Instructions for use

eazyplex® SuperBug basic

Molecular biological rapid test for the detection of carbapenemases producing bacteria

for use with Genie® II Mk2 devices

For in vitro diagnostic use

CE

eazyplex® SuperBug basic		REF: 7603
language: english	valid from:	April 2019

Explanation of symbols

IVD	in vitro diagnostic medical device
LOT	Batch code
REF	Catalogue number
	Use by
	Temperature limitation
TESTSTRIP	Teststrip
	Contains sufficient for <n> tests
	Consult instructions for use
	No re-use
	Manufacturer

Document Revision Information:
Actualization of symbols according to EN ISO 15223-1, page numbers inserted, 7./8.2 swabs with liquid Amies medium added, software version actualised (4.2), Ăselect the test manuallyñ deleted (8.1), Documentation under 9. amended by PDF report and CSV file, Warning messages inserted under 9., 11. Troubleshooting amended, general improvement of phrases.

1. Intended Use

The **eazyplex®** **SuperBug basic** test system (Cat. No. 7603) is a qualitative in vitro diagnostic medical device for the detection of bacteria that are capable, from a genetic stand point, of producing certain carbapenemases.

eazyplex® **SuperBug basic** detects all described variants of carbapenemases of the **VIM**-, **NDM-**, **KPC**-type, and the **OXA-48** family including **OXA-181/-232**.

The test can be performed at any time by qualified professional staff in a medical laboratory. The intended use includes:

- screening of asymptomatic patients via rectal swab
- diagnosis (confirmatory assay to verify results of previous testing) and aid to diagnosis (providing additional information to assist in the determination or verification of a patient´s clinical status, test is not the sole determinant) of all kind of patients via testing bacterial colonies.

2. Carbapenemases

The increase in antibiotic resistance among gram-negative bacteria is a notable example of how bacteria can procure, maintain, and express new genetic information that can confer resistance to one or several antibiotics. Reports of resistance vary, but a general consensus appears to prevail that quinolone and broad-spectrum ß-lactam resistance is increasing in members of the family *Enterobacteriaceae* and *Acinetobacter* spp. and that treatment regime for the eradication of *Pseudomonas aeruginosa* infections are becoming increasingly limited. While the advent of carbapenems in the 1980s heralded a new treatment option for serious bacterial infections, carbapenem resistance can now be observed in *Enterobacteriaceae* and *Acinetobacter* spp. and is becoming commonplace in *P. aeruginosa*. The common form of resistance is either through lack of drug penetration (i.e., outer membrane protein (OMP) mutations and efflux pumps), hyperproduction of an AmpC-type ß-lactamase, and/or carbapenem-hydrolyzing ß-lactamases. Two types of carbapenem-hydrolyzing enzymes have been described: serine enzymes possessing a serine moiety at the active site, and metallo-ß-lactamases (MBLs), requiring divalent cations, usually zinc, as metal cofactors for enzyme activity. The serine carbapenemases are invariably derivatives of class A or class D enzymes and usually mediate carbapenem resistance in *Enterobacteriaceae* or *Acinetobacter* spp. Despite the avidity of these enzymes for carbapenems, they do not always mediate high-level resistance and not all are inhibited by clavulanic acid.
MBLs, like all ß-lactamases, can be divided into those that are normally chromosomally mediated and those that are encoded by transferable genes. However, in the past 5 years many new transferable types of MBLs have been studied and appear to have rapidly spread. In some countries, *P. aeruginosa* possessing MBLs constitute nearly 20 % of all nosocomial isolates, whereas in other countries the number is still comparatively small. In recent years MBL genes have spread from *P. aeruginosa* to *Enterobacteriaceae*, and a clinical scenario appears to be developing that could simulate the global spread of extended-spectrum ß-lactamases. Moreover, given that MBLs will hydrolyze virtually all

classes of ß-lactams and that we are several years away from the implementation of a therapeutic inhibitor, their continued spread would be a clinical catastrophe.

Metallo-ß-lactamases (MBLs):

All MBLs hydrolyze imipenem, but their ability to achieve this varies considerably and the rate of hydrolysis may or may not correlate with the bacteriumôs level of resistance to carbapenems. However, these enzymes possess the characteristic hallmark of being universally inhibited by EDTA as well as other chelating agents of divalent cations, a quintessential feature of MBLs that correlates with their mechanistic function.
Acquired metallo-ß-lactamases (MBLs) are emerging resistance determinants in *Pseudomonas aeruginosa* and other gram-negative pathogens. These enzymes can hydrolyze most ß-lactams, including carbapenems, and can confer a broad-spectrum ß-lactam resistance phenotype to the bacterial host, which is not reversible by conventional ß-lactamase inhibitors. MBLs are commonly encoded by genes carried on mobile elements (integron-borne gene cassettes) that can spread horizontally among different replicons and strains.
Originally thought to be uncommon and restricted to some geographical areas, acquired MBLs are presently known to be widespread, and at least four different types of these enzymes, IMP, VIM, SPM, and GIM, have been identified, with the **VIM**-types being prevalent.
The VIM-type MBLs were originally detected in Europe, where these enzymes apparently prevail over IMP-type enzymes. Subsequently, VIM-type enzymes were also reported in Asia and America. MBLs of the VIM type are more common among non-fermenting gram-negative bacteria. However, during the last few years, studies have reported on the dissemination of VIM-type MBLs in members of the family *Enterobacteriaceae*, suggesting the ongoing spread of these resistance determinants among pathogens with higher infectivities.

NDM-1 was first identified in December 2009 and was named after New Delhi, as it was first described by Yong et al. in a Swedish national who fell ill with an antibiotic-resistant bacterial infection that he acquired in India. The infection was unsuccessfully treated in a New Delhi hospital and after the patient's repatriation to Sweden; a carbapenem-resistant *Klebsiella pneumoniae* strain bearing the novel gene was identified. It was later detected in bacteria in India, Pakistan, the United Kingdom, the United States, Canada, Japan and several European countries. The most common bacteria that make this enzyme are *Escherichia coli* and *Klebsiella pneumoniae*, but the gene for NDM-1 can spread from one strain of bacteria to another by horizontal gene transfer and was found *in Morganella morganii*, *Providencia* spp., *Citrobacter freundii* and *Acinetobacter baumannii*, too.

Klebsiella pneumonia carbapenemase (KPC):

The initial report of a KPC ƀ-lactamase which is capable of hydrolysing carbapenems, penicillins, cephalosporins and aztreonam, was from a carbapenem-resistant *K. pneumoniae* strain isolated in USA, and subsequently KPC producers have also been detected in other regions all over the world. There are currently nine recognized variants, with KPC-2 and KPC-3 being more commonly isolated.
Recently, isolates producing KPC-2 /-3 enzyme have been detected in European countries such as Greece, the UK, France and Germany. In addition, the spread of KPC producers may be underestimated, as the detection of KPC- and also MBL-producing *K. pneumoniae* may be unsuccessful because these enzymes do not always confer obvious carbapenem resistance.

OXA-48 carbapenemase:

The OXA-48-carbapenemase was first described in 2004 in a *K. pneumoniae*-isolate from Turkey. Recently, isolates producing such carbapenemase were detected in various countries like Belgium, Israel, India, UK and Greece. In Germany it was found the first time 2008 in the south-western part of the country. A further variant of this enzyme type is OXA-181, mainly present in the arabic and indian area. Like in KPC-producing bacteria, the phenotypic detection of this resistance type seems to be difficult and unreliable.

3. Principle of the test

A single **eazyplex®** test strip contains six oligonucleotide primers in each filled cap and these provide the means for simultaneous, specific amplification of different genes in a single isothermal amplification reaction. In the presence of relevant DNA sequences, specific amplification products are generated and visualised by real-time fluorescence measurement of a fluorescence dye bound to double-stranded DNA. Thus, positive signals indicate the presence of one of the corresponding genes in the sample to be investigated. Therefore, a clear genotypic determination of present resistances is possible.
Data interpretation is based on an algorithm in the eazyReport™ software.

The following protective mechanisms prevent the use of false results:
Performance of ñinhibition controlòwith each sample prevents the use of false negative test results due to inhibition of the amplification reaction and simultaneously serves as reagent control.
As required, a test strip can be processed as negative / contamination control by testing **RALF** without addition of sample material. In this case, only the inhibition control is allowed to create a positive signal.

tube-n°	Assay parameter (abbreviation in result display)	Specificity	Colour of curve
1	KPC	KPC-2 to -15	**red**
2	NDM	NDM-1 to -7	**orange**
3	OXA-48	OXA-48, -162, -204, -244	**yellow**
4	VIM	VIM-1 to -37, without -7	**light green**
5	Inhibition control	Inhibition control	**dark green**
6	OXA-181	OXA-181,-232	**turquois**
7	-	-	**purple**
8	-	-	**pink**

4. Reagents

4.1 Content

The reagents contained in one kit are sufficient for 24 determinations.
Each kit contains:

TESTSTRIP	Test strips with 6 filled tubes, each containing lyophilized, ready-to-use mix for isothermal amplification. The mix contains DNA-polymerase, buffer components, Mg_2SO_4, dNTPs, oligonucleotide primers and a fluorescence dye.	24 strips
RALF	2ml ï tubes with 500 µl ĂRALF - **R**esuspension **a**nd **L**ysis **F**luidñeach (ready for use)	24 x 500 µl

4.2 Additional accessories required

- GENIE® II Mk 2 with eazyReport™ - software version 2.34 or higher (including Instructions for Use in PDF format)
- Inoculation needle
- Heating block for 2 ml tubes
- centrifuge for 2 ml tubes (in the case of urine as sample material)
- Pipettes with sterile disposable filter tips
- optional: USB bar code scanner
- optional: printer DYMO® Labelwriter 450 (Dymo) with labels 54x101mm

5. Warnings and precautions

☝ All reagents and materials which come into contact with potentially infectious samples must be treated with suitable disinfectant or autoclaved.

☝ Suitable disposable gloves must be worn during the entire test.

☝ **Never** open a test strip after use! Autoclave used test strips!

6. Handling notes ï preparation of assay realization

The components of **eazyplex® SuperBug basic** have to be stored from 15°C to 30°C.
The kits have an expiry date. Quality cannot be guaranteed after this date.
Before beginning the test, remove a test strip from the bag. The test strip may only be used if the white pellets in the filled tubes are visible.

As with any test procedure, good laboratory practice is essential to the proper performance of this assay.

7. Sample material

The sample material has to be:

-bacterial colony from agar plate, selective media recommended
-or rectal swab taken with a swab with Liquid Amies Medium according to instructions for use

Any other swabs, liquid culture, blood or stool samples **CANNOT** be used.

8. Test procedure

8.1 Preparation of the system

- Turn on GENIE® II Mk2
- Touch the Screen
- Enter user name and password
- Select ÄRunñ
- Scan test barcode via barcode scanner or enter test barcode manually; then select test profile which matches the respective sample material.
- Check display if the right test profile is selected
- Enter patient´s / sample ID (via barcode scanner or keyboard)
- Confirm the selection with ñEnterò

8.2 Preparing the amplification reaction

Rectal swabs (screening):

After short vortexing of the swab (see 7.) transfer 25 µl of the Liquid Amies Medium into 500 µl **RALF**.

- **Caution! Too much cell material may considerably reduce the effectiveness of the reaction and lead to invalid test runs.**

This **RALF**-suspension has to be incubated at 99°C for 2 minutes for cell lysis.

Carefully remove the protective foil from the test strip.

Pipette 25 µl of the **RALF**-suspension onto the ready-to-use mix in each filled tube of the test strip, taking care not to allow the pipette tip to make contact with the pellet. Do not vortex, shake heavily or pipette up and down. Remove any air bubbles by tapping the test strip gently.

Once the pellets have dissolved, place the test strip immediately into the GENIE® II Mk2 device and start the run (8.3).

Bacterial colony from agar plate:

Suspend a small part of a single bacterial colony in 500 µl **RALF** by an inoculation needle. As soon as a little amount of cell material is visible on the inoculation needle, it is sufficient sample material for the test.

- **Caution! Too much cell material may considerably reduce the effectiveness of the reaction and lead to invalid test runs.**

Incubate this **RALF**-suspension at 99°C for 2 minutes for cell lysis.
If you wish further microbiological testing, transfer 50 µl of the cell suspension in a sterile tube **before** cell lysis.

Carefully remove the protective foil from the test strip.

Pipette 25 µl of the **RALF**-suspension onto the ready-to-use mix in each filled tube of the test strip, taking care not to allow the pipette tip to make contact with the pellet. Do not vortex, shake heavily or pipette up and down. Remove any air bubbles by tapping the test strip gently.

Once the pellets have dissolved, place the test strip immediately into the GENIE® II Mk2 device and start the run (8.3).

8.3 Realization of the amplification reaction

- Select ĂStartñ
- Select block A or B
- Place the test strip into the selected block
- Close the lid
- Start test run by selecting ĂYesñ
- If the second block is not in use, a second test run can be initiated by the button ñstart test runò(see 8.1)
- Note: the directory path and number of test run data file can be seen on the display
- Once the run is complete, open the lid and remove the test strip, taking care as the block could still be hot!
- **Never** open a test strip after use! Danger of contamination!

9. Evaluation

The test run can be monitored in real time mode (choose ĂAmplificationñ). Positive results are indicated by a strong rise in fluorescence signal (in the form of a typical amplification curve). Unambiguous assignment of the curves to the test parameters takes place by coloring.

After completion of the test run select ĂResultsñ:

Valid test run:
Positive results are colored red.

Invalid test run:
The result of ĂInhibition Controlñ is colored red (invalid). In this case, data interpretation of the eazyReport™ software is displayed above the result table as follows:
ĂInvalid controlò(colored red)

Warning messages:
ĂWARNING! Kit expired!ñ
A kit has been used which is out of date (see 6.).

ĂWARNING! Too much sample material!ñ
Too much sample material was used; this could have been the reason for an invalid test run (see 11.)

Documentation:

- Result printout via Dymo® Labelwriter 450 printer: select ĂprintñorCreate a PDF result report: select ĂPDFñ, the generated PDF file is stored in the folder ĂReportñon the device and can be exported via USB stick (according to Instructions for Use Genie® II Mk2).orcreate a result file in CSV format: select ĂCSVñ, the generated CSV file is stored in the folder ĂReportñon the device.

The stored run file can be reviewed at any time:

- select symbol ĂFolderñ
- select ĂLOGñand confirm with ĂüñThe data files are numbered consecutively and archived according to creation date

10. Interpretation of the test results

The **eazyplex® SuperBug basic** system is a rapid screening and confirmatory test for the detection of five different genes encoding carbapenemases directly from rectal swabs or bacterial colonies.
Positive results of the **eazyplex® SuperBug basic** system demonstrate the presence of resistance genes in a sample. This does not mean that the genes are also actually expressed. The pathogens found in the tested sample, however, possess the potential to express the genes. In addition, no conclusions on, for example, the minimal inhibiting concentration of certain ß-lactam antibiotics, and in special carbapenems, for the pathogen can be made based on the results of this test system.

The **eazyplex® SuperBug basic** system is neither intended to diagnose an infection with carbapenem resistant bacteria (it cannot be distinguished between colonisation and infection) nor to guide or monitor medical treatment.
The test solely generates a test result. The attending doctor is responsible for achieving a decision about diagnosis or treatment of a patient or taking hygienic measures.

The **eazyplex® SuperBug basic** system is able to detect some few genome copies within 30 minutes under optimal conditions. But it is not possible to detect one single copy of the respective resistance gene. Therefore, a negative test result can be generated despite a weak colonization of the patient´s intestinal tract.

11. Troubleshooting

All signals negative (incl. inhibition control):

- Reaction is inhibited due to inhibitory substances in the sample and must not be interpreted (invalid test).

- In case of testing bacterial colonies: Too much cell material was used for amplification ➔ suspend just a small part of one colony in 500 µl RALF or dilute already suspended cell material with RALF.
- If assay with diluted sample is invalid again ➔ perform assay with RALF without sample.
- If inhibition control is negative again ➔ device may be damaged, please contact our support team.

All signals positive (incl. inhibition control):

Very occasionally cell lysis in a sample will not complete within the first 3 minutes of the test run (signals are not displayed at the beginning of the run). If cell lysis occurs later on during the amplification reaction, newly appearing dsDNA will lead to unspecific amplification signals. This phenomenon can be identified easily because it will happen simultaneously in all wells (but the IC curve or correct positive amplification curves could appear earlier). ➔It is recommended to repeat the test run with fresh sample material with an extended incubation time of 10 minutes for complete cell lysis.
➔If the phenomenon reoccurs, the sample should be interpreted as "invalidñor "not valid".

12. Performance data

As part of a retrospective evaluation study (Prof. Dr. Neil Woodford, 2014) at the Antibiotic Resistance Monitoring and Reference Laboratory (Health Protection Agency Centre for Infections, London, United Kingdom), 450 different isolates of *Enterobacteriaceae* were tested in comparison to in-house PCR with the following results*:

Carbapenemase	**n**	**eazyplex® SuperBug complete B Sensitivity**
KPC	100	100 %
NDM	100	100 %
VIM	100	100 %
OXA-48 (exklusive OXA-181)	83	100 %
OXA-181	17	100 %
NDM + OXA-48 (exklusive OXA-181)	1	100 %
NDM + OXA-181	1	100 %
	n	**Specificity ***
Carbapenemase negative (but Carbapenem-resistant)	24	100 %

* The study was carried out with eazyplex® SuperBug complete A and eazyplex® SuperBug complete B and can be transferred to eazyplex® SuperBug basic due to the identical composition of the concerned parameters.

** In addition, no false positive results occurred within all of the parameters (specificity 100%).

See: Findlay J, Hopkins KL, Meunier D, Woodford N.: ÄEvaluation of three commercial assays for rapid detection of genes encoding clinically relevant carbapenemases in cultured bacteria.òJ Antimicrob Chemother. 2015 May;70(5):1338-42.

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