



# CRYPTOCOCCAL ANTIGEN LATERAL FLOW ASSAY

*“First and only test of its kind”*

**FDA** 510(K) - CLEARED

QUALITATIVE OR SEMI-QUANTITATIVE DETECTION

NO SPECIMEN PRETREATMENT

MOST SENSITIVE ASSAY ON THE MARKET





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# RESULTS IN 10 MINUTES

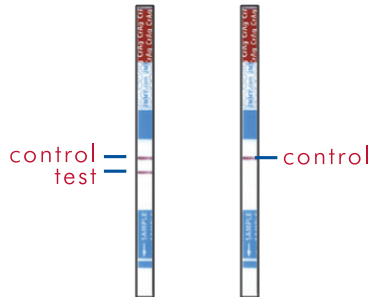
## 5 Easy Steps

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**1** add 1 drop of specimen diluent
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**2** add 40  $\mu$ l of specimen
- 

**3** insert strip
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**4** incubate 10 minutes
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**5** 1 line = negative  
2 lines = positive

*“The LFA has several advantages over the LA [latex agglutination] CrAg assay...”*



– World Health Organization, December 2011, *Rapid advice: Diagnosis, prevention, and management of cryptococcal disease in HIV-infected adults, adolescents, and children.*

# HIGH VOLUME CAPABILITIES

« 30 specimens tested in 15 minutes »

## CrAg LFA vs. Culture/India Ink

### Serum

CrAg LFA	Culture/India Ink		Sensitivity	Calculated	95% CI
	Positive	Negative			
Positive	91	0	100%	100%	96.0 – 100%
Negative	0	123	Specificity	100%	97.0 – 100%

### CSF

CrAg LFA	Culture/India Ink		Sensitivity	Calculated	95% CI
	Positive	Negative			
Positive	65	1	100%	98.7%	94.4 – 100%
Negative	0	77	Specificity	98.7%	93.1 – 99.8%



## LATEX AGGLUTINATION

## ENZYME IMMUNOASSAY

**SENSITIVITY: 96–100%**  
**SPECIFICITY: 98–100%**  
**(1)**

Sensitivity: 91–100%  
Specificity: 83–100%  
**(2)**

Sensitivity: 93–100%  
Specificity: 93–100%  
**(3)**

**10 MINUTES TO RESULTS**

Up to 60 minutes to results

Up to 60 minutes to results

**OBJECTIVE RESULTS:**  
**1 LINE = NEGATIVE**  
**2 LINES = POSITIVE**

Subjective results:  
1+, 2+, 3+, or 4+

Objective results

**NO PRONASE  
TREATMENT REQUIRED**

Pronase treatment  
required for serum

No pronase  
treatment required



1) Jarvis 2011, Lindsley 2011, Govender, Harrison, Boulware 2011, IMMY 2010, and IMMY 2011; Settings: South Africa, Uganda, USA, and Thailand

(2) Chuck 1989, Calvo 1991, Swinne 1992, Rozenbaum 1994, Tanner 1994, Bogaerts 1999, Chen 2000, Antinori 2001, Likasitwatanakul 2004, Wadhwa 2008, Saha 2009, Desmet 1989, Nelson 1990, Asawavichienjinda 1999, Batungwanayo 1994, Lin 2009, Sekhon 1993, Swinne 1992, Warren 1992, Batungwanayo 2002, French 2002, Frank 1993, Gade 1992, Knight 1992, IMMY 2010, and IMMY 2011; Settings: Australia, Brazil, Canada, India, Italy, Rwanda, Thailand, USA, Zaire, UK, Uganda, and Taiwan

(3) Saha 2009, Tanner 1994, Gade 1991, Frank 1993, Jarvis 2011, Knight 1992, IMMY 2010, IMMY 2011, and Lindsley 2011; Settings: USA, UK, Thailand, and South Africa









# SAVING LIVES

ONE DIAGNOSTIC AT A TIME



ev. 2/29/12

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