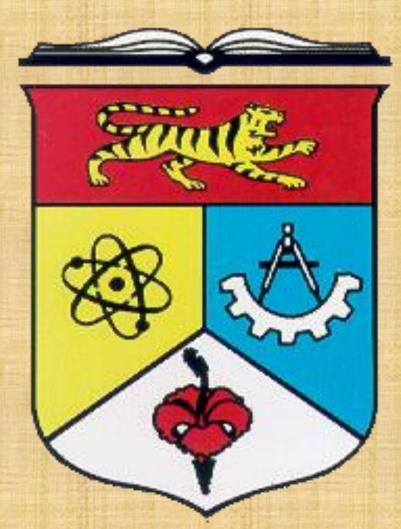


Evaluation of the Dynamiker Cryptococcal Antigen Lateral Flow Assay in detecting the capsular polysaccharide antigen of *Cryptococcus* species

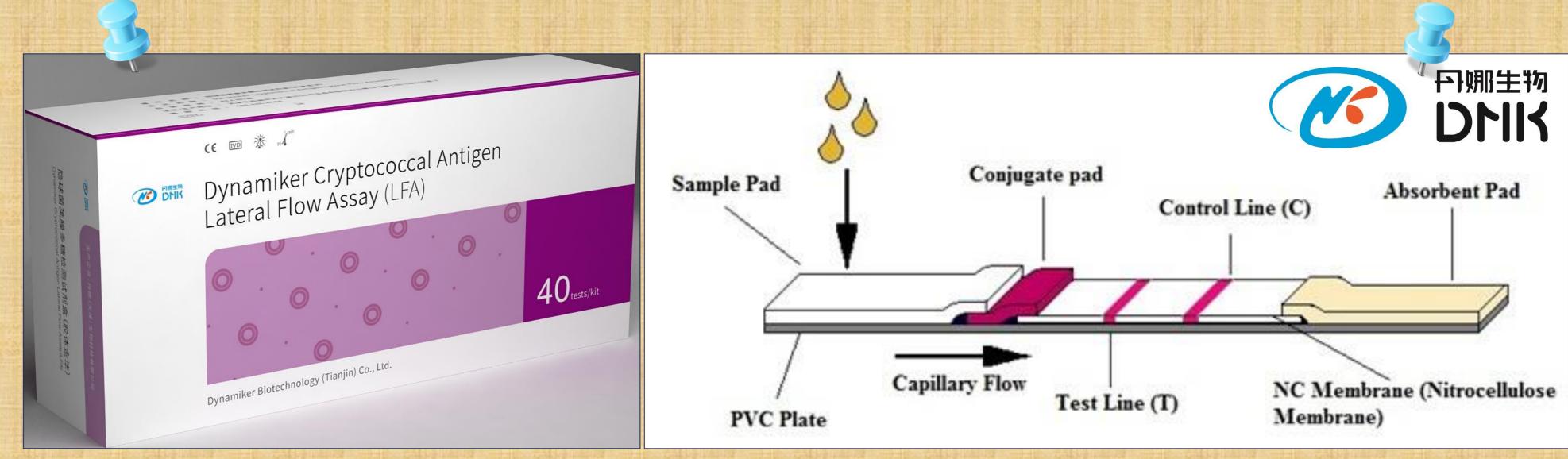
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### **INTRODUCTION**

Worldwide, approximately 957,900 cases of cryptococcal meningitis occur annually, and in South and Southeast Asia alone, the annual case estimation is 120,000 cases (Park et al.



detection The non-molecular 2009). of cryptococci can be achieved through direct microscopy for encapsulated yeast cells, culture artificial media, and/or detection of on glucuronoxylomannan (GXM) antigen. Direct microscopy and culture are specific but suffer from low sensitivity (50-80%), and culture has added disadvantage of being timethe consuming (Saha et al. 2009). Thus, GXM antigen detection is an important alternative and several commercial kits are available.

The Dynamiker Cryptococcal Antigen Lateral Flow Assay (CrAg LFA) by Dynamiker Biotechnology (Tianjin) Co., Ltd., China, is a relatively new dipstick sandwich immunoA total number of **34** samples which had already been tested using an established commercial GXM kit (IMMY Cryptococal Antigen Lateral Flow Assay, Immuno-Mycologics, Inc., USA) were retested using the Dynamiker kit, as per the manufacturer's instructions.

#### RESULTS

Interpretation of test results were made by following the manufacturer's instructions. By using the IMMY kit's results to determine the specimens which were truly positive and truly negative, the Dynamiker kit's sensitivity and

		Dynamiker CrAg LFA		
		Positive	Negative	Total
MMY CrAg LFA reference)	Positive	15 (TP)	0 (FN)	15
	Negative	2 (FP)	17 (TN)	19
	Total	17	17	34

Number of true positive (TP), true negative (TN), false positive (FP) and false negative (FN) results

As shown above, using the IMMY kit's results as reference, all 15/15 positive samples were also positive with the Dynamiker kit and 17/19 negative specimens also tested negative using the Dynamiker kit. Thus, the sensitivity of the Dynamiker kit was 100% and its specificity was 89.5%. The kappa statistic was 0.882 (strong

chromatographic assay for the detection of the capsular polysaccharide antigens of *Cryptococcus* species complex in serum and cerebral spinal fluid (CSF) specimens. The advent of various CrAg LFA kits has empowered health care providers in all clinical settings with rapid, reliable, and robust diagnostic results.

# **MATERIALS & METHODS**

This was a method evaluation study on archived serum (stored at -80°C) and archived CSF samples (stored between 2 and 8°C) from patients with suspected or confirmed cryptococcosis admitted to UKM Medical Centre.

specificity values were calculated using the

standard formulae.

Type of	Dynamiker CrAg LFA	IMMY CrAg LFA
Sample	result	result
Serum	+ve	+ve
Serum	( <mark>+ve</mark>	-ve
Serum	+ve	-ve
Serum	-ve	-ve
Serum	-ve	-ve
Serum	-ve	-ve
CSF	+ve	+ve
CSF	+ve	+ve
CSF	-ve	-ve

agreement).

#### CONCLUSION

The Dynamiker CrAg LFA kit performed satisfactorily and may be considered for routine diagnostic use by medical mycology laboratories to detect the capsular polysaccharide antigen of *Cryptococcus* species.

# ACKNOWLEDGEMENT

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for sponsoring the Dynamiker CrAg LFA kits.

Archived quality assurance serum specimens received as part of the Royal College of Pathologists of Australasia's (RCPA) Quality Assurance Programme and archived sera from the inter-laboratory comparison exercise with the Institute of Medical Research (IMR), Malaysia were also be included in the study.



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