PACT MED

Photodynamic Therapy

Operation Manual
UPDATE - 2020

briggatemedicalcompany

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1 x PactMED LED.

1 x Light Conductor (Optical Wave Guide)

1 x Short Stand (floor application)

1 x Telescopic Stand (patient chair application)

10 x Autoclavable Anti-glare Shields

1 x Tube PACT Nail Fungus Gel

1 x Practitioner's Guide

1 x Packet of Patient Information Leaflets

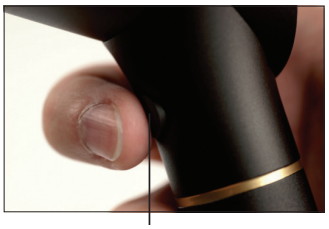
1 x Wall Poster

Additional PACT Nail Fungus Gel is available for purchase from Briggate Medical Company

Assembly Instructions

1. Insert light conductor into PactMED LED.
2. Attach anti-glare shield to light conductor.
3. Insert base of handle into selected stand.
4. To activate LED press the start button.
5. Treatment times can be entered on the control panel and range from 0.5 to 9.5 minutes.
6. A flashing light on the control panel indicates a low battery.

Please Note
Irradiation level is not affected even when flashing light appears.



1. Start button
2. Light Conductor (optical wave guide)
3. Anti-glare shield
4. Control Panel and display
5. Increase/decrease Irradiation time
6. Irradiation time display
7. Power Supply

Photodynamic Therapy Explained

PDT is an acronym and a scientific term for photodynamic therapy. The basis of PDT is the interaction of light with photosensitive agents to produce an energy transfer and local chemical effect. Using this method, bacteria, viruses and fungi can be effectively destroyed on the skin surface or nails.

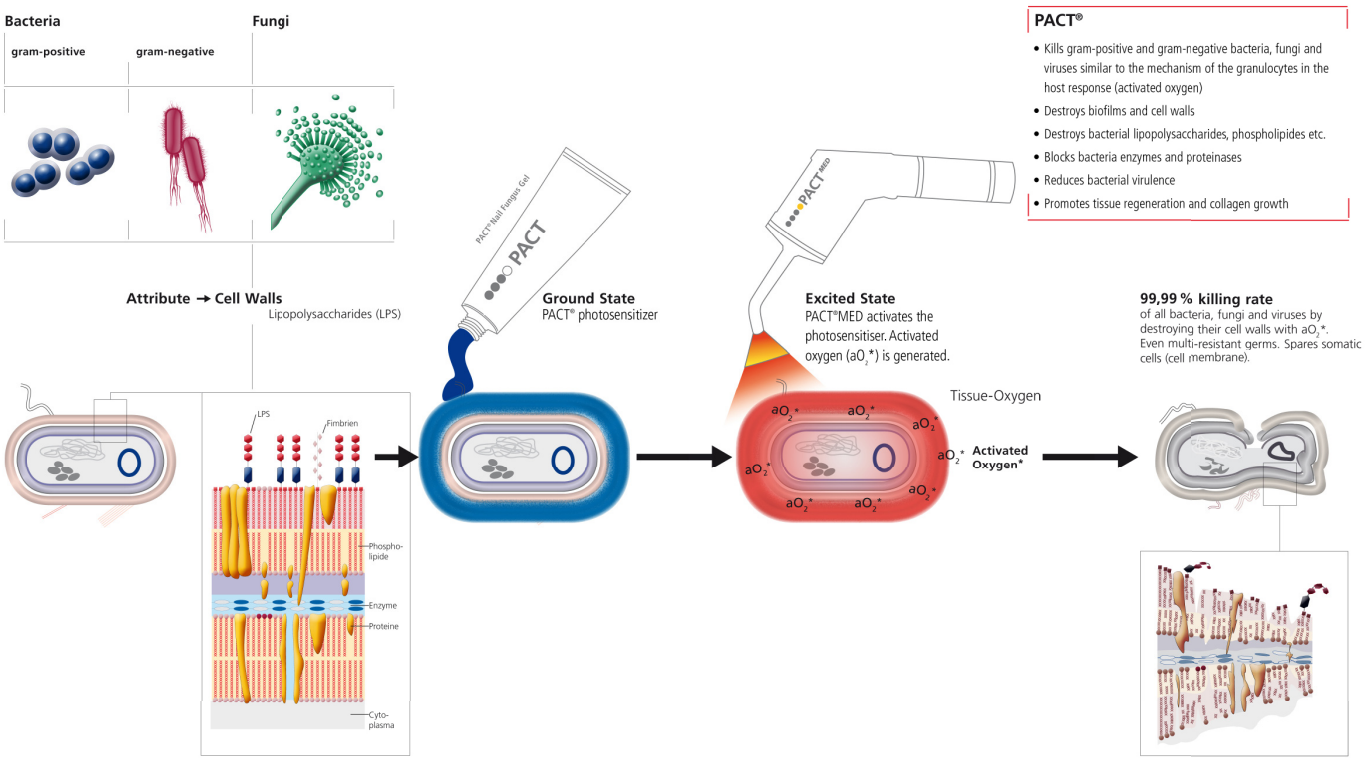
The earliest recorded treatments that exploited a photosensitiser and a light source for medical effect, in this case sunlight, can be dated to over 3000 years ago to ancient Egypt and India. Records suggest the use of topically applied vegetable and plant substances in combination with sunlight to produce photo-reactions in skin which caused a re-pigmentation of de-pigmented skin lesions, as seen with vitiligo.

Reports concerning the prevalence of onychomycosis are conflicting, but estimates ranging from 2-3% to 13% in western populations have been noted [3].

In Australia alone, it is suggested that approximately 1.6 million people have a fungal infection of the nails.

Whilst there is currently an assortment of treatment options for onychomycosis ranging from nail lacquers to oral antifungal medications, the challenge of patient compliance in regard to topical antifungals and concerns regarding drug interactions and adverse effects of oral antifungals has resulted in the need for an alternative treatment option. Photodynamic therapy has been developed and adapted for the successful treatment of fungal nails without damaging side effects.

3. Heikkala H, Stubbs S. The prevalence of onychomycosis in Finland. Br J. Dermatology 1995; 133:699-701Elewski Be, Charif MA. Prevalence of onychomycosis in patients attending a dermatology clinic in North Eastern Ohio for other conditions. Arch Dermatology 1997; 133:1172-3.



Mechanism of Action

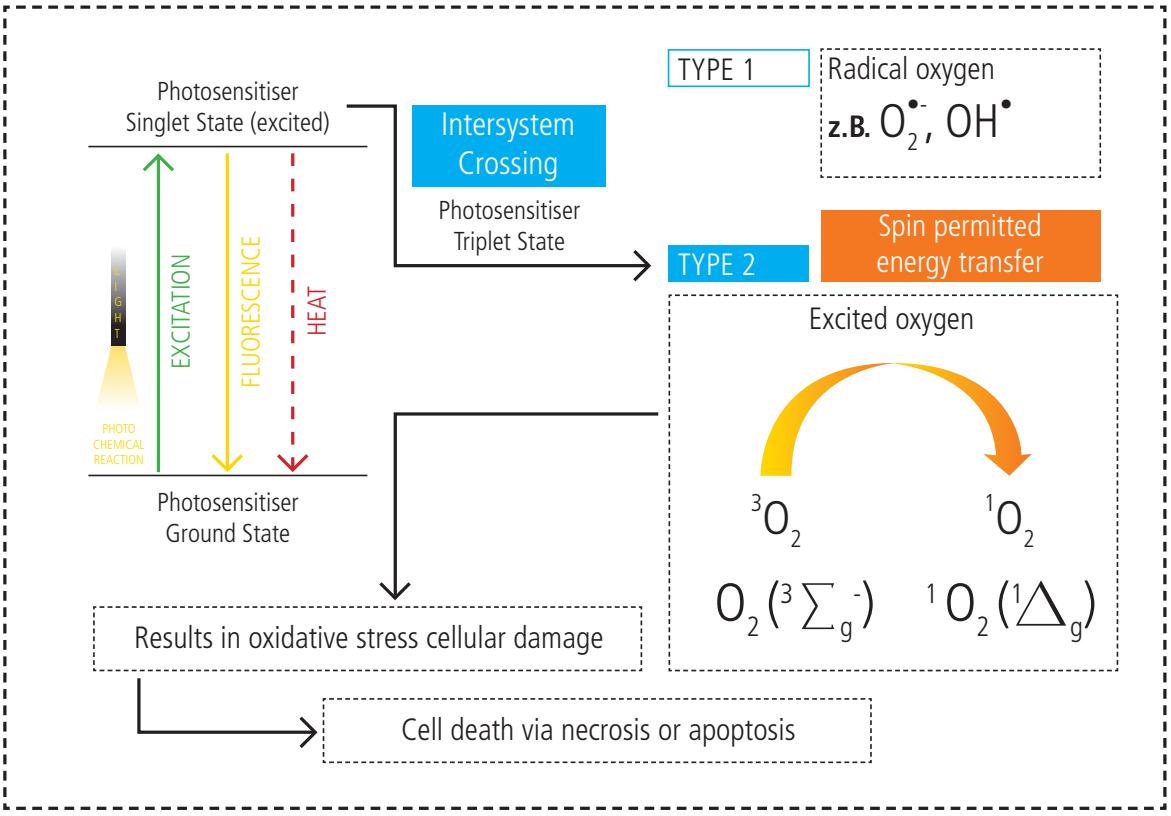
Photodynamic therapy comprises three key components:

· A Photosensitiser - non-toxic dye, Phenothiazine such as Toludine blue (tolonium chloride)
· A light source – LED light
· Tissue oxygen

Photodynamic therapy (PDT) involves the use of photochemical reactions mediated through the interaction of photosensitising agents, light, and oxygen.
When the photosensitiser, PACT Fungal Nail Gel is exposed to a specific wavelength of light (630nM) delivered by PactMED LED, it becomes activated from a 'ground' to an 'excited' state. As it returns to the ground state, it releases energy, which is transferred to oxygen to generate reactive oxygen species (ROS), such as singlet oxygen and free radicals.

These ROS mediate cellular toxicity and induce fungal cell death without affecting surrounding tissue whose cells are impenetrable by the photo-sensitiser.

Energy diagram of the photochemical reaction

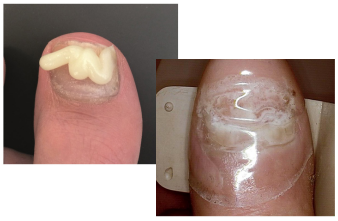


Protocol Summary

In-clinic Test

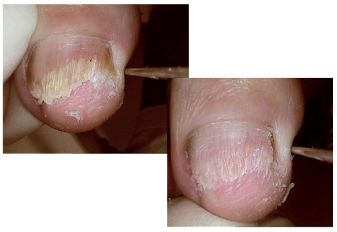
Obtain Correct Diagnosis

Send nail sample to pathology

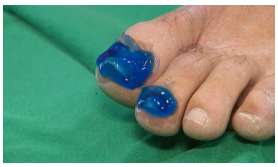


Chemical Debridement

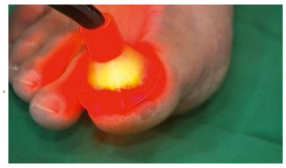
Intensive Debridement



Mechanical Debridement



PACT Photodynamic Therapy



9.5 mins **PACT** → 7-10 days → 9.5 mins **PACT** → 7-10 days → 9.5 mins **PACT** → 4-12 week review

Tips for better results:

- Apply topical anti-fungal adjunct on the exposed nailbed to aid treatment (e.g: SolvEasy).
- Advise patient to apply a small amount of Urea 40% to the nailbed daily to keep it soft and encourage it to laminate to nailbed during re-growth.
- Encourage patient to maintain good foot hygeine.

Protocol

The following protocol is a guide only and may need to be altered to best suit the presenting patient. Clinical judgement should be used to determine best treatment pathway for each patient.

1. Diagnose onychomycosis. Clinical guidelines state that it is best practice to establish a formal diagnosis prior to treatment. There is now a simple in-clinic fungal nail test available called Diafactory Dermatophyte Test that can accurately determine the presence of dermatophytes in a nail sample (refer to page 17 for further information) (Tsunemi & Hiruma, 2017).
2. Determine severity of infection using an assessment tool such as the Onychomycosis Severity Index (OSI - refer to following page) (Carney et al., 2011). Severe infections extending past the proximal nail fold have a lower success rate and patient expectations should be managed accordingly.
3. Prepare the nail prior to Pact treatment by mechanically and chemically debriding the overlying infected nail plate. It is important to remove as much of the underlying hyperkeratosis on the nail bed as possible as this can harbour the infection.
4. Apply urea 40% to the patient's nailbed at the end of the first consult and occlude nail with a film dressing to stop urea spreading to surrounding skin and into socks. This will help soften the remainder of the infected nail plate and hyperkeratosis (if present) and make the nailbed more permeable to the Tolonium blue gel. Supply the patient with some film dressings and urea 40% for daily application at home until their next appointment in 2-3 days.
5. Liberally apply gel to nail bed, covering the whole nail and surrounding nail fold. (Ensure the gel has not expired. Use within 3 months after opening). Allow the gel to remain for 10 minutes prior to exposure to Pact light source.
6. Apply Pact light source for 9.5 minutes. Ensure the silicon shield is in contact with, and surrounding the area being treated.
7. Review patient in 7-10 days. Advise them to apply a topical antifungal daily between visits and until infection clears. With the nail bed exposed, a tinea cream is recommended for use as it will be readily absorbed into the nailbed without having to penetrate the nail plate.
8. Repeat steps 5-7 at the second review. Debride and clean the nail if necessary. Patient to continue applying topical antifungal.
9. Complete 3rd treatment. Have patient continue applying topical anti-fungal until next review in approximately 8 weeks. Depending on severity, further Pact treatment may be required.
10. Ensure patient is taking all other measures to reduce risk of reinfection i.e. washing and drying feet thoroughly and regularly, cleaning shower floors regularly, using Anti-fungal washing powder, wearing clean socks and shoes, avoid wearing nail polish for long periods, et cetera.
11. Review every 3-6 months for a single Pact treatment if necessary.

Important note:
Pact photodynamic therapy is dependent on the Tolonium chloride gel coming in contact with fungal or bacterial cells. If this doesn't occur, the light will have no fungicidal effect and treatment will be ineffective.

Reference: Reference: Carney, C. et al. (2011). A New Classification System for Grading the Severity of Onychomycosis. Arch Dermatol. 147:11. 1277-1282 doi:10.1001/archdermatol.2011.267

Tsunemi, Y. & Hiruma, M. (2017). Clinical Study of Dermatophyte Test Strip, An Immunochromatographic Method to Detect Tinea Unguium Dermatophytes. Journal of Dermatology, 43:1417–1423. Doi: 10.1111/1346-8138.13348

Onychomycosis Classification using Onychomycosis Severity Index (OSI):

Carney, C. et al. A New Classification System for Grading the Severity of Onychomycosis: Onychomycosis Severity Index Arch Dermatol. 2011;147(11):1277-1282.

A consensus conference was convened to develop an objective, reproducible numeric grading system describing the extent and involvement of distal subungual onychomycosis (DSO) that separates the nail involvement into a mild, moderate, or severe category.

This new classification system can be utilised to modify the treatment protocol for the use of PACT.

The OSI is determined by a calculation relating to the following characteristics:
1. Area of involvement (%)
2. Proximity of disease to matrix
3. Presence of dermatophytoma or subungual hyperatosis > 2mm

Area of Involvement

X

Proximity of Disease to Matrix

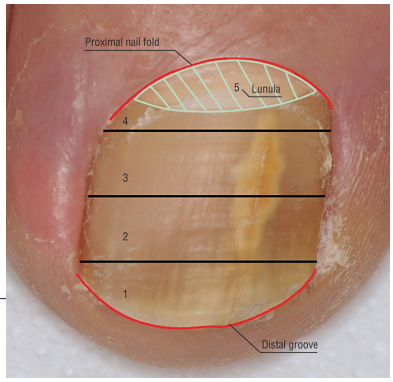
+10

ONLY if Dermatophytoma or Subungal Hyperkeratosis greater than 2mm is present

=

OSI

1. Area of Involvement



% of affected nail
0 = 0
1-10% = 1
11-25% = 2
26-50% = 3
51-75% = 4
76-100% = 5

2. Proximity of Disease to Matrix

The nail is divided transversely into quarters.

Involvement of the various segments provides the scoring:

Distal groove = 1
1st half of nail = 2
3rd quarter = 3
Proximal quarter = 4
Lunula (highlighted in aqua) & proximal nail fold (matrix) = 5

3. Presence of Dermatophytoma or Subungual Hyperkeratosis > 2mm

% of affected nail
No = 0
Yes = 10

OSI Classification
Mild = Score 5 or less
Moderate = 6 – 15
Severe = 16 – 35

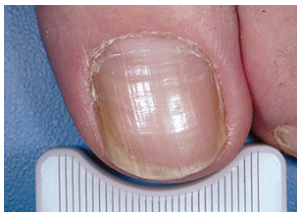
Refer to next page for OSI examples

Examples of Onychomycosis Severity Index (OSI):

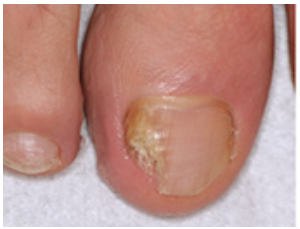
Refer to the scoring system for each characteristic using the information on the previous page.

11-25% Nail Area = 2 (Area of Involvement) X 1st Half of Nail = 2 (Proximity of Disease to Matrix) + Not Present = 0 (No presence of Dermatophytoma or Subungal Hyperkeratosis greater than 2mm) = MILD 4 OSI

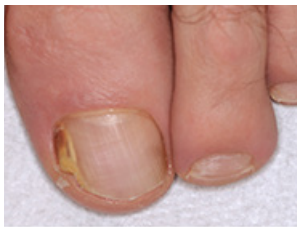
1-10% Nail Area = 1 (Area of Involvement) X 3rd Quarter = 3 (Proximity of Disease to Matrix) + Not Present = 0 (No presence of Dermatophytoma or Subungal Hyperkeratosis greater than 2mm) = MILD 3 OSI



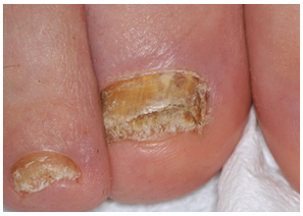
26-50% Nail Area = 3 (Area of Involvement) X Proximal Quarter = 4 (Proximity of Disease to Matrix) + Not Present = 0 (No presence of Dermatophytoma or Subungal Hyperkeratosis greater than 2mm) = MODERATE 12 OSI



1-10% Nail Area = 1 (Area of Involvement) X Matrix = 5 (Proximity of Disease to Matrix) + Present = 10 (Presence of Dermatophytoma or Subungal Hyperkeratosis greater than 2mm) = MODERATE/SEVERE 15 OSI



76-100% Nail Area = 5 (Area of Involvement) X Lunula &Matrix = 5 (Proximity of Disease to Matrix) + Present = 10 (Presence of Dermatophytoma or Subungal Hyperkeratosis greater than 2mm) = SEVERE 35 OSI



Frequency of Application

The frequency of treatment should be determined by the severity and duration of the infection, as well as the general health and age of the patient and any co-morbidities.

Refer to pages 10 and 11 for how to determine infection severity.

SEVERITY	Complete initial 3 Applications	Review and PACT Treatment (1 Application)	Review and Repeat PACT Treatment (1 application)
MILD	Within 1 Month	After 3 Months	Every 3 Months
MODERATE	Within 1 Month	After 1 Month	Every Month to 3 Months
SEVERE	Within 1 Month	After 2 Weeks to 1 Month	Every Month

Poor Prognostic Factors

Patient Characteristic	Nail Characteristic	Organism
Immunosuppression	Subungual hyperkeratosis >2mm	Nondermatophyte molds
Poor peripheral circulation	Significant lateral disease	Yeasts
Poorly controlled diabetes mellitus	Dermatophytoma (streak or patch) >50% involvement Slow rate of nail growth Severe onycholysis Total dystrophic onychomycosis Matrix involvement	Mixed bacterial/fungal infections

Treatment Protocol for Paronychia

1. Gel Application - Apply PACT Nail Fungus Gel liberally to the affected area and leave for 1 minute
2. Light Application - Treat with PACTmed LED light continuously for between 2 and 5 minutes.

The treatment time can be extended up to 9.5 minutes depending on the severity and duration of the infection. Although one treatment is typically sufficient, in cases of severe and prolonged infection the treatment can be repeated.

Contra-indications & Side Effects

There are no known contra-indications for the PactMED, however it is important to note the ingredients of the gel and identify those patients who may experience an allergic reaction.

The nail retains a blue discolouration that will vanish soon after treatment, however in rare cases it may remain for up to one week.

The effectiveness of the treatment can only be assessed after a period of approximately 3 months due to the time it takes for the nail to grow.

If the affected part of the nail fails to grow out and spreads to the base of the nail, application can be repeated and prolonged if required.

For the purpose of prophylaxis after a successful treatment it is recommended to repeat the treatment every 6 months for 9.5 minutes. Note that extended exposure does not have any adverse affects.

Tips to Prevent Re-Infection

To optimise the success of the PactMED treatment, it is essential to minimise the risk of re-infection.

Some tips include

- Use of a topical anti-fungal solution applied daily
- Regular rotation of patient's shoes for drying and aeration
- Treat shoes with an anti-fungal prior to commencement of treatment and regularly after its completion.
- A UV light sanitiser can be used as an alternative to treat the shoes
- Wash hosiery in hot water and even apply antifungal solution to the washing cycle
- Patients should be encouraged to wear thongs in public showers and swimming centres
- The use of hosiery/socks containing silver can also minimise re-infection
- Disinfect shower floor
- Minimise micro trauma to the nails (which makes the nails more susceptible to infection) by ensuring correct shoe fit
- Patient should not share nail clippers

Safety Features

The PactMED system is constantly monitored by internal software on a micro-controller to ensure it is operating properly. The LED and its current intensity, voltage, temperature and output voltage are all controlled, monitored and in the event a malfunction the system is automatically reset. In the case of an electrical fault an internal fuse provides protection.

Important

· Do not use magnifying glass near PactMED

· Protective goggles are not required to be worn

· Always use the anti-glare shield

· No damage to any tissue can occur even if the maximum treatment length is chosen

· Keep at least 1cm distance between the PACT and the treatment area

· PactMED should only be operated under the supervision of a qualified medical practitioner

Power Supply

· DC Adaptor 100-220V/50-60 Hz - connection to mains power is required for operation

Cleaning & Maintenance

The PactMED device can be wiped with moist alcohol swabs or suitable disinfecting products.

The anti-glare shield can be autoclaved at 134 °C.

Important

· Do NOT soak the device and/or attachments

· Do NOT use aggressive cleaning products

· Avoid any contamination to ensure optimal efficiency and lifespan of the device

· None of the components of the device should be exchanged or serviced by the user

· Do NOT open the device

· In case of any malfunction - please contact Briggate Medical Company

Technical Specifications

Wavelength	620-640 nm
Class	Class IIA (93/42/EEC)
Capacity of the LED	10W
Power	600mW
Treatment Length	0.5 – 9.5 minutes depending on indication
Current Input	Max. 4.5 A
Power Supply	DC Adaptor 100-220V/50-60 Hz
Operating Temperature	10 – 45 °C
Storage Temperature	-5 – 50 °C
Dimensions	55 x 110 x 160 mm
ARTG#	268012

Warranty Details
The unit and parts have a warranty of 12 months against manufacturing defects.

Manufacturer
Cumdente GmbH
Hahn Medical Systems GmbH
Paul-Ehrlich-Straße 11
72076 Tübingen, Germany

Australasian Sponsor
Briggate Medical Company
23-25 Lakewood Blvd
Braeside Victoria 3195
Australia
Ph: (03) 8586 7800
briggate@briggate.com.au

PACT Nail Fungus Gel

PACT Nail Fungus Gel is a photosensitising nontoxic dye containing tolonium chloride.

Ingredients of the Nail Gel
Water, Propylene Glycol, Natrosol (Hydroxyethyl Cellulose), Potassium Sorbate, Lactic Acid, Tolonium Chloride

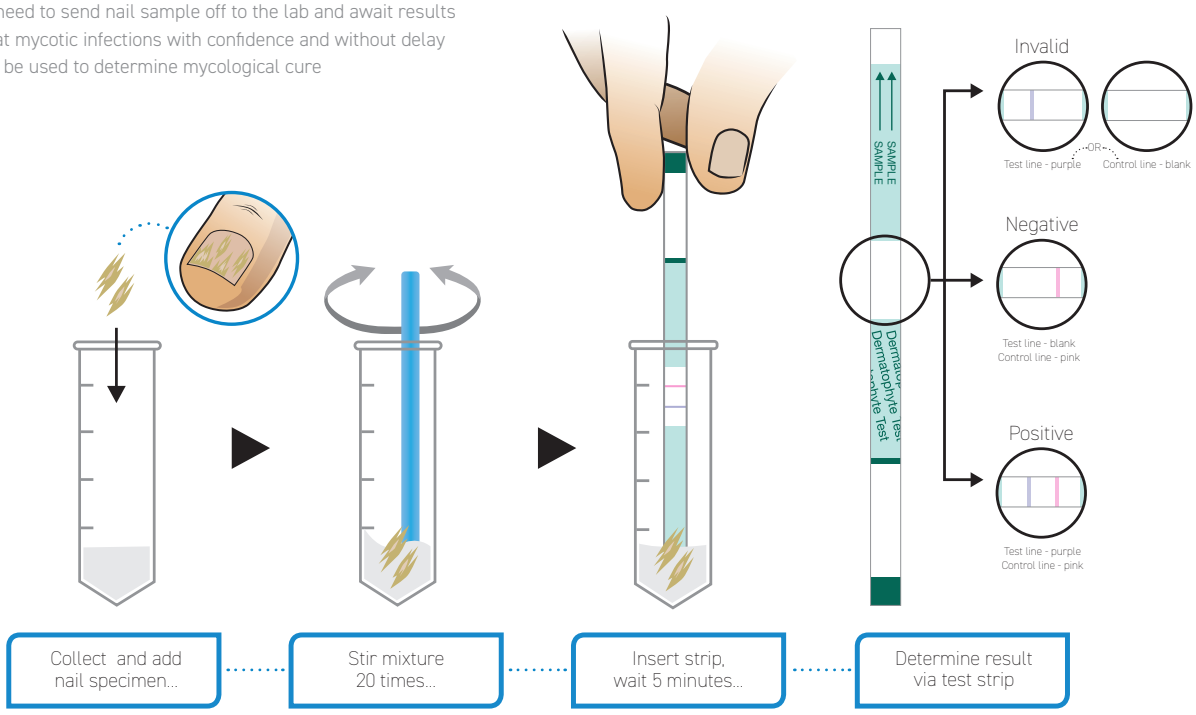
- Do NOT use if tube is damaged
- Apply using an applicator
- The tube has an expiration date of 3 months after opening

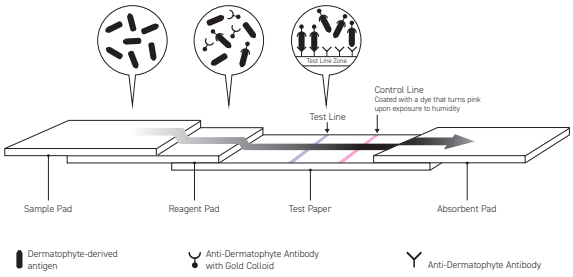
Diafactory

Dermatophyte Test Strip

IN-CLINIC 5 MINUTE TEST FOR ONYCHOMYCOSIS

- Diagnosis in just 5 minutes
- 97% accurate
- Results unaffected by topical or oral anti-fungal treatments
- Detects 99% of all common dermatophyes with only a 1mg specimen
- No need to send nail sample off to the lab and await results
- Treat mycotic infections with confidence and without delay
- Can be used to determine mycological cure





The test strip contains anti-dermatophyte antibodies with gold colloid. In the presence of dermatophyte derived antigens, the antibodies with gold colloid bind to, and form an immune complex.

Diafactory - Tinea Ungium

Dermatophyte Test Stips

Includes:

- 1 x Bottle of Extraction Buffer
- 10 x Test Strips
- 10 x Test Tubes
- 10 x Stirring Rods

DIAFACTORY

Dermatophyte Testing Kit

Pkt 10

Log-in to www.briggatemedical.com or contact us for pricing.

Will test positive for all common dermatophytes including:

- T. mentagrophytes
- T. rubrum
- T. tonsurans
- T. violaceum
- T. verrucosum
- M. gypseum
- M. canis
- E.floccosum

PACT MED

Photodynamic Therapy

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