

INSTRUCTIONS FOR USE

REF 783025 IVD

For Professional Use

For in vitro diagnostic use.

INTENDED USE

The statID Pro COVID-19/Flu A&B 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 US, 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 statID Pro COVID-19/Flu A&B 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

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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 statID Pro COVID-19/Flu A&B 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 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.**

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.

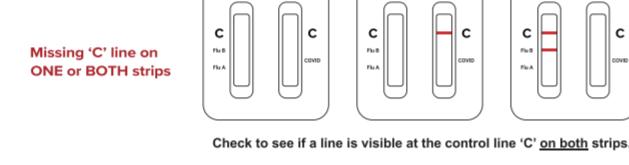
Additional Information: Reading Results

Scan the QR code for more information on reading results.

Webpage: <https://www.meridianbioscience.com>



Invalid test result



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



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

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 'COVID', 'Flu A' or 'Flu 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.

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Table 1.3: statID Pro COVID-19/Flu A&B – Results for FLU A

RT-PCR Comparator

Flu A Test Result

Positives

Negatives

Total

161 (90.4%)

0 (0.0%)

166

53

50

4

1068

1072

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: statID Pro COVID-19/Flu A&B – Results for FLU B

RT-PCR Comparator

Flu B Test Results

Positives

Negatives

Total

38

1

39

4

1079

1083

1080

1122

Positive Percent Agreement = (38/42) = 90.5% (95% CI: 77.3% - 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)

Age: Median [Min, Max]

Age Group

≥2 - <14 years of age

≥14 - <24 years of age

≥24 - <65 years of age

≥65 years of age

Total

Sex at Birth

Female

Male

Ethnicity

Hispanic/Latino

Not Hispanic/Latino

Race

American Indian or Alaskan Native

Asian

Black or African American

Native Hawaiian/Pacific Islander

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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/29221106/2002	2.00E+05	TCID ₅₀ /mL	ND	ND
P2	Parainfluenza virus 2, Strain Gree	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 2048	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	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-Pj	1.30E+07	CFU/mL	ND	ND

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*ND: Not Detected.

*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 statID Pro COVID-19/Flu A&B 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 statID Pro COVID-19/Flu A&B showed no competitive interference from the analytes co-existed in the specimens at the concentrations indicated in Table 7.

Table 7: Competitive Interference Results

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

* SARS-CoV-2 strain – 1X LoD + 3.95E+02 TCID₅₀/mL
 Flu A – H3N2A/Darwin/6/2021 – 1X LoD – 2.09E+02 TCID₅₀/mL
 Flu B – Yamagata/B/Florida/4/2006 – 1X LoD – 1.46E+01 TCID₅₀/mL

REFERENCES

- Julien Favresse, Constant Gillot, Maxime Olivera, Julie Cadrobbi, Marc Elsen, Christine Eucher, Kim Laffineur, Catherine Rosseels, Sandrine Van Eeckhoudt, Jean-Baptiste Nicolas, Laure Moiremont, Jean-Michel Dogné and Jonathan Douxflis. Head-to-Head Comparison of Rapid and Automated Antigen Detection Tests for the Diagnosis of SARS-CoV-2 Infection. *J. Clin. Med.* 2021, 10, 265.
- Ignacio Torres, Sandrine Poujols, Eliseo Albert, Gabriela Alvarez, 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.
- Moghadami M. A Narrative Review of Influenza: A Seasonal and Pandemic Disease. *Iran J Med Sci.* 2017

SYMBOL INDEX

	Do not reuse		See Instruction for Use		Expiration Date
	Tests per Kit		Store Between 2-30°C (36-86°F)		Keep Dry
	Batch Number		Catalog#		Keep Away from Sunlight
	Unique Device Identifier		For in vitro Diagnostic use only		Do not use if package is damaged

Manufactured For		Meridian Bioscience, Inc. 3471 River Hills Drive Cincinnati, OHIO - 45244 USA www.meridianbioscience.com	
Contacts: Main Telephone (+1)513.271.3700 Toll-Free Customer Service/Orders 800.543.1980 Toll-Free Technical Support Center 800.343.3858 Monday - Friday 8AM and 6PM, EST Information Fax: 513.272.5432 Ordering Fax: 513.271.0124 E-mail: info@meridianbioscience.com			

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INTERFERING SUBSTANCES

The statID Pro COVID-19/Flu A&B 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/Flu A/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 Healign 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. Cream lotion-based hand sanitizer (15% v/v), hand sanitizer with 80% ethanol (15%v/v) and liquid gel hand soap (>0.1% w/v) interfered with the detection of Flu B resulting in false negative results.

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	
		0.5% w/v	0/3	0/3	0/3	0.5% w/v	0/3
Body Lotion, with 1.2% dimethicone	0.5% w/v	0/3	0/3	0/3	0/3	0/3	0/3
Hand Lotion	5% w/v	0/3	0/3	0/3	0/3	0/3	0/3
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% w/v	0/3	0/3	0/3	0/3	0/3	0/3
Hand Sanitizer cream lotion	15% v/v	0/3	0/3	0/3	0/3	0/3	0/3
Hand Sanitizer, 80% ethanol	15% v/v	0/3	0/3	0/3	0/3	0/3	0/3
Hand soap liquid gel	0.1% w/v	0/3	0/3	0/3	0/3	0/3	0/3
	0.05% w/v	0/3	0/3	0/3	0/3	0/3	0/3

PRECISION

The Precision study for the statID Pro COVID-19/Flu A&B 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 negative control samples. Samples were prepared 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	Analyt e	Lot 1		Lot 2		Lot 3		Total	Percent Lot-to-Lot Agreement	95% CI
Count*	% Agreement	Count*	% Agreement	Count*	% Agreement					
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