Molecular carbapenemase tests Eazyplex SuperBug Complete B, Novodiag CarbaR+, and Amplidiag CarbaR+MCR, provide high sensitivity in the detection of carbapenemase-positive bacteria

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Introduction

- Carbapenemase-producing *Enterobacteriaceae* (CPE), MDR *Pseudomonas aeruginosa*, and MDR *Acinetobacter*: rapid screening needed
- The new regulations by the European Union regarding in vitro diagnostic medical devices → replacement of in-house methods with commercial tests
- Aim: to compare three CE-IVD marked carbapenemase tests:
  - Eazyplex SuperBug Complete B (Amplex Diagnostics)
  - Novodiag CarbaR+ (Mobidiag)
  - Amplidiag CarbaR+MCR (Mobidiag)

Materials and methods

- Workflow and the basic characteristics of the tests: see Fig. 1
- Material (Table 1):
  - Clinical bacterial isolates (n=32) and quality control strains (n=5)
  - Clinical samples (n=34), mostly from rectum, urine, or wounds
  - Some strains/samples included several target genes
- Methods:
  - One colony
    - in RALF for Eazyplex
    - in eNAT (Copan) for Novodiag and Amplidiag
  - Clinical swabs or 300 µl of liquid samples in eSwab (Copan)
    - as such for Eazyplex
    - 200 µl into an eNAT for Novodiag and Amplidiag
  - Comparison to traditional culture:
    - mSuperCARBA (CHROMagar) plate overnight
    - ID with MALDI-TOF MS (bioMérieux)
    - in-house carbapenemase PCR (Pasanen et al., 2014)

Figure 1. Workflow chart

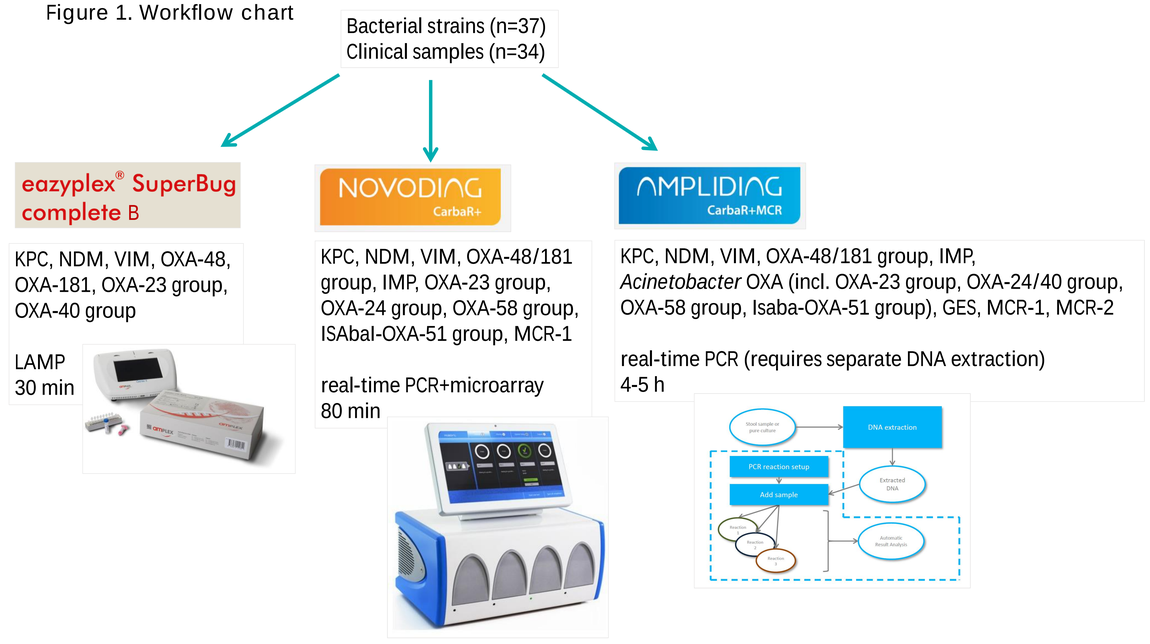

Table 1. Bacterial strains and samples

Target genes	Clinical bacterial isolates (n=32)	Quality control strains (n=5)	Clinical samples (n=34)
KPC	4	0	6
NDM	3	1	7
IMP	2	1	0
VIM	2	1	0
OXA-48/181	6	2	10
MCR	0	1	0
GES	1	0	0
OXA-23	2	0	1
OXA-58	2	0	0
OXA-24/40	0	0	1
OXA-51	0	0	0
NEG	12	0	10

Some strains/samples had several target genes.

Results

- Results: see Table 2
- High sensitivity: 100% with isolates and samples
- Specificity: 100% with strains
- Lower specificity (60%) with clinical samples (directly without culturing) can be explained by the higher sensitivity of these methods compared with the culture:
  - 6/7 of false positive samples were from patients who had matching strains and genes in other samples
  - The only "real" false positive was OXA-40 which was only detected with Eazyplex SuperBug Complete B, and the matching strain/gene could not be identified in other samples of the same patient

Table 2. Results

		eazyplex® SuperBug complete B	NOVODIAG CarbaR+	AMPLIDIAG CarbaR+MCR
Bacterial isolates	Sensitivity	100%	100%	100%
	Specificity	100%	100%	100%
	True POS	21	28	27
	True NEG	18	13	12
	False POS	0	0	0
	False NEG	0	0	0
Clinical samples	Sensitivity	100%	100%	100%
	Specificity	59%	63%	63%
	True POS	25	25	25
	True NEG	10	10	10
	False POS	7	6	6
	False NEG	0	0	0

Conclusions

- Sensitivity: 100% (isolates and samples)
- Specificity: 100% (isolates)
  ca. 60% (samples): this can be explained by the superiority of molecular methods to our reference culture method
- All three commercial CPE tests were easy-to-use and reliable methods for the detection of carbapenemase genes from bacterial colonies and clinical samples

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Disclosures

The authors have no conflict of interest.

References

Pasanen T, Koskela S, Mero S, Tarkka E, Tissari P, Vaara M, Kirveskari J. PLoS One. 2014;9(1):e85854. doi: 10.1371/journal.pone.0085854. Rapid molecular characterization of Acinetobacter baumannii clones with rep-PCR and evaluation of carbapenemase genes by new multiplex PCR in Hospital District of Helsinki and Uusimaa.