Diafactory

Dermatophyte Test Strip

Information & Instruction Guide

briggatemedicalcompany

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
- Diagnose mycotic infections with confidence and without delay
- Can be used to determine mycological cure

ARTG#: 402694

Will test positive for all common dermatophytes including:

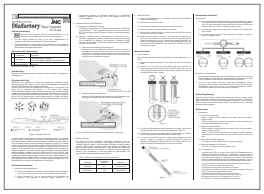
- T. mentagrophytes
- T. rubrum
- T. tonsurans
- T. violaceum
- T. verrucosum
- M. gypseum
- M. canis
- E.floccosum

VIDEO - How to use Diafactory

We have produced the following video to display the simple and quick procedure for the Diafactory® Test Strip:

Diafactory
Instructions of Use - Summary

Click here to view full instructions supplied with the Diafactory® Testing Kit:



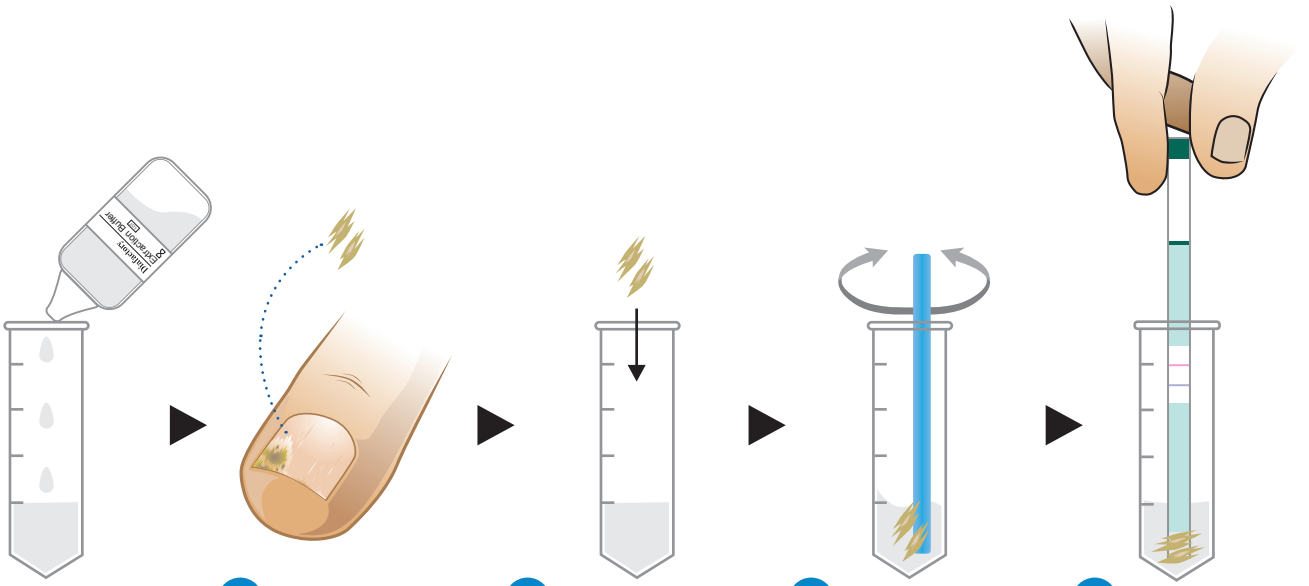
Each Diafactory® Testing Kit includes the following:
- 1 x Bottle of Extraction Buffer
- 10 x Test Strips
- 10 x Test Tubes
- 10 x Stirring Rods


10 x Test Tubes

10 x Stirring Rods


1 x Bottle of Extraction Buffer

10 x Test Strips

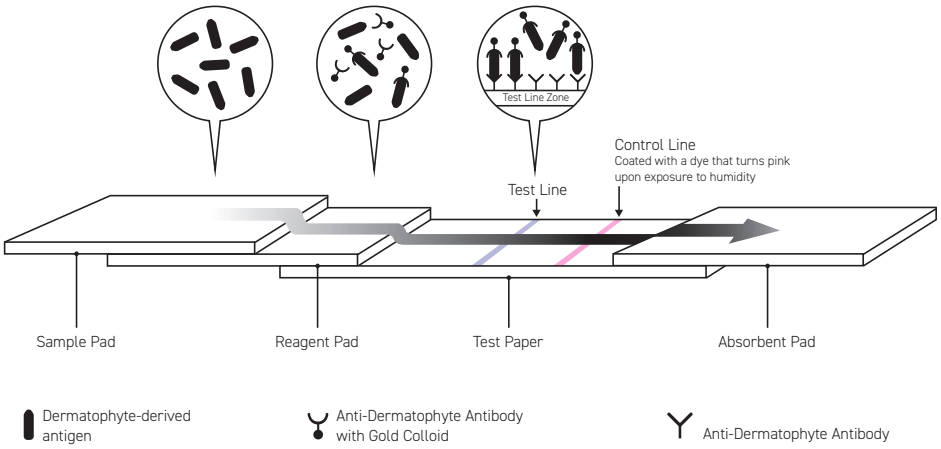


1. Add 0.25ml to 0.50ml of Extraction Buffer to Test Tube
2. Take a small sample of the infected nail (at least 1mg)
3. Add nail specimen to the Extraction Buffer in the Test Tube
4. Use the Stirring Rod to stir at least 20 times ensuring to push the specimen down
5. Insert the Test Strip (Sample side down) and wait 5 minutes
6. Determine result via test strip

Positive	Negative	Invalid	
Test line - purple Control line - pink	Test line - blank Control line - pink	Test line - purple	Control line - blank

Diafactory

Diafactory® Test Strips are an immunochromatography kit intended to detect Trichophyton-derived antigens in nails using anti-Trichophyton mouse monoclonal antibody that has been immobilized on a nitrocellulose membrane.



Key Materials

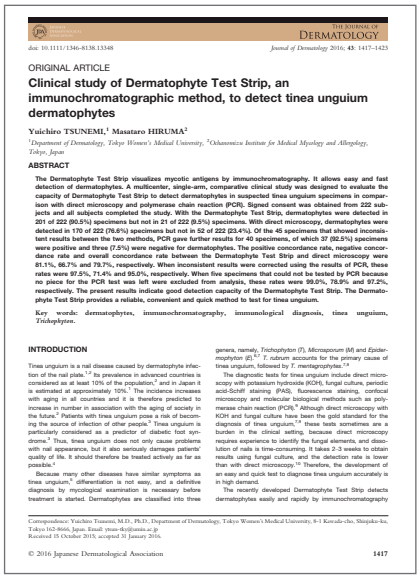
The test strip used in this kit is composed of a sample pad, a reagent strip, a judgment strip and an absorbent pad.
The reagent strip contains gold colloid-labeled anti-Trichophyton mouse monoclonal antibody in the dry state, and the judgment strip contains anti-Trichophyton mouse monoclonal antibody in the dry state affixed on the test line zone and the dye in the dry state affixed on the control line zone.
This dye is a colorless dye at a pH of 3 that turns pink at a pH of approximately 4 or higher, and allows the user to confirm that a sample has correctly passed through the test line zone.

From sample to result

A sample that has infiltrated the sample pad (hereinafter called, "the extracted sample") moves to the reagent strip, on which a Trichophyton-derived antigen in the extracted sample binds to a gold colloid-labeled anti-Trichophyton mouse monoclonal antibody to form an immune complex.
While proceeding through the judgment strip, the immune complex is captured by the anti-Trichophyton mouse monoclonal antibody affixed on the test line zone, resulting in the appearance of a purple line of gold colloid (in case it is positive).
If the sample does not contain Trichophyton-derived antigen, no immune complexes are formed and the sample containing unbound gold colloid-labeled anti-Trichophyton mouse monoclonal antibody passes over the test line zone without producing a visible band on the test line zone.
The extracted sample containing unused gold colloid labeled anti-Trichophyton mouse monoclonal antibodies, whether it is Trichophyton-derived antigen positive or negative, passes through the test line zone and reaches the control line zone, where the extracted sample reacts with immobilised dye, resulting in the appearance of a pink band.

Diafactory
Research

Click the links below to access research papers on Diafactory®:



THE JOURNAL OF DERMATOLOGY

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ORIGINAL ARTICLE

Clinical study of Dermatophyte Test Strip, an immunochromatographic method, to detect tinea unguium dermatophytes

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ABSTRACT

The Dermatophyte Test Strip visualizes mycotic antigens by immunochromatography. It allows easy and fast detection of dermatophytes. A multicenter, single-arm, comparative clinical study was designed to evaluate the capacity of Dermatophyte Test Strip to detect dermatophytes in suspected tinea unguium specimens in comparison with direct microscopy and polymerase chain reaction (PCR). Signed consent was obtained from 222 subjects and all subjects completed the study. With the Dermatophyte Test Strip, dermatophytes were detected in 201 of 222 (90.5%) specimens but not in 21 of 222 (9.5%) specimens. With direct microscopy, dermatophytes were detected in 170 of 222 (76.6%) specimens but not in 52 of 222 (23.4%). Of the 45 specimens that showed inconsistent results between the two methods, PCR gave further results for 40 specimens, of which 37 (92.5%) specimens were positive and three (7.5%) were negative for dermatophytes. The positive concordance rate, negative concordance rate and overall concordance rate between the Dermatophyte Test Strip and direct microscopy were 91.1%, 68.7% and 79.7%, respectively. When inconsistent results were corrected using the results of PCR, these rates were 97.5%, 71.4% and 95.0%, respectively. When five specimens that could not be tested by PCR because no piece for the PCR test was left were excluded from analysis, these rates were 99.0%, 78.9% and 97.2%, respectively. The present results indicate good detection capacity of the Dermatophyte Test Strip. The Dermatophyte Test Strip provides a reliable, convenient and quick method to test for tinea unguium.

Key words: dermatophytes, immunochromatography, immunological diagnosis, tinea unguium, *Trichophyton*.

INTRODUCTION

Tinea unguium is a nail disease caused by dermatophyte infection of the nail plate.[1,2] Its prevalence in advanced countries is considered as at least 10% of the population,[3] and in Japan it is estimated at approximately 10%.[1] The incidence increases with aging in all countries and it is therefore predicted to increase in number in association with the aging of society in the future.[4] Patients with tinea unguium pose a risk of becoming the source of infection of other people.[4] Tinea unguium is particularly considered as a predictor of diabetic foot syndrome.[5] Thus, tinea unguium does not only cause problems with nail appearance, but it also seriously damages patients' quality of life. It should therefore be treated actively as far as possible.[4]

Because many other diseases have similar symptoms as tinea unguium,[1] differentiation is not easy, and a definitive diagnosis by mycological examination is necessary before treatment is started. Dermatophytes are classified into three genera, namely, *Trichophyton* (*T*), *Microsporum* (*M*) and *Epidermophyton* (*E*).[6,7] *T. rubrum* accounts for the primary cause of tinea unguium, followed by *T. mentagrophytes*.[1,8]

The diagnostic tests for tinea unguium include direct microscopy with potassium hydroxide (KOH), fungal culture, periodic acid-Schiff staining (PAS), fluorescence staining, confocal microscopy and molecular biological methods such as polymerase chain reaction (PCR).[9] Although direct microscopy with KOH and fungal culture have been the gold standard for the diagnosis of tinea unguium,[1,8] these tests sometimes are a burden in the clinical setting, because direct microscopy requires experience to identify the fungal elements, and dissolution of nails is time-consuming. It takes 2–3 weeks to obtain results using fungal culture, and the detection rate is lower than with direct microscopy.[10] Therefore, the development of an easy and quick test to diagnose tinea unguium accurately is in high demand.

The recently developed Dermatophyte Test Strip detects dermatophytes easily and rapidly by immunochromatography

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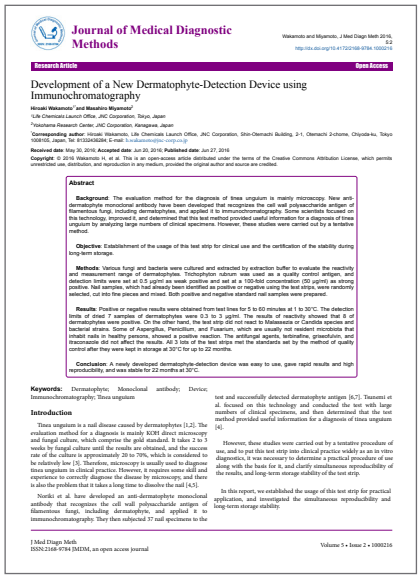
Clinical study of Dermatophyte Test Strip, an immunochromatographic method, to detect tinea unguium dermatophytes



Journal of Medical Diagnostic Methods

Research Article — Open Access

Development of a New Dermatophyte-Detection Device using Immunochromatography

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Abstract

Background: The evaluation method for the diagnosis of tinea unguium is mainly microscopy. New anti-dermatophyte monoclonal antibody have been developed that recognizes the cell wall polysaccharide antigen of filamentous fungi, including dermatophytes, and applied it to immunochromatography. Some scientists focused on this technology, improved it, and determined that this test method provided useful information for a diagnosis of tinea unguium by analyzing large numbers of clinical specimens. However, these studies were carried out by a tentative method.

Objective: Establishment of the usage of this test strip for clinical use and the certification of the stability during long-term storage.

Methods: Various fungi and bacteria were cultured and extracted by extraction buffer to evaluate the reactivity and measurement range of dermatophytes. Trichophyton rubrum was used as a quality control antigen, and detection limits were set at 0.5 μg/ml as weak positive and set at a 100-fold concentration (50 μg/ml) as strong positive. Nail samples, which had already been identified as positive or negative using the test strips, were randomly selected, cut into fine pieces and mixed. Both positive and negative standard nail samples were prepared.

Results: Positive or negative results were obtained from test lines for 5 to 60 minutes at 1 to 30°C. The detection limits of dried 7 samples of dermatophytes were 0.3 to 3 μg/ml. The results of reactivity showed that 8 of dermatophytes were positive. On the other hand, the test strip did not react to Malassezia or Candida species and bacterial strains. Some of Aspergillus, Penicillium, and Fusarium, which are usually not resident microbiota that inhabit nails in healthy persons, showed a positive reaction. The antifungal agents, terbinafine, griseofulvin, and itraconazole did not affect the results. All 3 lots of the test strips met the standards set by the method of quality control after they were kept in storage at 30°C for up to 22 months.

Conclusion: A newly developed dermatophyte-detection device was easy to use, gave rapid results and high reproducibility, and was stable for 22 months at 30°C.

Keywords: Dermatophyte; Monoclonal antibody; Device; Immunochromatography; Tinea unguium

Introduction

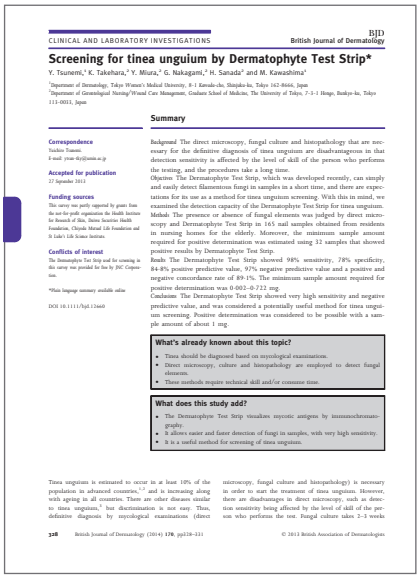
Tinea unguium is a nail disease caused by dermatophytes [1,2]. The evaluation method for a diagnosis is mainly KOH direct microscopy and fungal culture, which comprise the gold standard. It takes 2 to 3 weeks by fungal culture until the results are obtained, and the success rate of the culture is approximately 20 to 70%, which is considered to be relatively low [3]. Therefore, microscopy is usually used to diagnose tinea unguium in clinical practice. However, it requires some skill and experience to correctly diagnose the disease by microscopy, and there is also the problem that it takes a long time to dissolve the nail [4,5].

Noriki et al. have developed an anti-dermatophyte monoclonal antibody that recognizes the cell wall polysaccharide antigen of filamentous fungi, including dermatophyte, and applied it to immunochromatography. They then subjected 37 nail specimens to the test and successfully detected dermatophyte antigen [6,7]. Tsunemi et al. focused on this technology and conducted the test with large numbers of clinical specimens, and then determined that the test method provided useful information for a diagnosis of tinea unguium [4].

However, these studies were carried out by a tentative procedure of use, and to put this test strip into clinical practice widely as an in vitro diagnostics, it was necessary to determine a practical procedure of use along with the basis for it, and clarify simultaneous reproducibility of the results, and long-term storage stability of the test strip.

In this report, we established the usage of this test strip for practical application, and investigated the simultaneous reproducibility and long-term storage stability.

Development of a New Dermatophyte Detection Device using Immunochromatography



CLINICAL AND LABORATORY INVESTIGATIONS — BJD British Journal of Dermatology

Screening for tinea unguium by Dermatophyte Test Strip*

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Conflicts of interest
The Dermatophyte Test Strip used for screening in this survey was provided for free by JNC Corporation.

*Plain language summary available online

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Summary

Background The direct microscopy, fungal culture and histopathology that are necessary for the definitive diagnosis of tinea unguium are disadvantageous in that detection sensitivity is affected by the level of skill of the person who performs the testing, and the procedures take a long time.

Objectives The Dermatophyte Test Strip, which was developed recently, can simply and easily detect filamentous fungi in samples in a short time, and there are expectations for its use as a method for tinea unguium screening. With this in mind, we examined the detection capacity of the Dermatophyte Test Strip for tinea unguium.

Methods The presence or absence of fungal elements was judged by direct microscopy and Dermatophyte Test Strip in 165 nail samples obtained from residents in nursing homes for the elderly. Moreover, the minimum sample amount required for positive determination was estimated using 32 samples that showed positive results by Dermatophyte Test Strip.

Results The Dermatophyte Test Strip showed 98% sensitivity, 78% specificity, 84·8% positive predictive value, 97% negative predictive value and a positive and negative concordance rate of 89·1%. The minimum sample amount required for positive determination was 0·002–0·712 mg.

Conclusions The Dermatophyte Test Strip showed very high sensitivity and negative predictive value, and was considered a potentially useful method for tinea unguium screening. Positive determination was considered to be possible with a sample amount of about 1 mg.

What's already known about this topic?

- Tinea should be diagnosed based on mycological examinations.
- Direct microscopy, culture and histopathology are employed to detect fungal elements.
- These methods require technical skill and/or consume time.

What does this study add?

- The Dermatophyte Test Strip visualizes mycotic antigens by immunochromatography.
- It allows easier and faster detection of fungi in samples, with very high sensitivity.
- It is a useful method for screening of tinea unguium.

Tinea unguium is estimated to occur in at least 10% of the population in advanced countries,[1,2] and is increasing along with ageing in all countries. There are other diseases similar to tinea unguium,[3] but discrimination is not easy. Thus, definitive diagnosis by mycological examinations (direct microscopy, fungal culture and histopathology) is necessary in order to start the treatment of tinea unguium. However, there are disadvantages in direct microscopy, such as detection sensitivity being affected by the level of skill of the person who performs the test. Fungal culture takes 2–3 weeks

Screening for tinea unguium by Dermatophyte Test Strip

GUIDELINES — BJD British Journal of Dermatology

British Association of Dermatologists' guidelines for the management of onychomycosis 2014

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Conflicts of interest
J.T.L. has acted as a consultant for Novartis (nonprofit); M.R. has acted as a consultant for Bedrit Bioclear (profit).

The authors are listed in alphabetical order.

M.A., J.T.L., V.M. and M.R. are members of the guideline development group, with technical support provided by M.F.M.M.

This is an updated guideline prepared for the British Association of Dermatologists (BAD) Clinical Standards Unit, which includes the Therapy & Guidelines (T&G) Subcommittee. Members of the Clinical Standards Unit who have been involved are: J.E. Hughes (Chairman T&G), A. Sahota, M. Griffiths, A.J. McDonagh, S. Forsyth, D.A. Buckley, J. Nasr, V.J. Seale, C.J. Duarte Williamson, P.M. McHenry, N.J. Lovell, T. Leslie, E. Mullins, K. Tosney (British National Formulary), R. Davis (British Dermatological Nursing Group), C. Saunders (British Dermatological Nursing Group), S.E. Stevens (BAD Scientific Administrator), L.S. Eston (BAD Information Scientist) and M.F. Mohd Mustapa (BAD Clinical Standards Manager).

Produced in 2003 by the British Association of Dermatologists; reviewed and updated 2014.

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NICE accredited — NICE has accredited the process used by the British Association of Dermatologists to produce guidelines. Accreditation is valid for 5 years from May 2010. More information on accreditation, and full details of our accreditation can be viewed at www.nice.org.uk/accreditation

1.0 Purpose and scope

The overall objective of the guideline is to provide up-to-date, evidence-based recommendations for the management of onychomycosis. The document aims to (i) offer an appraisal of all relevant literature since January 2002, focusing on any key developments; (ii) address important, practical clinical questions relating to the primary guideline objective, for example accurate diagnosis and identification of cases, and suitable treatment to minimize the duration of disease and discomfort; (iii) provide guideline recommendations and, where appropriate, with some health economic implications; and (iv) discuss potential developments and future directions.

The guideline is presented as a detailed review with highlighted recommendations for practical use in the clinic, in addition to an updated patient information leaflet [available on the British Association of Dermatologists' (BAD) website, www.bad.org.uk].

2.0 Stakeholder involvement and peer review

The guideline development group consisted of consultant dermatologists and a consultant mycologist. The draft document was circulated to the BAD membership, the British Dermatological Nursing Group, the Primary Care Dermatological Society and the North West Region Kidney Patient Association for comments, and was peer reviewed by the Clinical Standards Unit of the BAD (made up of the Therapy & Guidelines Subcommittee) prior to publication.

3.0 Methodology

This set of guidelines has been developed using the BAD's recommended methodology[1] and with reference to the Appraisal of Guidelines Research and Evaluation (AGREE II) instrument (www.agreetrust.org).[2] Recommendations were developed for implementation in the National Health Service using a process of considered judgement based on the evidence. The PubMed, Medline and Embase databases were searched for meta-analyses, randomized and nonrandomized controlled clinical trials, case series, case reports and open studies involving onychomycosis published in the English language from January 2002

British Association of Dermatologists' guidelines for the management of onychomycosis 2014

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