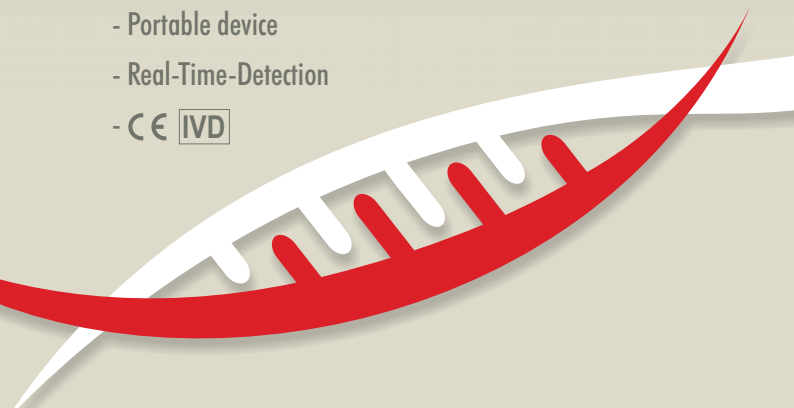


eazyplex®

Molecular Diagnostics made eazy!



- Isothermal Amplification
- Lyophilized tests
- 2 min sample pretreatment
- No DNA/RNA extraction necessary
- Portable device
- Real-Time-Detection
- CE 



amplex
DIAGNOSTICS GMBH



What to expect:

30 minutes meningitis diagnostics

P. 4-5

eazyplex[®] CSF panel

Stool diagnostics

P. 6-7

eazyplex[®] C. difficile panel

eazyplex[®] TyphiTyper

eazyplex[®] EHEC panel

Classic eazyplex[®] HAI panel

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eazyplex[®] MRSA panel

eazyplex[®] VRE panel

eazyplex[®] Candida auris

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Candida auris

Molecular Diagnostics made easy!

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eazyplex[®] at a glance

MRE diagnostics regarding Gram negatives

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The new topic hypervirulent K. pneumoniae

P. 20-21

eazyplex[®] hv-K. pneumoniae

20 minutes Sepsis diagnostics

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eazyplex[®] BloodScreen panel

Respiratory diseases diagnostics in 25 minutes

P. 24-25

eazyplex[®] PneumoBug expert

eazyplex[®] Pneumocystis jirovecii

Diagnostic of Sexually Transmitted Diseases

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eazyplex[®] STD panel

General Information

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Evaluated sample material

Distribution

30 minutes meningitis diagnostics with the eazyplex[®] CSF panel!

An early diagnosis and a rapid beginning of the treatment of bacterial meningitis / meningo-encephalitis is very important, because the lethality increases strongly with a decelerated therapy start.

For a rapid diagnosis within 30 minutes and an effective treatment: eazyplex[®] CSF direct panel.

eazyplex[®] CSF direct

HSV-1, HSV-2, VZV, N. meningitidis, S. pneumoniae, S. agalactiae, L. monocytogenes



eazyplex[®] CSF direct M

N. meningitidis, S. pneumoniae, S. agalactiae, L. monocytogenes, E. coli, H. influenzae



eazyplex[®] CSF direct V

HSV-1, HSV-2, VZV



D'Inzeo et al



Case report Karrasch et al

Evaluated sample materials for the eazyplex system:



= Cerebrospinal fluid



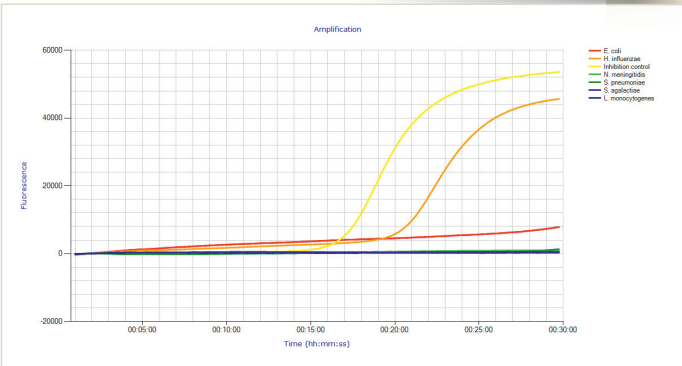
= Stool



= Urine



= Bacterial culture of agar plates, optimal selective media



Fast and easy to perform pre-analytics with magnetic beads.



= bronchoalveolar lavage fluid (BAL), broncheal secretion (BS), tracheal secretion (TS)



= Nasal, throat, rectal, wound, vaginal and urethral swab



= Grown („positive“) blood culture-liquid media

The time saving clear and easy stool diagnostics within minutes!

About half of the world population suffers from diarrhoea at least once a year. This makes diarrhoea one of the most common symptoms of illness, along with flu-like infections. The causes of diarrhoea are manifold and often caused by bacteria. It is important to differentiate between harmless diarrhoea and longer lasting diarrhoea that requires treatment and can lead to death, especially in weakened patients and children, due to loss of water and electrolytes. With the eazyplex[®] stool diagnostic panel you save a lot of time and get clear results within minutes. Due to different target combinations and with a shelf life of 18 months you have optimal user-friendliness and cost efficiency.

eazyplex[®] C. difficile panel:

eazyplex[®] C. difficile complete
GDH, Toxin A, Toxin B, Binary Toxin



eazyplex[®] C. difficile classic
GDH, Toxin B



eazyplex[®] C. difficile basic
Toxin B



eazyplex[®] TyphiTyper:



- Species *Salmonella enterica* and the following serovars:
- *Salmonella enterica* Serovar Typhi
- *Salmonella enterica* Serovar Paratyphi A, B and C in the itemization
- *Salmonella enterica* Serovar Choleraesuis



Rödel et al

Evaluated sample materials for the eazyplex system:



= Cerebrospinal fluid



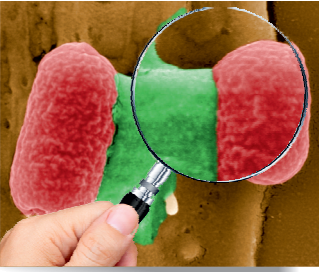
= Stool



= Urine



= Bacterial culture of agar plates, optimal selective media



eazyplex[®] EHEC panel:

eazyplex[®] EHEC complete

Verotoxin 1, Verotoxin 2, Intimin, Haemolysin,
EIEC/Shigella, EAggEC, Verotoxin 2f



eazyplex[®] EHEC basic

Verotoxin 1, Verotoxin 2



eazyplex[®] EHEC classic

Verotoxin 1, Verotoxin 2, Intimin



Penzel et al



= bronchoalveolar lavage fluid (BAL), broncheal secretion (BS), tracheal secretion (TS)



= Nasal, throat, rectal, wound, vaginal and urethral swab



= Grown („positive“) blood culture-liquid media

The classic eazyplex[®] HAI panel!

With the well proven classical eazyplex[®] hygiene panel you are on the safe side and get clear results within minutes.

Take care of your patients and prevent the spread of nosocomial infections in your hospital!

eazyplex[®] MRSA panel:

eazyplex[®] MRSA

S. aureus, *S. epidermidis*, *mecA*, *mecC*,
Sample control



eazyplex[®] MRSA plus

S. aureus, *mecA*, *mecC*, PVL toxin



eazyplex[®] VRE:

eazyplex[®] VRE

VanA, VanB, Sample controls



eazyplex[®] VRE basic

VanA, VanB



Evaluated sample materials for the eazyplex system:



= Cerebrospinal fluid



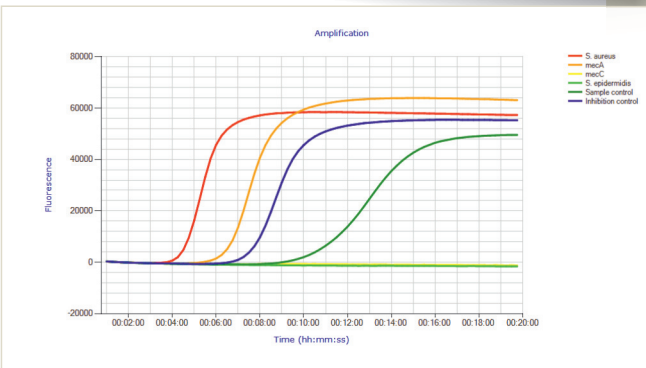
= Stool



= Urine



= Bacterial culture of agar plates, optimal selective media



 = bronchoalveolar lavage fluid (BAL), broncheal secretion (BS), tracheal secretion (TS)

 = Nasal, throat, rectal, wound, vaginal and urethral swab

 = Grown („positive“) blood culture-liquid media

Avoid ineffective therapy and hygiene management!

Direct diagnosis from swabs or culture confirmation in just 25 minutes.

"Candida auris poses a risk to patients in healthcare settings across Europe due to its propensity to cause outbreaks and its resistance to antifungal drugs. Difficulties in laboratory identification and a lack of awareness of this Candida species can delay early detection and reduce the potential increase for a horizontal transfer. C. auris was first identified in 2009 and within a few years has become a cause of healthcare-related infections. Outbreaks have been reported in countries on five continents. The number of reported C. auris cases in European countries has increased significantly since the last ECDC rapid assessment of the risk of C. auris in December 2016. There remains a need to raise awareness of C. auris in European healthcare settings so that they can adapt their laboratory testing strategies and implement improved infection prevention and control measures where appropriate."¹

What's more, unlike all other Candida species, Candida auris is regularly transmitted from patient to patient, with intermediate stations such as hands, surfaces or medical equipment often paving the way. This is very unusual for Candida species. Commonly, endogenous pathways (from the colonized intestinal tract) lead to infection in related species such as C. albicans and C. glabrata. It is assumed that smear infections cause the spread and rapid infection of other patients with Candida auris.

¹European Center for Disease Prevention and Control. Candida auris in healthcare settings - Europe - first update, 23 April 2018. Stockholm: ECDC; 2018

Be aware and take care!

Candida auris – a worldwide risk for hospitalised patients.



eazyplex[®] Candida auris
Candida auris



Hernández et al



= Nasal, throat, rectal, wound, vaginal and urethral swab



= Bacterial culture of agar plates, optimal selective media

Molecular Diagnostics made easy!

The eazyplex[®] test kit line is a freeze-dried amplification reaction which is ready to use and can be stored direct at the workplace at room temperature; no extra preparing of buffers or reactions. The eazyplex system needs no DNA/RNA extraction; just a 5 min sample pretreatment. The paraplex technic allows fast target updates and provides you with up to eight findings in one test run.

The eazyplex[®] system offers a steadily increasing portfolio of clinically relevant and highly topical tests and a growing portfolio of a modern and customer-friendly diagnostic device series.



This includes a state-of-the-art designed eazyMini, the classical Genie II, the basic eazyOne and, as high throughput version, the Genie HT. All these instruments are light and robust devices for fast individual 24/7 testing. The units have different options of heating blocks. All the blocks can be controlled independently with random access and thus in connection with our very short run times offer maximum flexibility.

Evaluated sample materials for the eazyplex system:



= Cerebrospinal fluid



= Stool



= Urine



= Bacterial culture of agar plates, optimal selective media

All devices are controlled via a large display with resistive touch screen, which can also be operated with protective gloves. From this interface the instruments can be set up to perform any eazyplex[®] test. The data input is optimized with a barcode scanner.

The signal detection is graphically displayed in real time during a run and all data are stored in the large internal FLASH memory of the instrument. This data is permanently saved and can be viewed on the high-resolution display at any time after the run is completed, printed out by a label writer or exported as a PDF file via a USB connection; HIS/LIS connectivity is provided on some devices.



The new eazyMini is the latest and most modern member of the eazyplex[®] appliance family. The device has two independent heating blocks, intuitive software, an integrated barcode scanner and can be connected to the HIS/LIS system via an HL7 interface. The device with the best price-performance ratio fulfils all the requirements of a modern molecular diagnostics laboratory in a state-of-the-art design.



= bronchoalveolar lavage fluid (BAL), broncheal secretion (BS), tracheal secretion (TS)



= Nasal, throat, rectal, wound, vaginal and urethral swab



= Grown („positive“) blood culture-liquid media

The classic and proven Genie II has two independent heating blocks and, as a special feature, an integrated battery, which also makes diagnostics particularly mobile. A common barcode scanner can easily be connected as well as a label writer.



The Genie HT is a modular version with the option of 1 up to 12 independent working blocks for high throughput settings. The number of blocks can be freely selected and be changed subsequently. This device can be connected to an HIS/LIS system via customized middleware.



Evaluated sample materials for the eazyplex system:



= Cerebrospinal fluid



= Stool



= Urine



= Bacterial culture of agar plates, optimal selective media

The eazyOne is the clear winner in terms of price. It is characterized by intuitive menu navigation, generates an integrated run report with all relevant data and offers device-specific calibration reagents in its product range. The device is supported by a very light and portable construction.



	eazyMini	Genie II	Genie HT	eazyOne
blocks	2	2	1-12	1
real-time-data - display	yes	yes	yes	no
scanner	internal	external	external	external
USB port	yes	yes	yes	yes
HIS/LIS	HL7	no	customized *	no
PDF creation	yes	yes	yes	yes
label print	yes	yes	yes	no
battery	no	integrated	no	no
calibration	integrated	no	no	external

*HIS/LIS connectivity only one direction

-  = bronchoalveolar lavage fluid (BAL), broncheal secretion (BS), tracheal secretion (TS)
-  = Nasal, throat, rectal, wound, vaginal and urethral swab
-  = Grown („positive“) blood culture-liquid media



Take advantage of the optimal combination of the most innovative nucleic acid amplification technology and the user-friendly format of the eazyplex[®] system.

eazyplex[®] your 24/7 system, fast, flexible, reliable!

The eazyplex[®] test system



Freeze-dried aliquoted reagents included, minimal handling, detection directly from the sample without DNA/RNA extraction, real-time detection, fast and clear results, large parameter selection and completely CE IVD certified and now with a selection of a modern and customer-friendly range of devices.

The eazyplex[®] SuperBug panel!

„In the case of Gram negative bacteria, the worldwide spread of carbapenemases is currently the most threatening development of resistance. The approval of new antibiotics against Gram negative pathogens cannot be expected in the next few years. Therefore, an increase in strains with resistance to the reserve antibiotics from the class of carbapenems - often associated with resistance to almost all other antibiotic classes - is of great importance both clinically and hygienically.“

Resistance to antibiotics in Gram negative pathogens is nothing new for sure. Nevertheless, there is always a need for still rare targets in order to close a complete diagnosis. With this test kit panel you can quickly and reliably detect all common carbapenemases as well as the still rare IMP, IMI, GES and GIM, the resistances associated to *Acinetobacter baumannii* and not to forget the common AmpCs.

Citation: „Zur aktuellen Situation bei Carbapenemase-bildenden gramnegativen Bakterien. Epidemiologisches Bulletin des Robert-Koch-Instituts, 13. Mai 2013“.

eazyplex[®] SuperBug CRE
KPC, NDM, OXA-48-like,
OXA-181-like, VIM, CTX-M-1 group
and CTX-M-9 group



García-Fernández et al



Findlay et al



Zboromyrska et al

eazyplex[®] SuperBug mcr-1
mcr-1



Evaluated sample materials for the eazyplex system:



= Cerebrospinal fluid



= Stool



= Urine



= Bacterial culture of agar plates, optimal selective media

eazyplex® SuperBug complete A, B and C

A: KPC, NDM, OXA-48-like, VIM,
OXA-23 group, OXA-40 group,
OXA-58 group



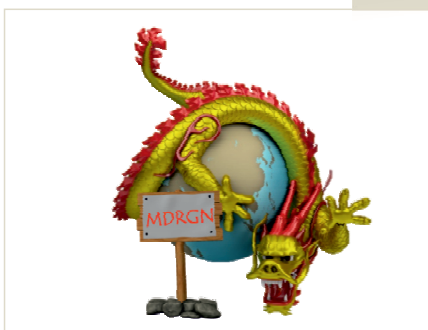
B: KPC, NDM, OXA-48-like, VIM,
OXA-23 group, OXA-40 group,
OXA-181-like



C: KPC, NDM, OXA-48-like, VIM, OXA-181-like, IMP



Vergara et al



eazyplex® SuperBug basic

KPC, NDM, OXA-48-like, VIM,
OXA-181-like



eazyplex® SuperBug expert

IMP, IMI, GES and GIM



eazyplex® SuperBug Acineto

OXA-51, OXA-23-, -40- and -58-like



eazyplex® SuperBug AmpC

ACC, CMY-II, DHA, MOX



= bronchoalveolar lavage fluid (BAL), broncheal secretion (BS), tracheal secretion (TS)



= Nasal, throat, rectal, wound, vaginal and urethral swab



= Grown („positive“) blood culture-liquid media

The new topic of hypervirulent *Klebsiella pneumoniae*!

The increasing emergence of hypervirulent *K. pneumoniae* (hvKp) strains producing carbapenemases in Europe has led to a risk assessment by the European Centre for Disease Prevention and Control (ECDC) that carbapenem-resistant hvKp can cause difficult-to-treat or untreatable invasive infections in both immunocompromised patients and previously healthy people and that surveillance is needed to prevent further spread in healthcare settings *

"Since the last ECDC rapid risk assessment in 2021, the number of European Union/European Economic Area (EU/EEA) countries reporting cases of hypervirulent *Klebsiella pneumoniae* (hvKp) sequence type (ST) 23 has increased from four to 10 countries, and the number of isolates submitted for analysis by these countries has increased from 12 to 143 isolates. " (official website ECDC).

*European Centre for Disease Prevention and Control. Emergence of Hypervirulent *Klebsiella pneumoniae* ST23 Carrying Carbapenemase Genes in EU/EEA Countries; ECDC: Stockholm, Sweden, 2021.

Available online: Emergence-of-hypervirulent-Klebsiella-pneumoniae-ST23-carrying-carbapenemase-genes.pdf accessed on 1 September 2021).



ECDC Risk Assessment hvKp

Evaluated sample materials for the eazyplex system:



= Cerebrospinal fluid



= Stool



= Urine



= Bacterial culture of agar plates, optimal selective media



String test: String formed by elongation of the hypervirulent *Klebsiella pneumoniae* colony with a loop.

Read the new publication on our eazyplex[®] hv-K. pneumoniae:

Screening of *Klebsiella pneumoniae* Isolates for Carbapenemase and Hypervirulence-Associated Genes by Combining the eazyplex[®] Superbug CRE and hvKp Assays Jürgen Rödel, Yvonne Pfeifer, Martin A. Fischer, Birgit Edel, Sylvia Stoll, Wolfgang Pfister and Bettina Löffler



Rödel et al

eazyplex[®] hv-K. pneumoniae



K. pneumoniae, Aerobactin (iucC), Salmochelin (iroC), Hypermucoviscosity (rmpA2), Yersinabactin (ybt), Colibactin (clb) and Hypermucoviscosity (rmpA).



= bronchoalveolar lavage fluid (BAL), broncheal secretion (BS), tracheal secretion (TS)



= Nasal, throat, rectal, wound, vaginal and urethral swab



= Grown („positive“) blood culture-liquid media

The eazyplex® BloodScreen panel!

An early diagnosis and a prompt, appropriate clinical therapy of sepsis is crucial to increase the chance of survival. Antimicrobial resistance is a key factor determining clinical unresponsiveness to treatment and rapid progression in sepsis and septic shock.

With the eazyplex® BloodScreen tests as a Gram positive and Gram negative panel, you can detect the most common bacterial pathogens of sepsis and associated antibiotic resistances, that strongly influence the outcome of the disease. You get the result without DNA extraction directly from positive blood culture in 20 minutes.

eazyplex® BloodScreen GP

VanA, VanB, Enterococcus faecalis, Enterococcus spec., Streptococcus pneumoniae, Streptococcus spec.



eazyplex® BloodScreen GN

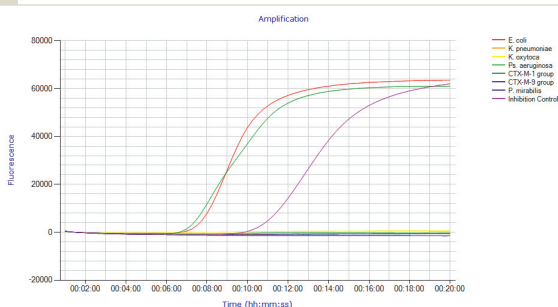
E. coli, K. pneumoniae, K. oxytoca, P. aeruginosa, CTX-M-1 group, CTX-M-9 group, P. mirabilis



Rödel et al



Fiori et al



Evaluated sample materials for the eazyplex system:



= Cerebrospinal fluid



= Stool



= Urine



= Bacterial culture of agar plates, optimal selective media



 = bronchoalveolar lavage fluid (BAL), broncheal secretion (BS), tracheal secretion (TS)

 = Nasal, throat, rectal, wound, vaginal and urethral swab

 = Grown („positive“) blood culture-liquid media

The eazyplex[®] Pneumo panel!

A pneumonia is an inflammation of the alveolar space and/or interstitial lung tissue, which is mainly caused by bacteria. It is the most common infectious disease leading to death in industrial nations. The pathogen spectrum differs according to age group and cause of infection (acquired on an outpatient or hospital basis).

The "classical" pneumonia is often caused by pneumococci. However, the disease can progress atypically with attenuated symptoms and without physical signs of infiltration, especially in older patients or certain pathogens. *P. jirovecii* is the causative agent for Pneumocystis pneumonia (PCP), one of the most frequent and severe opportunistic infections in immunocompromised individuals. It is still under debate if PCP is a result from reactivation of latent childhood infection or from de novo infection.

Of special interest for hygiene management is that a nosocomial patient-to-patient transmission was shown to be possible. To be able to treat a patient suffering from PCP or even general pneumonia as fast as possible, the eazyplex[®] Pneumo panel can be performed out of bronchoalveolar lavage fluid (BAL), broncheal secretion (BS) and tracheal secretion (TS) without DNA extraction. The complete result will be shown in real-time and delivered as result report after 25 min.



Huber et al

Evaluated sample materials for the eazyplex system:



= Cerebrospinal fluid



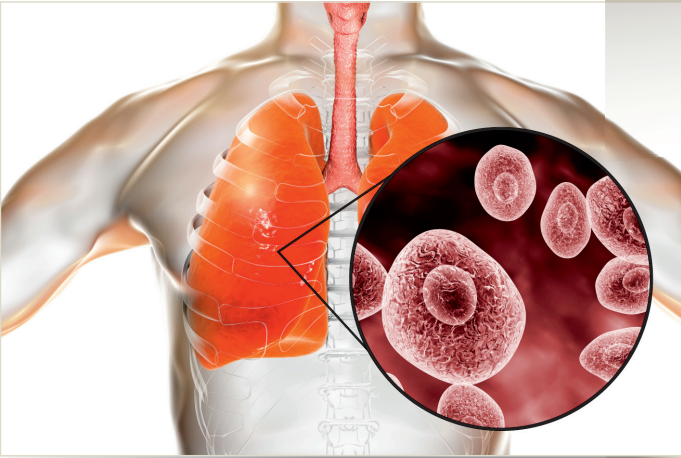
= Stool



= Urine



= Bacterial culture of agar plates, optimal selective media



eazyplex® PneumoBug expert

Mycoplasma pneumoniae, *Legionella pneumophila*,
Chlamydia pneumoniae



eazyplex® Pneumocystis jirovecii

Pneumocystis jirovecii



= bronchoalveolar lavage fluid (BAL), broncheal secretion (BS), tracheal secretion (TS)



= Nasal, throat, rectal, wound, vaginal and urethral swab



= Grown („positive“) blood culture-liquid media

The eazyplex[®] STD panel!

According to the WHO, one million people worldwide are infected with Sexually Transmitted Diseases every day.¹ This implies that timely diagnosis and therapy of this STD can not only prevent sequelae but can also reduce the risk of transmission to sexual partners. Hence a quick and uncomplicated diagnosis is a good preventive tool to reduce the prevalence and further spread of STDs. The diagnosis of these pathogens is not unimportant with regard to their transmission to the baby during birth.

¹ [https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-\(stis\)](https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis))

eazyplex[®] STD complete

Chlamydia trachomatis, Neisseria gonorrhoeae,
Ureaplasma urealyticum, Mycoplasma hominis,
Mycoplasma genitalium, Treponema pallidum



eazyplex[®] STD CT/NG

Chlamydia trachomatis, Neisseria gonorrhoeae



eazyplex[®] STD CT

Chlamydia trachomatis



Evaluated sample materials for the eazyplex system:



= Cerebrospinal fluid



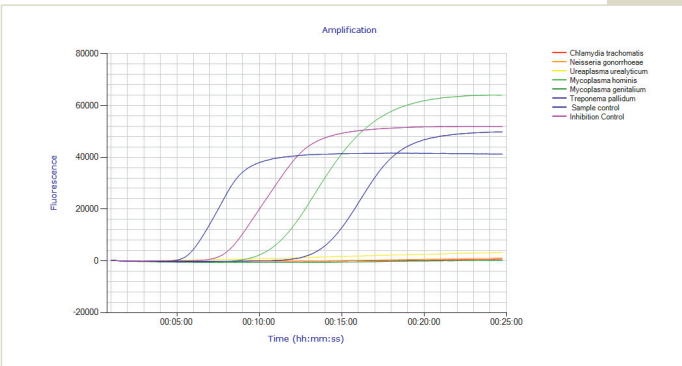
= Stool



= Urine



= Bacterial culture of agar plates, optimal selective media



= bronchoalveolar lavage fluid (BAL), broncheal secretion (BS), tracheal secretion (TS)



= Nasal, throat, rectal, wound, vaginal and urethral swab



= Grown („positive“) blood culture-liquid media

Evaluated sample materials for the eazyplex system:



= Cerebrospinal fluid



= Stool



= Urine



= Bacterial culture of agar plates, optimal selective media



= bronchoalveolar lavage fluid (BAL),
broncheal secretion (BS), tracheal secretion (TS)



= Nasal, throat, rectal, wound, vaginal and urethral swab



= Grown („positive“) blood culture-liquid media

The run times of our eazyplex tests: 15 – 30 min.

One platform for your diagnostics!

You would like to learn more about the eazyplex[®] system?

Please have a look under www.eazyplex.com
or contact us under support@eazyplex.com

Rapid Isothermal Amplification

- Time to result less than 30 min
- Lyophilised reagents
- Ready-to-use
- Shipping and storage at room temperature
- No DNA/RNA extraction

The eazyplex[®] device family:

- Compact, portable and robust
- Single testing and high throughput
- Mains or battery-powered
- Easy access to data via USB interface
- HIS/LIS connectivity
- Stand-alone-device

To notify:

Your eazyplex[®] distributor:



We are represented in numerous countries by our distributors.
You are welcome to contact them directly or request a contact through
us.

You can easily find your distributor under:



<https://www.eazyplex.com/en-gb/distribution>

Find out more under
www.eazyplex.com
or contact us under
support@eazyplex.com

AmplexDiagnostics GmbH

Werkstraße 2
83555 Gars-Bahnhof
info@eazyplex.com
www.eazyplex.com



Publish date: 02.2025