



LIMING BIO

# FungusClear™ Fungal Fluorescence Staining Solution

|                   |             |  |
|-------------------|-------------|--|
| REF               | 500180      | Specimen: scraping, nail and hair; sputum, BAL, bronchial wash, and tissue biopsies. |
| Language: English | Version: 01 |  |
| Effective Date:   | 2017-07     |  |

For professional *In vitro* diagnostic use only.

## INTENDED USE

The FungusClear™ Fungal fluorescence staining solution is used for the rapid identification of various fungal infections in human fresh or frozen clinical specimens, paraffin or glycol methacrylate embedded tissues. Typical specimens include scraping, nail and hair of dermatophytosis such as tinea cruris, tinea manus and pedis, tinea unguium, tinea capitis, tinea versicolor. Also include sputum, bronchoalveolar lavage (BAL), bronchial wash, and tissue biopsies from invasive fungal infection patients.

## INTRODUCTION

Fungi are eukaryotic organisms. Beta-linked polysaccharides are found in fungi cell walls of various organisms such as chitin and cellulose. Various fungal and yeast types will stain fluorescently including *Microsporum* sp., *Epidermophyton* sp., *Trichophyton* sp., *Candida* sp., *Histoplasma* sp. and *Aspergillus* sp. among others. The kit will also stain *Pneumocystis carinii* cysts, parasites such as *Plasmodium* sp., and regions of fungal hyphae undergoing differentiation. Keratin, collagen, and elastin fibers are also stained and may provide structural guidelines for diagnosis.

## PRINCIPLE

Calcofluor White Stain is a non-specific fluorochrome that binds with cellulose and chitin contained in the cell walls of fungi and other organisms. Evans blue present in the stain act as a counterstain and diminishes background fluorescence of tissues and cells when using blue light excitation. 10% potassium hydroxide are included in the solution for better visualization of fungal elements.

A range of 320 to 340 nm can be taken for emission wavelength and the excitation occurs around 355nm.

Fungal or parasitic organisms appear fluorescent bright green to blue, while other material is reddish-orange fluorescent. Non-specific reactions may occur when tissues samples are used. May a yellowish-green background fluorescence is observed with such specimens but fungal and parasitic structures appear with much more intense. As well as amebic cysts are fluorescent but trophozoites will not stain or fluoresce.

## KIT COMPONENTS

| Specification                  | 20 tests/<br>box       | 100tests/<br>box       | 200tests/<br>box       | 300tests/<br>box       | 400tests/<br>box       | 500<br>tests/box       |
|--------------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| Fluorescence staining solution | 1 bottle (1mL/ bottle) | 1 bottle (5mL/ bottle) | 2 bottle (5mL/ bottle) | 3 bottle (5mL/ bottle) | 4 bottle (5mL/ bottle) | 5 bottle (5mL/ bottle) |
| Package insert                 | 1                      | 1                      | 1                      | 1                      | 1                      | 1                      |
| Box                            | 1                      | 1                      | 1                      | 1                      | 1                      | 1                      |

Fluorescence staining solution includes calcofluor white stain, Evans blue, KOH, purified water.

## MATERIALS REQUIRED BUT NOT PROVIDED

|                         |                          |
|-------------------------|--------------------------|
| Fluorescence microscope | For examine the results. |
|-------------------------|--------------------------|

## PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the label.
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.

- Do not eat, drink or smoke in any area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The solution contains potassium hydroxide which is classified as an irritant. Exercise normal care in handling.
- Used testing materials should be discarded according to local regulations.

## STORAGE AND STABILITY

- The kit should be stored at 2-30 °C until the expiry date printed on the label and protected from light.
- The valid date is 2 years.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

## SPECIMEN COLLECTION AND STORAGE

- Specimens of skin, nail and hair: sterilize diseased region with 75% alcohol, and scrape skin or nail with a dull knife. Pull out a few infected hairs and put on the slide.
- Tissue liquid or pathological slide should be prepared with fixation, dehydration and dewax according to routine pathologic method prior to staining.

## PROCEDURE

Bring solution, specimens, buffer and/or controls to room temperature (15-30 °C) before use.

- Put the sample to be examined onto a clean glass slide.
- Add one drop of FungusClear™ Fungal fluorescence staining solution. The entire specimen should be covered or flooded.
- Place a coverslip over the specimen and let stand for 1 minute.
- Examine the slide under Fluorescence Microscope at x100 to x400 magnification.

## INTERPRETATION OF RESULTS

Fungal organisms appear fluorescent bright green to blue when specimens are stained, while bacterial organisms appear non-fluorescent color or weak fluorescence.

## QUALITY CONTROL

| Test Organisms (ATCC)           | Result                  |
|---------------------------------|-------------------------|
| <i>Candida albicans</i> (10231) | Fluorescence            |
| <i>Escherichia coli</i> (25922) | No or weak fluorescence |












## LIMITATIONS OF THE TEST

- The FungusClear™ Fungal fluorescence staining solution is intended for use as a non-specific fluorescent stain for various fungal types and elements. The kit cannot be used to identify specific organisms on the basis of fluorescence alone. Morphological staining features must be used in conjunction with other laboratory data to identify a particular organism.
- Cotton fibers will fluoresce strongly and must therefore be differentiated from fungal hyphae.
- Staining results may be diminished because of fluorescence quenching. It is recommended to redye the specimens with the solution in the same operation procedure as the first staining.
- It is recommended to select fluorescence microscope or install fluorescent illuminator on general microscope for the best observation effects. Waveband of excitation light in range of 320 to 340 nm should be selected. The fluorescence intensity may be diminished or disappear if microscope or fluorescent illuminator with other waveband of excitation light is selected, which may affect observation results. For more questions about microscope please consult the manufacturer.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

## LITERATURE REFERENCES

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## GLOSSARY OF SYMBOLS

|  |   |   |   |
|--|---|---|---|
|  | Catalog number  |  | Temperature limitation                              |
|  | Consult instructions for use                                  |  | Batch code  |
|  | In vitro diagnostic medical device                            |  | Use by  |
|  | Manufacturer  |  | Contains sufficient for <n> tests                   |
|  | Do not reuse  |  | Authorized representative in the European Community |
|  | CE marked according to IVD Medical Devices Directive 98/79/EC |   |   |


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