00570

Dynamiker® cryptococcal antigen ELISA, CLIA and LFA test kits for the diagnosis of cryptococcal infection: an update

06. Fungal infection & disease

6b. Diagnostic mycology (incl molecular)

Chun Long Liu [1, 2], Jie Peng [1, 2], Jun Yang Du [1, 2], Yuan Zhang [1, 2], Ze Qi Zhou [1, 2], He Wang [1, 2]

[1]Dynamiker Sub-Center of Beijing Key Laboratory for Mechanisms Research and Precision Diagnosis of Invasive Fungal Disease - Tianjin (China), [2]Tianjin Enterprise Key Laboratory for precision diagnosis technology of invasive fungal diseases - Tianjin (China)

Background Cryptococcosis is a global invasive fungal disease associated with significant morbidity and mortality in both immunocompromised and immunocompetent hosts. Rapid diagnosis and effective combination therapy for cryptococcosis is crucial for improving patient outcomes. Cryptococcal glucuronoxylomannan (GXM) antigen test in CSF or blood are included in the 2019 revised EORTC/MSG consensus criteria for proven cryptococcosis.At present, the approved GXM antigen detection kits mainly include enzyme linked immunosorbent assay (ELISA), chemiluminescence immunoassay (CLIA) and lateral flow assay (LFA). The ELISA shows high sensitivity and specificity but with complicated and time-consuming operation (turn-around time 1-1.5 h). The CLIA based on an automatic chemiluminescence analyzer shows high precision, accuracy and wide linearity, which suitable for high-throughput and semi-quantitative detection (turn-around time 30 min). Compared with ELISA and CLIA, LFA is easy to operate and doesn't require large instruments, which is the low-cost, simple, rapid (turn-around time 15 min) and portable detection devices, can be widely accepted by primary medical. The above detection kits were all matched with the corresponding automatic detector (Fig 1). We conducted a comparative study of GXM antigen detection kits (ELISA, CLIA and LFA) from the same manufacturer (Dynamiker Biotechnology (Tianjin) Co., Ltd.).

Methods A total of 33 patients (19 serum and 14 CSF samples) with proven cryptococcal infection were collected. All the samples were tested by antigen kits based on ELISA, CLIA and LFA provided by Dynamiker Biotechnology (Tianjin) Co., Ltd. Moreover, the concentration of antigen in 6 patients during anti-fungal treatment were dynamically monitored by the antigen detection based on ELISA.

Results The results demonstrated that the sensitivity of the three Cryptococcal antigen detection kits based on ELISA, CLIA, LFA were all 100.00% in serum samples, 100.00%, 92.86%, and 100.00%, respectively in CSF samples (Table1). Meanwhile, Cryptococcal antigen titer slowly decreased with successful therapy in 6 patients monitored by the ELISA kits (Fig 2).

Conclusions Three Cryptococcal GXM antigen detection kits based on ELISA, CLIA and LFA all have great clinical value for the diagnosis of Cryptococcosis. GXM antigen concentration of serum and CSF is associated with patient's condition, which is of great significance for monitoring disease progression in patients.

Figure 1

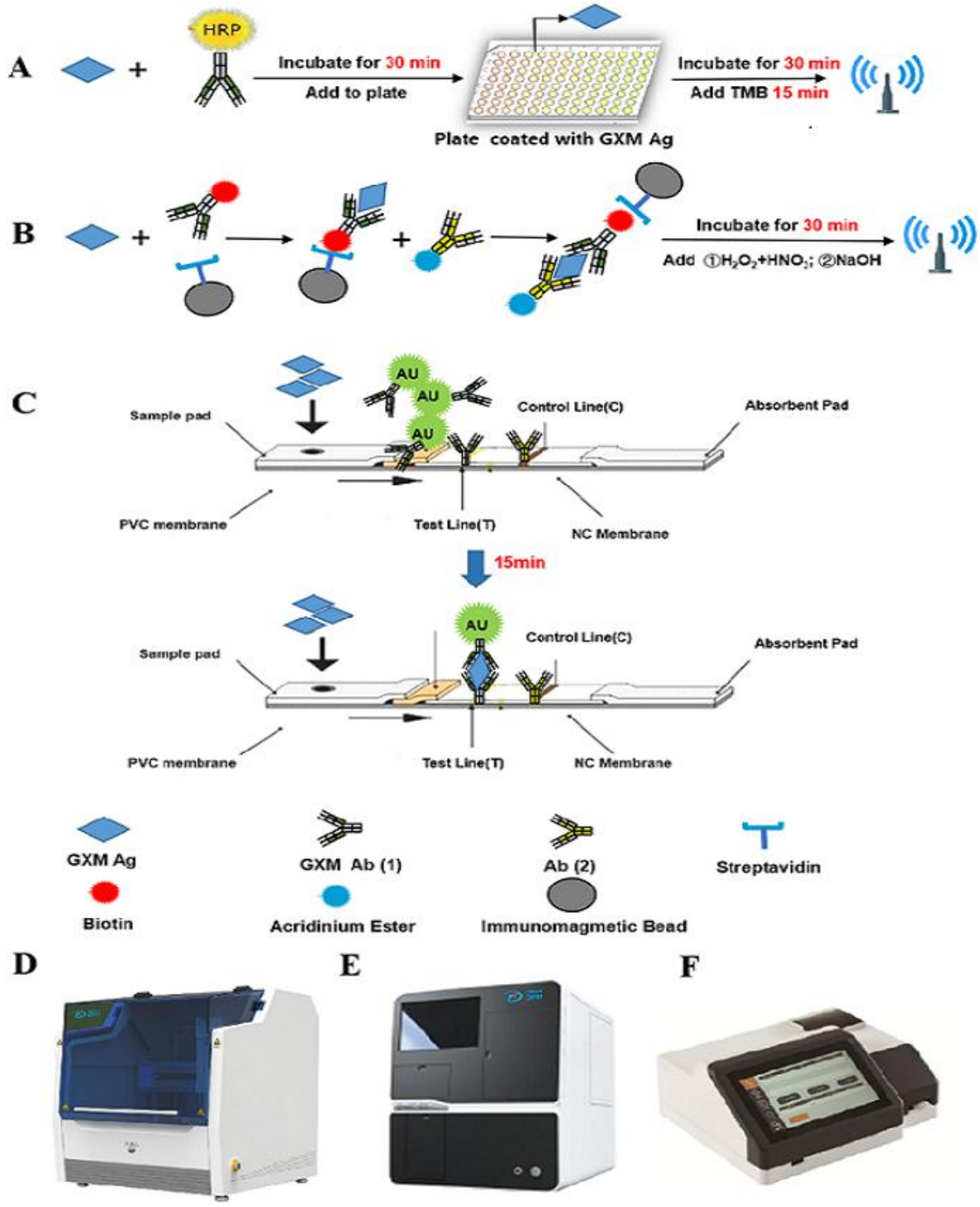

Figure 1 Schematic of the ELISA (A), Schematic of the CLIA (B), Schematic of the LFA (C), The automatic microbiology analyzer DNK-A200 matched with ELISA (D), The automatic chemiluminescence analyzer Smart-500S matched with CLIA (E), The fluorescent immunoanalyzer AFS-1000 matched with LFA (F).

Table 1

Sample(n)	Sensitivity %		
	ELISA	CLIA	LFA
serum(19)	100.00%(19/19)	100.00%(19/19)	100.00%(19/19)
CSF(14)	100.00%(14/14)	92.86%(13/14)	100.00%(14/14)

Figure 2

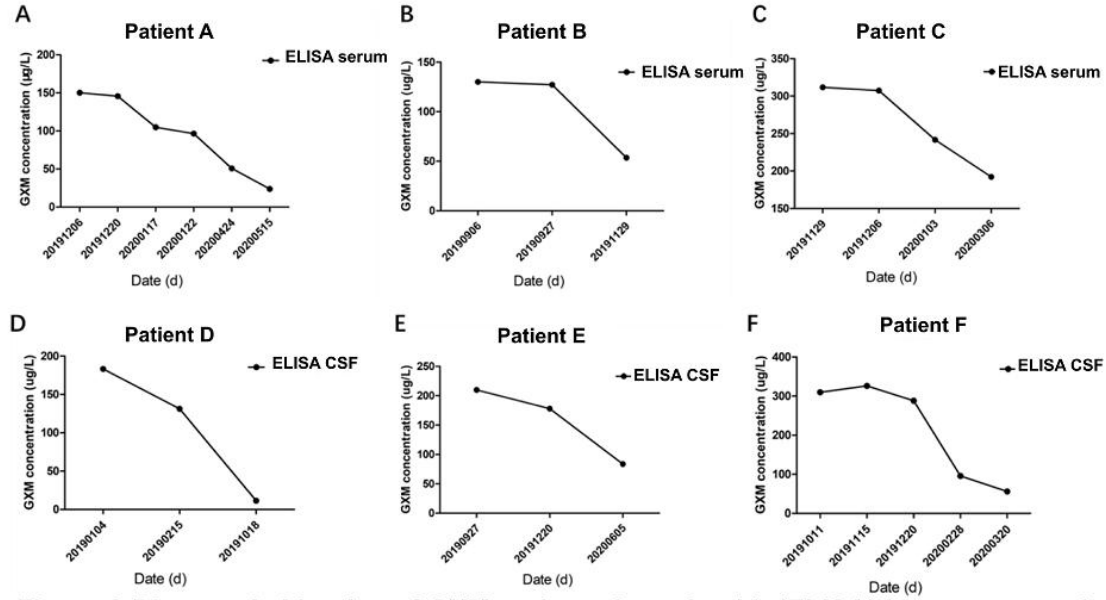

Figure 2 Diagnostic kinetics of GXM antigen detection kit (ELISA) in serum samples of 3 patients (A-C); Diagnostic kinetics of GXM antigen detection kit (ELISA) in CSF samples of 3 patients (D-F).

Keyword 1
Cryptococcosis
Keyword 2
Cryptococcal antigen
Keyword 3
ELISA CLIA and LFA

Conflicts of interest

Do you have any conflicts of interest to declare?
I have no potential conflict of interest to report