IFU

Instructions for Use

GLABRATAQUICK™ KIT

Cat. no. Z298	GlabrataQuick™ Kit	24 tests/kit
	Each kit contains:	
	8-Well Reaction Strips	24 strips
	Color Reaction Reader	1 reader
	Inoculation Buffer, 1ml	24 tubes

INTENDED USE

Hardy Diagnostics GlabrataQuick™ Kit is a rapid test for the identification of *Candida* (*Torulopsis*) *glabrata* . GlabrataQuick™ Kit uses acid production from three carbohydrates to identify *Candida* (*Torulopsis*) *glabrata* in one to two hours.

SUMMARY

In clinical laboratories, *Candida albicans* is the most frequently isolated species as the cause of disease. However, the need to screen for *Candida glabrata* has risen in importance as it has been isolated as the cause of major infections, particularly in immunosuppressed patients. Increasing resistance to fluconazole is common. Apart from multifocal, disseminated disease, it is often recovered from urine specimens and has been estimated to account for as many as 21% of urinary yeast isolates.

Hardy Diagnostics GlabrataQuick™ Kit is a rapid test method for the identification of *C. glabrata* on the basis of rapid trehalose assimilation at 35ºC.

Rapid Trehalose Medium is derived from the formula described by Stockman and Roberts.[6] It utilizes yeast nitrogen base as a source of nitrogenous compounds. The yeast nitrogen base is low in other carbohydrates that might interfere with the rapid test. Bromcresol green is the indicator, allowing the visualization of an acid shift that is indicative of a positive reaction. Trehalose is incorporated into the medium at a high concentration as the carbon source. This product is best used in conjunction with HardyCHROM™ Candida (Cat. no. G301). On this medium, *C. glabrata* will appear as smooth pink colonies, often with a darker pink or mauve center, and should be confirmed with the trehalose test.

The GlabrataQuick™ Kit reduces the time required to determine acid production to one to two hours. *C. glabrata* will be positive in the trehalose wells and negative in the maltose and sucrose wells. Rare strains of *C. albicans* , *C. parapsilosis* , *C. guilliermondii* , *C. lusitaniae* , *C. tropicalis* , *C. krusei* and *Saccharomyces cerevisiae* that might produce a positive reaction in trehalose wells will also produce a positive reaction in maltose or sucrose wells.

FORMULA

Ingredients per liter of deionized water:*

GlabrataQuick™ Medium Base (well A)	
Yeast Nitrogen Base	13.4gm
Bromcresol Green	0.8gm
In addition, the following wells are supplemented with a specific carbohydrate:	

Trehalose (wells in row C) Maltose (wells in row D) Sucrose (wells in row E)

GlabrataQuick™ Inoculation Buffer, 1ml	
pH Buffers	13.6gm

Final pH 5.4 +/- 0.1 at 25ºC.

* Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8ºC. away from direct light. The kit should not be used if there is any discoloration or if the expiration date has passed. Do not use if desiccant is missing or if lids have been removed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and 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

Specimen Collection: This product is not intended for the primary isolation of patient specimens. This product is intended to be used to identify cultures of isolated organisms.

The appropriate organisms for performing the GlabrataQuick™ test are non-capsulated yeast, germ tube negative or smooth pink colonies often with a darker pink center that have been isolated on the HardyCHROM™ Candida plates (Cat. no. G301).

Method of use:

1. Remove caps from the test well strips to be used and leave the strips in the base. Unused well strips should be removed from the base and stored in the bag (with caps on) until needed.

2. Obtain isolated colonies that are 24-48 hours old, preferably from HardyCHROM™ Candida (Cat. no. G301). Prepare a very heavy suspension using the Inoculation Buffer tubes provided. Vortex suspension for 30 seconds. If

multiple specimens are processed at the same time, make sure to vortex again before inoculating the wells, to prevent settling of the yeast cells. A low density inoculum may result in false-negative reactions.

3. Aseptically transfer approximately 0.1ml (or four to five drops from a transfer pipet) of the suspension into wells A, C, D, and E of the strip so that the wells are half full. **Do not add any suspension to the second (B) or sixth (F) wells.** These wells are intentionally left empty. Do not remove the test well strips from the base holder.

4. Incubate well strips uncovered at 35ºC. aerobically. Do not incubate in a CO_2 atmosphere. The carbohydrate wells (rows A, C, D and E) may be read after one hour. A final reading may be done at two hours. See "Limitations" below.

5. Place the tray with the wells on the "Color Reaction Reader" card, included with the kit, to record the results.

INTERPRETATION OF RESULTS

A change of color from blue or blue-green to yellow or greenish-yellow is considered positive for the carbohydrate wells (rows C, D and E). Well A is used as a reference and should remain negative (blue or blue-green) throughout incubation, since it contains no carbohydrate. Final results must be read no later than three hours after incubation is started.
Note: Color changes in the carbohydrate wells that take place after three hours of incubation time should be disregarded.

Organism	**Negative Control (well A)**	**Trehalose (well C)**	**Maltose (well D)**	**Sucrose (well E)**
C. glabrata	- blue / blue-green	+ yellow / greenish-yellow	- blue / blue-green / green	- blue / blue-green / green
Non- *C. glabrata*	- blue / blue-green		if yellow to greenish-yellow in well D or E then isolate is not *C. glabrata* regardless of trehalose reaction	

* Some strain to strain variation may occur, and isolates may require more biochemical and/or serological tests for complete identification. Refer to the listed references for more information regarding the identification and differentiation of *Candida* species.

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.

This medium is intended to be used an identification method for *C. glabrata* . Other biochemical and/or serological tests may be required for complete identification of this organism.

It is recommended to report final results at two hours. If the inoculation time inadvertently extends beyond two hours the results are still valid. The test must be repeated if the incubation time extends beyond three hours.

A very heavy inoculum must be used. Wells that are inoculated too lightly may give false-negative reactions.

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, swabs, applicator sticks, other culture media, incinerators, and incubators, etc., as well as serological and biochemical 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	Well	Incubation			Results
		Time	Temperature	Atmosphere	
Candida glabrata ATCC® 66032	Control Trehalose Maltose Sucrose	2hr	35°C	Aerobic	Blue/blue-green Positive, yellow/greenish-yellow Negative, blue/blue-green/green Negative, blue/blue-green/green
Saccharomyces cerevisiae ATCC® 9763	Control Trehalose Maltose Sucrose	2hr	35°C	Aerobic	Blue/blue-green Negative, blue/blue-green Negative, blue/blue-green Positive, yellow/greenish-yellow

* 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

- Un-inoculated strips: Dehydrated wells A, C, D, and E should appear dark yellow (wells will be blue or blue-green upon inoculation).
- Wells B, F, G, and H should be empty.

- Inoculation Buffer should appear clear and colorless.

GlabrataQuick™ Kit (Cat. no. Z298). *Candida glabrata* wil be positive for trehalose and negative for both the maltose and sucrose wells.

Showing Non- *C. glabrata* results for the GlabrataQuick™ Kit (Cat. no. Z298). If the maltose and/or sucrose well(s) is positive then the isolate is not *Candida glabrata* , regardless of the trehalose reaction.

REFERENCES

Showing all results for the GlabrataQuick™ Kit (Cat. no. Z298).

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

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

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