INSTRUCTIONS FOR USE

REF IND-HG-CVFPOC-10PPK
IND-HG-CVFPOC-25PPK

IVD

INDICAID™

COVID-19 / INFLUENZA A&B ANTIGEN TEST

For *in vitro* diagnostic use
For professional use

INTENDED USE

The INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza and SARS-CoV-2 or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should therefore seek follow-up care from their healthcare provider.

Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.

SUMMARY

COVID-19 and influenza are acute and highly contagious viral infections of the respiratory tract. The causative agents of the diseases are immunologically diverse, single-strand RNA viruses known as SARS-CoV-2 viruses and influenza viruses, respectively. There are three types of influenza viruses: A, B and C. Type A viruses are the most prevalent and are associated with more serious disease whereas Type B infection is generally milder. Type C virus has never been associated with a large epidemic of human disease.

A patient can be infected with a single virus or co-infected with SARS-CoV-2 and one or more types of influenza viruses. These viral infections occur more often during the respiratory illness season (in the U.S. this includes the fall and winter seasons) and the symptoms generally appear 3 to 7 days after the infection. Transmission for all of these viruses occurs through coughing and sneezing of aerosolized droplets from infected people, who may be either symptomatic or asymptomatic. For symptomatic patients, the main symptoms include fever, fatigue, dry cough, and loss of taste and smell. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea were also associated symptoms.

Rapid diagnosis of SARS-CoV-2 and influenza A & B viral infection will help healthcare professionals treat patients and control these diseases more effectively.

PRINCIPLE

The INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST is an immunochromatographic assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein antigens extracted from COVID-19, influenza virus types A and B with anterior nares swab samples.

The test device is a plastic housing, known as a cassette, containing two test strips, each composed of the following parts: sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pads contain colloidal gold conjugated with monoclonal antibodies (mAb) specific for SARS-CoV-2, Influenza A, and Influenza B target proteins. When the test sample is added into the sample well (S) of the cassette, mAb conjugates dried in the reagent pad are dissolved and interact with the viruses' proteins in the sample (if present). These complexes migrate along the test strip and across the reaction lines on the membrane. The reaction line contains a second antibody specific to available target protein-mAb complexes with each of the virus antigens of the test, resulting in visible test lines for the viruses in the sample.

Results completely develop after 15 minutes. Reactions for each virus occur independently at their respective locations on the test reaction membrane. If the sample contains influenza type A or B antigens, a pink-to-red test line (A or B) will develop; if SARS-CoV-2 antigens are present, a pink-to-red test line (T) will develop. The procedural control line (C) must always appear on both strips for the test to be valid. The INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST is validated for testing direct samples without transport media and does not use biotin-streptavidin/avidin chemistry in any of the steps for coupling reagents.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

1. Read the instructions fully and carefully before performing the procedure. Failure to follow the instructions may result in inaccurate or invalid results.
2. **Do not use the test if the patient has had symptoms for more than 5 days or no symptoms at all.**
3. **Do not use under 2 years of age.**
4. Do not use the test kit after its expiration date.
5. Do not use the test if the pouch is damaged or open.
6. Do not reuse the test cassette, processing solution, or swab.
7. Not for use with viral transport media (VTM).
8. Do not open the test contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.
9. When collecting a sample, only use the swab provided in the kit.
10. Inadequate or inappropriate sample collection, storage, or transport may yield false test results.
11. Testing should be performed in an area with good lighting.
12. **Keep the testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

Hazard Category (mixture)	Hazard Class	GHS Hazard Statement for mixture	Hazardous Ingredients (%)
2	Skin irritation	Causes skin irritation (H315)	Tris (2.4%) 1,2-Benzisothiazolin-3-One (0.04%)
2	Eye irritation	Causes eye irritation (H320)	1,2-Benzisothiazolin-3-One (0.04%) Tris (2.4%) Ethylenediamine ethoxylated propoxylated polymer (S9) (0.75%)

STORAGE AND STABILITY

- Store the test kit between 36-86°F (2-30°C) in a place out of direct sunlight.
- Reagents and devices must be used at room temperature (59-86°F/15-30°C).
- The unsealed cassette is valid for 1 hour. It is recommended to use the test kit immediately after opening. The expiration date is on the package.

MATERIALS PROVIDED

- 10/25 Sealed Test Cassettes
- 10/25 Sterile Nasal Swabs
- 10/25 Pre-filled Extraction Tubes
- 10/25 Extraction Tube Tips
- 2 Tube Holders
- 1 Instructions For Use (IFU)
- 1 Quick Reference Instructions (QRI)

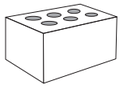
MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or clock.

PREPARING FOR THE TEST

NOTE:

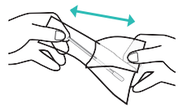
- **Do not open the test contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.**
- **Allow the test device and reagents to come to room temperature (15-30°C/59-86° F) prior to testing.**



1. **Check the test's expiration date printed on the outer test packaging.**
2. Wash your hands with soap and water for 20 seconds and dry them thoroughly, or use hand sanitizer.
3. Remove the tube holder from the box.
4. Insert the extraction tube into the tube holder. Ensure that the tube is stable and upright.
5. Tear off the sealing film on the extraction tube gently to avoid spilling the liquid.
6. Remove test cassette from sealed pouch and lay it on a flat surface.

SAMPLE COLLECTION

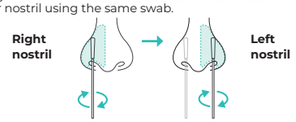
1 Remove the swab from the pouch. Carefully insert the sterile swab no more than 3/4 inch (1.5 cm) into the nostril.



⚠ **Be careful not to touch the swab tip (soft end) with hand.**

2 Slowly rotate the swab **at least 5 times** against the nostril wall **for at least 15 seconds**. Remove the swab and repeat in the other nostril using the same swab.

⚠ **If you are swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than ½ to ¾ of an inch, and you may require another adult to hold the child's head while swabbing**



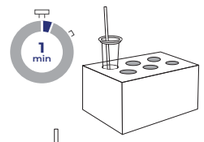
5x for 15 seconds, each nostril

RUNNING THE TEST

3 Immerse the swab into the prefilled extraction tube and swirl the swab in the buffer. Ensure the sample is mixed thoroughly by **making at least 6 circles.**

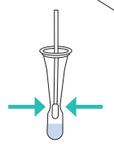
⚠ **Sample must be mixed in the extraction buffer within 1 hour of sample collection.**

4 Leave the swab in the extraction tube for **1 minute**. A timer is recommended for this step.

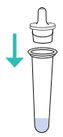


5 After 1 minute, pinch the tip of the swab from the outside of the tube to remove any excess sample in the swab.

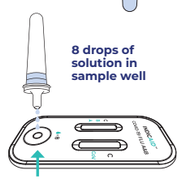
Remove and discard the swab.



6 Hold the tube upright and insert extraction tube tip into tube opening. Ensure a tight fit to prevent leaking.



7 Invert the extraction tube and **squeeze 8 drops** of test sample into the sample well. Then discard the tube.



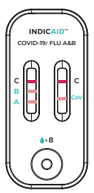
⚠ **Sample must be applied to the test cassette within one hour of completing step 3.**

8 Start timer. **Read results between 15 minutes and 20 minutes.**

⚠ **Do not read the test results before 15 minutes or after 20 minutes as this can give false or invalid results.**

INTERPRETING YOUR RESULT

Control line = **C**
Flu B line = **B**
Flu A line = **A**



C = Control line
CoV = COVID-19 line

- **Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may result in false or invalid results.**
- This test is using an internal procedural control that is needed to generate a valid result for this test. If a colored line appears in the control line regions (C) in the test window this confirms that membrane wicking has occurred and the test reagents are functional. A test result is valid when **BOTH** strips have a visible control line.
- Look for lines next to 'C' (Control), 'B', 'A' and 'CoV'.
- Look closely! Any faint line is still a line.
- If uncertain how to proceed, contact Technical Assistance at care@indicaidusa.com or 877-625-1603 (Monday-Friday 9 a.m. to 5 p.m. CST).

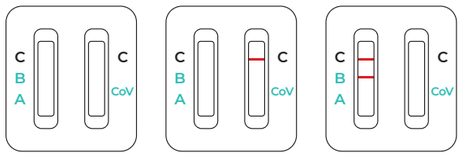
Additional Information: Reading Results

Scan QR code for more information on reading results.

Webpage: https://www.phasescientificamericas.com/products-and-services/indicaid-poc/indicaid-covid-19-influenza-a-b-antigen-test

INVALID TEST RESULT

Missing 'C' line on ONE or BOTH strips



Check to see if a line is visible at the control line 'C' on BOTH strips.

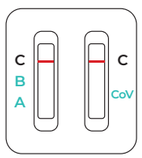
STOP **If you do not see any C line, or only see one C line, DO NOT CONTINUE reading the results. The test is invalid.**

NOTE: The 3 images displayed are examples only; additional invalid outcomes are possible.

An invalid test result means that the test is unable to determine if the patient is infected with influenza or SARS-CoV-2 (COVID-19) or not. The test needs to be repeated with a new kit and sample.

NEGATIVE TEST RESULT

Both 'C' lines only

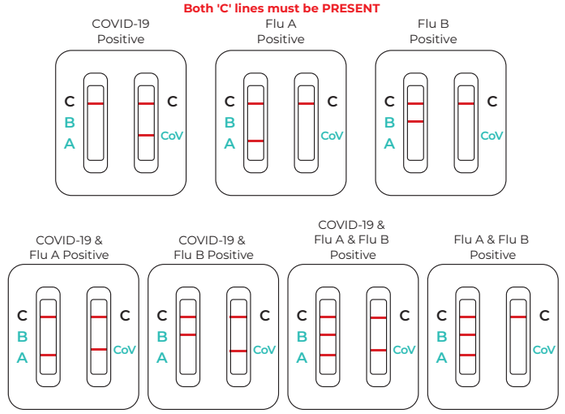


If a line is not seen at 'CoV', 'A' or 'B', these viruses were not detected in the sample.

A negative result is presumptive because despite a negative result patient may still have COVID-19, Flu A, and/or Flu B infection. This is because the amount of virus in the sample may be too low for the test to detect it, which is called a 'false negative result'. False negative results can occur if the test result is read before 15 minutes or when the sample has only a low amount of virus in it. Low amounts of virus can occur if the sample is taken at a time when symptoms are just appearing, or when the patient has already started to feel better at the end of infection. If the patient tested negative and continues to experience COVID-19, Flu A and/or Flu B-like symptoms, the patient should seek follow-up care with the healthcare provider. The healthcare provider can also determine if confirmation of the patient's test result with a molecular assay is necessary.

POSITIVE TEST RESULT

Both 'C' lines must be PRESENT



If any line is seen at any one, or multiple, of the 'CoV', 'A' or 'B' areas, the test result is positive and the virus annotated next to the positive line was detected in the sample.

A positive test result means that any one, or multiple, of the viruses detected by this test were detected in the sample. Individuals may also have co-infections with other bacteria or viruses that this test is not designed to detect. This means that the virus detected by this test may not be the definitive or the only cause of a disease. There is a very small chance this test can give a positive result that is incorrect (a false positive).

LIMITATIONS

- The clinical performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February 2024 through April 2024. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. There is a risk of false negative results due to the presence of novel, emerging respiratory virus variants. Test accuracy may change as new virus variants of COVID-19 and influenza emerge.
- This test provides a presumptive negative result; this means the test only provides preliminary results that should be confirmed using an independent, highly sensitive molecular test to make well-informed clinical decisions.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the sample is collected, handled or transported improperly.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- False positive test results are more likely when the prevalence of SARS-CoV-2, influenza A, and/or influenza B is low in the community.
- Positive results do not rule out co-infection with other respiratory pathogens.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., young children, elderly individuals, chronic lung disease, heart disease, compromised immune system, diabetes, and other conditions) should contact a healthcare provider; users should also contact a healthcare provider if symptoms persist or worsen.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This device is a qualitative test and cannot provide information on the amount of virus present in the specimen.
- This test detects both viable (live) and non-viable influenza A, influenza B, and SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the sample.
- Exposure to hand sanitizer and hand soap liquid gel may cause false negative results with this test.
- Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive influenza test results after vaccination.
- This test does not distinguish between SARS-CoV and SARS-CoV-2.

PERFORMANCE CHARACTERISTICS

A prospective study was completed at ten sites in the United States for clinical validation of the INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST for the detection of the SARS-CoV-2/Flu A/Flu B in self-collected anterior nasal (AN) swab samples. The study evaluated the INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST performance in symptomatic individuals who were currently experiencing symptoms associated with COVID-19, influenza A and/or influenza B. A total of 1156 subjects experiencing symptoms associated with COVID-19/Flu A/Flu B with symptom onset between 0 and 5 days were enrolled in the study. 1122 were evaluable, of which 1122 subjects were evaluable for Flu A/B, and 1097 were evaluable for SARS-CoV-2.

Each enrolled subject either self-collected a dual anterior nares (AN) sample or had a dual AN sample collected from him/her by another individual for the investigation test. Each subject also had a dual AN sample collected from him/ her by one of the study personnel for the comparator testing, which were FDA cleared RT-PCR assays. Swab collections for investigation and comparator samples were alternated by subject. The comparator tests were performed according to their respective instructions for use. Test results from the INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST were compared to the results generated from comparator tests. Results are shown in Tables 1.1-1.4.

Table 1.1: INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST – Results for SARS-CoV-2

SARS-CoV-2 Test Results	RT-PCR Comparator		Total
	Positives	Negatives	
Positives	69	10	**79**
Negatives	6	1012	**1018**
Total	**75**	**1022**	**1097**

Positive Percent Agreement = (69/75) = 92.0% (95% CI: 83.6% - 96.3%)
Negative Percent Agreement = (1012/1022) = 99.0% (95% CI: 98.2% - 99.5%)

Table 1.2: SARS-CoV-2 Clinical Performance Stratified by Days Post Symptoms Onset (DPSO)

DPSO	Total Number of Subjects	INDICAID™ Test Positive	Comparator Positives	Positivity Rate by Comparator	PPA	95% CI
Day 0	24	0	0	0.0%	NA	
Day 1	180	12	13	7.2%	**92.3%**	**66.7% - 99.6%**
Day 2	341	15	17	5.0%	**88.2%**	**65.7% - 96.7%**
Day 3	285	16	17	6.0%	**94.1%**	**73.0% - 99.7%**
Day 4	194	21	21	10.8%	**100.0%**	**84.5% - 100.0%**
Day 5	73	5	7	9.6%	**71.4%**	**35.9% - 91.8%**
Total	**1097**	**69**	**75**	**6.8%**	**92.0%**	**83.6% - 96.3%**

Table 1.3: INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST – Results for FLU A

Flu A Test Results	RT-PCR Comparator		Total
	Positives	Negatives	
Positives	49	1	**50**
Negatives	4	1068	**1072**
Total	**53**	**1069**	**1122**

Positive Percent Agreement = (49/53) = 92.5% (95% CI: 82.1% - 97.0%)
Negative Percent Agreement = (1068/1069) = 99.9% (95% CI: 99.5% - 100.0%)

Table 1.4: INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST – Results for FLU B

Flu B Test Results	RT-PCR Comparator		Total
	Positives	Negatives	
Positives	38	1	**39**
Negatives	4	1079	**1083**
Total	**42**	**1080**	**1122**

Positive Percent Agreement = (38/42) = 90.5% (95% CI: 77.9% - 96.2%)
Negative Percent Agreement = (1079/1080) = 99.9% (95% CI: 99.5% - 100.0%)

SUBJECT DEMOGRAPHICS

Table 2: Subject Demographics of All Enrollments

Demographic	Subjects (by lay-user collection and testing (N=178)	Self-collecting and testing (N=944)	Overall (N=1122)
Age: Mean (SD)	8.2 (6.0)	41.3 (15.9)	36 (19.1)
Age: Median [Min, Max]	8 [2, 71]	40 [14, 89]	35 [2, 89]
Age Group			
≥2 - <14 years of age	171 (96.1%)	0 (0.0%)	171 (15.2%)
≥14 - <24 years of age	6 (3.4%)	147 (13.1%)	153 (13.6%)
≥24 - <65 years of age	0 (0.0%)	710 (75.2%)	710 (61.6%)
≥65 years of age	1 (0.6%)	87 (9.2%)	88 (7.8%)
Total	178 (100.0%)	944 (100.0%)	1122 (100.0%)
Sex at Birth			
Female	83 (46.6%)	550 (58.3%)	633 (56.4%)
Male	95 (53.4%)	394 (41.7%)	489 (43.6%)

Demographic	Subjects (by lay-user collection and testing (N=178)	Self-collecting and testing (N=944)	Overall (N=1122)
Ethnicity			
Hispanic/Latino	108 (60.7%)	427 (45.2%)	535 (47.7%)
Not Hispanic/Latino	70 (39.3%)	517 (54.8%)	587 (52.3%)
Race			
American Indian or Alaskan Native	1 (0.6%)	2 (0.2%)	3 (0.3%)
Asian	0 (0.0%)	4 (0.4%)	4 (0.4%)
Black or African American	8 (4.5%)	145 (15.4%)	153 (13.6%)
Native Hawaiian/Pacific Islander	0 (0.0%)	0 (0.0%)	0 (0.0%)
White	161 (90.4%)	730 (77.3%)	891 (79.4%)
Unknown/Prefer not to answer	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other (Mixed race/biracial)	8 (4.5%)	63 (6.7%)	71 (6.3%)
Total	**178 (100.0%)**	**944 (100.0%)**	**1122 (100.0%)**

ANALYTICAL PERFORMANCE

ANALYTICAL SENSITIVITY: LIMIT OF DETECTION (LoD)

The LoD of the device was performed to determine the lowest detectable concentration of SARS-CoV-2, influenza A and influenza B at which at least 95% of all true positive replicates are consistently detected as positive. The LoD was assessed for each analyte in two parts, a preliminary range finding study, followed by a confirmatory LoD study. A preliminary LoD was determined by first testing serial ten-fold dilutions of live influenza A and B, and inactivated SARS-CoV-2 virus stocks diluted into pooled negative swab matrix (PNSM) or pooled nasal wash (PNW) in 3 replicates per dilution and confirmatory testing was conducted with 20 replicates. Single analyte virus dilutions (50 µL/swab) were each spiked onto dry sterile swabs and tested per the IFU. The lowest concentration that generated ≥95% positive detection rate was set as the LoD concentration.

The LoD for the analytes is identical when analytes are co-spiked into the same sample. The results of LoD confirmation testing for each virus are summarized in Table 3a.

Table 3a: LoD Confirmation for SARS-CoV-2, Flu A, and Flu B

Analyte	Isolate/ Lineage	Strain	LoD Concentration ($TCID_{50}$/mL)	LoD Concentration ($TCID_{50}$/swab)	#Positive/ # Total	# device lots tested
SARS-CoV-2	USA-WA1/2020 (UV inactivated)	NA	3.95E+02	1.98E+01	20/20	1
	USA-WA1/2020 (Heat inactivated)	NA	3.09E+03	1.5E+02	60/60	3
	USA/COR-22-063113/2022 (BA.5 Omicron variant)	NA	1.09E+03	5.45E+01	58/60	3
Flu A	H3N2	Darwin/6/21	2.09E+02	1.05E+01	20/20	1
	H1N1	Victoria/4897/22	2.02E+02	1.01E+01	20/20	1
		A/California/07/2009 pdm09	1.05E+03	5.25	60/60	3
		Guangdong-Maonan/SWL 1536/19 (PROtrol inactivated)	5.62E+01	2.81	60/60	3
Flu B	Yamagata	Florida/04/06	1.46E+01	7.30E-01	20/20	1
	Victoria	Washington/02/19	1.58E+03	7.90E+01	20/20	1
	Victoria	Washington/02/19 (PROtrol inactivated)	1.75E+04	8.75E+02	58/60	3
	Victoria	B/Florida/78/2015	1.7E+04	8.5E+02	60/60	3

The First WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) was also tested in a similar manner to determine the LoD of SARS-CoV-2 antigen and the results are included in Table 3b.

Table 3b: WHO SARS-Cov2 Standard Antigen LoD

Description	Source	NIBSC. No.	Dilution Factor	Concentration (IU/mL)	Concentration (IU/swab)
WHO International Standard SARS-Cov-2 Ag	NIBSC	21/368	1:80	250	12.5

INCLUSIVITY (IN SILICO & ANALYTICAL SENSITIVITY)

Inclusivity testing was conducted to determine the analytical reactivity of the device with different strains of SARS-CoV-2, Flu A and Flu B.

A selection of temporal, geographic and genetically diverse Influenza A and B strains and SARS-CoV-2 were tested on the INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST for inclusivity. Each strain was tested for reactivity in a dilution series and the lowest dilution in which 100% of replicates detected is included in Table 4.

Table 4: Inclusivity Summary – Lowest Concentrations Tested Positive for Relevant Virus Strains

Virus	Virus Strains	Concentration	Units	#positive/ #tested
Flu A - H1N1	A/California/04/2009	2.80E+03	$TCID_{50}$/mL	3/3
	A/Brisbane/02/2018	1.51E+02	$TCID_{50}$/mL	3/3
	A/Michigan/45/2015	9.30E+00	$TCID_{50}$/mL	3/3
	A/Guangdong-Maonan/SWL 1536/2019	1.04E+03	$TCID_{50}$/mL	3/3
	A/NY/03/2009	2.29E+04	$TCID_{50}$/mL	3/3
	A/Indiana/02/2020	9.70E+06	$CEID_{50}$/mL	3/3
	A/Wisconsin/588/2019	1.4E+04	FFU/mL	3/3
	A/Sydney/5/2021	4.80E+03	$TCID_{50}$/mL	3/3
	A/Hawaii/66/2019	3.70E+07	$CEID_{50}$/mL	3/3
	A/Wisconsin/67/2022	1.05E+03	$TCID_{50}$/mL	3/3
Flu A - H3N2	A/New York/21/2020	2.6E+05	FFU/mL	3/3
	A/Tasmania/503/2020	6.5E+04	FFU/mL	3/3
	A/Hong Kong/2671/2019	3.1E+06	$CEID_{50}$/mL	3/3
	A/Hong Kong/45/2019	1.5E+04	FFU/mL	3/3
	A Alaska/01/2021	1.50E+04	FFU/mL	3/3
	A/Indiana/08/2011	8.10E+02	$TCID_{50}$/mL	3/3
Flu A - H1N1	A/Ohio/09/2015	7.0E+05	$CEID_{50}$/mL	3/3
Flu A - H1N2	A/Minnesota/19/2011	8.00E+06	$CEID_{50}$/mL	3/3
Flu A - H5N1	A/mallard/Wisconsin/2576/2009	2.10E+05	GE/mL	3/3
	A/mallard/Wisconsin/2576/2009 (live) (H5N1)	800,000	$CEID_{50}$/mL	3/3
	A/Bovine/Ohio/ B24OSU-439/2024	1,550	$TCID_{50}$/mL	3/3
	A/duck/Guangxi/S11002/2024	3.38E+05	EID_{50}/mL	5/5
Flu A - H5N6	A/duck/Guangxi/S10888/2024	7.90E+05	EID_{50}/mL	5/5
Flu A - H5N8	A/goose/Liaoning/S1266/2021	1.69E+05	EID_{50}/mL	5/5
Flu A - H7N3	A/northern pintail/ Illinois/10OS3959/2010	7.0E+05	$CEID_{50}$/mL	3/3
Flu B - Victoria Lineage	B/ Brisbane/60/2008	6.45E-01	$TCID_{50}$/mL	3/3
	B/Colorado/6/2017	5.85E+00	$TCID_{50}$/mL	3/3
	B/Texas/02/2013	6.13E+00	$TCID_{50}$/mL	3/3
	B/Michigan/01/2021	2.85E+03	$TCID_{50}$/mL	3/3
Flu B - Yamagata Lineage	B/Texas/06/2011	8.00E+05	$CEID_{50}$/mL	3/3
	B/Utah/09/2014	1.26E+02	$TCID_{50}$/mL	3/3
	B/Wisconsin/1/10	1.78E+01	$TCID_{50}$/mL	3/3
Flu B – non-Victoria, non-Yamagata	B/Maryland/1/1959	1.69E+03	$CEID_{50}$/mL	3/3
SARS-CoV-2 Delta	B.1.617.2	2.82E+5	genome copies/mL	3/3
SARS-CoV-2 Beta	B.1.351	2.12E+5	genome copies/mL	3/3
SARS-CoV-2 Alpha	B.1.1.7	6.48E+5	genome copies/mL	3/3
SARS-CoV-2 Omicron	B.1.1.529	2.51E+2	$TCID_{50}$/mL	3/3
SARS-CoV-2 Gamma	P1	6.30E+2	$TCID_{50}$/mL	3/3
SARS-CoV-2 Kappa	B.1.617.1	1.90E+2	$TCID_{50}$/mL	3/3
SARS-CoV-2 Omicron	JN1*	26.4	Ct Values	5/5

*The pooled JN1 positive clinical sample was provided by and tested at Emory using the INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST for reactivity in a dilution series. All five replicates at mean ≤ 26.4 were tested positive.

HOOK EFFECT

The hook effect study was conducted to evaluate if high levels of antigen present in the sample could result in a false negative test result. In this study, 50 µL of the highest concentration possible of UV inactivated SARS-CoV-2 virus stock, each of the live Influenza A virus stock, H1N1 pdm09 and H3N2, and each live Influenza B virus stock, Victoria and Yamagata, were spiked onto the sterile swab and tested in triplicate on the INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST to test for a high-dose hook effect. The INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST showed no hook effect for SARS-CoV-2, Flu A, and Flu B, at the concentrations listed in Table 5.

Table 5: Summary of Hook Effect

Virus	Subtype or Lineage	Concentration without Hook Effect	
		($TCID_{50}$/mL)	($TCID_{50}$/swab)
SARS-CoV-2	N/A	3.16E+06	1.58E+05
Influenza A	H1N1	2.02E+05	1.01E+04
Influenza A	H3N2	4.17E+05	2.09E+04
Influenza B	Victoria	3.16E+06	1.58E+05
Influenza B	Yamagata	1.17E+05	5.85E+03

ANALYTICAL SPECIFICITY: CROSS REACTIVITY (EXCLUSIVITY) AND MICROBIAL INTERFERENCE

The analytical specificity/interference of the INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST was evaluated by testing various commensals and pathogenic microorganisms in the absence (cross-reactivity) and presence (microbial interference) of SARS-CoV-2/Flu A/Flu B at 3x LoD. Each organism was tested in replicates of three (3) with or without SARS-CoV-2/ FluA/FluB present in the sample. No cross-reactivity and no microbial interference was observed for any of the listed organisms when tested in the concentrations listed in Table 6.

Table 6: Summary of Cross-reactivity and Microbial Interference

ID	Organism	Concentration tested	Units	Cross-reactivity	Microbial Interference
SARS	SARS-CoV-1	1.25E+05	PFU/mL	ND*	ND
MERS	MERS-coronavirus	1.47E+05	$TCID_{50}$/mL	ND	ND
OC43	Human coronavirus OC43	7.00E+05	$TCID_{50}$/mL	ND	ND
229E	Human coronavirus 229E	1.58E+05	$TCID_{50}$/mL	ND	ND
NL63	Human coronavirus NL63	8.00E+04	$TCID_{50}$/mL	ND	ND
AV1	Adenovirus, Type 1 (Adenoid 71)	2.23E+05	$TCID_{50}$/mL	ND	ND
AV7	Adenovirus Type 7, Type 7A (Species B)	1.58E+05	$TCID_{50}$/mL	ND	ND
CMV	Cytomegalovirus, Strain AD-169	7.05E+04	$TCID_{50}$/mL	ND	ND
EBV	Epstein Barr Virus, Strain B95-8	1.83E+06	CP/mL	ND	ND
hMPV	Human Metapneumovirus (hMPV), Strain TN/91-316	3.50E+05	$TCID_{50}$/mL	ND	ND
P1	Parainfluenza virus 1, Strain FRA/29221106/2009	2.00E+05	$TCID_{50}$/mL	ND	ND
P2	Parainfluenza virus 2, Strain Greer	1.75E+05	$TCID_{50}$/mL	ND	ND
P3	Parainfluenza virus 3, Strain C243	7.00E+05	$TCID_{50}$/mL	ND	ND
P4	Parainfluenza virus 4, Strain N/A	2.39E+05	$TCID_{50}$/mL	ND	ND
EV68	Enterovirus Type (e.g. 68), Species D Type 68	2.23E+05	$TCID_{50}$/mL	ND	ND
RSVA	Respiratory syncytial virus A, Strain A-2	3.50E+05	$TCID_{50}$/mL	ND	ND
RSVB	Respiratory syncytial virus B, Strain CH93(18)-18	2.29E+05	$TCID_{50}$/mL	ND	ND
RV	Rhinovirus 1A, Strain N/A	7.05E+04	$TCID_{50}$/mL	ND	ND
BP	Bordetella pertussis, Strain A639	2.50E+08	CFU/mL	ND	ND
CA	Candida albicans, Strain Z006	6.03E+06	CFU/mL	ND	ND
CP	Chlamydia pneumoniae, Strain Z500	4.33E+06	IFU/mL	ND	ND
CB	Corynebacterium xerosis	2.30E+07	CFU/mL	ND	ND
EC	Escherichia coli, Strain mcr-1	1.79E+08	CFU/mL	ND	ND
HI	Hemophilus influenzae, type b; Eagan	9.68E+06	CFU/mL	ND	ND
LB	Lactobacillus sp., Lactobacillus Acidophilus, Strain Z048	1.21E+07	CFU/mL	ND	ND
LP	Legionella spp pneumophila, Strain Philadelphia-1	6.50E+06	CFU/mL	ND	ND
MC	Moraxella catarrhalis, Strain 59632	2.50E+08	CFU/mL	ND	ND
MP	Mycoplasma pneumoniae, Strain PI 1428	2.50E+07	CFU/mL	ND	ND
MT	Mycobacterium tuberculosis avirulent, Strain H37Ra-1	4.15E+06	CFU/mL	ND	ND
NM	Neisseria meningitidis, serogroup A	3.43E+06	CFU/mL	ND	ND
NS	Neisseria sp. Elongata Z071	2.68E+08	CFU/mL	ND	ND
PJ	Pneumocystis jirovecii, Strain W303-Pji	1.30E+07	CFU/mL	ND	ND
PA	Pseudomonas aeruginosa, Strain N/A	3.45E+08	CFU/mL	ND	ND
SA	Staphylococcus aureus Protein A producer, e.g., Cowan strain, NCTC 8530 [S11] Cowan's serotype 1	2.60E+08	CFU/mL	ND	ND
SE	Staphylococcus epidermidis (PCI 1200)	9.00E+07	CFU/mL	ND	ND
SS	Streptococcus salivarius, Strain C699 [S30D]	1.01E+06	CFU/mL	ND	ND
SPN	Streptococcus pneumoniae, Strain Z022	1.81E+07	CFU/mL	ND	ND
SPY	Streptococcus pyogenes, Strain MGAS 8232	7.50E+07	CFU/mL	ND	ND
ME	Measles, Strain Edmonston	8.48E+05	$TCID_{50}$/mL	ND	ND
MU	Mumps (Isolate 1)	8.48E+05	$TCID_{50}$/mL	ND	ND
HKU1[a]	Human coronavirus HKU1	1:20	-	-	ND

ND: Not Detected.
[a] *1:10 dilution of cultured stock HKU1 sample from Emory*

COMPETITIVE INTERFERENCE

Competitive interference of the test's analytes was tested with different combinations of low (3x LoD) and high concentrations of Flu A, Flu B and SARS-CoV-2 spiked together onto a swab and then tested with one lot of INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST device strains to determine if the assay can detect target analytes across a variety of analyte concentration combinations. All testing conditions have been tested in 3 replicates. The study used inactivated SARS-CoV-2 but live influenza A and B virus. The INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST showed no competitive interference from the analytes co-existed in the specimens at the concentrations indicated in Table 7.

Table 7: Competitive Interference Results

Virus	Analyte Concentration Added to Sample* (# of positive replicates / # of total replicates)		
	Flu A	Flu B	SARS-CoV-2
Analyte Concentration Added	**667X LoD**	**3X LoD**	-
Results	3/3	3/3	0/3
Analyte Concentration Added	**667X LoD**	-	**3X LoD**
Results	3/3	0/3	3/3
Analyte Concentration Added	**3X LoD**	**2667X LoD**	-
Results	3/3	3/3	0/3
Analyte Concentration Added	-	**2667X LoD**	**3X LoD**
Results	0/3	3/3	3/3
Analyte Concentration Added	**3X LoD**	-	**2667X LoD**
Results	3/3	0/3	3/3
Analyte Concentration Added	-	**3X LoD**	**2667X LoD**
Results	0/3	3/3	3/3

* SARS-CoV-2 strain – 1X LoD - 3.95E+02 $TCID_{50}$/mL
Flu A – H3N2:A/Darwin/6/2021 – 1X LoD – 2.09E+02 $TCID_{50}$/mL
Flu B – Yamagata: B/Florida/4/2006 – 1X LoD - 1.46E+01 $TCID_{50}$/mL

INTERFERING SUBSTANCES

The INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST was evaluated for performance in the presence and absence of potentially interfering substances that might be present in a respiratory specimen at concentrations listed in the below table. Negative specimens were evaluated in triplicates to confirm that the potentially interfering substances would not cause false positive results with the test. Substances that did not cause a false-positive result was further evaluated for interference by testing substance spiked negative clinical matrix mixed 1:1 with co-spiked (with SARS-CoV-2/FluA/Flu B virus) negative clinical matrix to achieve a final virus concentration of 3X single analyte LoD and tested in triplicate. If interference was observed at the level tested, an additional titration study would have been performed to determine the highest interfering substance level the INDICAID™ multiplex test can tolerate.

With the exception of Flu Mist Quadrivalent live influenza vaccine, none of the substances caused a false-positive test result in unspiked samples. While the presence of Flu Mist Quadrivalent live influenza vaccine at 15% v/v concentration did not interfere with the detection of true positive results of the 3x LoD co-spiked samples, the vaccine also resulted in positive results for Flu A and Flu B (as expected based on the composition of the vaccine). When diluted down to 0.15% v/v, the results of the unspiked samples were negative. Hand sanitizer cream lotion and hand sanitizer 80% ethanol fast drying at 15% v/v showed false negative results for Flu B, but all analytes were detected at 7.5% v/v of hand sanitizer cream lotion and hand sanitizer 80% ethanol fast drying. Hand soap liquid gel at 0.1% w/v and higher concentrations showed false negative results for Flu B, but all analytes were detected at 0.05% w/v of hand soap liquid gel..

The interfering substances test results are shown in Table 8.

Table 8: Potential Interfering Substances

Interfering Substance	Concentration	Cross-reactivity (no analyte) (# pos/ # total)			Interference 3x co-spiked analyte LoD) (# pos/ # total)		
		SARS-CoV-2	Flu A	Flu B	SARS-CoV-2	Flu A	Flu B
Human Whole Blood (EDTA tube)	4% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Leukocytes	1.67 x 10^{A6} cells/mL	0/3	0/3	0/3	3/3	3/3	3/3
Throat Lozenges (Menthol/ Benzocaine)	3 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Mucin, bovine submaxillary gland	2.5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Zinc (Therazinc throat Spray)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Naso GEL (NeilMed)	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Drops (Phenylephrine)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Spray (Oxymetazoline)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Spray (Cromolyn)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Corticosteroid (Dexamethasone)	1 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Corticosteroid (Fluticasone Propionate)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal gel (Galphimia glauca, Histanium hydrocloricum, Luffa operculate, Sulfur)	1.25%	0/3	0/3	0/3	3/3	3/3	3/3
Homeopathic allergy relief (Histaminum hydrochloricum)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Zicam nasal spray (Galphimia glauca, Luffa operculata)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal spray (Alkalol)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Sore Throat Phenol Spray	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Tobramycin	4 µg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Mupirocin	10 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Anti-viral drug (Remdesvir)	10 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Tamiflu (Oseltamivir)	5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
FluMist (Quadrivalent/Live)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
	0.15% v/v	0/3	0/3	0/3	NA	NA	NA
Zanamivir	282 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Biotin	3500 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Body & Hand Lotion	0.5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Body Lotion, with 1.2% dimethicone	0.5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Lotion	5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer cream lotion	15% v/v	0/3	0/3	0/3	3/3	3/3	0/3
	7.5% v/v	NA	NA	NA	3/3	3/3	3/3
Hand Sanitizer, 80% ethanol	15% v/v	0/3	0/3	0/3	3/3	3/3	0/3
	7.5% v/v	NA	NA	NA	3/3	3/3	3/3
Hand soap liquid gel	10% w/v	0/3	0/3	0/3	3/3	3/3	0/3
	0.1% w/v	NA	NA	NA	3/3	3/3	0/3
	0.05% w/v	NA	NA	NA	3/3	3/3	0/3

PRECISION

The Precision study for the INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST was evaluated in two different in-house studies using the same 3 lots of test kits and the same operators.

Study 1 was conducted by 2 trained operators. Three sample levels (2X LoD co-spiked, 5X LoD co-spiked and Negative Pooled Nasal Wash) were tested on each day, one replicate per run, per operator, and per lot of devices. Two (2) runs (morning and afternoon) were conducted each day per operator, per lot, per day. This exact testing scheme was carried out over 10 days (same 3 sample levels tested, on the same 3 lots, by the same 2 operators, in 2 runs per day). This resulted in 120 total tests per sample level. All samples were randomized and blinded for each day. For all three lots and operators, the results for this study shown in the table below were identical and concordant with the expected results.

Study 2 was specifically conducted to further evaluate potential differences between lots. The study used negative samples (without virus analytes) and very low positive samples at 0.75x LoD, commonly referred to as high negative sample. Samples were prepared near the C95 concentration for all three analytes and were randomized and blinded. This supplemental precision testing was carried out over 3 days only, but otherwise followed the same study design as above. This resulted in 72 total tests per analyte and sample level (24 replicates for each analyte with each lot). Data from this testing are integrated into Table 9 below.

Table 9: Summary of Precision Results

Sample	Analyte	Lot 1		Lot 2		Lot 3		Total Percent Lot-to-Lot Agreement	95% CI
		Count*	% Agreement	Count*	% Agreement	Count*	% Agreement		
Negative	SARS-CoV-2	0/64	100%	0/64	100%	0/64	100%	100%	98.0-100%
	Flu A	0/64	100%	0/64	100%	0/64	100%	100%	98.0-100%
	Flu B	0/64	100%	0/64	100%	0/64	100%	100%	98.0-100%
0.75 x LoD	SARS-CoV-2	20/24	83.3%	22/24	91.7%	17/24	70.8%	81.9%	71.5-89.1%
	Flu A	15/24	62.5%	15/24	62.5%	15/24	62.5%	62.5%	50.9-72.8%
	Flu B	18/24	75.0%	17/24	70.8%	14/24	58.3%	68.0%	56.6-76.7%
2 x LoD	SARS-CoV-2	40/40	100%	40/40	100%	40/40	100%	100%	93.9-100%
	Flu A	40/40	100%	40/40	100%	40/40	100%	100%	93.9-100%
	Flu B	40/40	100%	40/40	100%	40/40	100%	100%	93.9-100%
5 x LoD	SARS-CoV-2	40/40	100%	40/40	100%	40/40	100%	100%	93.9-100%
	Flu A	40/40	100%	40/40	100%	40/40	100%	100%	93.9-100%
	Flu B	40/40	100%	40/40	100%	40/40	100%	100%	93.9-100%

REFERENCES

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2. Ignacio Torres, Sandrine Poujois, Eliseo Albert, Gabriela Álverez, Javier Colomina and David Navarro. Point-of-care evaluation of a rapid antigen test for diagnosis of SARS- CoV-2 infection in symptomatic and asymptomatic individuals February 11, 2021
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HEALTHCARE PROVIDER APPENDIX

For use in a professional healthcare environment, quality control testing should be performed.
For *in vitro* diagnostic use.

EXTERNAL CONTROLS - INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST

The External Controls - INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST are for prescription use only (Rx) and are sold separately from the INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST. The controls are designed to verify proper test procedure and performance of the INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST.

REF	External Controls Kit Contents		
IND-HG-CVFCTL-1PPK	1 Positive swab	1 Negative swab	1 External Controls Instructions for Use
IND-HG-CVFCTL-20PPK	10 Positive swabs	10 Negative swabs	
IND-HG-CVFCTL-40PPK	20 Positive swabs	20 Negative swabs	

Quality control testing is recommended in the following situations:
- Once for each untrained operator (proficiency testing).
- Once for each new lot of kits.
- Once for each shipment of kits – provided each different lot received in the shipment is tested separately.
- As deemed necessary by your internal quality control procedures, and in accordance with Local, State, and Federal regulations or accreditation requirements.

External Control Positive Control Swabs and Negative Control Swabs should be tested and interpreted according to the Instructions For Use of the INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST Kit.

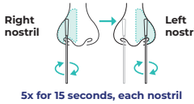
The Positive Control Swabs are composed of a SARS-CoV-2 recombinant antigen, Influenza A recombinant antigen and Influenza B recombinant antigen extract dried onto a swab, with a red shaft, containing 0.05% ProClin™ 300 as a preservative.

Do not proceed with testing patient samples if either the Positive Control or Negative Control fails to produce the expected results. If either of the quality control test results fails, repeat the test or contact 877-625-1603 or care@indicaidusa.com. For repeat testing of either the Positive or Negative Controls, obtaining additional external control swabs may be necessary.

Additional external controls can be ordered as External Controls - INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST (see reference codes above in External Controls Kit Contents table) and be purchased separately as needed.

SPECIMEN COLLECTION AND HANDLING (HEALTH CARE PROVIDERS)

Nasal Swab Sample:



Use the nasal swab supplied in the kit.
Prior to collecting the nasal swab, the patient should be instructed to blow their nose.

To collect a nasal swab sample, insert the entire absorbent tip of the swab, no more than 3/4 inch (1.5cm) into the nostril and firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least five times (5x) for at least 15 seconds. Remove the swab and repeat in the other nostril using the same swab. Be sure to collect any nasal drainage that may be present on the swab.

SAMPLE TRANSPORT AND STORAGE (HEALTH CARE PROVIDERS ONLY)

Samples should be tested as soon as possible after collection. Based on data generated with the INDICAID™ COVID-19 / INFLUENZA A&B ANTIGEN TEST, nasal swabs are stable for up to 1 hour after sample collection.

SYMBOL INDEX

Consult instructions for use
For *in vitro* diagnostic use only
Store at 36-86°F / 2-30°C
Unique device identifier
Tests per kit
Use-by date (Expiration date)
Batch code
Keep dry
Keep away from sunlight
Do not re-use
Catalogue number
Do not use if package is damaged

Distributed by
PHASE Diagnostics Inc.
10527 Garden Grove Blvd., Garden Grove, CA 92843
Toll-Free: +1 (877) 625-1603 (Monday-Friday 9 a.m. to 5 p.m. CST)
Customer Service: care@indicaidusa.com
Website: www.phasescientificamericas.com

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