KarbaDiag – Selected References

Published Articles and Guidelines

Author(s)	Journal	Year	Title
Jenkins et al.	*J Clin Microbiol.*	*2020*	*Evaluation of NG-Test Carba 5 for Rapid Phenotypic Detection and Differentiation of Five Common Carbapenemase Families: Results of a Multicenter Clinical Evaluation*

Summary:
For the multicenter method comparison study, the overall positive percent agreement (PPA) and the overall negative percent agreement (NPA) of NG-Test Carba 5 with the composite reference method were 100% for both blood and MacConkey agars. The medium comparison study at the fourth site showed that the **PPA ranged from 98.9% to 100% and that the NPA ranged from 95.2% to 100% for blood**, Mac-Conkey, and Mueller-Hinton agars. NG-Test Carba 5 accurately detected and differentiated five common carbapenemase families from Enterobacterales and P. aeruginosa colonies on commonly used agar media. The results of this test will support a streamlined laboratory work flow and will expedite therapeutic and infection control decisions.

Author(s)	Journal	Year	Title
Takissian et al.	*Antimicrob Agents Chemother.*	*2019*	*NG-Test Carba 5 for Rapid Detection of Carbapenemase-Producing Enterobacterales from Positive Blood Cultures*

Summary:
The immunochromatographic assay, has been evaluated for detection of carbapenemase-producing Enterobacterales (CPE) from spiked blood cultures (n=205). It detected and discriminated in less than 30 minutes KPC, IMP, VIM, NDM, and OXA-48-like producers with a **sensitivity and specificity of 97.7% and 96.1%, respectively.** Thus, it might help the rapid optimization of treatment of bloodstream infections due to CPE.

Author(s)	Journal	Year	Title
Hopkins et al.	*J Antimicrob Chemother.*	*2018*	*Evaluation of the NG-Test CARBA 5 multiplex immunochromatographic assay for the detection of KPC, OXA-48-like, NDM, VIM and IMP carbapenemases*

Summary:
When calculating analytical sensitivity and specificity, we considered each NG-Test CARBA 5 assay to be five individual tests, meaning a total of 985 (197 x 5) tests were performed. After the first round of testing, i.e. including the false-positives but ex-cluding the true-negatives due to gene loss, the **overall sensitivity and specificity of the Test were 97.31% (95% CI 93.84%–99.12%) and 99.75% (95% CI 99.12%–99.97%), respectively**.

Author(s)	Journal	Year	Title
Boutal et al.	*J. Clin. Microbiol.*	*2017*	*Development and validation of a lateral flow immunoassay for the rapid detection of NDM-producing Enterobacteriaceae*

Summary:
We evaluated the NDM LFIA using 175 reference enterobacterial isolates with characterized β-lactamase gene content and 74 nonduplicate consecutive carbapenem-resistant clinical isolates referred for expertise to the French National Reference Center (NRC) for Antibiotic Resistance. Overall, the **sensitivity and specificity of the assay were 100%** for NDM-like carbapenemase detection with strains cultured on agar. The NDM LFIA was efficient, rapid, and easy to implement in the routine workflow of a clinical microbiology laboratory for the confirmation of NDM-like carbapenemase-producing Enterobacteriaceae.

Author(s)	Journal	Year	Title
Rösner et al.	*Journal of Medical Microbiology*	*2019*	*Evaluation of a novel immunochromatographic lateral flow assay for rapid detection of OXA-48, NDM, KPC and VIM carbapenemases in multidrug-resistant Enterobacteriaceae*

Summary:
Rapid diagnostic techniques for carbapenemase detection are of the utmost importance to prevent delays in efficient antibiotic therapy and the control of spread in hospitals. Recently, multiplex

immunochromatographic lateral flow tests (ICTs) for the fast detection of carbapenemase-producers have become commercially available. We evaluated a novel multiplex ICT for the rapid detection of OXA-48, KPC, NDM and VIM carbapenemases. One hundred well-characterized multidrug-resistant Enterobacteriaceae were analysed by rapid test. The reference standard included confirmation at the molecular level at the German National Reference Laboratory for multidrug-resistant Gram-negative bacteria (Ruhr-University Bochum, Germany). **The tested ICT was highly reliable, showing 100 % sensitivity and 100 % specificity**

Fauconnier et al.	*J Antimicrob Chemother*	*2019*	*Lateral flow immunochromatographic assay for rapid screening of faecal carriage of carbapenemase-producing Enterobacteriaceae*

Summary:
In this study, we assessed the performance of the Rapid test for the rapid detection of OXA-48, KPC and NDM CPE directly from rectal swab samples. A total of 149 residual rectal swabs, routinely screened for CPE through selective culture and confirmed by PCR, were tested with a defined protocol consisting of a 2.5 h incubation of the swab in an enrichment medium containing meropenem followed by OKN K-SeT testing after centrifugation. This method displayed an **overall sensitivity of 96% and a specificity of 100% with a limit of detection ranging between 10^4 and 10^5 cfu/mL.**

Bodendoerfer et al.	*J. Antimicrobial Chemotherapy*	*2019*	*Rapid identification of NDM-, KPC-, IMP-, VIM- and OXA-48-like carbapenemase-producing Enterobacteriales from blood cultures by a multiplex lateral flow immunoassay*

Summary:
A collection of 158 carbapenem-resistant (meropenem inhibition zone diameter <25mm) CRE, including 31 carbapenemase-negative isolates, 26 Ambler class A producers (KPC), 43 class B producers (29 NDM, 11 VIM and 3 IMP), 57 class D OXA-48-like producers and 1 isolate containing both an NDM and an OXA-48-like enzyme, were used in this evaluation. Rapid test Carba-5 allowed **detection of all 127 CPE (100% sensitivity**) and produced **no band with the 31 carbapenemase-negative isolates (100% specificity).**

Glupczynski et al.	*J. Antimicrobial Chemotherapy*	*2019*	*Evaluation of the RESIST-4 K-SeT assay, a multiplex immunochromatographic assay for the rapid detection of OXA-48-like, KPC, VIM and NDM carbapenemases*

Summary:
The assay was first evaluated using a collection of isolates with well-characterized resistance mechanisms to β-lactams (n = 134) and against an international external quality assessment carbapenemase panel (n = 8). The assay was then challenged prospectively using 345 consecutive, non-duplicate isolates including 279 Enterobacteriaceae and 66 non-fermenters (mostly Pseudomonas spp.). Globally, for the collection of retrospective and prospective clinical isolates (n = 479), the assay showed a **sensitivity ranging from 99% for the detection of VIM to 100% for the detection of OXA-48-like, KPC and NDM** carbapenemase-producing strains. The **specificity was 100%** for each carbapenemase and a perfect match in results was observed for the external quality assessment for the carbapenemases targeted by the assay.

Ratnayake et al.	*J Med Microbiol.*	*2020*	*An optimized algorithm with improved turnaround time for detection of carbapenemase-producing Enterobacterales using the NG Test CARBA 5 in a routine laboratory*

Summary:
Our goals were to compare turnaround time (TAT), costs and staff requirements between the old and new algorithm, and to evaluate the performance of the CARBA 5 test directly on colonies grown on CARBA Smart agar. Of 197 isolates included in the evaluation of the new algorithm, 64 were positive for carbapenemases by both CARBA 5 and Xpert Carba-R assay. Of the 133 that were negative, two were found to harbour NDM and IMI genotypes. Significant improvements in TAT were achieved with 88.7 % of cultures with CPE, reported on the same day as growth was observed on CARBA Smart agar compared to none in the old algorithm. **The new algorithm incurred lower costs and, based on our workload, the new algorithm is estimated to save 28.9 man-hours annually.**