StrongStep®

Dermatophytosis Diagnostic kit

Instructions For Use

CE IVD

Specimen: Swab / Nails / Scurf / hair	
Language: English	**Version:** 01
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For professional in vitro diagnostic use only

INTENDED USE

The StrongStep® Dermatophytosis Diagnostic kit is a rapid visual immunoassay for the qualitative presumptive detection of α-1, 6 mannose in fungi belonging to dermatophytes. This kit is intended to be used as an aid in the diagnosis of Dermatophytosis.
TheDermatophytosis Diagnostic kit covers a wide variety of test subjects, including nails, scurf and hair (hair roots in particular) of humans and animals.

INTRODUCTION

Dermatophytosis is the most prevalent infectious skin disease in the population and can occur in both healthy and immunocompromised patients with a high recurrence rate. Because the clinical manifestations of dermatophytosis are sometimes similar to those of other skin diseases such as seborrheic dermatitis, psoriasis, candidal intertriginous eruptions, erythrodermatitis, and eczema, its clinical diagnosis can be more difficult in immunocompromised patients. The current traditional methods for identifying dermatophytes are mainly morphological, including direct observation under the microscope and fungal culture.
Our device targets α-1, 6 mannose in fungi. It has broad-spectrum immunogenicity for common dermatophytes, and can effectively and rapidly detect dermatophytes such as Trichophyton spp, Microsporum spp. and epidermophyton.

PRINCIPLE

StrongStep® Dermatophytosis Diagnostic kit has been designed to detect α-1, 6 mannose through visual interpretation of color development in the internal strip. The membrane was immobilized with monoclonal anti-α-1, 6 mannose antibodies on the test region. During the test, the specimen is allowed to react with colored monoclonal anti-α - 1, 6 mannose antibodies colored particals conjugates, which were precoated on the conjugate pad of the test. The mixture then moves on the membrane by capillary action, and interact with reagents on the membrane. If there were enough α - 1, 6 mannose in specimens, a colored band will form at the test region of the membrane. Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

Content	Purpose
20 individually packed test devices	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions.
20 swabs	For specimen collection.
20 sampling paper	For placing scurf samples.
20 extraction tubes with pre-filled dilution buffer	For specimen preparation use.
1 workstation	Place for holding buffer vials and tubes.
1 package insert	For operation instruction.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer	For timing use.

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the 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 the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
- Humidity and temperature can adversely affect results.
- When the assay procedure is completed, dispose the swabs carefully after autoclaving them at 121 ℃ for at least 20 minutes. Alternatively, they can be treated with 0.5% sodium hypochloride (or house-hold bleach) for 1 hour before disposal. The used testing materials should be discarded in accordance with local, state and/or federal regulations.

STORAGE AND STABILITY

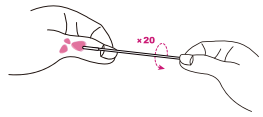
- The kit should be stored at 2-30 ℃ until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- **For swab samples:**
  Rub the swab vigorously at least 20 times at the junction of the lesioned and normal area.
- **For nail, scurf or hair samples:**
  Use appropriate devices (tweezers, scissors or a knife), etc. to scrape at least a rice-sized amount of nail, scurf or hair (hair roots in particular) from the lesion area and place it on the sampling paper.

Do not place the scurf or swab in any transport device containing medium since transport medium interferes with the assay and viability of the organisms is not required for the assay. Put the scurf or swab to the extraction tube, if the test may be run immediately. If immediate testing is not possible, the patient specimens should be placed in a dry transport tube for storage or transport. The specimens may be stored for 1 week at room temperature (15 ℃ to 30 ℃) or 1 month at 4 ℃ or no more than 12 months at -20 ℃.

- For swab samples:
  Rub the swab vigorously at least 20 times at the junction of the lesioned and normal area.



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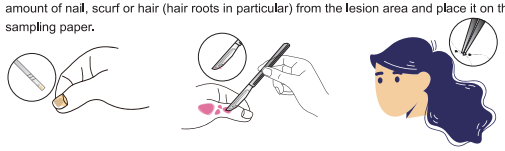
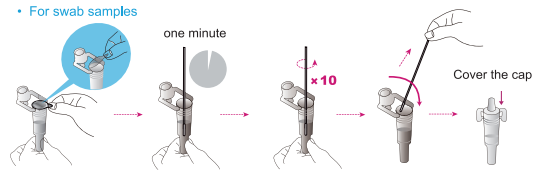


PROCEDURE

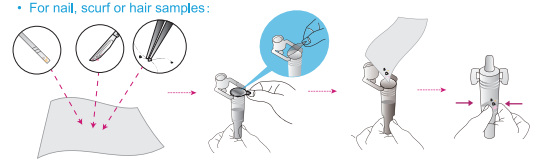
Bring tests, specimens, buffer and/or controls to room temperature (15 ℃ to 30 ℃) before use.

1. Prepare specimens
   - **For swab samples:**
     Place the extraction tube in the designated area of the workstation.
     Allow the swab to soak in the Extraction Buffer for one minute prior to the next Step.
     Mix the solution by squeeze the swab vigorously against the side of the tube for at least 10 times (while submerged). At least 1/2 of the sample buffer solution must remain in the tube for adequate capillary migration to occur. Put the cap onto the extracted tube.
   - **For nail, scurf or hair samples:**
     Place the extraction tube in the designated area of the workstation.
     Carefully pour the sample from the sampling paper into the extraction tube. Shake the dilution buffer to ensure that all the scurf is in the liquid. Squeeze the tube forcefully to mix the solution thoroughly. Best results are obtained when the specimen is completely mixed in the solution. Allow the specimen to soak in the Dilution Buffer for 1 minute prior to the next step.
2. The specimens extracted can retain at room temperature for 30 minutes without affecting the result of the test.
3. Remove the test device from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be performed within 30 minutes.
4. Add 3 drops (approximately 100 μL) of extracted sample from the extraction tube to the round sample well on the test device.
   Avoid trapping air bubbles in the sample well (S), and do not drop any solution in observation window.
   As the test begins to work, you will see color move across the membrane.
5. Wait for the colored band(s) to appear. The result should be read by visual at 15 minutes. Do not interpret the result after 20 minutes.

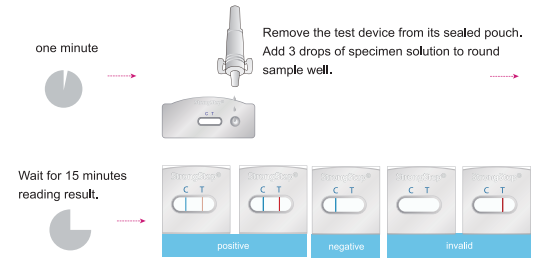
- For swab samples



- For nail, scurf or hair samples:

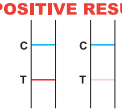
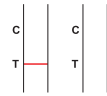


Test operation



Note:Result after 15 minutes may not be accurate.

INTERPRETATION OF RESULTS

POSITIVE RESULT 	Two colored bands appear on the membrane. One band appears in the control region (C) and another
NEGATIVE RESULT 	Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).
INVALID RESULT 	Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. But the substances level cannot be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The test only demonstrates the presence of dermatophytes antigen in the specimen and does not

indicate the activity of dermatophytes. The dermatophyte antigen can remain in the body of a person who has been treated for a short period of time.
2. The test is only a qualitative test for dermatophytes.
3. When the specimen volume is low, the concentration of dermatophytes antigen may be below the detectable range. Therefore, it is necessary to ensure that the specimen volume is adequate and that further clinical testing should be done when the test is negative and clinical symptoms are still present. A negative result still does not completely exclude dermatophytes infection.
4. Failure to follow the Procedure may adversely affect test performance and/or invalidate the test result.
5. Positive test results do not rule out co-infections with other pathogens.
6. The test does not allow for detailed typing of dermatophytes infections.
7. The test results of this kit are for clinical reference only and should not be used as the single basis for clinical diagnosis and treatment. The clinical management of patients should be considered in conjunction with their symptoms/signs, medical history, other laboratory tests and response to treatment.

PERFORMANCE CHARACTERISTICS

Table: StrongStep®Dermatophytosis Diagnostic kit and Cancer vs. Microscopy

		Microscopy		
		+	-	Total
StrongStep® Dermatophytosis Diagnostic kit	+	102	3	105
	-	9	204	213
	Total	111	207	318

Relative Sensitivity: 91.89% (85.17%～96.23%)*
Relative Specificity: 98.55% (95.82%～99.70%) *
Overall Agreement: 96.23% (93.50%～98.04%)%
Kappa: 0.9159 (0.8693～0.9625，highly consistent)*
*95% Confidence Interval

The antibody used in the StrongStep®Dermatophytosis Diagnostic kit has been shown to detect dermatophytosis. The following organisms can be detected with suspensions of 10^5 org/ml using the test:

Trichophyton rubrum	Trichophyton mentagrophytes
Trichophyton tonsurans	Trichophyton verrucosum
Trichophyton equinum	Trichophyton violaceum
Trichophyton concentricus	Trichophyton schoenleinii
Trichophyton ajello	Microsporum canis
Microsporum fulvum	Microsporum ferrugineum
Microsporum audouinii	Microsporum cookei
Microsporum persicolor	Microsporum gallinae
Microsporum racemosum	Microsporum nanum
Mucor irregular	Epidermophyton floccosum
	Rhizipus arrhizus

The following organisms cannot be detected with suspensions of 10^6 org/ml using the test:

Candida albicans	Candida tropicalis
Candida parapsilosis	Pichia kudriavzevii
Candida glabrata	Cryptococcus neoformans
Cryptococcus neoformans var. grubii	Cryptococcus gattii
Cryptococcus laurentii	Malassezia furfur
Malassezia pachydermatitidis	Malassezia sympodialis
Trichosporon asahii	Cystobasidium minutum
Trichosporosis beigelii	Geotrichum candidum
Saccharomyces cerevisiae	Aspergillus fumigatus
Aspergillus terreus	Aspergillus flavus
Aspergillus niger	Sporotrichum globosa
Staphylococcus epidermidis	Corynebacterium parvum
Corynebacterium acnes	Staphylococcus aureus
Pseudomonas aeruginosa	

LITERATURE REFERENCES

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5. Leung AK, Newman R, Kumar A et al. Rapid antigen detection testing in diagnosing group A beta -hemolytic streptococcal phryngitis. Expert Rev Mol Diagn 2006; 6: 761–766.
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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use-by date
	Manufacturer	Σ	Contains sufficient for<n>tests
	Do not re-use	EC REP	Authorized representative in the European Community / European Union
	Caution		Keep dry
	Keep away from sunlight		Do not use if package is damaged and consult instructions for use
	Manufacture date		Biological risks
CE	CE marked according to IVD Medical Devices Directive 98 /79/EC		

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