

CRE DETECTION

HardyCHROM™ CRE
and NG-TEST® CARBA-5®



Where **EASY-TO-READ** chromogenic culture media meets **RAPID, CLEAR RESULTS** for **CARBAPENEM-RESISTANT ENTEROBACTERIALES (CRE)** detection.

CRE

IS A WORLDWIDE
PUBLIC HEALTH THREAT.

Often called the "nightmare bacteria" CRE are a family of germs that are difficult to treat because they are resistant to nearly all antibiotics, including carbapenems, some of our most powerful drugs.

Rapid spread of CRE in parts of the United States and other countries in both humans and animals points to a need to more aggressively detect and control CRE spread.



13,100

Estimated cases
in hospitalized
patients



1,100

Estimated
deaths

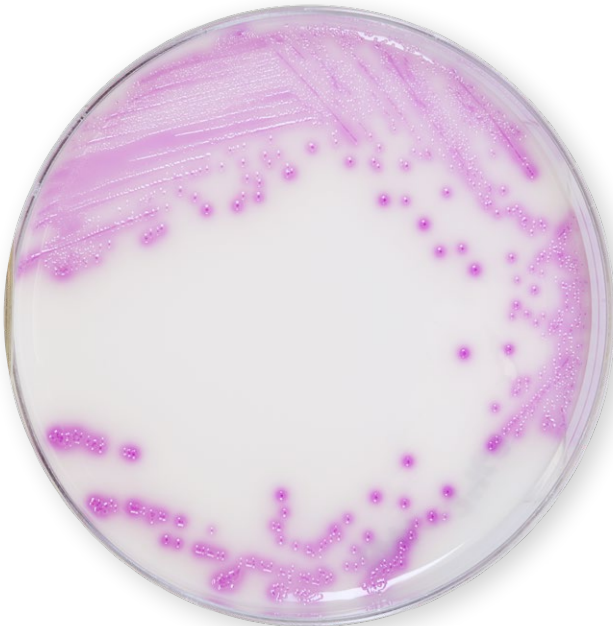


\$130M

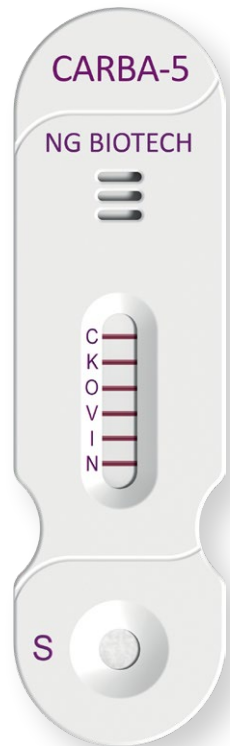
Estimated attributable
healthcare costs in

CARBAPENEM- RESISTANT **Enterobacterales**

With these two tools, you are in the fight against the worldwide threat of CRE.



15x100mm, 10/pk
Cat. no. G323



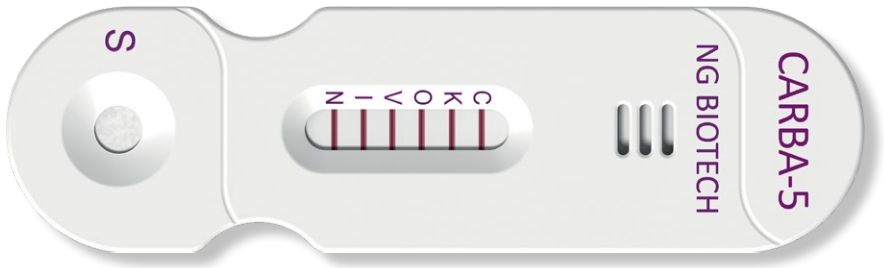
20/pk
Cat. no. CARBA5

Using HardyCHROM™ CRE + CARBA-5®, saves time, money and resources, but more importantly, accelerates detection for faster and more accurate treatment.

NG-TEST® **CARBA-5**®

NG-TEST® CARBA-5® is the only rapid, multiplex, phenotypic test capable of simultaneously detecting **KPC, OXA-48-like, VIM, IMP, and NDM** carbapenemases produced by Enterobacterales and *P. aeruginosa*.

20/pk, Cat. no. CARBA5



Cost effective - Per test, **NG-TEST® CARBA-5®** is more economical than molecular methods. Reimbursement for up to five CPT codes.

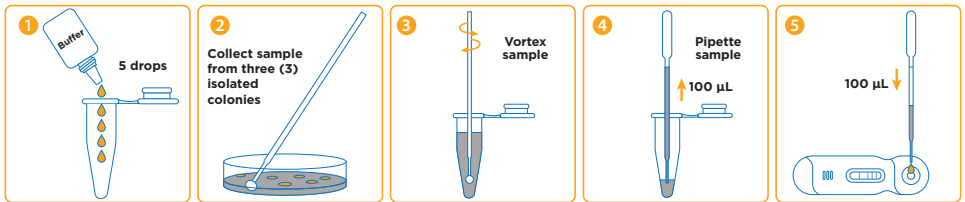
Accurate - **NG-TEST® CARBA-5®**, unlike molecular methods, detects the carbapenemase enzyme which is crucial to aiding therapeutic decisions.

RAPID • 15 minutes

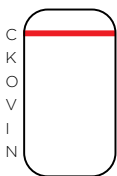
ACCURATE • 100% sensitivity + 95% specificity

USER FRIENDLY • 5 simple steps!

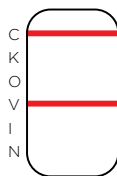
5 simple steps!



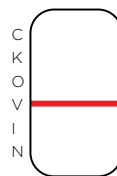
Example of interpretation. A "LINE" means an ENZYME!



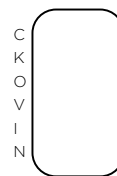
Negative



**VIM
Positive**



INVALID
No control line



INVALID
No control line

Variants comparison

Xpert Carba-R vs CARBA-5®

Data from both kit's IFU

Carbapene mase	Variants tested and detected by Xpert Carba-R	Variants predicted to be detected by Xpert Carba-R (but not tested)	Variants detected by NG-TEST® CARBA-5® in U.S. clinical trial	NG-TEST® CARBA-5® variants detected analytically and in publications
KPC	2, 3, 4	5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16	2, 3, 4, 12	2, 3, 4, 5, 6, 7, 9, 12, 14, 23, 28, 31, 33, 39
NDM	1, 2, 4, 5	3, 6, 7, 8, 9	1, 5, 6, 7	1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 19
VIM	1, 2, 4, 10, 19	5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16, 17, 18, 20, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38	1, 2, 4, 5, 6, 23, 27, 31	1, 2, 4, 5, 6, 11, 23, 26, 27, 31, 39, 46, 51, 52, 54, 56, 58, 59
OXA	48, 181	162, 163, 204, 232, 244, 245, 247	48, 181, 232	48, 162, 163, 181, 204, 232, 244, 245, 370, 405, 436, 484, 505, 517, 519, 793
IMP	1, 2, 4, 6, 10, 11	3, 8, 9, 10, 11, 13, 19, 20, 21, 22, 24, 25, 27, 28, 30, 31, 33, 37, 40, 42	1, 4, 7, 8/47, 19, 26	1, 2, 4, 5, 6, 7, 8/47, 10, 11, 13, 15, 16, 18, 19, 22, 26, 29, 31, 37, 39, 46, 56, 58, 63, 71, 79

- More variants are validated with CARBA-5® compared to Xpert Carba-R according to IFUs.
- Cepheid gives a list of variants predicted to be detected but not tested.

Performance of NG-TEST® CARBA-5® vs. the comparator method

Plate	Organism Group	NG-TEST® CARBA-5®	Reference method	Percent Agreement ¹	
5% Sheep's Blood and MacConkey agar	Enterobacterales and <i>Pseudomonas aeruginosa</i>	169	169	100%	Positive agreement
		137	144	95.1%	Negative agreement
		306	313	97.8%	Overall agreement
HardyCHROM™ CRE agar	<i>E. coli</i> , KES	284	284	100%	Positive agreement
		74	82	90.2%	Negative agreement
		358	366	97.8%	Overall agreement

¹After discrepant analysis, the overall percent agreement increased to 100% for NG-TEST® CARBA-5® results for all organisms tested from each plate type.

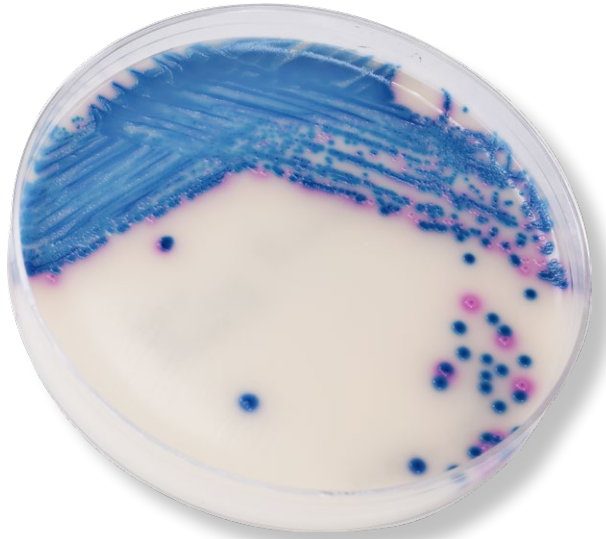
HardyCHROM™

CRE

FOR THE SCREENING OF *ESCHERICHIA COLI*,
KLEBSIELLA AEROGENES, *KLEBSIELLA*
OXYTOCA, *KLEBSIELLA PNEUMONIAE*,
ENTEROBACTER CLOACAE COMPLEX, AND
SERRATIA MARCESCENS.

HardyCHROM™ CRE is a selective and differential chromogenic agar medium intended for the qualitative and presumptive detection from stool specimens of *Escherichia coli* that are non-susceptible to carbapenems as pink colonies and KES (*Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Enterobacter cloacae* complex, and *Serratia marcescens*) that are non-susceptible to carbapenems as blue colonies.

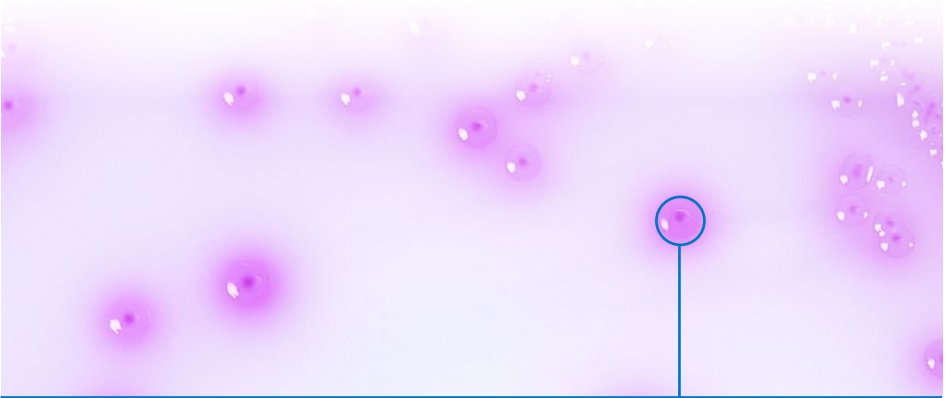
HardyCHROM™ CRE is intended as an aid in the detection, identification of colonization and control of these bacteria in a healthcare setting. HardyCHROM™ CRE is not intended to diagnose infection or guide therapy. Results can be interpreted after incubation for 18-24 hours. Subculture to non-selective medium is required for confirming identification, antimicrobial susceptibility testing and epidemiological typing.



Colonies that are not pink to magenta, blue, or blue with pink halos are negative; no carbapenem non-susceptible *Escherichia coli* or KES detected.

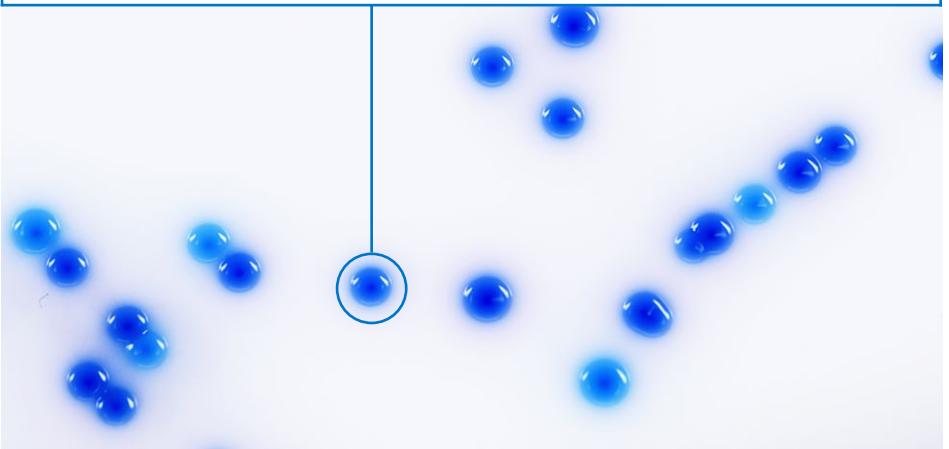
15x100mm, 10/pk
Cat. no. G323

EASY TO READ RESULTS



Non-susceptible *Escherichia coli* produces colonies that are rose to magenta in color with darker pink centers.

Klebsiella, *Enterobacter*, and *Serratia* spp. produce large, dark blue colonies (with or without pink halos) are presumptive positive for carbapenem non-susceptible KES (*Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Enterobacter cloacae* complex, and *Serratia marcescens*).





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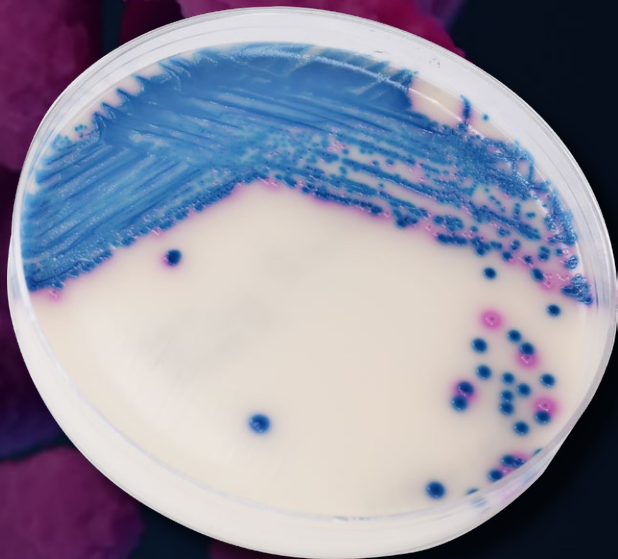
Hardy Diagnostics has a Quality Management System that is certified to ISO 13485 and is a FDA licensed medical device manufacturer.

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