BSS (n=1),Beijing Lepu (n=1),Beijing Lepu - SARS-CoV-2 Antigen Rapid Test (n=1),UD-Bio (n=1),UD-Bio - SARS-CoV-2 Antigen Test Kit (n=1),MyBio (n=1),MyBio - MyBio COVID-19 Rapid Antigen Test (n=1),INDICAID (n=1),INDICAID - COVID-19 Rapid Antigen Test (n=1),Acon Biotech (n=1),Acon Biotech - Flowflex SARS-CoV-2 Antigen Rapid Test (n=1),Boditech Med Inc (n=3),Boditech Med Inc - Afias 6 (n=3),Diasorin (n=2),Diasorin - LIAISON SARS-CoV-2 Ag (n=2),SD BIOSENSOR POC (n=2),SD BIOSENSOR POC - Standard F COVID-19 Ag FIA (n=2),Quidel (n=1),Quidel - Sofia SARS Antigen FIA (n=1),Becton Dickinson (n=1),Becton Dickinson - BD Veritor System Rapid Detection SARS-CoV-2 (n=1),ArcDia (n=1),ArcDia - mariPOC® COVID-19 test (n=1),Laboratory ELISA / Immunoassay Test (n=2),Not Specified (ELISA) (n=1),Not Specified (ELISA) - Chemiluminescent Microparticle Immunoassays (n=1),Ortho Clinical (n=1),Ortho Clinical - VITROS SARS-CoV-2 Antigen (n=1)

Groups Rolled Up: Abbott - Panbio COVID-19 Ag Rapid (n=27),SD BIOSENSOR - Q COVID-19 Ag Test (n=24),Innova - SARS-CoV-2 Antigen (n=9),Roche - SARS-CoV-2 Rapid Antigen (n=7),nal von minden - NADAL COVID-19 Ag Rapid (n=5),LumiraDx - SARS-CoV-2 Ag Test (n=34)

Individual Report	QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study					
Catalogue Code: QAS214224	**Ref Code:** SCV2Ag21	**Challenge:** C1A	**Analysis Type:** POC	**Dataset:** 458322	**Report UID:** 12332/1730/3552	**Laboratory** CN047

SCV2Ag21C1A-05 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Reference Value[1]	Detection Frequency[2]	Sample Status[3]	Percentage Correct (All)[4]	
						(%)	*(n)*
SCV2Ag21C1A-05	SARS-CoV-2 Lineage B.1	Transport Medium	5.4 log10 dc/ml	Infrequently Detected	Educational	33.8	143



Groups below n=5: Xiamen Boson (n=2),Xiamen Boson - Rapid SARS-CoV-2 Antigen Test (n=2),Not Specified (LF) (n=2),Not Specified (LF) - Lateral Flow Ag Test (manufacturer not specified) (n=2),Siemens (n=2),Siemens - CLINITEST Rapid COVID-19 Antigen Test (n=2),Healgen Scientific (n=2),Healgen Scientific - Coronavirus Ag Rapid Test (n=2),Aikang Diganostics (n=2),Aikang Diganostics - COVID-19 Antigen Test Kit (Immunochromatography) (n=1),Aikang Diganostics - COVID-19 Antigen Rapid Test Kit (Colloidal Gold) (n=1),Wuhan Life Origin Biotech (n=2),Wuhan Life Origin Biotech - COVID-19 Antigen Rapid Test Kit (Saliva) (n=1),Wuhan Life Origin Biotech - SARS-CoV-2 Antigen Assay Kit (Immunochromatography) (n=1),SureScreen Diagnostics (n=2),SureScreen Diagnostics - SureScreen COVID-19 Rapid Antigen Test (n=2),Abbott/Roche/Wondfo (n=1),Abbott/Roche/Wondfo - Multiple Lateral Flow Kits (n=1),Assure Tech. (Hangzhou) (n=1),Assure Tech. (Hangzhou) - COVID-19 Antigen Rapid Test (n=1),BIOMAXIMA (n=1),BIOMAXIMA - SARS-CoV-2 ANTIGEN RAPID TEST (n=1),NG Biotech (n=1),NG Biotech - Ninonasal Antigen (n=1),Medomics (n=1),Medomics - SARS-CoV-2 Antigen Test (n=1),BIOSYNEX (n=1),BIOSYNEX - COVID-19 Ag BSS (n=1),Beijing Lepu (n=1),Beijing Lepu - SARS-CoV-2 Antigen Rapid Test (n=1),UD-Bio (n=1),UD-Bio - SARS-CoV-2 Antigen Test Kit (n=1),MyBio (n=1),MyBio - MyBio COVID-19 Rapid Antigen Test (n=1),INDICAID (n=1),INDICAID - COVID-19 Rapid Antigen Test (n=1),Acon Biotech (n=1),Acon Biotech - Flowflex SARS-CoV-2 Antigen Rapid Test (n=1),Boditech Med Inc (n=3),Boditech Med Inc - Afias 6 (n=3),Diasorin (n=2),Diasorin - LIAISON SARS-CoV-2 Ag (n=2),SD BIOSENSOR POC (n=2),SD BIOSENSOR POC - Standard F COVID-19 Ag FIA (n=2),Quidel (n=1),Quidel - Sofia SARS Antigen FIA (n=1),Becton Dickinson (n=1),Becton Dickinson - BD Veritor System Rapid Detection SARS-CoV-2 (n=1),ArcDia (n=1),ArcDia - mariPOC® COVID-19 test (n=1),Laboratory ELISA / Immunoassay Test (n=2),Not Specified (ELISA) (n=1),Not Specified (ELISA) - Chemiluminescent Microparticle Immunoassays (n=1),Ortho Clinical (n=1),Ortho Clinical - VITROS SARS-CoV-2 Antigen (n=1)

Groups Rolled Up: Abbott - Panbio COVID-19 Ag Rapid (n=27),SD BIOSENSOR - Q COVID-19 Ag Test (n=24),Innova - SARS-CoV-2 Antigen (n=9),Roche - SARS-CoV-2 Rapid Antigen (n=7),nal von minden - NADAL COVID-19 Ag Rapid (n=5),LumiraDx - SARS-CoV-2 Ag Test (n=34)

Individual Report	QCMD 2021 SARS-CoV-2 Antigen Testing EQA Pilot Study					
Catalogue Code: QAS214224	**Ref Code:** SCV2Ag21	**Challenge:** C1A	**Analysis Type:** POC	**Dataset:** 458322	**Report UID:** 12332/1730/3552	**Laboratory** CN047