INDICAID™ INSTRUCTION GUIDE

COVID-19 RAPID ANTIGEN TEST Ref # IN-COVAG-001SG01A

IVD

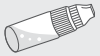
INTENDED USE

INDICAID™ COVID-19 Rapid Antigen Test is an in vitro diagnostic test for determining the presence of SARS-CoV-2 antigen in direct nasal swab samples or nasopharyngeal swab sample. This test is intended for self-testing and/or professional use.

PRINCIPLE

During COVID-19 infection, the virus SARS-CoV-2 is found in the upper respiratory tract. SARS-CoV-2 antigens are substances of the virus that serve as markers for disease exposure.

CONTAINED IN THIS BOX

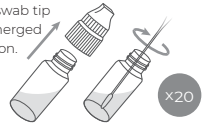
1 individually-wrapped test device	1 vial of buffer solution	1 individually-wrapped swab	1 instruction guide
			

HOW TO USE

01 Remove the test device and swab from their packaging.

02 Tilt your head back. Gently insert the swab about 2.5cm into one of your nostrils. Rub the swab against the wall of one of your nostrils **at least 5 times** in a large circular path. Repeat with your other nostril.

03 The buffer solution vial cap is composed of two parts. Remove the entire cap. Stir the swab into the buffer solution by twisting the swab back and forth **20 times**. Slightly tilt the vial to ensure the swab tip is fully submerged in the solution.



04 Close the entire vial cap tightly. Immediately perform Steps 5-7.

05 Remove the top half of the vial cap to expose the dropper tip.

06 Hold the vial vertically. Squeeze and drip 3 drops of the solution into the circular opening of the test device.

07 Leave for **20 minutes** and read the results. Do not read after **25 minutes**. Refer to the "Interpreting Your Results" section below.

*Watch the how-to-use video by scanning the QR code.

INTERPRETING YOUR RESULTS:

	INDICATOR	RESULTS	INTERPRETATION
	A line appears in regions (C) and (T)	Positive	This result indicates the presence of SARS-CoV-2 antigen in the sample.
	A line appears in the region (C)	Negative	This results indicates no SARS-CoV-2 antigen is detected in the sample. Regular testing (at least once every week) is recommended. If you have been in contact with a known or suspected COVID-19 case, we recommend that you arrange a PCR test to confirm your negative result.
	No line appears in the region (C)	Invalid	There was an issue with the specimen collection or the test processing. Repeat the test with a new test kit.

IMPORTANT

- For in vitro diagnostic use
- User should not make any decision of medical relevance without first consulting their health care provider
- All components in this test kit should remain sealed until ready for use
- The test must be performed between 15-30°C
- All components in this test kit are for one-time use only. Do not reuse
- Store at 2-30°C. Do not freeze. Avoid direct sunlight
- Do not swallow or inhale
- Avoid contact with your eyes. If contact occurs, flush with water immediately and seek medical help
- Do not use the test kit after the expiration date
- Samples with low levels of antigen may give a faint test line. Any visible pink/purple colored line is positive, do not compare the color intensity of each indicator line to another
- If you have questions about the product, please contact Customer Service at indicaid@sdt-molecular.com

LIMITATIONS

- The test is designed for using direct nasal swab sample or nasopharyngeal swab sample.
- Negative results do not rule out COVID-19 infection, especially if you have been in contact with the virus. A follow-up PCR test should be considered to rule out infection
- Positive results may be due to current infection with non-SARS-CoV-2 coronavirus strains
- Results from antigen testing should not be used as the sole basis to diagnose or exclude COVID-19 infection
- The presence of Fluticasone Propionate (Flonase) in the nasal swab specimen may give inaccurate results

FREQUENTLY ASKED QUESTIONS (FAQs)

I ACCIDENTALLY SPILLED THE TEST SOLUTION. IS IT HARMFUL?

If the test solution has been spilled, flush abundantly with water upon disposal.

Avoid having the test solution come into contact with your eyes, skin and mouth. If contact occurs with the eyes, flush with water immediately and seek medical help. If contact occurs with your skin, wash the area with soap and rinse with water.

Do not ingest or inhale the test solution. If accidental ingestion occurs, please seek medical help immediately.

HOW DEEP SHOULD I INSERT THE SWAB INTO MY NOSTRILS?

Inserting the swab 2.5cm into the nostril should be deep enough to collect samples for this test. Once you feel a slight resistance, proceed to gently collect your sample. Check the swab after collection to ensure the tip is covered in nasal secretion.

WHAT DO I DO WITH THE TEST KIT AFTER READING THE RESULTS?

After completing the test and recording your results, carefully wrap all product components and dispose them into the garbage just like any other household trash. Wash your hands thoroughly with soap and water after handling the components.

HOW ACCURATE IS THE TEST?

In a study using prospective nasal and retrospective nasopharyngeal swab specimens, the INDICAID™ COVID-19 Rapid Antigen Test has been clinically validated to achieve a high detection accuracy, reaching a relative detection specificity of >95% and relative detection sensitivity of 91% respectively (Table A).

Table A (Study with prospective nasal and retrospective nasopharyngeal swab specimens)

INDICAID™ COVID-19 Rapid Antigen Test	Comparator Method (RT-qPCR)		
	Positive	Negative	Total
Positive	91	12	103
Negative	9	278	287
Total	100	290	390
Positive Percentage Agreement (PPA)	91% (95% CI: 83.8% - 95.2%)		
Negative Percentage Agreement (NPA)	96% (95% CI: 92.9% - 97.6%)		

PHASESCIENTIFIC.COM

MANUFACTURER
PHASE Scientific International Limited
32 & 33/F, Gravity, 29 Hing Yip Street,
Kwun Tong, Kowloon, Hong Kong

INDICAID™ 妥析™ 使用说明

新冠病毒快速抗原测试
Ref # IN-COVAG-001SG01A

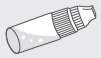
产品用途

INDICAID™ 妥析™ 新冠病毒快速抗原检测试剂盒是一款体外诊断测试工具，用于检测人体鼻拭子或鼻咽拭子中的新冠病毒 (SARS-CoV-2) 抗原。此测试适用于自我测试和/或专业用途。

检测原理

新冠病毒感染期间，SARS-CoV-2 病毒可以在上呼吸道中被检测出来。SARS-CoV-2 抗原存在于病毒中，可作为检测体内病毒的指标。

本盒内配有

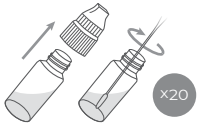
1 支独立包装的测试棒	1 瓶测试溶液	1 支独立包装的采样棒	1 份使用说明
			

如何使用

01 打开包装，取出测试棒和采样棒。

02 把头向后倾，轻轻地把采样棒伸进鼻孔（约2.5厘米），沿鼻孔内壁在内**至少打5个**大圈。在另一侧鼻孔里重复同样的步骤。

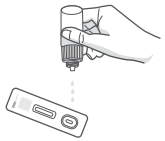
03 测试溶液小瓶的盖子分为两部分，分别是上半部及整个盖子。扭开小瓶的整个盖子，然后把采样棒浸在测试溶液中来回转动**20次**。转动时须确保采样棒顶端完全浸泡在溶液中。



04 扭紧盖子。立即进行5-7的步骤。

05 扭开小瓶的盖子的上半部分，露出滴头。

06 把小瓶垂直置于测试棒上的圆形开口上方，挤出3滴溶液到开口里。



07 置于室温**20分钟后**（不可多于**25分钟**）查看检测结果。请仔细阅读以下"如何解读检测结果"部分。

*扫描二维码观看使用视频

如何解读检测结果：

	指示线	结果	解释
	在 (C) 和 (T) 区内 分别显示一条线	阳性	结果显示样本中检测到 SARS-CoV-2 抗原。
	只在(C) 区内 显示一条线	阴性	结果显示样本中未检测到SARS-CoV-2 抗原。 建议您定期进行检测 (每星期一次)。如果您曾经与疑似或确诊新冠病毒病例接触，我们建议您进行一次核酸检测确定您的结果。
	在(C) 区内 没有显示一条线	无效	样本采样过程或测试处理中出现了问题，请使用新的试剂盒再检测一次。

重要事项

- 本试剂盒只供体外诊断之用
- 请勿在未事先咨询医护人员的情况下，做出任何与医学相关的决定
- 进行测试前，本试剂盒内的所有部件应保持密封
- 测试必须在15-30°C环境下进行
- 所有部件仅为一次性使用，不可重复使用
- 本试剂盒应储存于温度2-30°C之间。避免阳光直接照射
- 不可吞咽或吸入本试剂盒内任何部件
- 避免接触眼睛。如发生意外接触，请立即用清水冲洗并向医护人员求助
- 请勿使用过期试剂盒
- 指示线有时会显得模糊，但仍然应视作指示线进行结果解读；指示线的颜色强度不一致是正常情况，进行结果解读时毋须比较线条的颜色强度
- 如果您对产品存有疑问，请电邮至indicaid@sdt-molecular.com与我们的客户服务人员联络

产品局限性

- 本试剂盒用于检测人体鼻拭子或鼻咽拭子样本
- 阴性结果不能完全排除新冠病毒感染的可能，如果您曾经处于有可能感染病毒的环境，您应当考虑做进一步的核酸检测
- 阳性结果也可能是由于感染了非 SARS-CoV-2 的其他冠状病毒所引致
- 本抗原测试的结果不应用作诊断新冠病毒感染的唯一依据
- 鼻拭子样本中存在丙酸氟替卡松 (Flonase) 可能会产生不准确的检测结果

常见问题和解答

我意外倒翻了溶液，是否有害？

若不慎倒翻溶液，请立即使用大量清水充分清洗受影响的地方。

请避免眼睛、皮肤或口部接触溶液。如果溶液接触了眼睛，请立即用清水冲洗并向医护人员求助。如果接触了皮肤，用肥皂洗净该部位后再用清水冲洗即可。

切勿吞咽或吸入溶液。如意外吞食了溶液，请立即求医。

在采集鼻拭子样本时，我应该把采样棒插入多深？

把采样棒伸进鼻孔内2.5厘米即可。如果您在把采样棒伸入鼻孔的过程中感到轻微阻力，则继续轻轻地收集样本。收集样本后，检查采样棒以确保其顶端被鼻腔分泌物覆盖。

读完检测结果后，如何处理用过的测试棒及其他部件？

完成测试后，请先记录您的检测结果，然后把测试棒及其他部件包好，再用处理普通家庭垃圾的方式丢弃在垃圾桶里。处理完毕后切记洗手。

此产品的结果准确吗？

在一项使用前瞻性鼻拭子样本和回顾性鼻咽拭子样本的研究中，INDICAID™ 妥析™ 新冠病毒快速抗原检测经临床验证其检测精准度非常之高，相对特异度和相对灵敏度分别为96%和91% (表A)。

表A (前瞻性鼻拭子及回溯性鼻咽拭子样本的临床研究结果)

INDICAID™妥析™ 新冠病毒快速抗原检测	比对RT-qPCR结果		
	阳性	阴性	总数
阳性	91	12	103
阴性	9	278	287
总数	100	290	390
灵敏度	91% (95% CI: 83.8% - 95.2%)		
特异度	96% (95% CI: 92.9% - 97.6%)		

PI-0005 | Rev B | 仅供体外诊断之用 |

PHASESCIENTIFIC.COM

制造商
相达生物科技国际有限公司
香港九龙观塘兴业街29号万有引力32及33楼

INDICAID™ INSTRUCTION GUIDE

COVID-19 RAPID ANTIGEN TEST Ref # IN-COVAG-025SG01A

IVD

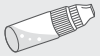
INTENDED USE

INDICAID™ COVID-19 Rapid Antigen Test is an in vitro diagnostic test for determining the presence of SARS-CoV-2 antigen in direct nasal swab samples or nasopharyngeal swab sample. This test is intended for self-testing and/or professional use.

PRINCIPLE

During COVID-19 infection, the virus SARS-CoV-2 is found in the upper respiratory tract. SARS-CoV-2 antigens are substances of the virus that serve as markers for disease exposure.

CONTAINED IN THIS BOX

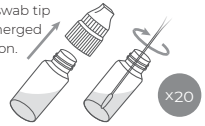
25 individually-wrapped test devices	25 vials of buffer solution	25 individually-wrapped swabs	1 instruction guide
			

HOW TO USE

01 Remove the test device and swab from their packaging.

02 Tilt your head back. Gently insert the swab about 2.5cm into one of your nostrils. Rub the swab against the wall of one of your nostrils **at least 5 times** in a large circular path. Repeat with your other nostril.

03 The buffer solution vial cap is composed of two parts. Remove the entire cap. Stir the swab into the buffer solution by twisting the swab back and forth **20 times**. Slightly tilt the vial to ensure the swab tip is fully submerged in the solution.



04 Close the entire vial cap tightly. Immediately perform Steps 5-7.

05 Remove the top half of the vial cap to expose the dropper tip.

06 Hold the vial vertically. Squeeze and drip 3 drops of the solution into the circular opening of the test device.

07 Leave for **20 minutes** and read the results. Do not read after **25 minutes**. Refer to the "Interpreting Your Results" section below.

*Watch the how-to-use video by scanning the QR code.

INTERPRETING YOUR RESULTS:

	INDICATOR	RESULTS	INTERPRETATION
	A line appears in regions (C) and (T)	Positive	This result indicates the presence of SARS-CoV-2 antigen in the sample.
	A line appears in the region (C)	Negative	This results indicates no SARS-CoV-2 antigen is detected in the sample. Regular testing (at least once every week) is recommended. If you have been in contact with a known or suspected COVID-19 case, we recommend that you arrange a PCR test to confirm your negative result.
	No line appears in the region (C)	Invalid	There was an issue with the specimen collection or the test processing. Repeat the test with a new test kit.

IMPORTANT

- For in vitro diagnostic use
- User should not make any decision of medical relevance without first consulting their health care provider
- All components in this test kit should remain sealed until ready for use
- The test must be performed between 15-30°C
- All components in this test kit are for one-time use only. Do not reuse
- Store at 2-30°C. Do not freeze. Avoid direct sunlight
- Do not swallow or inhale
- Avoid contact with your eyes. If contact occurs, flush with water immediately and seek medical help
- Do not use the test kit after the expiration date
- Samples with low levels of antigen may give a faint test line. Any visible pink/purple colored line is positive, do not compare the color intensity of each indicator line to another
- If you have questions about the product, please contact Customer Service at indicaid@sdt-molecular.com

LIMITATIONS

- The test is designed for using direct nasal swab sample or nasopharyngeal swab sample.
- Negative results do not rule out COVID-19 infection, especially if you have been in contact with the virus. A follow-up PCR test should be considered to rule out infection
- Positive results may be due to current infection with non-SARS-CoV-2 coronavirus strains
- Results from antigen testing should not be used as the sole basis to diagnose or exclude COVID-19 infection
- The presence of Fluticasone Propionate (Flonase) in the nasal swab specimen may give inaccurate results

FREQUENTLY ASKED QUESTIONS (FAQs)

I ACCIDENTALLY SPILLED THE TEST SOLUTION. IS IT HARMFUL?

If the test solution has been spilled, flush abundantly with water upon disposal.

Avoid having the test solution come into contact with your eyes, skin and mouth. If contact occurs with the eyes, flush with water immediately and seek medical help. If contact occurs with your skin, wash the area with soap and rinse with water.

Do not ingest or inhale the test solution. If accidental ingestion occurs, please seek medical help immediately.

HOW DEEP SHOULD I INSERT THE SWAB INTO MY NOSTRILS?

Inserting the swab 2.5cm into the nostril should be deep enough to collect samples for this test. Once you feel a slight resistance, proceed to gently collect your sample. Check the swab after collection to ensure the tip is covered in nasal secretion.

WHAT DO I DO WITH THE TEST KIT AFTER READING THE RESULTS?

After completing the test and recording your results, carefully wrap all product components and dispose them into the garbage just like any other household trash. Wash your hands thoroughly with soap and water after handling the components.

HOW ACCURATE IS THE TEST?

In a study using prospective nasal and retrospective nasopharyngeal swab specimens, the INDICAID™ COVID-19 Rapid Antigen Test has been clinically validated to achieve a high detection accuracy, reaching a relative detection specificity of >95% and relative detection sensitivity of 91% respectively (Table A).

Table A (Study with prospective nasal and retrospective nasopharyngeal swab specimens)

INDICAID™ COVID-19 Rapid Antigen Test	Comparator Method (RT-qPCR)		
	Positive	Negative	Total
Positive	91	12	103
Negative	9	278	287
Total	100	290	390
Positive Percentage Agreement (PPA)	91% (95% CI: 83.8% - 95.2%)		
Negative Percentage Agreement (NPA)	96% (95% CI: 92.9% - 97.6%)		

PHASESCIENTIFIC.COM

MANUFACTURER
PHASE Scientific International Limited
32 & 33/F, Gravity, 29 Hing Yip Street,
Kwun Tong, Kowloon, Hong Kong

INDICAID™ 妥析™ 使用说明

新冠病毒快速抗原测试
Ref # IN-COVAG-025SG01A

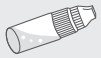
产品用途

INDICAID™ 妥析™ 新冠病毒快速抗原检测试剂盒是一款体外诊断测试工具，用于检测人体鼻拭子或鼻咽拭子中的新冠病毒 (SARS-CoV-2) 抗原。此测试适用于自我测试和/或专业用途。

检测原理

新冠病毒感染期间，SARS-CoV-2 病毒可以在上呼吸道中被检测出来。SARS-CoV-2 抗原存在于病毒中，可作为检测体内病毒的指标。

本盒内配有

25 支独立包装的测试棒	25 瓶测试溶液	25 支独立包装的采样棒	1 份使用说明
			

如何使用

打开包装，取出测试棒和采样棒。

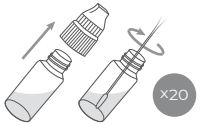
01

把头向后倾，轻轻地把采样棒伸进鼻孔（约2.5厘米），沿鼻孔内壁在内**至少打5个**大圈。在另一侧鼻孔里重复同样的步骤。

02

测试溶液小瓶的盖子分为两部分，分别是上半部及整个盖子。扭开小瓶的整个盖子，然后把采样棒浸在测试溶液中来回转动**20次**。转动时须确保采样棒顶端完全浸泡在溶液中。

03



扭紧盖子。立即进行5-7的步骤。

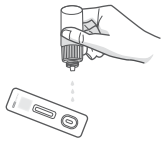
04

扭开小瓶的盖子的上半部分，露出滴头。

05

把小瓶垂直置于测试棒上的圆形开口上方，挤出3滴溶液到开口里。

06



置于室温**20分钟后**（不可多于**25分钟**）查看检测结果。请仔细阅读以下"如何解读检测结果"部分。

07

*扫描二维码观看使用视频

如何解读检测结果：

	指示线	结果	解释
	在 (C) 和 (T) 区内 分别显示一条线	阳性	结果显示样本中检测到 SARS-CoV-2 抗原。
	只在(C) 区内 显示一条线	阴性	结果显示样本中未检测到SARS-CoV-2 抗原。 建议您定期进行检测 (每星期一次)。如果您曾经与疑似或确诊新冠病毒病例接触，我们建议您进行一次核酸检测确定您的结果。
	在(C) 区内 没有显示一条线	无效	样本采样过程或测试处理中出现了问题，请使用新的试剂盒再检测一次。

重要事项

- 本试剂盒只供体外诊断之用
- 请勿在未事先咨询医护人员的情况下，做出任何与医学相关的决定
- 进行测试前，本试剂盒内的所有部件应保持密封
- 测试必须在15-30°C环境下进行
- 所有部件仅为一次性使用，不可重复使用
- 本试剂盒应储存于温度2-30°C之间。避免阳光直接照射
- 不可吞咽或吸入本试剂盒内任何部件
- 避免接触眼睛。如发生意外接触，请立即用清水冲洗并向医护人员求助
- 请勿使用过期试剂盒
- 指示线有时会显得模糊，但仍然应视作指示线进行结果解读；指示线的颜色强度不一致是正常情况，进行结果解读时毋须比较线条的颜色强度
- 如果您对产品存有疑问，请电邮至indicaid@sdt-molecular.com与我们的客户服务人员联络

产品局限性

- 本试剂盒用于检测人体鼻拭子或鼻咽拭子样本
- 阴性结果不能完全排除新冠病毒感染的可能，如果您曾经处于有可能感染病毒的环境，您应当考虑做进一步的核酸检测
- 阳性结果也可能是由于感染了非 SARS-CoV-2 的其他冠状病毒所引致
- 本抗原测试的结果不应用作诊断新冠病毒感染的唯一依据
- 鼻拭子样本中存在丙酸氟替卡松 (Flonase) 可能会产生不准确的检测结果

常见问题和解答

我意外倒翻了溶液，是否有害？

若不慎倒翻溶液，请立即使用大量清水充分清洗受影响的地方。

请避免眼睛、皮肤或口部接触溶液。如果溶液接触了眼睛，请立即用清水冲洗并向医护人员求助。如果接触了皮肤，用肥皂洗净该部位后再用清水冲洗即可。

切勿吞咽或吸入溶液。如意外吞食了溶液，请立即求医。

在采集鼻拭子样本时，我应该把采样棒插入多深？

把采样棒伸进鼻孔内2.5厘米即可。如果您在把采样棒伸入鼻孔的过程中感到轻微阻力，则继续轻轻地收集样本。收集样本后，检查采样棒以确保其顶端被鼻腔分泌物覆盖。

读完检测结果后，如何处理用过的测试棒及其他部件？

完成测试后，请先记录您的检测结果，然后把测试棒及其他部件包好，再用处理普通家庭垃圾的方式丢弃在垃圾桶里。处理完毕后切记洗手。

此产品的结果准确吗？

在一项使用前瞻性鼻拭子样本和回顾性鼻咽拭子样本的研究中，INDICAID™ 妥析™ 新冠病毒快速抗原检测经临床验证其检测精准度非常之高，相对特异度和相对灵敏度分别为96%和91% (表A)。

表A (前瞻性鼻拭子及回溯性鼻咽拭子样本的临床研究结果)

INDICAID™妥析™ 新冠病毒快速抗原检测	比对RT-qPCR结果		
	阳性	阴性	总数
阳性	91	12	103
阴性	9	278	287
总数	100	290	390
灵敏度	91% (95% CI: 83.8% - 95.2%)		
特异度	96% (95% CI: 92.9% - 97.6%)		

PI-0006 | Rev B | 仅供体外诊断之用 |

PHASESCIENTIFIC.COM

制造商
相达生物科技国际有限公司
香港九龙观塘兴业街29号万有引力32及33楼