

# Instructions for Use

## ALBIQUICK™

<a href="#">Cat. no. Z121</a>	AlbiQuick™ Test Kit	25 tests/kit
-------------------------------	---------------------	--------------

## INTENDED USE

Hardy Diagnostics AlbiQuick™ Test Kit is a rapid test for the identification of *Candida albicans* by detecting the enzymes beta-galactosaminidase and L-proline aminopeptidase in yeasts.

## SUMMARY

Hardy Diagnostics AlbiQuick™ Test Kit is based on the ability of yeast species to rapidly hydrolyze the compounds proline-p-nitroanilide (PRO) using the enzyme L-proline aminopeptidase; and 4-methylumbelliferyl-n-acetyl-beta-galactosamine (NAG), using the enzyme beta-galactosaminidase. The test card consists of two separate test circles each containing one of the substrates. When hydrolyzed, the PRO substrate forms a colored end product, and if the NAG substrate is hydrolyzed it produces a fluorescent reaction. *Candida albicans* produces both enzymes, while other commonly encountered yeasts may be positive for one or the other enzyme but not for both. The total incubation time for AlbiQuick™ is only six minutes.<sup>(4,7,8)</sup>

## FORMULA

Circle A is impregnated with 4-methylumbelliferyl-n-acetyl-beta-galactosamine dissolved in a solvent. Circle B is impregnated with proline-p-nitroanilide dissolved in a solvent. The developers, Reagent A and Reagent B, consist of p-dimethylaminocinnamaldehyde and phosphate buffer, respectively.

## STORAGE AND SHELF LIFE

**Storage:** Upon receipt, store at 2-8°C. away from direct light. Product should not be used if there are any signs of contamination, deterioration, discoloration, or if the expiration date has passed. Protect reagents from freezing.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "[Storage](#)" for more information.

## PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual Universal Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic use only. It is to be used only by adequately trained and qualified laboratory

personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "[Guidelines for Isolation Precautions](#)" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections*.

Sterilize all biohazard waste before disposal.

Refer to the document "[Precautions When Using Media](#)" for more information.

## PROCEDURE

Use a culture that is between **24 to 96 hours** old to inoculate the AlbiQuick™ Test Card. Isolates may be tested from primary isolation media such as Blood Agar (Cat. no. A10), Chocolate Agar (Cat. no. E14) or may be subcultured onto Sabouraud Dextrose Agar (Cat. no. W70) incubated at room temperature before being tested.

1. Moisten both Circle A and Circle B with one drop of deionized water. **Do not oversaturate the test area.**
2. Using a sterile loop or applicator stick, remove a heavy, visible paste of yeast cells (2-3 yeast colonies), and smear the paste onto Circle A. Repeat this step for Circle B.
3. Incubate the test card for 5 minutes at room temperature (15-30°C.).
4. After incubation, add **one drop** of Reagent B to Circle B. The development of a blue-purple color within 30 seconds (usually immediately) is a positive test for PRO hydrolysis. If no color develops, the test is negative.
5. Add **one drop** of Reagent A to Circle A. After 30 seconds, examine Circle A under long-wave UV light (366nm). A bright, blue-white fluorescence is a positive test for the hydrolysis of NAG. If no fluorescence is present, the test is negative.

## INTERPRETATION OF RESULTS

A positive test for NAG hydrolysis (Circle A) is the appearance of a blue-white fluorescence. No fluorescence is a negative NAG test.

A positive test for PRO hydrolysis (Circle B) is the appearance of a blue-purple color. No change in color is a negative PRO test.

A positive reaction in **both** circles is a presumptive identification of *Candida albicans*. Other yeast species will yield negative reactions in one or both circles.

## LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification of bacteria and/or fungi.

If the culture is mixed, either with other bacteria or with other yeasts, the test will not give reliable results.

If the yeast culture used is less than 24 hours old or if a small inoculum is used, false results may occur.

The AlbiQuick™ test provides only a presumptive identification of *Candida albicans*. Other serological and biochemical tests may be performed for a complete identification. Consult listed references for more information.<sup>(1,5)</sup>

Some strains of *Candida parapsilosis* may be positive for both NAG and PRO hydrolysis.

Refer to the document "[Limitations of Procedures and Warranty](#)" for more information.

## MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, long-wave UV lamp, other culture media, microscopes, incinerators, incubators, etc., as well as other biochemical and serological reagents, are not provided.

## QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
<i>Candida albicans</i> ATCC® 10231	G	5 min	15-30°C	Aerobic	<b>NAG Hydrolysis</b> (Circle A) positive: blue-white fluorescence under UV light <b>PRO Hydrolysis</b> (Circle B) positive: blue-purple color change
<i>Candida krusei</i> ATCC® 14243	G	5 min	15-30°C	Aerobic	<b>NAG Hydrolysis</b> (Circle A) negative: no fluorescence under UV light <b>PRO Hydrolysis</b> (Circle B) negative: no color change

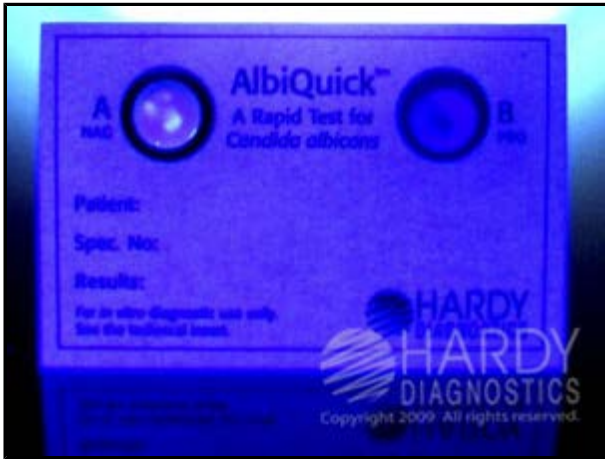
\* Refer to the document "[Inoculation Procedures for Media QC](#)" for more information.

## USER QUALITY CONTROL

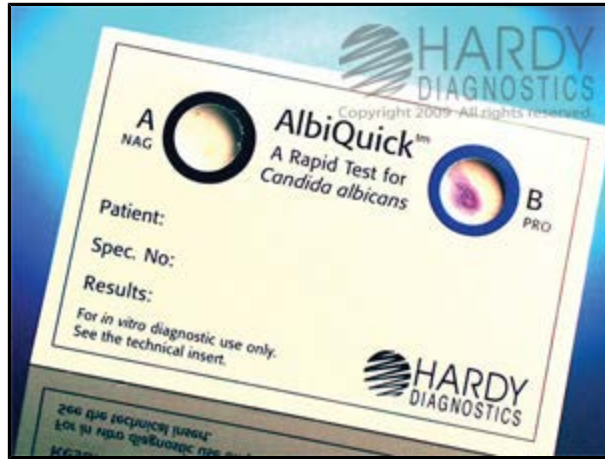
End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificate of analysis (CofA) available from Hardy Diagnostics [Certificate of Analysis](#) website. Also refer to the document "[Finished Product Quality Control Procedures](#)," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

## PHYSICAL APPEARANCE

- The two circles on the AlbiQuick™ Test Card should appear slightly off-white in color.
- Reagent A should be clear, and blue in color.
- Reagent B should appear clear, and straw-yellow to light pink in color.



*Candida albicans* (ATCC® 10231) smear showing NAG hydrolysis on AlbiQuick™ Test Card (Cat no. Z121) shown under UV light. Incubated aerobically for 5 minutes at room temperature.



*Candida albicans* (ATCC® 10231) smear showing PRO hydrolysis on AlbiQuick™ Test Card (Cat no. Z121) shown under ambient light. Incubated aerobically for 5 minutes at room temperature.

## REFERENCES

1. Anderson, N.L., et al. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory*, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.
2. Versalovic, J., et al. *Manual of Clinical Microbiology*. American Society for Microbiology, Washington, D.C.
3. Tille, P.M., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.
4. Dealler, S.F. *J. Clin. Microbiology*; 29:1081-1082.
5. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.
6. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology*. J.B. Lippincott Company, Philadelphia, PA.
7. Perry, J.L., et al. *J. Clin. Microbiology*; 25:2424-2425.
8. Smitka, C.M., et al. *J. Clinical Microbiology*; 27:203-206.

ATCC is a registered trademark of the American Type Culture Collection.

IFU-10018[A]



1430 West McCoy Lane, Santa Maria, CA 93455, USA

Phone: (805) 346-2766 ext. 5658

Fax: (805) 346-2760

Website: [HardyDiagnostics.com](http://HardyDiagnostics.com)

Email: [TechnicalServices@HardyDiagnostics.com](mailto:TechnicalServices@HardyDiagnostics.com)

[Ordering Information](#)

Distribution Centers:

California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

Copyright© 2020 by Hardy Diagnostics. All rights reserved.

HDQA 2207F [D]