sōna *Aspergillus* Galactomannan LFA

REF #: AF2003

For the detection of *Aspergillus* Galactomannan in serum and bronchoalveolar lavage (BAL) samples

This product has not been approved for use in the US

Rx ONLY

IVD

INTENDED USE

The sōna *Aspergillus* Galactomannan Lateral Flow Assay (AGM LFA) is a non-automated, immunochromatographic test system for the qualitative detection of *Aspergillus* galactomannan in serum and bronchoalveolar lavage (BAL) samples from patients with suspected aspergillosis infections.

The sōna AGM LFA is a test which, when used in conjunction with other diagnostic procedures such as microbiological culture, histological examination of biopsy samples, and radiographic evidence, can be used as an aid in the diagnosis of aspergillosis. The test is intended to be used with the IMMY sōna LFA Cube Reader (REF #: LFARDR).

This test is intended to be performed by trained, laboratory professional users.

SUMMARY AND EXPLANATION OF THE TEST

Aspergillus spp. are filamentous fungi found worldwide and can live both indoors and outdoors. Invasive aspergillosis (IA) is the most severe form of aspergillosis. Aspergillosis is caused by breathing in fungal spores. IA develops when an aspergillosis infection spreads rapidly from the lungs to the brain, heart, kidneys, or skin. IA is one of the most significant threats to recipients of hematopoietic stem cell and solid organ transplants. Individuals with suppressed immune systems due to illnesses such as HIV/AIDS infection are also at high risk[1-3]. There has been a significant rise in the incidence of IA in the last two decades due to the widespread use of treatments for some of these conditions, such as chemotherapy and immunosuppressive agents[4,5]. It has been reported that *Aspergillus* infections account for up to 41% of infections within all transplant patients and have a staggering mortality rate of up to 92% within this population[2]. Early detection and treatment of infection are key to reducing the mortality associated with this disease[6,7].

BIOLOGICAL PRINCIPLES

The sōna AGM LFA is a non-automated, sandwich immunochromatographic test system which detects *Aspergillus* galactomannan in serum and BAL specimens. Serum and BAL specimens require heat pretreatment prior to testing. After pretreatment, specimens are pipetted into a clean receptacle. *Aspergillus* GM LFA Running Buffer (REF #: AFLFRB) is added followed by an *Aspergillus* GM Lateral Flow Test Strip (REF #: LFAF50). The test is run for 30 minutes, and results should be read within 10 minutes of completing the test. The test is intended to be used with the IMMY sōna LFA Cube Reader (REF #: LFARDR). The sōna LFA Cube Reader was developed to minimize human interpretation errors, therefore the results cannot be visually interpreted by the operator.

The sōna AGM LFA is constructed by having *Aspergillus* galactomannan specific antibodies conjugated to colloidal gold that bind to any galactomannan that may be present in the specimen sample as it wicks up the test strip. If any binding occurs, the antibody-antigen complex will migrate up the strip by capillary flow until it is captured by the *Aspergillus* galactomannan specific antibodies in the test line. This results in the formation of a visible test line. Additionally, control antibodies conjugated to gold are present that wick along with the specimen and will be captured by the control antibodies present on the control line, regardless of positive or negative test results.

The IMMY sōna LFA Cube Reader (REF #: LFARDR) is a portable, battery powered, bench top analyzer used to read and interpret results of the sōna AGM LFA. The Cube Reader uses an LED at 525 nm to read results on the sōna AGM LFA. Index values ≥ 0.50 are considered positive and will display as POS. Index values < 0.50 are considered negative and will display as NEG. Invalid results will read as INV.

REAGENTS PROVIDED

Each kit contains sufficient reagents for 50 tests.

1	AFSPB1	**Sample Pretreatment Buffer** 4% EDTA solution; contains 0.2% ProClin	7 mL
2	AFLFRB	***Aspergillus* GM Running Buffer** LFA running buffer; contains 0.2% ProClin, 0.5% Tergitol, 0.125% SDS, and 2.5% Boric Acid	3 mL
3	LFAF50	***Aspergillus* GM Lateral Flow Test Strips** 50 LFA dipsticks packaged into a desiccant vial with an attached cap	50 Ea
+	AFPC01	***Aspergillus* GM Positive Control** 50 – 70 ng/mL *Aspergillus* galactomannan in a saline solution; contains 0.2% ProClin, < 0.2% Tergitol, and < 2% Boric Acid	3 mL

Refer to the AF2003 Safety Data Sheets for more information on hazards and warnings.

MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable gloves
- Protective glasses
- Pipette(s) capable of measuring and delivering 300, 100, 80, and 40 µL and associated disposable tips
- Glass beaker or appropriate container for boiling water
- Hot plate
- 1.5-2.0 mL microcentrifuge screw cap tubes able to support heating up to 100 °C boiling water bath (REF #: SCT050 is recommended for use)
- Vortex mixer
- Floating microcentrifuge rack for a beaker
- Centrifuge capable of reaching at least 10,000 x g
- Disposable flat-bottom micro-centrifuge tubes, test tubes, or a micro-titer plate
- Timer
- Biohazard waste receptacle

REAGENT STABILITY AND STORAGE

The entire sōna AGM LFA test kit should be stored at 2-30 °C until the expiration date printed on the product label. The quality of the product cannot be guaranteed after the expiration date.

Unused test strips should be stored in the desiccant vial with the attached cap firmly closed.

REAGENT PRECAUTIONS

1. At the time of each use, kit components should be visually inspected for obvious signs of microbial contamination, leakage, or significant physical damage to the test strip. Discard if these conditions are found.
2. IMMY cannot guarantee the performance of its products when used with materials purchased from other manufacturers. Do not interchange reagents from different kit lot numbers or other manufacturers.
3. The user assumes full responsibility for any modification to the procedures published herein.
4. Do not use kit or any kit reagents after the stated expiration date.
5. *Aspergillus* GM Running Buffer (REF #: AFLFRB) and *Aspergillus* GM Positive Control (REF #: AFPC01), are labeled:

Danger

H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H360	May damage fertility or the unborn child.
H401	Toxic to aquatic life.
H412	Harmful to aquatic life with long lasting effects.
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P264	Wash skin thoroughly after handling.
P270	Do not eat, drink, or smoke when using this product.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P312 + P338	IF SWALLOWED, call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
P305 + P351 + P338	IF IN EYES, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313	If exposed or concerned, get medical advice/attention.
P337 + P313	If eye irritation persists, get medical advice/attention.
P405	Store locked up.

P501	Dispose of contents/container in accordance with local regulations.

WARNINGS AND PRECAUTIONS FOR USERS

1. For In Vitro Diagnostic use only.
2. This assay should only be performed by trained, laboratory professional users.
3. Wear protective clothing, including lab coat, eye/face protection, and disposable gloves, and handle the kit reagents and patient samples with the requisite Good Laboratory Practices. Wash hands thoroughly after performing the test.
4. Avoid splashing samples or solutions.
5. Biological spills should be wiped thoroughly with an effective disinfectant. Disinfectants that can be used include (but are not limited to) a solution of 10% bleach, 70% ethanol, or 0.5% Wescodyne Plus™. Materials used to wipe up spills may require biohazardous waste disposal.
6. Use of this kit with samples other than human serum and BAL fluid is not recommended.
7. **FROZEN SERUM OR BAL SAMPLES STORED IN UNKNOWN CONDITIONS MAY GIVE FALSE POSITIVE RESULTS DUE TO CONTAMINATION WITH FUNGI AND/OR BACTERIA.**
8. Use clean, dust-free materials (tubes, tips, containers, etc.) to minimize the possibility of contamination with *Aspergillus* spores from the environment. Because galactomannan is heat-stable, sterilization of material used does not guarantee the absence of contaminating antigen. Pyrogen-free materials are optimal, but standard material can be used with adequate precautions.
9. Limit exposure of samples and kit components (sera, BAL fluid, Sample Pretreatment Buffer, Running Buffer, Test Strips) or open containers (plates, tubes, pipette tips) to the air.
10. Boiling water temperature should be confirmed by a separate thermometer to independently assess actual temperature.
11. Only pretreat the number of specimens that will fit in a balanced configuration in the centrifuge. Avoid delays in processing during the pretreatment, for optimal reactivity specimens should be centrifuged immediately.
12. If sample has inadequate volume for testing (80 µL) after pretreatment, repeat pretreatment steps with a fresh sample. Incomplete pretreatment may lead to erroneous results.
13. Dispose of all specimens and materials used to perform the test as though they contain an infectious agent. Laboratory chemical and biohazardous wastes must be handled and discarded in accordance with all local, regional, and national regulations.
14. The *Aspergillus* GM Lateral Flow Test Strips (REF #: LFAF50) may be biohazardous after running specimens. Handle and dispose of accordingly.
15. Safety Data Sheets are available upon request.
16. Results read after the 10-minute reading window are invalid.
17. Since the assay is qualitative, index values cannot be compared to other A*spergillus* galactomannan assays.
18. A very low-positive specimen could become negative after long-term storage at -20°C**.**
19. A negative specimen could become positive due to galactomannan contamination from multiple tube manipulations such as opening and closing and/or aliquoting samples.

SPECIMEN COLLECTION

Collect samples aseptically using established techniques by qualified personnel. When handling patient specimens, adequate measures should be taken to prevent exposure to potentially present etiologic agents. The use of specimens other than serum or BAL has not been established. For optimal results, sterile samples should be used. Process and test samples upon arrival. If a delay is encountered in specimen processing, storage for up to 2 weeks at <-20 °C is permissible. However, a very low-positive specimen could become negative after storage. Specimens in transit between labs should be maintained at 2-8 °C. Specimens should be brought to room temperature prior to testing.

SPECIMEN PREPARATION

PRETREATMENT OF SERUM AND BAL USING THE HOT PLATE METHOD

1. Fill a glass beaker (or appropriate container for boiling water) with water and place on a hot plate. Be sure the beaker (or appropriate container for boiling water) is large enough to hold the number of specimens you are pre-treating.
   NOTE: *There should be enough water in the beaker so that the specimen will not touch the bottom of the beaker during pre-treatment but not so full the user risks overflow of the boiling water.*
2. Bring water in the glass beaker (or appropriate container for boiling water) to a rolling boil, verify water has reached 100 °C.
   NOTE: *Use a calibrated thermometer to determine the temperature of water.*
   NOTE: *If you have too many specimens to boil at one time, ensure that the water is at 100 °C before placing additional specimens in the water.*
3. Place 300 µL of specimen into a screw cap, heat resistant microcentrifuge tube (REF #: SCT050).
4. Add 100 µL of Sample Pretreatment Buffer (REF #: AFSPB1, 1) to the same tube.
5. Screw the lid on tightly and vortex the sample.
6. Place tube in a floating microcentrifuge rack and place directly in the boiling water for 8 minutes.
7. Carefully remove the microcentrifuge tube and immediately centrifuge specimen for 5 minutes at 10,000-14,000 x g at room temperature.
   NOTE: *Laboratory tongs or heat-resistant gloves can be used to remove the floating microcentrifuge rack from the boiling water safely.*
8. After pretreatment, treated specimen(supernatant with pellet) can be stored at 2-8°C for up to 7 hours prior to testing. If specimen analysis requires retesting, a separate aliquot of the specimen must be pretreated for retesting.

PROCEDURE

1. Add 120 µL of *Aspergillus* GM Positive Control (REF #: AFPC01, +) into a clean tube or microwell and add 120 µL of *Aspergillus* GM LFA Running Buffer (REF #: AFLFRB, 2) [Negative Control] into another clean tube or microwell. It is recommended that controls be tested 1 time per run.
   NOTE**:** *Do not boil positive and/or negative controls.*
2. Pipette 40 µL of *Aspergillus* GM LFA Running Buffer (REF #: AFLFRB, 2) into a separate clean tube or microwell.
3. Pipette 80 µL of supernatant from the pretreated serum/BAL to each tube or microwell from step 2. Mix well.
4. Place one *Aspergillus* GM Lateral Flow Test Strip (REF #: LFAF50, 3) in each tube or microwell containing a sample or control.
5. Allow the test to run for 30 minutes at room temperature.
6. Read and record results within 10 minutes of completing the test with the sōna LFA Cube Reader (see "READING THE TEST PROCEDURE" below).

QUALITY CONTROL PROCEDURE

Positive and negative controls verify the kit is working as intended and ensure no product failure or no contamination has occurred. A positive control (*Aspergillus* GM Positive Control +) can be evaluated by adding 120 µL to a tube. A negative control (*Aspergillus* GM LFA Running Buffer 2) can be evaluated by adding 120 µL to a separate tube. Insert a test strip (*Aspergillus* GM Lateral Flow Test Strip 3) into the tubes and read after 30 minutes.

The positive control should produce an index value of ≥ 0.50 and the negative control should produce an index value of < 0.50. Invalid results will read as INV. If controls produce results other than this, contact IMMY Customer Support.

Recommended Quality Control frequency is 1 time per run. Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.

READING THE TEST PROCEDURE

Results read after the 10-minute reading window are invalid.

Results ≥ 0.50 are considered positive and will display as POS.
Results < 0.50 are considered negative and will display as NEG.
Invalid results will read as INV.

1. Run the sōna AGM LFA according to the above procedure.
2. Press the button on the top of the sōna LFA Cube Reader (REF #: LFARDR) twice until the display reads "RFID".
3. Scan the lot-specific RFID tag located on the bottom of the *Aspergillus* GM Lateral Flow Test Strip Tube (REF #: LFAF50) by placing it over the display on the cube reader. An audible signal will confirm scanning of RFID tag and "TEST" will appear on the display.
4. Visually inspect the test strip and verify there are no interfering artifacts such as large pieces of dirt or lint in the reading frame between the test and control line.
5. When the test strip is ready to be analyzed, properly insert the *Aspergillus* GM Lateral Flow Test Strip (REF #: LFAF50, 3) into the cube reader so the sample arrows of the strip are facing the same direction as the sample arrows on the adapter itself. Results should be read within 10 minutes of completion of the test's 30-minute incubation.
6. While "TEST" is still displayed on the cube reader, press the button once to run. "RUN" will appear on the display while the strip is being read.
7. Results will display as a numerical value for the test line, followed by "POS" or "NEG", followed by a numerical value for the control line. Record the displayed test results.
8. To test another strip of the same lot, remove the strip and press the button on the cube reader three times until "TEST" appears on the display, repeat steps 4-6.

RESULTS

Result	Display	Index Value
Positive	POS	≥ 0.50
Negative	NEG	< 0.50
Invalid	INV	N/A

The control line must be present for a valid test. If the control line is not present or is too weak, the cube reader will read as INV and the test is considered invalid. The lack of a control line or a weak control line can be indicative of an incomplete specimen pretreatment.

Results ≥ 0.50 are considered positive and will display as POS. Results < 0.50 are considered negative and will display as NEG.

Negative results do not rule out the diagnosis of disease. The specimen may be drawn before detectable antigen is present.

CLEANING THE CUBE READER

1. Remove the sōna LFA Cube Reader from the adapter by gently applying downwards pressure on the adapter tab and lifting the cube reader out of adapter.
2. Clean the LFA Cube Reader Adapter with a disinfectant. See Precautions.
3. Clean the cube reader lens with a lint-free cloth.
4. Place the cube reader back in the adapter by matching the angled corner of the cube reader with the angled corner of the cube reader adapter. Gently apply downwards pressure to the adapter tab and insert the cube reader, backside first. Press the cube reader firmly into place and release adapter tab. The cube reader should be firmly seated into the adapter before use.

LIMITATIONS OF THE PROCEDURE

1. The assay performance characteristics have not been established for matrices other than serum and BAL fluid.
2. Testing hemolyzed serum samples could lead to false negatives and false positives due to the high background color on the strip.
3. Cross-reactivity of BAL fluid samples with *Mycoplasma pneumoniae* or anesthetic drugs/lubricants used to numb the neck/throat area for the aspiration process has not been evaluated.
4. Cross-reactivity was observed with some histoplasmosis, candidiasis, and coccidioidomycosis specimens.
5. Positive tests should be confirmed in areas or patient groups where organisms that are known to cross-react with *Aspergillus spp.* are endemic or at risk. Histoplasmosis should be considered in endemic areas, including parts of the United States.
6. The sōna AGM LFA may exhibit reduced detection of galactomannan in patients with chronic granulomatous disease (CGD) and Job's Syndrome[8, 9].
7. The sōna AGM LFA is not intended for monitoring therapy.
8. The use of mold-active anti-fungal therapy in some patients with IA may result in reduced sensitivity with the sōna AGM LFA.
9. The sōna AGM LFA has not been evaluated in neonatal patients.
10. Testing should not be performed as a screening procedure for the general population. The predictive value of a positive or negative serologic result depends on the pretest likelihood of aspergillosis disease being present. Testing should only be done when clinical evidence suggests the diagnosis of aspergillosis disease.
11. Sufficient contact between the screw cap tube and the boiling water must be maintained throughout the boil during the pretreatment step. Contact IMMY Technical Support for assistance and for further information.
12. Partial test lines that only develop on one half of the test strip should be interpreted as invalid and repeat testing should be performed to confirm positive or negative results.

EXPECTED VALUES

The frequency of aspergillosis is dependent on several factors including patient population, type of institution, and epidemiology. The expected prevalence of invasive aspergillosis varies from 5 – 20%[10].

SPECIFIC PERFORMANCE CHARACTERISTICS

CLINICAL SENSITIVITY AND SPECIFICITY

The sōna AGM LFA was compared to EORTC/MSG clinical criteria to show sensitivity (proven and probable) and specificity (negative). These studies contained prospective specimens that were submitted for Asp Ag EIA testing. Summary tables of the data collected are included below.

	Serum Sens.	Serum Spec.	BAL Fluid Sens.	BAL Fluid Spec.
Point Estimate	100%	94%*	100%	46%**
95% CI	29-100%	87-98%	3-100%	28-66%

*An EIA for detection of *Aspergillus* antigen had a specificity of 93% using the same dataset

** An EIA for detection of *Aspergillus* antigen had a specificity of 39% using the same dataset

ANALYTICAL SENSITIVITY

The sōna AGM LFA was evaluated for analytical sensitivity by spiking serum at 7 different concentrations and by spiking BAL at 5 different concentrations with *Aspergillus* galactomannan antigen. Each of the concentrations across serum and BAL were tested for a total of 20 replicates. The limit of detection (LoD) was determined by finding the intercept where 95% of the results were positive and is approximately 0.75 ng/mL for serum and 0.70 ng/mL for BAL.

CROSS-REACTIVITY

The sōna AGM LFA was evaluated for cross-reactivity against a panel of patients' sera across a variety of different pathologies. The results of this testing are shown in the tables below.

NOTE: Galactomannan EIA results are unknown. Specimens may be positive by the EIA.

Pathology	# of Samples	% Positive
ANA-Positive	1	0% (0/1)
Syphilis	3	0% (0/3)
Rubella	2	0% (0/2)
Mycoplasma	2	0% (0/2)
Toxoplasmosis	3	0% (0/3)
CMV Infection	3	0% (0/3)
Rheumatoid factor	3	0% (0/3)
Hepatitis C Virus	2	0% (0/2)
Cancer	5	20% (1/5)
Solid Organ Transplant	5	0% (0/5)

Additionally, cross-reactivity was assessed by testing infections of other fungal pathogens using the sōna AGM LFA. Cross-reactivity was observed with some histoplasmosis, candidiasis, and coccidioidomycosis specimens.

Pathology	# of Samples	% Positive
Blastomycosis	4	0% (0/4)
Candidiasis	5	20% (1/5)
Coccidioides Serology	5	20% (1/5)
Histoplasmosis	6	33% (2/6)
Cryptococcosis	6	0% (0/6)
Mucormycosis	1	0% (0/1)

Characterized specimens of the following infections were tested and exhibited no cross-reactivity: blastomycosis and cryptococcosis.

INTERFERENCE

The sōna AGM LFA was evaluated for interference by testing icteric, hemolyzed, and lipemic patients' sera both unspiked and spiked with *Aspergillus* galactomannan antigen. The unspiked sera all tested negative while the spiked sera all tested positive; thus, interference was not observed. Hemolyzed patients' sera produced high background reactivity of the lateral flow test strip which could lead to false negative and false positive results.

REPRODUCIBILITY AND PRECISION

The sōna AGM LFA was evaluated for reproducibility and precision by spiking serum and artificial BAL (aBAL) with *Aspergillus* galactomannan antigen to produce 5 panels consisting of negative samples, low-positive samples, and moderate-positive samples. Four operators, from two sites, blinded to sample identity, tested each of the five panels each day over the course of 5 days. The results of this study are shown in the tables below.

	% Pos.	Average	% CV
Negative Serum	1%	0.12*	N/A**
Low Pos. Serum	100%	1.18	27%
Mod. Pos. Serum	100%	2.77	20%
Negative BAL	0%	0.07*	N/A**
Low Pos. BAL	99%	1.09	29%
Mod. Pos. BAL	100%	2.49	19%

* The average t-index of the negative serum and negative BAL was calculated based on 53 and 17 results (respectively) only, as there were 37 and 73 <0.000 results for serum and BAL, respectively.

** % CV were not calculated for negatives because 37 serum samples and 73 BAL samples resulted in a result of <0.000.

HIGH DOSE HOOK EFFECT (PROZONING)

The sōna AGM LFA was evaluated for high dose hook effect by spiking serum and artificial BAL (aBAL) with *Aspergillus* galactomannan antigen to produce 5 high concentration samples. Each concentration was serial diluted and results were read using the sōna LFA Cube Reader. Although rare, extremely high concentrations (> 0.225 mg/mL) of *Aspergillus* galactomannan antigen can result in a reduction in test and control line index values.

MEASURING RANGE

The sōna AGM LFA measuring range of the assay falls between the LoD and the High Dose Hook Effect. For serum, the measuring range is 0.75 ng/mL to 225 mg/mL; for BAL, the measuring range is 0.70 ng/mL to 225 mg/mL.

REFERENCE PROCEDURES AND MATERIALS

There are no available reference measurement procedures or materials for the user.

BIBLIOGRAPHY

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INTERNATIONAL SYMBOL USAGE

	Storage 2-30 °C	LOT	Lot Number
	Manufactured by	REF	Reference Number
	Expiration Date	IVD	In Vitro Diagnostic
	Protect from Humidity		Sufficient for "#" Tests
	Consult Instructions for Use	℞ ONLY	Prescription Use Only
	Single Use Only		

Rev. Date 2025-08-13
Rev. 0
For a list of IFU changes, email info@immy.com
To locate country specific IFUs, visit IMMY.com/resources

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