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**Multicenter evaluation of the BYG Carba test v2.0, a simplified electrochemical assay for the rapid laboratory detection of carbapenemase-producing Enterobacteriaceae**

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**Background:** Accurate, timely detection of carbapenemase-producing *Enterobacteriaceae* (CPE) is a major challenge for microbiology laboratories. The BYG Carba test v2.0 is an electrochemical carbapenemase detection technique based on an electro-active polymer biosensor. It detects CPE in less than 30 minutes from a direct deposit of 1 to 3 single bacterial colonies on the electrodes without preliminary suspension in any buffer. BYG v2.0 was assessed in a multicentre study in four European reference laboratories (Centres A to D).

**Material/methods:** Firstly, in centre A the BYG Carba test v2.0 was compared with the BYG v1.0 against a collection of 57 isolates for which  $\beta$ -lactam resistance mechanisms had been previously characterized. The test was then evaluated in the four reference centres against a collective total of 1181 isolates (408, 198, 376, and 199 tested in centres A, B, C and D, respectively gathering 511 retrospective isolates and 670 prospective isolates referred in 2015 on suspicion of CPE). These comprised CPE [n=704] with OXA-48-like [n=359], KPC [n=114], NDM [n=107], VIM [n=78], IMP [n=17], NDM + OXA-48-like [n=14] and other less common carbapenemases [n=15] as well as non-CPE [n=477]. Results obtained by the BYG v2.0 were compared with those of in-house PCR/sequencing assays, which were taken as the gold standard.

**Results:** For the initial 57 isolates, the BYG v2.0 showed a significant improvement in the positivity signal strength (in arbitrary units, AU) compared with BYG v1.0 (Mean value 97.8 AU vs 44.0 AU,  $p < 0.00001$ ) with accuracy remaining unchanged on this collection. For the 1181 isolates tested across four reference centres, BYG v2.0 yielded overall sensitivity of 96.3 % and specificity of 99.8 %. Compared with molecular results, 26 false-negative results were observed (OXA-48-like [n=10], NDM [n=5], GES-5 [n=4], VIM [n=3], IMP [n=2] and IMI [n=2]) and one false-positive result was reported for one carbapenem-resistant *E. cloacae*. Considering only the 670 isolates tested prospectively, the BYG v2.0 displayed overall positive and negative predictive values of 100% and 98.4% (respectively, 100% and 99.1% in centre A; 100% and 97.5% in centre B; 100% and 97.2% in centre C; and 100% and 98.2% in centre D). No false-positive results were observed, but five OXA-48-like, two VIM and one NDM producer were not detected. Regarding time to positivity, 45% and 85% of CPE detected were positive in 5 and 10 minutes, respectively. Even for OXA-48-like-producers, which are often more difficult to detect phenotypically, 44% were detected within 5 minutes and 89 % within 10 minutes.

**Conclusions:** The BYG v2.0 is a new highly simplified, rapid and efficient assay discriminating between CPE and non CPE in under 30 min. The real-time quantified electrochemical signal allows the objective and traceable interpretation of the results.