Performance of the GenMark ePlex blood culture identification fungal pathogen panel (ePlex BCID-FP): a prospective French bicentric evaluation using clinical samples

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Introduction - Purpose

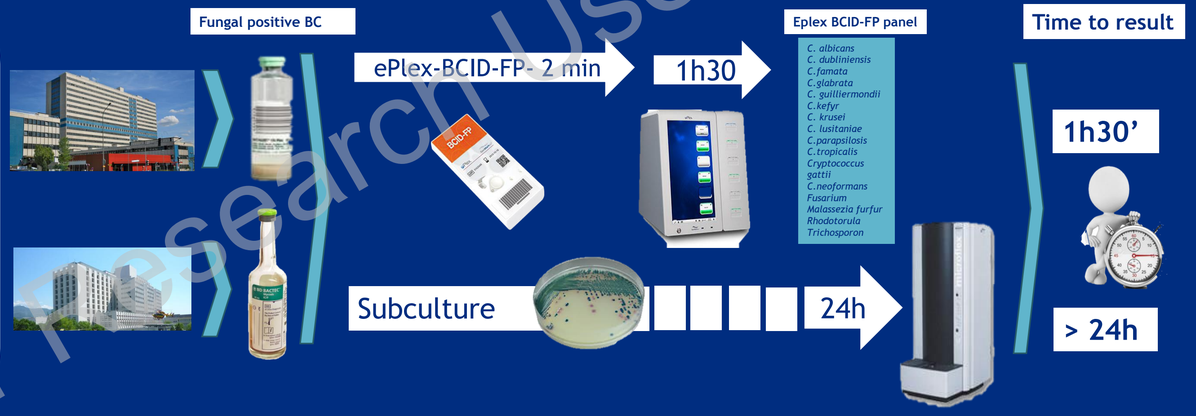
Fungemia presents high morbi-mortality and **rapid microbiological identification contributes to adapt quickly antifungal therapy.**

Among kits based on molecular technologies, the ePlex blood culture identification fungal pathogen panel (**ePlex BCID-FP, GenMark Dx)** is a fully automated easy-to-use cartridge designed to detect **16 fungal targets** including common and emerging ones, from positive blood culture (BC).

This study aimed to prospectively evaluate the performances of this recently CE-IVD marked test, using clinical BC samples.

Methods

- ✓ Sixty-one tests were achieved prospectively over a 11-month period, on **56 fungal positive BC** from 54 patients hospitalized in two University hospitals (Henri Mondor and Grenoble-Alpes University hospitals, France).
- ✓ The Bactec Plus Aerobic/F, Anaerobic/ F and Mycosis IC/F bottles (BD Diagnostics) and BacT/ALERT bottles 3D (Biomérieux), were incubated in their respective automated systems.
- ✓ Once detected positive for fungi, the BC underwent classical subculture step and MALDI-TOF-MS identification (time to identification 24h).
- ✓ In parallel to this conventional procedure, **ePlex BCID-FP** (RUO cartridges) were tested (hands-on-time <5 min and time-to-result: 1.5h).



Results

- Among the 52 valid results, 48 results were fully concordant with classical identification process (92.3%).
- Discrepancies were due to the presence of species absent from the BCID-FP panel (1 *C. nivariensis*, 1 *C. metapsilosis*, 1 *C. orthopsilosis*, 1 *C. inconspicua*).
- BCID-FP evidenced three mixed infection among these, two were missed with classical identification procedure (*C. glabrata*/*C. krusei* and *C. nivariensis* (off panel)/*C. parapsilosis*).
- A disseminated fusariosis was correctly detected by the BCID-FP (*Fusarium* sp).
- Internal control was invalid in 5 blood cultures (8.9%) which needed to be tested again (possibly due to the use of RUO cartridges)

Final species identification	Blood culture (n)	Tests	Valid RESULT	Concordance of valid tests with classical identification	Specific comment
C. albicans	12	12	11	100%	Invalid BC not retested
C. glabrata	11	13	9	100%	Accurate detection of one co-infection with *C. krusei* Two BC re-tested
C. parapsilosis	12	12	12	100%	Accurate detection of co-infection with *C. lusitaniae*
C. tropicalis	4	5	4	100%	One BC re-tested
C. krusei	3	4	3	100%	Accurate detection of one co-infection with *C. glabrata* One BC re-tested
C. kefyr	4	5	4	100%	One BC re-tested
C. dubliniensis	1	1	1	100%	
C. guilliermondii	2	2	2	100%	
C. lusitaniae	1	1	1	100%	Correct detection of co-infection with *C. parapsilosis*
C. orthopsilosis	2	2	1	0%	Off panel
C. nivariensis	1	1	1	0%	Off panel
Fusarium sp	1	1	1	100%	*Fusarium solani*
C. inconspicua	1	1	1	0%	Off panel
C. metapsilosis	1	1	1	0%	Off panel
Total	56	61	52 (93%)	92.3%	

Conclusion

- This is the first prospective evaluation of the ePlex BCID-FP on clinical samples.
- ePlex BCID-FP accurately identified more than 92% of the fungal species from positive blood culture in this everyday situation.
- Focusing on targets which are actually present in the panel, 100% of correct identification was achieved.
- The test allowed identifications of mixed fungal infections and disseminated fusariosis
- A prospective clinical study evaluating the time-to-result benefit on antifungal stewardship and on hospital length of stay is ongoing.