Elisabeth® Pharmacon

EliGene® DNA DIAGNOSTICS

PRODUCT CATALOG

DNA / RNA PCR DETECTION

Bacterial Infections
Viral Infections
Human Genetics

*Only experts work with our **EliGene**® kits...*

*Se soupravami **EliGene**® pracují jen profesionálové...*

Introduction

Dear Customers,

ELISABETH PHARMACON is an innovative company developing advanced products for clinical and scientific laboratories. In our portfolio you will

and RNA isolation, DNA diagnostics and human genetics, and RUO kits that are presented in this catalog.

EliGene® kits satisfy not only real experts

In the catalog we present a wide range of DNA/RNA kits designed for bacterial and viral detection, as well as kits for human genetics. The diagnostic kits have been developed for laboratories that want to provide accurate results and will not be satisfied with lower accuracy of diagnostics.

EliGene® kits are universal

Design of our kits allows compatibility with a wide range of standard Real-Time PCR Cyclers from various manufacturers: Applied Biosystems, Roche, Thermo Fisher Scientific, Bio-Rad, Qiagen.

EliGene® kits are exceptionally sensitive

High analytical sensitivity ensures laboratories to provide high quality diagnostics and doctors to have the right information to set up effective treatment. Thereis no false negativity with our kits, which may occure with some multiplexes. EliGene® kits detect one to ten copies of pathogenic DNA/RNA in the amplified sample.

EliGene® kits can provide quantitative results

Most of EliGene® DNA/RNA detection kits are quantitative. They provide beside the information about presence of detected pathogens also information about their quantity.

Úvod

Vážení klienti,

ELISABETH PHARMACON je inovativní společnost vyvíjející moderní produkty pro klinické a vědecké laboratoře. V našem portfoliu najdete řadu speciálních polymeráz, soupravy pro izolaci DNA a RNA, dále kity pro DNA diagnostiku a lékařskou genetiku a RUO kity, které vám prezentujeme v tomto katalogu.

Kity EliGene® uspokojí nejen skutečné profesionály

V katalogu vám představujeme ucelenou řadu DNA/RNA kitů pro detekci virů a bakterií a dále soupravy určené k lékařské genetice. Diagnostické soupravy byly vyvinuty pro laboratoře, jejichž zájmem je vyléčený pacient, resp. chtějí poskytovat přesné výsledky a nespokojí se s nižší přesností diagnostiky.

Soupravy EliGene® jsou univerzální

Diagnostické soupravy jsou vyvinuty tak, aby byly kompatibilní s celou řadou běžných laboratorních Real-Time PCR cyclerů od výrobců: Applied Biosystems, Roche, Thermo Fisher Scientific, Bio-Rad, Qiagen.

Soupravy EliGene® jsou výjimečně citlivé

Soupravy mají vysokou analytickou citlivost proto, aby laboratoře dokázaly poskytovat kvalitní diagnostiku a lékaři měli správné informace pro nastavení účinné léčby. S našimi kity nehrozí falešná negativita, která je u multiplexů pravděpodobnější. EliGene® soupravy zachytí jednu až deset kopií DNA/RNA v amplifikovaném vzorku.

Soupravy EliGene® umí kvantifikovat detekované mikroorganizmy

Většina EliGene® DNA/RNA detekčních souprav jsou kvantifikační a umožňují laboratořím poskytovat výsledky nejen o přítomnosti detekovaných patogenů, ale také o množství přítomného

Content/Obsah

CERTIFICATES
ELISABETH PHARMACON

RUO

ELISABETH PHARMACON holds the following quality certificates:


IQNET

Building trust together.

Certificate

CQS has issued an IQNet recognized certificate that the organization:

ELISABETH PHARMACON, spol. s r.o.
Rokycanova 4437/5, Židenice, 615 00 Brno, Czech Republic

has implemented and maintains a
Quality Management System

for the following scope:
Purchase, storage and sale of medical devices and equipment for medical and laboratory use
Testing, measuring and analysis in the field of molecular biology, medical genetics and microbiology

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on: **2023 - 06 - 06**
First issued on: **2008 - 10 - 07**
Expires on: **2026 - 09 - 05**

Registration Number: **CZ - 2113/2023**

Alex Stoichitoiu
President of IQNet

Tomáš Hruška
President of CQS

CQS

This attestation is directly linked to the IQNet Member's original certificate and shall not be used as a stand-alone document.

IQNet Members*:
AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia ICS Bosnia and Herzegovina INTECO Costa Rica IRAM Argentina JQA Japan KFQ Korea LSQA Uruguay MATEC Greece MSZT Hungary Nemko AS Norway NQA Ireland NYCE Mexico PCBC Poland Quality Austria Austria SII Israel SIQ Slovenia SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TSE Türkiye YUQS Serbia

* The list of IQNet Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

ČSN EN ISO 9001:2016 Quality Management System

ČSN EN ISO 9001:2016 Systémy managementu kvality

ELISABETH PHARMACON je držitelem následujících certifikátů kvality:


IQNET

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Certificate

CQS has issued an IQNet recognized certificate that the organization:

ELISABETH PHARMACON, spol. s r.o.
Rokycanova 4437/5, Židenice, 615 00 Brno, Czech Republic

has implemented and maintains a
Quality Management System

for the following scope:
Design, development and manufacture of in vitro diagnostic medical devices
Purchase, storage and sale of medical devices

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **2023 - 09 - 06**
First issued on: **2008 - 10 - 07**
Expires on: **2026 - 09 - 05**

Registration Number: **CZ - 147/2023**

Alex Stoichitoiu
President of IQNet

Tomáš Hruška
President of CQS

CQS

This attestation is directly linked to the IQNet Member's original certificate and shall not be used as a stand-alone document.

IQNet Members*:
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* The list of IQNet Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

ČSN EN ISO 13485 ed. 2:2016 Medical devices – Quality management systems

ČSN EN ISO 13485 ed. 2:2016 Zdravotnické prostředky – Systémy managementu kvality

BACTERIAL INFECTIONS
BAKTERIÁLNÍ INFEKCE

EliGene® Legionella pneumophila UNI

Analytical specificity and sensitivity
Legionella pneumophila
1–10 copies of bacterial DNA in the amplified sample

Specimens
Sputum, bronchoalveolar lavage, nasopharyngeal swab/aspirate

Detection technology
TaqMan

Performance study and results
Within the frame of testing the functional characteristics of **EliGene® Legionella pneumophila UNI**, totally 50 clinical specimens were analyzed. The **EliGene® Legionella pneumophila UNI** kit diagnosed correctly as *Legionella pneumophila* positive 5 specimens. Totally 45 specimens were rightly determined by **EliGene® Legionella pneumophila UNI** Kit as negative.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Legionella pneumophila
1–10 kopií bakteriální DNA v amplifikovaném vzorku

Vzorky
Sputum, bronchoalveolární lavage, nazofaryngeální stěr/aspirát

Technologie detekce
TaqMan

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® Legionella pneumophila UNI** bylo analyzováno 50 klinických vzorků. Souprava **EliGene® Legionella pneumophila UNI** identifikovala správně všech 5 vzorků pozitivních na *Legionella pneumophila* a 45 vzorků negativních.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Heuner K, Swanson M. 2008. Legionella: Molecular Microbiology. Caister Academic Press. ISBN 978-1-904455-26-4.

Newton HJ, Ang DK, van Driel IR, Hartland EL. 2010. Molecular pathogenesis of infections caused by Legionella pneumophila. Clin Microbiol Rev. 23(2):274-98

EliGene® Legionella pneumophila UNI
REF / Cat. No.: 90056-UNI 50 reactions

Compatible devices / Kompatibilní přístroje

Roche: LightCycler® 480, LightCycler® Nano and LightCycler® 2.0

Thermofisher Scientific: QuantStudio 3 and 5

Applied Biosystems: Real-Time System ABI 7500FAST

Qiagen: Rotor-Gene 6000 or Rotor-Gene Q

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

RUO

Elisabeth Pharmacon®

EliGene® Chlamydia pneumoniae UNI

Analytical specificity and sensitivity
Chlamydia Pneumoniae
1–10 copies of bacterial DNA in the amplified sample

Specimens
Sputum, bronchoalveolar lavage, nasopharyngeal swab/aspirate

Detection technology
Molecular Beacons

Performance study and results
Within the frame of testing the functional characteristics of **EliGene® Chlamydia Pneumoniae UNI** kit, totally 50 clinical specimens were analyzed. The **EliGene® Chlamydia Pneumoniae UNI** kit detected correctly as *Chlamydia Pneumoniae* positive 6 specimens. Totally 44 specimens were rightly determined by **EliGene® Chlamydia Pneumoniae UNI** kit as negative.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Chlamydia Pneumoniae
1–10 kopií bakteriální DNA v amplifikovaném vzorku

Vzorky
Sputum, bronchoalveolární lavage, nazofaryngeální stěr/aspirát

Technologie detekce
Molecular Beacons

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® Chlamydia Pneumoniae UNI** bylo analyzováno 50 klinických vzorků. Souprava **EliGene® Chlamydia Pneumoniae UNI** identifikovala správně všech 6 vzorků pozitivních na *Chlamydia Pneumoniae* a 44 vzorků negativních.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Pignanelli S, Shurdhi A, Delucca F, et al. 2009. Simultaneous use of direct and indirect diagnostic techniques in atypical respiratory infections from Chlamydia pneumoniae and Mycoplasma pneumoniae. J Clin Lab Anal. 23 (4): 206–9.

Roulis E, Polkinghorne A, Timms P. 2013. Chlamydia pneumoniae: modern insights into an ancient pathogen. Trends Microbiol. 21(3):120-8.

EliGene® Chlamydia pneumoniae UNI
REF / Cat. No.: 90057-UNI 50 reactions

Compatible devices / Kompatibilní přístroje

Roche: LightCycler® 480, LightCycler® Nano and LightCycler® 2.0

Qiagen: Rotor-Gene 6000 or Rotor-Gene Q

Applied Biosystems: Real-Time System ABI 7500FAST

EliGene® DNA DIAGNOSTICS

CE IVD

EliGene® Mycoplasma pneumoniae UNI

Analytical specificity and sensitivity
Mycoplasma pneumoniae
1–10 copies of bacterial DNA in the amplified sample

Specimens
Sputum, bronchoalveolar lavage, nasopharyngeal swab/aspirate

Detection technology
Molecular Beacons

Performance study and results
Within the frame of testing the functional characteristics of **EliGene® Mycoplasma pneumoniae UNI** kit, totally 50 clinical specimens (swabs) were analyzed. The **EliGene® Mycoplasma pneumoniae UNI** kit diagnosed correctly 6 specimens as *Mycoplasma pneumoniae* positive. Totally 44 specimens were rightly determined by **EliGene® Mycoplasma pneumoniae UNI** as *Mycoplasma pneumoniae* negative.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Mycoplasma pneumoniae
1–10 kopií bakteriální DNA v amplifikovaném vzorku

Vzorky
Sputum, bronchoalveolární lavage, nazofaryngeální stěr/aspirát

Technologie detekce
Molecular Beacons

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® Mycoplasma pneumoniae UNI** bylo analyzováno 50 klinických vzorků. Souprava **EliGene® Mycoplasma pneumoniae UNI** identifikovala všech 6 vzorků pozitivních na *Mycoplasma pneumoniae* a 44 vzorků negativních.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Sánchez-Vargas FM, Gómez-Duarte OG. 2008. Mycoplasma pneumoniae-an emerging extrapulmonary pathogen. Clin Microbiol Infect. 14(2):105-17.

EliGene® Mycoplasma pneumoniae UNI
REF / Cat. No.: 90055-UNI 50 reactions

Compatible devices / Kompatibilní přístroje

Roche: LightCycler® 480, LightCycler® Nano and LightCycler® 2.0

Thermofisher Scientific: QuantStudio 3 and 5

Applied Biosystems: Real-Time System ABI 7500FAST

Qiagen: Rotor-Gene 6000 or Rotor-Gene Q

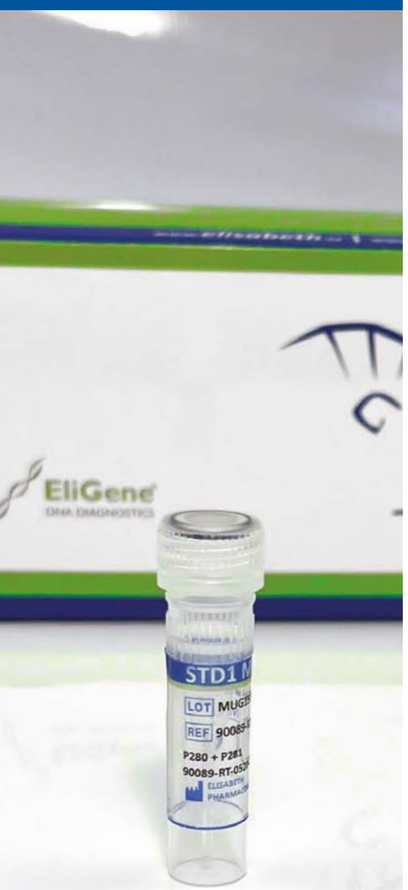
Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

CE IVD

Elisabeth Pharmacon®

EliGene® STD GAR/URE/MYC RT



Analytical specificity and sensitivity

Mycoplasma hominis, Mycoplasma genitalium, Ureaplasma urealyticum, Ureaplasma parvum and *Gardnerella vaginalis*
10 copies of bacterial DNA in the amplified sample

Specimens

Urine, swabs (cervical, urethral)

Detection technology

TaqMan

Performance study and results

Within the frame of testing the functional characteristics of **EliGene® STD GAR/URE/MYC RT** kit, totally 40 clinical specimens were analyzed. The **EliGene® STD GAR/URE/MYC RT** kit correctly identified all samples, with 29 positive for *Ureaplasma urealyticum/ Ureaplasma parvum*, 13 positive for *Mycoplasma genitalium/Mycoplasma hominis* and 31 positive for *Gardnerella vaginalis*.

Sensitivity: 100 %
Specifity: 100 %

Analytická specifita a senzitivita

Mycoplasma hominis, Mycoplasma genitalium, Ureaplasma urealyticum, Ureaplasma parvum a *Gardnerella vaginalis*
10 kopií bakteriální DNA v amplifikovaném vzorku

Vzorky

Moč, stěry (cervikální, uretrální)

Technologie detekce

TaqMan

Studie funkční způsobilosti a výsledky

V rámci testování funkční způsobilosti soupravy **EliGene® STD GAR/URE/MYC RT** bylo analyzováno 40 klinických vzorků. Souprava **EliGene® STD GAR/URE/MYC RT** všechny vzorky správně identifikovala, a to 29 pozitivních na *Ureaplasma urealyticum/ Ureaplasma parvum*, 13 pozitivních na *Mycoplasma genitalium/Mycoplasma hominis* a 31 pozitivních na *Gardnerella vaginalis*.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje

Edberg A, Jurstrand M, Johansson E, Wikander E,Höög A, Ahlqvist T, Falk L, Skov J, Fredlund H. 2008. A comparative study of three different PCR assays for detection of Mycoplasma genitalium in urogenital specimens from men and women. Journal of Medical Microbiology,57,304–309

Baczynska A, Svenstrup HF, Fedder J, Birkelund S, Christiansen G. 2004. Development of real-time PCR for detection of Mycoplasma hominis. BMC Microbiology, 4:35

Simpson T, Oh MK. 2004. Urethritis and cervicitis in adolescents. Adolesc Med Clin. 15(2):253-71

Le PT, Hamasuna R, Matsumoto M, Furubayashi K, Hatanaka M, Kawai S, Yamaguchi T, Uehara K, Murakami N, Yoshioka M, Nakayama K, Shiono Y, Muraoka K, Suzuki M, Fujimoto N, Matsumoto T. The detection of microorganisms related to urethritis from the oral cavity of male patients with urethritis. J Infect Chemother. 2017;23(10):668-673.

Allam AB, Alvarez S, Brown MB, Reyes L. 2011. Ureaplasma parvum infection alters filamin A dynamics in host cells. BMC Infect Dis. 11:101.

Pinna GS, Skevaki CL, Kafetzis DA. 2006. The significance of Ureaplasma urealyticum as a pathogenic agent in the paediatric population. Curr Opin Infect Dis. 19(3):283-9

Povlsen K, Jensen JS, Lind I. 1998. Detection of Ureaplasma urealyticum by PCR and Biovar Determination by Liquid Hybridization. J Clin Microbiol. 36(11):3211–3216

Simpson T, Oh MK. 2004. Urethritis and cervicitis in adolescents. Adolesc Med Clin. 15(2):253-71

EliGene® STD GAR/URE/MYC RT
REF / Cat. No.: 90089-RT 50 reactions

Compatible devices / Kompatibilní přístroje

Thermofisher Scientific: QuantStudio 5

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

EliGene® DNA DIAGNOSTICS

RUO

BACTERIAL INFECTIONS

EliGene® STD CHT/NEI/TRI RT

Analytical specificity and sensitivity

Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis
10 copies of bacterial DNA in the amplified sample

Specimens

Urine, swabs (cervical, urethral)

Detection technology

TaqMan

Performance study and results

Within the frame of testing the functional characteristics of **EliGene® STD CHT/NEI/TRI RT** kit, totally 110 clinical specimens were analyzed. The **EliGene® STD CHT/NEI/TRI RT** kit correctly identified all samples.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita

Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis
10 kopií bakteriální DNA v amplifikovaném vzorku

Vzorky

Moč, stěry (cervikální, uretrální)

Technologie detekce

TaqMan

Studie funkční způsobilosti a výsledky

V rámci testování funkční způsobilosti soupravy **EliGene® STD CHT/NEI/TRI RT** bylo analyzováno 110 klinických vzorků. Souprava **EliGene® STD CHT/NEI/TRI RT** všechny vzorky správně identifikovala.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje

Barbara A. Bannister, Norman T. Begg and Stephen H. Gillespie: Infectious Disease. Blackwell Science, 2th Ed., 2000

Whiley DM, Buda PP, Freeman K, Pattle NI, Bates J, Sloots TP. 2005. A real-time PCR assay for the detection of Neisseria gonorrhoeaein genital and extragenital specimens. Diagn Microbiol Infect Dis. 52(1):1-5

Whiley DM, Garland SM, Harnett G, Lum G, Smith DW, Tabrizi SN, Sloots TP, Tapsall JW. 2008. Exploring 'best practice' for nucleic acid detection of Neisseria gonorrhoea. Sex Health. 5(1):17-23.

EliGene® STD CHT/NEI/TRI RT
REF / Cat. No.: 90096-RT 50 reactions

Compatible devices / Kompatibilní přístroje

ThermoFisher Scientific: QuantStudio 5

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

CE IVD

Elisabeth Pharmacon®

EliGene® STD NEI/TRI RT

Analytical specificity and sensitivity
Neisseria gonorrhoeae, Trichomonas vaginalis
10 copies of bacterial DNA in the amplified sample

Specimens
Urine, swabs (cervical, urethral)

Detection technology
TaqMan

Performance study and results
Within the frame of testing the functional characteristics of **EliGene® STD NEI/TRI RT**, totally 50 clinical specimens were analyzed. **The EliGene® STD NEI/TRI RT** kit correctly identified all samples, with 3 positive for *Trichomonas vaginalis*, 8 positive for *Neisseria gonorrhoeae* and 39 negative for both of pathogens.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Neisseria gonorrhoeae, Trichomonas vaginalis
10 kopií bakteriální DNA v amplifikovaném vzorku

Vzorky
Moč, stěry (cervikální, uretrální)

Technologie detekce
TaqMan

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® STD NEI/TRI RT** bylo analyzováno 50 klinických vzorků. Souprava **EliGene® STD NEI/TRI RT** všechny vzorky správně identifikovala, a to 3 pozitivní na *Trichomonas vaginalis*, 8 pozitivních na *Neisseria gonorrhoeae* a 39 negativních pro oba patogeny.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Barbara A. Bannister, Norman T. Begg and Stephen H. Gillespie: Infcitous Discasc. Blaiktcll Siicnic, 2th Ed., 2000

Whiley DM, Buda PP, Freeman K, Patle NI, Bates J, Sloots TP. 2005. A rcal-tmc PCR assay for thc dctciton of Neisseria gonorrhoeaein gcnital and cxtragcnital spciimcns. Diagn Miirobiol Infcit Dis. 52(1):1-5

Whiley DM, Garland SM, Harnet G, Lum G, Smith DW, Tabrizi SN, Sloots TP, Tapsall JW. 2008. Exploring 'bcst praitic' for nuilcii aiid dctciton of Neisseria gonorrhoea. Scx Hcalth. 5(1):17-23.

EliGene® STD NEI/TRI RT
REF / Cat. No.: 90090-RT 50 reactions

Compatible devices / Kompatibilní přístroje

Thermofisher Scientific: QuantStudio 5

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

EliGene® DNA DIAGNOSTICS

CE IVD

EliGene® Mycoplasma Hom/Gen UNI

Analytical specificity and sensitivity
Mycoplasma hominis, Mycoplasma genitalium
10 copies of bacterial DNA in the amplified sample

Specimens
Urine, swabs (cervical, urethral), sperm

Detection technology
Molecular Beacons

Performance study and results
Within the frame of testing the functional characteristics of **EliGene® Mycoplasma hom/gen UNI** kit, totally 60 clinical specimens were analyzed. **The EliGene® Mycoplasma hom/gen UNI** kit diagnosed correctly as *Mycoplasma hominis* and *Mycoplasma genitalium* positive 7 specimens. Totally 53 specimens were rightly detrmined by **EliGene® Mycoplasma hom/gen UNI** kit as *Mycoplasma hominis* and *Mycoplasma genitalium* negative.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Mycoplasma hominis, Mycoplasma genitalium
10 kopií bakteriální DNA v amplifikovaném vzorku

Vzorky
Moč, stěry (cervikální, uretrální), sperma

Technologie detekce
Molecular Beacons

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® Mycoplasma hom/gen UNI** bylo analyzováno 60 klinických vzorků. Souprava **EliGene® Mycoplasma hom/gen UNI** všechny vzorky správně identifikovala, a to 7 pozitivních na *Mycoplasma hominis* a *Mycoplasma genitalium* a 53 vzorků negativních.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Edberg A, Jurstrand M, Johansson E, Wikander E,Höög A, Ahlqvist T, Falk L, Skov J, Fredlund H. 2008. A comparative study of three different PCR assays for detection of Mycoplasma genitalium in urogenital specimens from men and women. Journal of Medical Microbiology,57,304–309.

Baczynska A, Svenstrup HF, Fedder J, Birkelund S, Christiansen G. 2004. Development of real-time PCR for detection of Mycoplasma hominis. BMC Microbiology, 4:35.

Simpson T, Oh MK. 2004. Urethritis and cervicitis in adolescents. Adolesc Med Clin. 15(2):253-71.

EliGene® Mycoplasma hom/gen UNI
REF / Cat. No.: 90052-UNI 50 reactions

Compatible devices / Kompatibilní přístroje

Applied Biosystems: Real-Time System ABI 7500FAST

Roche: LightCycler® 480, LightCycler® Nano and LightCycler® 2.0

Qiagen: Rotor-Gene 6000 or Rotor-Gene Q

Thermofisher Scientific: QuantStudio 3 and 5

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

RUO

Elisabeth Pharmacon®

EliGene® Chlamydia trachomatis UNI

Analytical specificity and sensitivity
Chlamydia trachomatis, including "Sweden variant"
1–10 copies of bacterial DNA in the amplified sample

Specimens
Urine, swabs (cervical, urethral, rectal), sperm

Detection technology
Molecular Beacons

Performance study and results
110 clinical samples were analysed using the Elisabeth Pharmacon **EliGene® Chlamydia trachomatis UNI** test kit and the results were verified using the **Cobas Amplicor C. trachomatis test**. Of the 110 samples, 51 were correctly identified as positive for *Chlamydia trachomatis* and 59 were negative.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Chlamydia trachomatis, včetně „švédské varianty"
1–10 kopií bakteriální DNA v amplifikovaném vzorku

Vzorky
Moč, stěry (cervikální, uretrální, rektální), sperma

Technologie detekce
Molecular Beacons

Studie funkční způsobilosti a výsledky
Soupravou **EliGene® Chlamydia trachomatis UNI** bylo analyzováno 110 klinických vzorků a výsledek byl srovnán s výsledky **Cobas Amplicor C. trachomatis testu**. Ze 110 vzorků byly všechny výsledky správně indentifikovány, a to 51 vzorků pozitivních na *Chlamydia trachomatis* a 59 vzorků negativních.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Jurstrand M, Christerson L, Klint M, Fredlund H, Unemo M, Herrmann B. 2010. Characterisation of Chlamydia trachomatis by ompA sequencing and multilocus sequence typing in a Swedish county before and after identification of the new variant. Sex Transm Infect. 86(1): 56-60.

Kalwij S, Macintosh M, Baraitser P. 2010. Screening and treatment of Chlamydia trachomatis infections. BMJ. 21: 340:c1915.

EliGene® Chlamydia trachomatis UNI
REF / Cat. No.: 90046-UNI 50 reactions

Compatible devices / Kompatibilní přístroje

Roche: LightCycler® 480, LightCycler® Nano and LightCycler® 2.0

Thermofisher Scientific: QuantStudio 3 and 5

Applied Biosystems: Real-Time System ABI 7500FAST

Qiagen: Rotor-Gene 6000 or Rotor-Gene Q

Bio -Rad: CFX96 Touch Real -Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

EliGene® DNA DIAGNOSTICS

CE IVD

EliGene® Neisseria UNI

Analytical specificity and sensitivity
Neisseria gonorrhoeae
1–10 copies of bacterial DNA in the amplified sample

Specimens
Urine, swabs (cervical, urethral, conjunctival, rectal), sperm

Detection technology
Molecular Beacons

Performance study and results
88 Clinical samples were analysed and the results verified using the **Cobas Amplicor CT/NG test**. The **EliGene® Neisseria UNI** kit correctly identified 35 samples as positive and 53 samples as negative for *Neisseria gonorrhoeae*.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Neisseria gonorrhoeae
1–10 kopií bakteriální DNA v amplifikovaném vzorku

Vzorky
Moč, stěry (cervikální, uretrální, oční, rektální), sperma

Technologie detekce
Molecular Beacons

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® Neisseria UNI** bylo analyzováno 88 klinických vzorků a výsledky byly srovnány s **Cobas Amplicor CT/NG test**. Souprava **EliGene® Neisseria UNI** všechny vzorky správně identifikovala, a to 35 pozitivních na *Neisseria gonorrhoeae* a 53 vzorků negativních.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Whiley DM, Buda PP, Freeman K, Pattle NI, Bates J, Sloots TP. 2005. A real-time PCR assay for the detection of Neisseria gonorrhoeae in genital and extragenital specimens. Diagn Microbiol Infect Dis. 52(1):1-5.

Whiley DM, Garland SM, Harnett G, Lum G, Smith DW, Tabrizi SN, Sloots TP, Tapsall JW. 2008. Exploring 'best practice' for nucleic acid detection of Neisseria gonorrhoeae. Sex Health. 5(1):17-23.

EliGene® Neisseria UNI
REF / Cat. No.: 90047-UNI 50 reactions

Compatible devices / Kompatibilní přístroje

Roche: LightCycler® 480, LightCycler® Nano and LightCycler® 2.0

Qiagen: Rotor-Gene 6000 or Roto-rGene Q

Thermofisher Scientific: QuantStudio 3 and 5

Applied Biosystems: Real-Time System ABI 7500FAST

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

CE IVD

Elisabeth Pharmacon

EliGene® Ureaplasma UNI

Analytical specificity and sensitivity
Ureaplasma urealyticum, Ureaplasma parvum
1–10 copies of bacterial DNA in the amplified sample

Specimens
Urine, swabs (cervical, urethral, conjunctival, rectal), sperm

Detection technology
Molecular Beacons

Performance study and results
Within the frame of testing the functional characteristics of **EliGene® Ureaplasma UNI** kit, totally 68 clinical specimens were analyzed. The **EliGene® Ureaplasma UNI** kit diagnosed correctly as *Ureaplasma Urealyticum* or *Ureaplasma parvum* positive 20 specimens. Totally 48 specimens were rightly determined by **EliGene® Ureaplasma UNI** kit as *Ureaplasma Urealyticum* or *Ureaplasma parvum* negative.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Ureaplasma urealyticum, Ureaplasma parvum
1–10 kopií bakteriální DNA v amplifikovaném vzorku

Vzorky
Moč, stěry (cervikální, uretrální, oční, rektální), sperma

Technologie detekce
Molecular Beacons

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® Ureaplasma UNI** bylo analyzováno 68 klinických vzorků. Souprava **EliGene® Ureaplasma UNI** všechny vzorky správně identifikovala, a to 20 pozitivních na *Ureaplasma urealyticum/Ureaplasma parvum* a 48 vzorků negativních.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Allam AB, Alvarez S, Brown MB, Reyes L. 2011. Ureaplasma parvum infection alters filamin A dynamics in host cells. BMC Infect Dis. 11:101.

Pinna GS, Skevaki CL, Kafetzis DA. 2006. The significance of Ureaplasma urealyticum as a pathogenic agent in the paediatric population. Curr Opin Infect Dis. 19(3):283-9.

EliGene® Ureaplasma UNI
REF / Cat. No.: 90049-UNI 50 reactions

Compatible devices / Kompatibilní přístroje

Roche: LightCycler® 480, LightCycler® Nano and LightCycler® 2.0

Qiagen: Rotor-Gene 6000 or Rotor-Gene Q

Thermofisher Scientific: QuantStudio 3 and 5

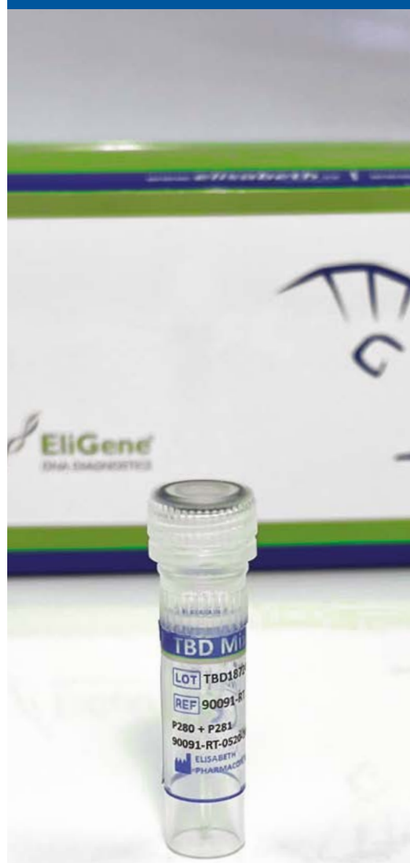
Applied Biosystems: Real-Time System ABI 7500FAST

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

EliGene® DNA DIAGNOSTICS

CE IVD



EliGene® Tick-borne diseases RT

Analytical specificity and sensitivity
Borrelia spielmanii, B. afzelii, B. garinii, B. valaisiana, B. burgdorferi s. s., Anaplasma phagocytophilum, tick-borne encephalitis virus (TBEV)
10 copies of bacterial DNA and 50 copies of viral RNA in the amplified sample

Specimens
Blood, urine, CSF, synovial fluid, tissue, ticks

Detection technology
TaqMan

Performance study and results
Within the frame of testing the functional characteristics of **EliGene® Tick-borne diseases RT**, totally 250 clinical and environmental specimens were analyzed. Of these, 20 were positive for tick-borne encephalitis virus, 56 were positive for *Anaplasma phagocytophilum* and 100 were positive for *B. burgdorferi senzu lato*.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Borrelia spielmanii, B. afzelii, B. garinii, B. valaisiana, B. burgdorferi s. s., Anaplasma phagocytophilum, virus klíšťové encefalitidy (TBEV)
10 kopií genomové DNA a 50 kopií RNA viru v amplifikovaném vzorku

Vzorky
Krev, moč, mozkomíšní mok, synoviální tekutiny, tkáně, klíšťata

Technologie detekce
TaqMan

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® Tick-borne diseases RT** bylo analyzováno 250 klinických a environmentálních vzorků. Z nich bylo 20 pozitivních na virus klíšťové encefalitidy, 56 pozitivních na *Anaplasma phagocytophilum* a 100 pozitivních na *B. burgdorferi senzu lato*.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Bannister BA, Begg NT, Gillespie SH. 2000. Infectious Disease. Blackwell Science, 2th Ed.

Barbara A. Bannister, Norman T. Begg and Stephen H. Gillespie: Infectious Disease. Blackwell Science, 2th Ed., 2000

Bonczek O, Žákovská A, Vargová L, Šerý O. Identification of Borrelia burgdorferi genospecies isolated from Ixodes ricinus ticks in the South Moravian region of the Czech Republic. Ann Agric Environ Med. 2015;22(4):637-41.

Gary P. Wormser et al. 2006. The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America. Clin Infect Dis. 43 (9): 1089-1134.

Hytönen J, Hartiala P, Oksi J, Viljanen MK. 2008. Borreliosis: recent research, diagnosis, and management. Scand J Rheumatol. 37(3):161-172

Johan S. Bakken, MD, Stephen Dumler. 2008. Human Granulocytic Anaplasmosis. Clin Infect Dis. 22 (3): 433–448

Josko D. Molecular virology in the clinical laboratory. Clin Lab Sci. 2010 Fall;23(4):231-6.

Priem S, Rittig MG, Kamradt T, Burmester GR, Krause A. 1997. An optimized PCR leads to rapid and highly sensitive detection of Borrelia burgdorferi in patients with Lyme borreliosis. J Clin Microbiol. 35(3): 685–690

EliGene® Tick-borne diseases RT
REF / Cat. No.: 90091-RT 50 reactions

Compatible devices / Kompatibilní přístroje

Thermofisher Scientific: QuantStudio 5

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

CE IVD

Elisabeth Pharmacon

EliGene® Babesia/Bartonella RT

Analytical specificity and sensitivity
All known species of microorganisms *Babesia* spp., *Bartonella* spp.
10 copies of genomic DNA in the amplified sample

Specimens
Blood, CSF, tissue, DNA isolated from ticks

Detection technology
TaqMan

Performance study and results
Within the frame of testing the functional characteristics of **EliGene® Babesia/Bartonella RT**, totally 45 culture and tick samples were analyzed. Of all samples, 10 were positive for Babesia spp. and 4 samples were positive for Bartonella spp. 31 samples were evaluated as negative.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Všechny známé druhy mikroorganismů *Babesia* spp., *Bartonella* spp
10 kopií genomové DNA v amplifikovaném vzorku

Vzorky
Krev, mozkomíšní mok, tkáně, DNA izolovaná z klíšťat

Technologie detekce
TaqMan

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® Babesia/Bartonella RT** bylo analyzováno 45 vzorků kultur a klíšťat. Ze všech vzorků bylo 10 pozitivních na Babesia spp. a 4 vzorky byly pozitivní na Bartonella spp. 31 vzorků bylo vyhodnoceno jako negativní.

Senzitivita: 100 %
Specifita: 100 %

EliGene® Babesia/Bartonella RT
REF / Cat. No.: 90094-RT 50 reactions

Compatible devices / Kompatibilní přístroje

Thermofisher Scientific: QuantStudio 5

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

EliGene® DNA DIAGNOSTICS

CE IVD

EliGene® MTB UNI

Analytical specificity and sensitivity
Mycobacterium tuberculosis, Mycobacterium bovis, **negative result for:** *Mycobacterium kansasii, Mycobacterium xenopi, Mycobacterium avium* and *Mycobacterium marinum*
1–10 copies of bacterial DNA in the amplified sample

Specimens
Urine, sputum, bronchoalveolar lavage, exudates, tissue, paraffin embedded tissue

Detection technology
Molecular Beacons

Performance study and results
Within the frame of performance study were tested by **EliGene® MTB UNI** kit totally 533 clinical samples. **EliGene® MTB UNI** kit detected correctly all 52 positive samples. Totally 481 samples were correctly diagnosed by **EliGene® MTB UNI** kit as negative.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Mycobacterium tuberculosis, Mycobacterium bovis, **negativní výsledek pro:** *Mycobacterium kansasii, Mycobacterium xenopi, Mycobacterium avium* a *Mycobacterium marinum*
1–10 kopií bakteriální DNA v amplifikovaném vzorku

Vzorky
Moč, sputum, bronchoalveolární lavage, exsudát, tkáně z parafinových bločků

Technologie detekce
Molecular Beacons

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® MTB UNI** bylo analyzováno 533 klinických vzorků. Souprava **EliGene® MTB UNI** všechny vzorky správně identifikovala, a to 52 pozitivních na *Mycobacterium tuberculosis*, *Mycobacterium bovis* a 481 vzorků negativních.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Kriz P, Kralik P, Slany M, Slana I, Svobodova J, Parmova I, Barnet V, Jurek V, Pavlik I. 2011. Mycobacterium pinnipedii in a captive Southern sea lion (Otaria flavescens): a case report. Veterinarni Medicina, 56:307-313.

Mendes A.C., Fernandes S.J., Ferreira L.C., Pereira M., Ramos H., Cabeda J.M. 2009. Evaluation of MTB Q Alert kit for detection of Mycobacterium tuberculosis directly on patient samples Clinical Microbiology and Infection, Suppl. 19, P1321.

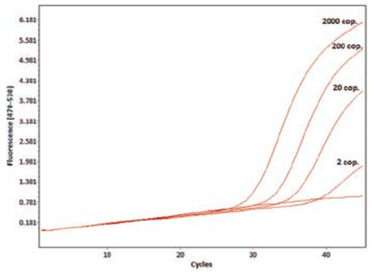


Figure: *Sensitivity test of* ***EliGene® MTB UNI*** *kit on LightCycler® 2.0 instrument shows the detection of* ***2 DNA copies*** *in reaction mix.*

Obrázek: *Test citlivosti* ***EliGene® MTB UNI*** *kitu na přístroji LightCycler® 2.0 ukazuje detekci* ***2 kopií DNA*** *bakterie v mixu.*

EliGene® MTB UNI
REF / Cat. No.: 90030-UNI 50 reactions

Compatible devices / Kompatibilní přístroje

Roche: LightCycler® 480, LightCycler® Nano, LightCycler® 2.0

Thermofisher Scientific: QuantStudio 3 and 5

Applied Biosystems: Real-Time System ABI 7500FAST

Qiagen: Rotor-Gene 6000 or Rotor-Gene Q

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

CE IVD

Elisabeth Pharmacon

EliGene® Borrelia UNI

Analytical specificity and sensitivity

Borrelia burgdorferi sensu stricto, Borrelia garinii, Borrelia afzelii
1–10 copies of bacterial DNA in the amplified sample

Specimens

Blood, urine, CSF, synovial fluid, tissue

Detection technology

Molecular Beacons

Performance study and results

Within the frame of performance study were tested by **EliGene® Borrelia UNI** kit 486 clinical samples. **EliGene® Borrelia UNI** kit detected correctly all 9 positive samples. Totally 477 samples were correctly diagnosed by **EliGene® Borrelia UNI** kit as *Borrelia* negative.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita

Borrelia burgdorferi sensu stricto, Borrelia garinii, Borrelia afzelii
1–10 kopií bakteriální DNA v amplifikovaném vzorku

Vzorky

Krev, moč, mozkomíšní mok, synoviální tekutiny, tkáně

Technologie detekce

Molecular Beacons

Studie funkční způsobilosti a výsledky

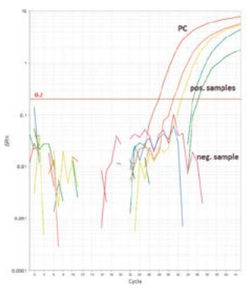
V rámci testování funkční způsobilosti soupravy **EliGene® Borrelia UNI** bylo analyzováno 486 klinických vzorků. Souprava **EliGene® Borrelia UNI** všechny vzorky správně identifikovala, a to 9 pozitivních na *Borrelia burgdorferi sensu lato* a 477 vzorků negativních.

Senzitivita: 100 %
Specifita: 100 %

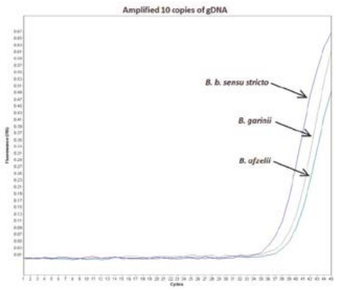
References / Zdroje

Hytönen J, Hartiala P, Oksi J, Viljanen MK. 2008. Borreliosis: recent research, diagnosis, and management. Scand J Rheumatol. 37(3):161-172.

Priem S, Rittig MG, Kamradt T, Burmester GR, Krause A. 1997. An optimized PCR leads to rapid and highly sensitive detection of Borrelia burgdorferi in patients with Lyme borreliosis. J Clin Microbiol. 35(3): 685–690.



Figures: *Detection of pathogenic Borrelia sp. in DNA samples (isolated from ticks) by **EliGene® Borrelia UNI** kit on ABI®7500FAST instrument.*



Obrázky: *Detekce patogenu Borrelia sp. ve vzorcích DNA (izolovaných z klíštěte) kitem **EliGene® Borrelia UNI** kit na přístroji ABI®7500FAST.*

EliGene® Borrelia UNI
REF / Cat. No.: 90024-UNI 50 reactions

Compatible devices / Kompatibilní přístroje

Roche: LightCycler® 480, LightCycler® Nano, LightCycler® 2.0

Thermofisher Scientific: QuantStudio 3 and 5

Applied Biosystems: Real-Time System ABI 7500FAST

Qiagen: Rotor-Gene 6000 or Rotor-Gene Q

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

EliGene® DNA DIAGNOSTICS

CE IVD

BACTERIAL INFECTIONS

EliGene® Anaplasma phagocytophilum UNI

Analytical specificity and sensitivity

Anaplasma phagocytophilum
1–10 copies of bacterial DNA in the amplified sample

Specimens

Blood, urine, CSF, synovial fluid, tissue

Detection technology

Molecular Beacons

Performance study and results

Within the frame of performance study were tested by **EliGene® Anaplasma phagocytophilum UNI** kit 527 samples of ticks. **EliGene® Anaplasma phagocytophilum UNI** kit detected correctly all positive 26 ticks samples. Totally 501 ticks samples were right determined by **EliGene® Anaplasma phagocytophilum UNI** kit as *Anaplasma phagocytophilum* negative.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita

Anaplasma phagocytophilum
1–10 kopií bakteriální DNA v amplifikovaném vzorku

Vzorky

Krev, moč, mozkomíšní mok, synoviální tekutiny, tkáně

Technologie detekce

Molecular Beacons

Studie funkční způsobilosti a výsledky

V rámci testování funkční způsobilosti soupravy **EliGene® Anaplasma phagocytophilum UNI** bylo analyzováno 527 vzorků klíšťat. Souprava **EliGene® Anaplasma phagocytophilum UNI** všechny vzorky správně identifikovala, a to 26 pozitivních na *Anaplasma phagocytophilum* a 501 vzorků negativních.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje

Gary P. Wormser et al. 2006. The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America. Clin Infect Dis. 43 (9): 1089-1134.

Johan S. Bakken, MD, Stephen Dumler. 2008. Human Granulocytic Anaplasmosis. Clin Infect Dis. 22 (3): 433–448

EliGene® Anaplasma phagocytophilum UNI
REF / Cat. No.: 90061-UNI 50 reactions

Compatible devices / Kompatibilní přístroje

Roche: LightCycler® 480, LightCycler® Nano, LightCycler® 2.0

Thermofisher Scientific: QuantStudio 3 and 5

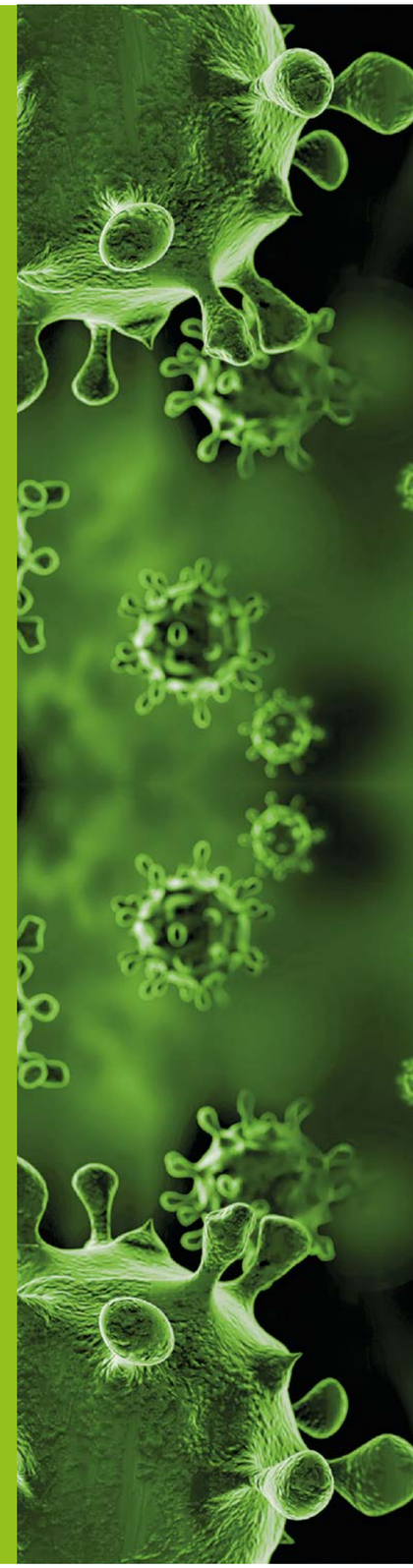
Applied Biosystems: Real-Time System ABI 7500FAST

Qiagen: Rotor-Gene 6000 or Rotor-Gene Q

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

VIRAL INFECTION
VIROVÉ INFEKCE



EliGene® COVID19 Triple RIC RT

Analytical specificity and sensitivity
SARS-CoV-2 virus, Influenza A virus (H1N1, H3N2, H5N1), Influenza B virus, Respiratory Syncytial Virus A and Respiratory Syncytial Virus B
5 genomic RNAs for SARS-CoV-2 and Influenza A/B and 50 genomic RNAs for RSV in the amplified sample

Specimens
Swabs (nasopharyngeal, buccal), saliva, sputum, urine, serum, plasma

Detection technology
TaqMan

Performance study and results
Within the frame of testing the functional characteristics of **EliGene® COVID19 Triple RIC RT**, totally 869 clinical samples (nasopharyngeal and oropharyngeal swabs) were analyzed. The **EliGene® COVID19 Triple RIC RT** kit showed 100% concordance in the detection of SARS-CoV-2 RNA in 838 clinical samples compared to the results obtained by reference methods, 100% concordance in the detection of influenza A and B virus RNA in 118 clinical samples compared to the results obtained by reference methods, and 100% concordance in the detection of RSV RNA in 113 clinical samples compared to the results obtained by reference methods.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
virus SARS-CoV-2, chřipkový virus typu A (H1N1, H3N2, H5N1), chřipkový virus typu B, respirační syncytiální virus A a respirační syncytiální virus B
5 genomových RNA SARS-CoV-2 a Influenza A/B a 50 genomových RNA u RSV v amplifikovaném vzorku

Vzorky
Stěry (nosohltan, bukální), sliny, sputum, moč, sérum, plasma

Technologie detekce
TaqMan

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® COVID19 Triple RIC RT** bylo analyzováno 869 klinických vzorků (výtěrů z nasopharyngu a oropharyngu). Souprava **EliGene® COVID19 Triple RIC RT** vykázala na 838 klinických vzorcích 100% shodu v detekci RNA viru SARS-CoV-2 ve srovnání s výsledky získanými referenční metodami, na 118 klinických vzorcích 100% shodu v detekci RNA chřipkových virů typu A a B ve srovnání s výsledky získanými referenčními metodami a 100% shodu na 113 klinických vzorcích v detekci RNA RSV viru ve srovnání s výsledky získanými referenční metodami.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
He F, Deng Y, Li W. Coronavirus Disease 2019 (COVID-19): What we know? J Med Virol. 2020 Mar 14. doi: 10.1002/jmv.25766.

Khan S, Siddique R, Shereen MA, Ali A, Liu J, Bai Q, Bashir N, Xue M. The emergence of a novel coronavirus (SARS-CoV-2), their biology and therapeutic options. J Clin Microbiol. 2020 Mar 11. pii: JCM.00187-20. doi: 10.1128/JCM.00187-20.

Ashour HM, Elkhatib WF, Rahman MM, Elshabrawy HA. Insights into the Recent 2019 Novel Coronavirus (SARS-CoV-2) in Light of Past Human Coronavirus Outbreaks. Pathogens. 2020 Mar 4;9(3). pii: E186. doi: 10.3390/pathogens9030186.

EliGene® COVID19 Triple RIC RT
REF / Cat. No.: 90079-RT 100 reactions

Compatible devices / Kompatibilní přístroje
Roche: LightCycler® 480
ThermoFisher Scientific: QuantStudio 5
Qiagen: Rotor-Gene Q
Bio-Rad: CFX96 Touch Real-Time PCR Detection System

CE IVD

Elisabeth Pharmacon®

EliGene® Influenza A/B/pandemic LC

Analytical specificity and sensitivity
Influenza virus A, B, A/H1N1
1–10 molecules of viral RNA in the amplified sample

Specimens
Serum, plasma, sputum, bronchoalveolar lavage, nasopharyngeal swab/aspirate

Detection technology
Molecular Beacons

Performance study and results
Within the frame of performance study of **EliGene® Influenza A/B/Pandemic LC** kit overall 100 clinical specimens were analyzed. From these specimens 61 blind specimens and 39 positive specimens were verified by **Cepheid Xpert® Flu kit** and **INFLUENZA A/B Q-PCR Alert kit**. From these 100 samples, 9 samples were Influenza A virus RNA positive, 6 samples Influenza B virus RNA positive and 24 Influenza A/H1N1 virus RNA positive. The **EliGene® Influenza A/B/Pandemic LC** kit diagnosed as Influenza A, B, A/H1N1 virus RNA positive all 39 and all 61 negative specimens. There were no discrepant results.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Influenza virus A, B, A/H1N1
1–10 molekul virové RNA v amplifikovaném vzorku

Vzorky
Sérum, plazma, sputum, bronchoalveolární lavage, nazofaryngeální stěr/aspirát

Technologie detekce
Molecular Beacons

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® Influenza A/B/Pandemic LC** bylo analyzováno 100 klinických vzorků, z nichž 61 bylo negativních a 39 pozitivních. Tyto vzorky byly přetestovány soupravami **Cepheid Xpert® Flu kit** a **INFLUENZA A/B Q-PCR Alert kit**. Ze 100 vzorků bylo 9 pozitivních na Influenza A virus RNA, 6 vzorků na Influenza B virus RNA a 24 vzorků na Influenza A/H1N1 virus RNA. Souprava **EliGene® Influenza A/B/Pandemic LC** diagnostikovala všech 39 vzorků pozitivních a 61 vzorků negativních. Hodnocení funkční způsobilosti bylo bez odchylek.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Rose N, Hervé S, Eveno E, Barbier N, Eono F, Dorenlor V, Andraud M, Camsusou C, Madec F, Simon G. 2013. Dynamics of influenza A virus infections in permanently infected pig farms: evidence of recurrent infections, circulation of several swine influenza viruses and reassortment events. Vet Res. 44(1):72.

Labella AM, Merel SE. 2013. Influenza. Med Clin North Am. 97(4):621-45.

Cha RM, Smith D, Shepherd E, Davis CT, Donis R, Nguyen T, Nguyen HD, Do HT, Inui K, Suarez DL, Swayne DE, Pantin-Jackwood M. 2013. Suboptimal protection against highly pathogenic avian influenza (H5N1) viruses from Vietnam in ducks vaccinated with commercial poultry vaccines. Vaccine. S0264-410X(13)01137-7.

EliGene® Influenza A/B/pandemic LC
REF / Cat. No.: 90058-LC 50 reactions

Compatible devices / Kompatibilní přístroje
Roche: LightCycler® 480
ThermoFisher Scientific: QuantStudio 5
Qiagen: Rotor-Gene Q
Bio-Rad: CFX96 Touch Real-Time PCR Detection System

EliGene® DNA DIAGNOSTICS

RUO

EliGene® HCV LC

Analytical specificity and sensitivity
Hepatitis C virus
50 IU/ml of serum

Specimens
Serum, plasma

Detection technology
Molecular Beacons

Performance study and results
Within the frame of performance study of **EliGene® HCV LC** kit overall 500 clinical specimens were analyzed. From these specimens, 300 HCV positive specimens and 200 HCV negative specimens were verified by **COBAS AMPLICOR HCV MONITOR Test,** version 2.0 (v2.0). The **EliGene® HCV LC** kit detected as HCV positive 299 specimens and 201 as negative.

100% sensitivity can be declared for the concentration of 50 IU/ml of serum isolated by **Magneto 1 ml Serum/Plasma DNA/RNA isolation kit** – extraction volume: 1.0 ml, elution volume: 50 µl. The linear range of the **EliGene® HCV LC** kit has been determined to cover concentrations from 1×10^5 IU/ml to at least 50 IU/ml.

Sensitivity: 100 % (50 IU/ml of serum)
Specificity: 100 %

Analytická specifita a senzitivita
Hepatitis C virus
50 IU/ml séra

Vzorky
Sérum, plazma

Technologie detekce
Molecular Beacons

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® HCV LC** bylo analyzováno 500 klinických vzorků. Tyto vzorky byly testovány pomocí **COBAS AMPLICOR HCV MONITOR Test,** verze 2.0 (v2.0) jako 300 pozitivních a 200 negativních. Souprava **EliGene® HCV LC** detekovala 299 vzorků HCV pozitivních a 201 vzorků negativních.

100% citlivost je deklarovaná pro koncentraci 50 IU/ml izolovaného séra soupravou **Magneto 1 ml Serum/Plasma DNA/RNA isolation kit** – extrakční objem: 1,0 ml, eluční objem: 50 µl. Lineární rozsah (analytická měření) soupravy **EliGene® HCV LC** kit byl stanoven analýzou ředící řady kvantifikačního standardu HCV v rozmezí od 1×10^5 IU/ml až do 50 IU/ml.

Senzitivita: 100 % (50 UI/ml séra)
Specifita: 100 %

References / Zdroje
Bannister BA, Begg NT, Gillespie SH. 2000. Infectious Disease. Blackwell Science. 2th Ed.

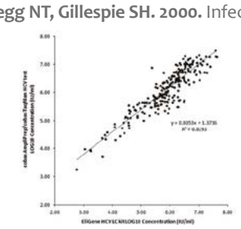


Figure: *Comparison of the COBAS AMPLICOR HCV MONITOR Test (v.2.0) against the **EliGene® HCV LC** Kit*

Obrázek: *Srovnání COBAS AMPLICOR HCV MONITOR Test (v.2.0) s **EliGene® HCV LC**.*

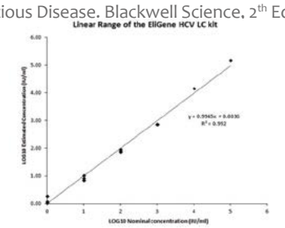
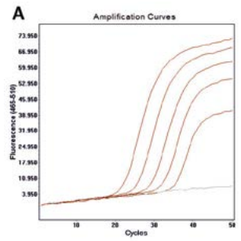


Figure: *Calculation of the linear range. The equation of the regression line is included in the figure.*

Obrázek: *Výpočet lineárního rozsahu. Regresní rovnice přímky je součástí obrázku.*



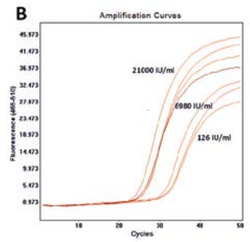


Figure: *Analysis of specimens with different concentration of HCV from 126 IU/ml to 21000 IU/ml with EliGene® HCV LC kit.*
A – amplification curves for five HCV standards,
B – amplification curves for HCV positive specimens.

Obrázek: *Analýzy vzorků s různou koncentrací viru HCV, a to od 126 IU/ml do 21000 IU/ml kitem EliGene® HCV LC kit.*
A – amplifikační křivky pěti HCV standardů,
B – amplifikační křivky HCV pozitivních vzorků.

EliGene® HCV LC
REF / Cat. No.: 90059-LC 50 reactions

Compatible devices / Kompatibilní přístroje
Applied Biosystems: Real-Time System ABI 7500FAST
Roche: LightCycler® 480, LightCycler® Nano, LightCycler® 2.0
Qiagen: Rotor-Gene 6000 or Rotor-Gene Q
Bio-Rad: CFX96 Touch Real-Time PCR Detection System
Bio Molecular Systems: MIC qPCR Cycler

RUO

EliGene® HBV RT
REF / Cat. No.: 90037-RT 50 reactions

Compatible devices / Kompatibilní přístroje

Applied Biosystems: ABI 7000, 7300, 7500FAST

Roche: LightCycler® 480, LightCycler® Nano

Qiagen: Rotor-Gene 6000 nebo Rotor-GeneQ

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

EliGene® HBV RT

Analytical specificity and sensitivity
Hepatitis B virus
0.1 IU/µl of isolated specimen

Specimens
Serum, plasma

Detection technology
Molecular Beacons

Performance study and results
Within the frame of performance study of **EliGene® HBV RT** kit overall 500 clinical specimens were analyzed. From these specimens, 300 HBV positive specimens and 200 HBV negative specimens were confirmed by **artus® HBV TM PCR Kit**. The **EliGene® HBV RT** kit detected as HBV positive 299 specimens and 201 as negative.

100% sensitivity can be declared for both kits for the concentration of 5 IU/ml of serum corresponding to concentration of 0.1 IU/µl of isolated specimen by **Magneto 1 ml Serum/Plasma DNA/RNA isolation kit** – extraction volume: 1.0 ml, elution volume: 50 µl. The linear range of the **EliGene® HBV RT** kit has been determined to cover concentrations from 1×10^5 IU/µl to at least 0.1 IU/µl.

Sensitivity: 100 % (0.1 IU/µl of isolated specimen)
Specificity: 100 %

Analytická specifita a senzitivita
Hepatitis B virus
0,1 IU/µl izolovaného vzorku

Vzorky
Sérum, plazma

Technologie detekce
Molecular Beacons

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® HBV RT** bylo analyzováno 500 klinických vzorků. Tyto vzorky byly testovány pomocí **artus® HBV TM PCR Kit** jako 300 pozitivních a 200 negativních na HBV. Souprava **EliGene® HBV RT** vzorky detekovala 299 vzorků HBV pozitivních a 201 vzorků negativních.

100% citlivost je deklarovaná pro koncentraci 5 IU/ml séra, což představuje koncentraci 0,1 IU/µl izolovaného vzorku pomocí soupravy **Magneto 1 ml Serum/Plasma DNA/RNA isolation kit** – extrakční objem: 1,0 ml, eluční objem: 50 µl. Lineární rozsah (analytická měření) soupravy **EliGene® HBV RT** byl stanoven analýzou ředící řady kvantifikačního standardu HBV v rozmezí od 1×10^5 IU/µl do 0,1 IU/µl.

Senzitivita: 100 % (0,1 IU/µl izolovaného vzorku)
Specifita: 100 %

References / Zdroje
Bannister BA, Begg NT, Gillespie SH. 2000. Infectious Disease. Blackwell Science, 2th Ed.

Ho SKN, Yam W-C, Leung ETK, Wong L-P, Leung JKH, Lai K-N, Chan TM. 2003. Rapid quantification of hepatitis B virus DNA by real-time PCR using fluorescent hybridization probes. J Med Microbiol. 52(5): 397-402.

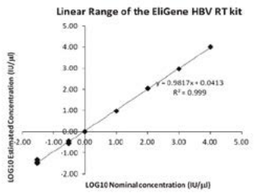
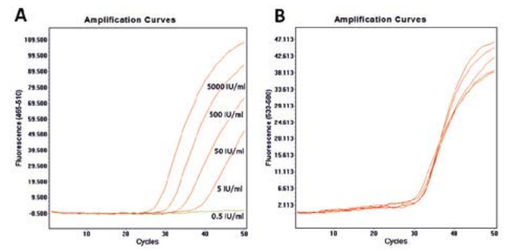


Figure: *Calculation of the linear range.*
Obrázek: *Výpočet lineárního rozsahu.*



Figures: *Analysis of specimens with different concentration of HBV from 0.5 IU/ml to 5000 IU/ml with* **EliGene® HBV RT** *kit:*
A – amplification curves for FAM channel (HBV detection),
B – amplification curves for HEX channel (Internal control).

Obrázky: *Analýza vzorků o různé koncentraci HBV (od 0.5 IU/ml do 5000 IU/ml séra) soupravou* **EliGene® HBV RT**:
A – amplifikační křivky kanálu FAM (HBV detekce),
B – amplifikační křivky kanálu HEX (interní kontrola).

EliGene® DNA DIAGNOSTICS

CE IVD

EliGene® HSV1/HSV2 UNI

Analytical specificity and sensitivity
Herpes virus 1 and 2
1–10 molecules of viral DNA in the amplified sample

Specimens
CSF, biopsy, swabs (skin, mucosa), blood

Detection technology
TaqMan

Performance study and results
Within the frame of performance study of **EliGene® HSV1/HSV2 UNI** kit overall 636 HSV1 clinical specimens and 211 HSV2 clinical specimens were analyzed. From 636 HSV1 clinical specimens were 201 positive. **EliGene® HSV1/HSV2 UNI** kit analyzed 197 samples as positive. Totally 435 clinical specimens were properly by **EliGene® HSV1/HSV2 UNI** kit analyzed as negative. From 211 HSV2 clinical specimens were 24 positive. **EliGene® HSV2 UNI** kit analyzed all 24 samples as positive. Totally 187 clinical specimens were properly by **EliGene® HSV2 UNI** kit analyzed as negative.

HSV1 Sensitivity: 98.04 %
HSV1 Specificity: 100 %
HSV2 Sensitivity: 100 %
HSV2 Specificity: 100 %

Analytická specifita a senzitivita
Herpes virus 1 and 2
1–10 molekul virové DNA v amplifikovaném vzorku

Vzorky
CSF, biopsie, stěr (z kůže, ze sliznice), krev

Technologie detekce
TaqMan

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti **EliGene® HSV1/HSV2 UNI** kitu bylo analyzováno celkem 636 klinických vzorků HSV1 a 211 klinických vzorků HSV2. Z těchto 636 klinických vzorků bylo 201 pozitivních. **EliGene® HSV1/HSV2 UNI** kit vyhodnotil 197 vzorků jako pozitivních. Celkem 435 klinických vzorků bylo kitem **EliGene® HSV1/HSV2 UNI** vyhodnoceno jako negativní. Z 211 klinických vzorků HSV2 bylo 24 pozitivních. **EliGene® HSV1/HSV2 UNI** kit analyzoval všech 24 klinických vzorků jako pozitivní. Zbývajících 187 klinických vzorků bylo analyzováno jako negativní.

HSV1 Senzitivita: 98,04 %
HSV1 Specifita: 100 %
HSV2 Senzitivita: 100 %
HSV2 Specifita: 100 %

References / Zdroje
Bannister BA, Begg NT, Gillespie SH. 2000. Infectious Disease. Blackwell Science, 2th Ed.

Hlinomazová Z, Loukotová V, Horáčková M, Šerý O. 2010. The treatment of HSV1 ocular infections using quantitative real-time PCR results. Acta Ophthalmol. 10: 1755-3768.

EliGene® HSV1/HSV2 UNI
REF / Cat. No.: 90062-UNI 50 reactions

Compatible devices / Kompatibilní přístroje

Applied Biosystems: Real-Time System ABI 7500FAST

Roche: LightCycler® 480, LightCycler® Nano, LightCycler® 2.0

Qiagen: Rotor-Gene 6000 or Rotor-Gene Q

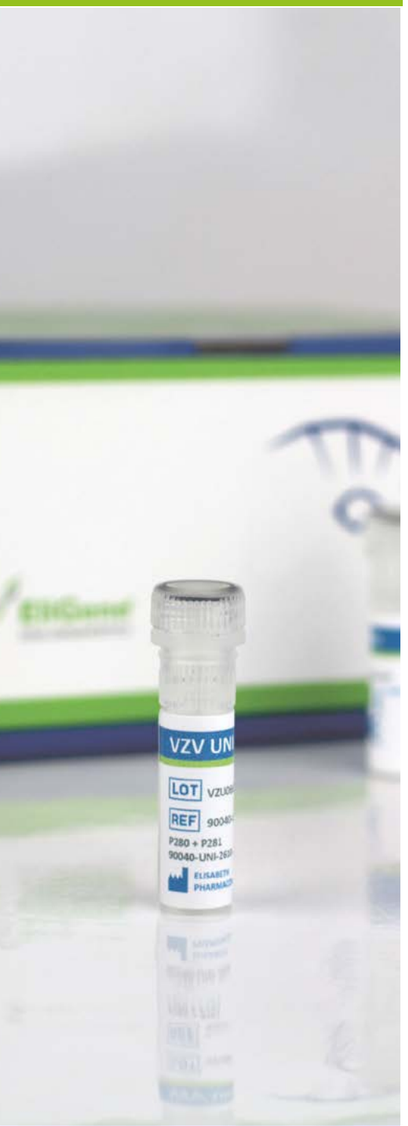
Thermofisher Scientific: QuantStudio 3 and 5

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

CE IVD

Elisabeth Pharmacon®



EliGene® VZV UNI

Analytical specificity and sensitivity
Varicella zoster virus
1–10 molecules of viral DNA in the amplified sample

Specimens
CSF, biopsy, swabs (skin, mucosa), blood

Detection technology
TaqMan

Performance study and results
Within the frame of performance study of **EliGene® VZV UNI** kit overall 481 clinical specimens were analyzed. From these 481 clinical specimens 51 were positive. **EliGene® VZV UNI** kit analyzed all 51 samples as positive. Totally 430 clinical specimens were properly by **EliGene® VZV UNI** kit analyzed as negative.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Varicella zoster virus
1–10 molekul virové DNA v amplifikovaném vzorku

Vzorky
CSF, biopsie, stěr (z kůže, ze sliznice), krev

Technologie detekce
TaqMan

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® VZV UNI** kitu bylo analyzováno celkem 481 klinických vzorků. Z těchto 481 klinických vzorků bylo 51 pozitivních. **EliGene® VZV UNI** kit vyhodnotil 51 vzorků jako pozitivních. Celkem 430 klinických vzorků bylo kitem **EliGene® VZV UNI** vyhodnoceno jako negativní.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Bannister BA, Begg NT, Gillespie SH. 2000. Infectious Disease. Blackwell Science, 2th Ed.

Dwyer DE, Cunningham AL. 2002. Herpes simplex and varicella-zoster virus infections. Med J Aust. 177(5):267-73.

Hlinomazová Z, Loukotová V, Horáčková M, Šerý O. 2010. The treatment of HSV1 ocular infections using quantitative real-time PCR results. Acta Ophthalmol. 10: 1755-3768.

EliGene® VZV UNI
REF / Cat. No.: 90040-LC 50 reactions

Compatible devices / Kompatibilní přístroje

Roche: LightCycler® 480, LightCycler® Nano, LightCycler® 2.0

Thermofisher Scientific: QuantStudio 3 a 5

Applied Biosystems: ABI 7500FAST

Qiagen: Rotor-Gene 6000 nebo Rotor-Gene Q

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

EliGene® DNA DIAGNOSTICS

CE IVD

EliGene® Adenovirus RT

Analytical specificity and sensitivity
All 51 types of Adenoviruses
1–10 molecules of viral DNA in the amplified sample

Specimens
Urine, CSF, feces, swabs, serum, plasma

Detection technology
TaqMan

Performance study and results
Within the frame of performance study of **EliGene® Adenovirus UNI** kit overall 350 clinical specimens were analyzed. From these 350 clinical specimens were 20 positive. **EliGene® Adenovirus UNI** kit analyzed 20 samples as positive. Totally 330 clinical specimens were properly by **EliGene® Adenovirus UNI** kit analyzed as negative.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Všech 51 typů Adenovirů
1–10 molekul virové DNA v amplifikovaném vzorku

Vzorky
Moč, CSF, stolice, stěry, sérum, plasma

Technologie detekce
TaqMan

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti **EliGene® Adenovirus UNI** bylo analyzováno 350 klinických vzorků. Z těchto 350 klinických vzorků bylo 20 pozitivních. Souprava **EliGene® Adenovirus UNI** všechny vzorky správně identifikovala, a to 20 vzorků pozitivních a 330 vzorků negativních.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Bannister BA, Begg NT, Gillespie SH. 2000. Infectious Disease. Blackwell Science, 2th Ed.

Jothikumar N, Cromeans TL, Hill VR, Lu X, Sobsey MD, Erdman DD. 2005. Quantitative real-time PCR assays for detection of human adenoviruses and identification of serotypes 40 and 41. Appl Environ Microbiol. 71(6):3131-6.

Hlinomazová Z, Loukotová V, Horáčková M, Serý O. 2010. The treatment of HSV1 ocular infections using quantitative real-time PCR results. Acta Ophthalmol. 10: 1755-3768.

EliGene® Adenovirus RT
REF / Cat. No.: 90036-RT 50 reactions

Compatible devices / Kompatibilní přístroje

Applied Biosystems: ABI 7000, 7300, 7500FAST

Roche: LightCycler® 480, LightCycler® Nano

Qiagen: Rotor-Gene 6000 nebo Rotor-Gene Q

CE IVD

Elisabeth Pharmacon®

EliGene® Norovirus LC

Analytical specificity and sensitivity
Norovirus genogroup 1 and 2
1–10 molecules of viral DNA in the amplified sample

Specimens
Serum, plasma, feces, water, CSF

Detection technology
Molecular Beacons

Performance study and results
Within the frame of performance study of **EliGene® Norovirus UNI** kit overall 100 clinical specimens were analyzed. From these specimens 100 blind specimens were verified by reference method (La Rosa et al. 2010). From these 100 samples 56 samples were Norovirus RNA positive. The **EliGene® Norovirus UNI** kit diagnosed as Norovirus RNA positive all 56 specimens. There were no discrepant results. Totally 44 specimens were right determined by the **EliGene® Norovirus UNI** kit as Norovirus RNA negative.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Norovirus 1 a 2
1–10 molekul virové DNA v amplifikovaném vzorku

Vzorky
Sérum, plazma, stolice, voda, CSF

Technologie detekce
Molecular Beacons

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® Norovirus UNI** kitu bylo analyzováno celkem 100 klinických vzorků. Z těchto 100 klinických vzorků bylo verifikováno referenční metodou (La Rosa et al. 2010) 56 vzorků Norovirus RNA pozitivních. **EliGene® Norovirus UNI** kit vyhodnotil správně všech 56 vzorků jako pozitivní a zbylých 44 jako negativní. Souprava **EliGene® Norovirus UNI** správně diagnostikovala všechny vzorky bez odchylek.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Bannister BA, Begg NT, Gillespie SH. 2000. Infectious Disease. Blackwell Science, 2th Ed.

Oberste MS, Maher K, Kilpatrick DR, Pallansch MA. 1999. Molecular evolution of the human Noroviruses: correlation of serotype with VP1 sequence and application to picornavirus classification". J. Virol. 73 (3):1941–8

EliGene® Norovirus LC
REF / Cat. No.: 90054-LC 50 reactions

Compatible devices / Kompatibilní přístroje
Roche: LightCycler® 480
Thermofisher Scientific: QuantStudio 3 and 5
Qiagen: Rotor-Gene Q
Bio-Rad: CFX96 Touch Real-Time PCR Detection System

EliGene® DNA DIAGNOSTICS

CE IVD

EliGene® Enterovirus LC

Analytical specificity and sensitivity
Enteroviruses (Coxsackie A, Coxsackie B and Echovirus)
1–10 molecules of viral RNA in the amplified sample

Specimens
CSF, feces, serum, plasma, sputum, blood

Detection technology
Molecular Beacons

Performance study and results
Within the frame of performance study of **EliGene® Enterovirus LC** kit overall 100 clinical specimens were analyzed. From these specimens 100 blind specimens were verified by reference method (La Rosa et al. 2010). From these 100 samples 56 samples were Enterovirus RNA positive. The **EliGene® Enterovirus LC** kit diagnosed as Enterovirus RNA positive all 56 specimens. There were no discrepant results. Totally 44 specimens were right determined by the **EliGene® Enterovirus LC** kit as Enterovirus RNA negative.

Sensitivity: 100 %
Specificity: 100 %

Analytická specifita a senzitivita
Enteroviry (Coxsackie A, Coxsackie B and Echovirus)
1–10 molekul virové RNA v amplifikovaném vzorku

Vzorky
CSF, stolice, sérum, plazma, krev, sputum

Technologie detekce
Molecular Beacons

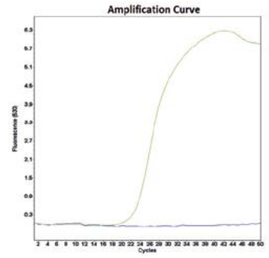
Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® Enterovirus LC** bylo analyzováno 100 klinických vzorků. Z těchto 100 vzorků bylo 56 vzorků pozitivních na enterovirovou RNA. Souprava **EliGene® Enterovirus LC** všechny vzorky správně identifikovala, a to 56 vzorků Enterovirus RNA pozitivních a 44 vzorků negativních.

Senzitivita: 100 %
Specifita: 100 %

References / Zdroje
Bannister BA, Begg NT, Gillespie SH. 2000. Infectious Disease. Blackwell Science, 2th Ed.

Jothikumar N, Cromeans TL, Hill VR, Lu X, Sobsey MD, Erdman DD. 2005. Quantitative real-time PCR assays for detection of human adenoviruses and identification of serotypes 40 and 41. Appl Environ Microbiol. 71(6):3131-6.

Hlinomazová Z, Loukotová V, Horáčková M, Serý O. 2010. The treatment of HSV1 ocular infections using quantitative real-time PCR results. Acta Ophthalmol. 10: 1755-3768.



Figures: *Figure: Analysis of Positive sample by* **EliGene® Enterovirus LC** *kit on LightCycler® 2.0 instrument showing results in 530 channel (Enterovirus detection)*
Obrázek: Analýza pozitivních vzorků soupravou **EliGene® Enterovirus LC** *na přístroji LightCycler® 2.0 ukazuje výsledek v kanále 530 (detekce Enteroviru)*

EliGene® Enterovirus LC
REF / Cat. No.: 90053-RT 50 reactions

Compatible devices / Kompatibilní přístroje
Roche: LightCycler® 480
Thermofisher Scientific: QuantStudio 3 and 5
Qiagen: Rotor-Gene Q
Bio-Rad: CFX96 Touch Real-Time PCR Detection System

RUO

EliGene® TBEV LC

Analytical specificity and sensitivity
Genome RNA of tick-borne encephalitis virus
50 molecules of viral RNA in the amplified sample

Specimens
Serum, plasma, CSF, ticks

Detection technology
TaqMan

Pathogen description
Tick-borne encephalitis (TBE) is a viral infectious disease involving the central nervous system. The disease most often manifests as meningitis, encephalitis, or meningoencephalitis. Although TBE is most commonly recognized as a neurological disorder, mild fever can also occur.

The tick-borne encephalitis virus is known to infect a range of hosts including ruminants, birds, rodents, carnivores, horses and humans. The disease can also be zoonotic.

Analytická specifita a senzitivita
Genomová RNA viru klíšťové encefalitidy
50 molekul virové RNA v amplifikovaném vzorku

Vzorky
Sérum, plazma, CSF, klíšťata

Technologie detekce
TaqMan

Popis patogenu
Klíšťová encefalitida je infekční onemocnění napadající mozek a mozkové blány. Onemocnění se nejčastěji projevuje jako meningitida, encefalitida nebo meningoencefalitida. Onemocnění je známé u přežvýkavců, hlodavců, ptáků, šelem, koní a lidí. Přenos původců ze skupiny Flaviciridae se uskutečňuje klíšťaty nebo alimentární cestou. Onemocnění může být zoonózou.

References / Zdroje
Mansfield, K.L., Johnson, N., Phipps, L.P., Stephenson, J.R., Fooks, A.R., and Solomon, T. (2009). Tick-borne encephalitis virus – a review of an emerging zoonosis. J Gen Virol 90, 1781–1794

Lindquist, L., Vapalahti, O. (2008). Tick-borne encephalitis. Lancet 371(9627), 1861–71

Suess, J. (2008) Tick-borne encephalitis in Europe and beyond -- the epidemiological situation as of 2007. Euro Surveillance 13(26)

EliGene® TBEV LC
REF / Cat. No.: 90070-LC 50 reactions

Compatible devices / Kompatibilní přístroje

Roche: LightCycler® 480

Qiagen: Rotor-Gene 6000 or Rotor-Gene Q

Thermofisher Scientific: QuantStudio 5

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

IVD

EliGene® Monkeypox RT

Analytical specificity and sensitivity
Orthopoxvirus (Monkeypox virus)
1–10 molecules of viral DNA in the amplified sample

Specimens
Swabs (from lesions, blisters, nasopharyngeal and throat swabs), tissue

Detection technology
TaqMan

Performance study and results
Within the frame of testing the functional characteristics of **EliGene® Monkeypox RT**, totally 30 clinical samples were analyzed. DNA of the Monkeypox virus target sequence was added to 20 samples at various concentrations. The **EliGene® Monkeypox RT** kit correctly identified all 30 samples, with 20 samples containing target virus DNA and 10 samples being negative.

Specificity: 100 %
Analytical sensitivity: 10 target DNA molecules per sample

Analytická specifita a senzitivita
Orthopoxvirus (virus opičích neštovic)
1–10 molekul virové DNA v amplifikovaném vzorku

Vzorky
Stěry (z lézí, puchýřků, nosohltanu a krku), tkáně

Technologie detekce
TaqMan

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® Monkeypox RT** bylo analyzováno 30 klinických vzorků. Do 20 vzorků byla přidána DNA cílové sekvence Monkeypox viru v různých koncentracích. Souprava **EliGene® Monkeypox RT** určila všech 30 vzorků správně a to 20 vzorků s cílovou DNA viru a 10 negativních vzorků.

Specifita: 100 %
Analytická senzitivita: 10 cílových DNA molekul v analyzovaném vzorku

References / Zdroje
Li Y, Zhao H, Wilkins K, Hughes C, Damon IK. Real-time PCR assays for the specific detection of monkeypox virus West African and Congo Basin strain DNA. J Virol Methods. 2010;169(1):223-227.

EliGene® Monkeypox RT
REF / Cat. No.: 90095-RT 50 reactions

Compatible devices / Kompatibilní přístroje

Roche: LightCycler® 480

Thermofisher Scientific: QuantStudio 3 and 5

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC qPCR Cycler

HUMAN GENETICS
LÉKAŘSKÁ GENETIKA

EliGene® CELIAC DQ PLUS RT

Intended use

Genotypization of the following alleles:
HLA-DQ2.5 (DQA1*05/DQB1*02)
HLA-DQ2.2 (DQA1*02/DQB1*02)
HLA-DQ8 (DQA1*03/DQB1*03:02)
HLA-DRB1*04

from isolated DNA

Specimens

Buccal swabs, blood

Detection technology

TaqMan LNA

Performance study and results

EliGene® Celiac DQ PLUS RT kit specificity was tested on 50 samples of human DNA with genotypes determined by CE-IVD kits for the detection of analysed alelles. Totally 50 samples were determined right by **EliGene® Celiac DQ PLUS RT.**

Analytical sensitivity: 5 ng of DNA in reaction mix
Specificity: 100 %

Účel použití

Genotypizace alel:
HLA-DQ2.5 (DQA1 * 05/DQB1 * 02)
HLA-DQ2.2 (DQA1 * 02/DQB1 * 02)
HLA-DQ8 (DQA1 * 03/DQB1 * 03:02)
HLA-DRB1 * 04

z izolované DNA

Vzorky

Stěr z bukální sliznice, krev

Technologie detekce

TaqMan LNA

Studie funkční způsobilosti a výsledky

Souprava **EliGene® Celiac DQ PLUS RT** byla testována na 50 vzorcích lidské DNA s genotypy určenými na základě referenčních CE-IVD souprav určených pro detekci analyzovaných alel. Celkem 50 vzorků bylo správně určeno soupravou **EliGene® Celiac DQ PLUS RT.**

Analytická citlivost: 5 ng DNA v reakční směsi
Specifita: 100 %

References / Zdroje

Bourgey M, Calcagno G, Tinto N, Gennarelli D, Margaritte-Jeannin P, Greco L, Limongelli MG, Esposito O, Marano C, Troncone R, Spampanato A, Clerget-Darpoux F, Sacchetti L. (2007) HLA related genetic risk for coeliac disease. Gut. 56(8):1054-9

Margaritte-Jeannin P, Babron MC, Bourgey M, Louka AS, Clot F, Percopo S, Coto I, Hugot JP, Ascher H, Sollid LM, Greco L, Clerget-Darpoux F. (2004) HLA-DQ relative risks for coeliac disease in European populations: a study of the European Genetics Cluster on Coeliac Disease. Tissue Antigens 63(6):562-7.

EliGene® CELIAC DQ PLUS RT
REF / Cat. No.: 90085-RT 50 reactions

Compatible devices / Kompatibilní přístroje

ThermoFisher Scientific: QuantStudio 5

Qiagen: Rotor-Gene Q

Bio-Rad: CFX96 Touch Real-Time PCR Detection System

Bio Molecular Systems: MIC cycler

CE IVD

Elisabeth Pharmacon®

EliGene® Coeliac 3.0 RT
EliGene® Coeliac RT

Specimens
EliGene® Coeliac 3.0 RT is used for allele genotyping:
HLA-DQ2.5 (DQA1*05/DQB1*02),
HLA-DQ2.2 (DQA1*02/DQB1*02),
HLA-DQ8 (DQA1*03/DQB1*03:02)
from isolated DNA

EliGene® Coeliac RT is used for allele genotyping:
HLA-DQ2 (DQA1*05/DQB1*02),
HLA-DQ8 (DQA1*03/DQB1*03:02),
HLA-DR4 (DRBR1*04)
from isolated DNA

Specimens
Buccal swabs, blood

Detection technology
TaqMan LNA

Performance study and results
EliGene® Coeliac RT kit specificity was tested on 50 samples of human DNA with genotypes determined by DNA sequencing. All the 50 samples were correctly identified by **EliGene® Coeliac RT**. The clinical specificity of **EliGene® Coeliac RT** kit is 100 %.

Analytical sensitivity: 10 ng of DNA in reaction mix
Specificity: 100 %

Účel použití
EliGene® Coeliac 3.0 RT slouží ke genotypizaci alel:
HLA-DQ2.5 (DQA1*05/DQB1*02),
HLA-DQ2.2 (DQA1*02/DQB1*02),
HLA-DQ8 (DQA1*03/DQB1*03:02)
z izolované DNA

EliGene® Coeliac RT slouží ke genotypizaci alel:
HLA-DQ2 (DQA1*05/DQB1*02),
HLA-DQ8 (DQA1*03/DQB1*03:02),
HLA-DR4 (DRBR1*04)
z izolované DNA

Vzorky
Stěr z bukální sliznice, krev

Technologie detekce
TaqMan LNA

Studie funkční způsobilosti a výsledky
Specifita kitu **EliGene® Coeliac RT** byla testována na 50 vzorcích lidské DNA s genotypy určenými na základě sekvenace. Všech 50 vzorků kit **EliGene® Coeliac RT** vyhodnotil správně. Klinická specifita **EliGene® Coeliac RT** kitu je 100 %.

Analytická citlivost: 10 ng DNA v reakční směsi
Specifita: 100 %

References / Zdroje
Bourgey M, Calcagno G, Tinto N, Gennarelli D, Margaritte-Jeannin P, Greco L, Limongelli MG, Esposito O, Marano C, Troncone R, Spampanato A, Clerget-Darpoux F, Sacchetti L. (2007) HLA related genetic risk for coeliac disease. Gut. 56(8):1054-9

Margaritte-Jeannin P, Babron MC, Bourgey M, Louka AS, Clot F, Percopo S, Coto I, Hugot JP, Ascher H, Sollid LM, Greco L, Clerget-Darpoux F. (2004) HLA-DQ relative risks for coeliac disease in European populations: a study of the European Genetics Cluster on Coeliac Disease. Tissue Antigens 63(6):562-7.

EliGene® Coeliac 3.0 RT
REF / Cat. No.: 90071-RT 50 reactions
EliGene® Coeliac RT
REF / Cat. No.: 90048-RT 50 reactions

Compatible devices / Kompatibilní přístroje
Roche: LightCycler® 480, LightCycler® Nano
Thermofisher Scientific: QuantStudio 3 and 5
Applied Biosystems: ABI 7000, 7300, 7500FAST
Qiagen: Rotor-Gene 6000 nebo Rotor-Gene Q
Bio -Rad: CFX96 Touch Real -Time PCR Detection System

EliGene® DNA DIAGNOSTICS

CE IVD

EliGene® Lactose intolerance RT

Intended use
Detection of C-13910T and G-22018A polymorphisms located in MCM6 gene.

Specimens
Buccal swabs, blood

Detection technology
TaqMan

Performance study and results
EliGene® Lactose intolerance RT kit specificity was tested using 31 samples of human DNA analyzed by reference method, when 8 samples were positive for the risk genotype. 100 % agreement was achieved when comparing the test results. The clinical specificity of **EliGene® Lactose intolerance RT** kit is 100 %.

Analytical sensitivity: 10 ng of DNA in reaction mix
Specificity: 100 %

Účel použití
Detekce polymorfismu C-13910T a G-22018A v genu MCM6.

Vzorky
Stěr z bukální sliznice, krev

Technologie detekce
TaqMan

Studie funkční způsobilosti a výsledky
Specifita soupravy **EliGene® Lactose intolerance RT** byla testována pomocí 31 vzorků analyzovaných referenční metodou, kdy bylo zjištěno 8 vzorků pozitivních na rizikový genotyp. Při porovnání výsledků testů byla dosažena stoprocentní shoda. Klinická specifita soupravy **EliGene® Lactose intolerance RT** je 100 %.

Analytická citlivost: 10 ng DNA v reakční směs
Specifita: 100 %

References / Zdroje
Ridefelt P, Håkansson LD. 2005. Lactose intolerance: lactose tolerance test versus genotyping. Scand J Gastroenterol. 40(7):822-6.

Bulhões AC, Goldani HA, Oliveira FS, Matte US, Mazzuca RB, Silveira TR. 2007. Correlation between lactose absorption and the C/T-13910 and G/A-22018 mutations of the lactase-phlorizin hydrolase (LCT) gene in adulttype hypolactasia. Braz J Med Biol Res. 40(11):1441-6.

Tomczonek-Moruś J, Wojtasik A, Zeman K, Smolarz B, Bąk-Romaniszyn L. 13910C>T and 22018G>A LCT gene polymorphisms in diagnosing hypolactasia in children. United European Gastroenterol J. 2019;7(2):210-216.

Friedrich, D. C., Santos, S. E. B., Ribeiro-Dos-Santos, Â. K. C., Hutz, M. H., Crawford, D. C., 2012. Several Different Lactase Persistence Associated Alleles and High Diversity of the Lactase Gene in the Admixed Brazilian Population. PLoS ONE. 7(9).

EliGene® Lactose intolerance RT
REF / Cat. No.: 90092-RT 50 reactions

Compatible devices / Kompatibilní přístroje
Thermofisher Scientific: QuantStudio 5
Bio-Rad: CFX96 Touch Real-Time PCR Detection System

CE IVD

Elisabeth Pharmacon®

EliGene® Spondylitis HLA-B27 RT

Intended use
Genotypization of HLA-B27 allele (subtypes B*2701-2759).

Specimens
Buccal swabs, blood

Detection technology
TaqMan

Performance study and results
Within the frame of performance study of **EliGene® Spondylitis HLA-B27 RT** kit overall 226 specimens were analyzed. From these specimens 226 blind specimens were verified by reference method (Roelandse-Koop EA et al., 2011). From these 226 samples 36 samples were HLA-B27 allele positive. The **EliGene® Spondylitis HLA-B27 RT** kit diagnosed as HLA-B27 allele positive all 36 specimens and 190 specimens were correctly determined as HLA-B27 allele negative.

Analytical sensitivity: 1 ng of DNA in reaction mix
Specificity: 100 %

Účel použití
Genotypizace alely HLA-B27 (subtypy B*2701-2759).

Vzorky
Stěr z bukální sliznice, krev

Technologie detekce
TaqMan

Studie funkční způsobilosti a výsledky
V rámci testování funkční způsobilosti soupravy **EliGene® Spondylitis HLA-B27 RT** bylo analyzováno 226 vzorků. Z těchto 226 klinických vzorků bylo verifikováno referenční metodou (Roelandse-Koop EA et al., 2011) 36 vzorků pozitivních na přítomnost alely HLA-B27. Souprava **EliGene® Spondylitis HLA-B27 RT** stanovila správně ve všech 36 vzorcích přítomnost alely HLA-B27 a ve zbylých 190 tuto alelu nedetekovala.

Analytická citlivost: 1 ng DNA v reakční směsi
Specifita: 100 %

References / Zdroje
Khan MA. Remarkable Polymorphism of HLA-B27: An Ongoing Saga. Curr Rheumatol Report. 2010; 12: 337-41

Robinson PC, Brown MA. 2012. The genetics of ankylosing spondylitis and axial spondyloarthritis. Rheum Dis Clin North Am. 38(3):539-53

Thomas GP, Brown MA. Genetics and Genomics of Ankylosing Spondylitis. Immunol Rev. 2010; 233:162-180.

EliGene® Spondylitis HLA-B27 RT
REF / Cat. No.: 90060-RT 50 reactions

Compatible devices / Kompatibilní přístroje

Applied Biosystems: ABI 7000, 7300, 7500FAST
Roche: LightCycler® 480, LightCycler® Nano
Qiagen: Rotor-Gene 6000 nebo Rotor-Gene Q

EliGene® DNA DIAGNOSTICS

CE IVD

EliGene® Spondylitis HLA-B27 C6
Optimized for cobas® 6800/8800 Systems

Intended use
Genotypization of HLA-B27 allele (subtypes B*2701-2759).

The kit is optimized for cobas® 6800/8800 Systems (Roche).

Specimens
Whole blood

Detection technology
TaqMan

Performance study and results
Within the frame of testing functional characteristic of the **EliGene® Spondylitis HLA-B27 C6** kit overall 166 specimens were analyzed, of which 124 were positive. DNA from the clinical samples was isolated using automated extraction with the **cobas® 6800 instrument (Roche)**. The **EliGene® Spondylitis HLA-B27 C6** kit subsequently correctly identified 124 samples as HLA-B27 positive, in comparison with the results obtained using the reference method EliGene® Spondylitis HLA-B27 RT, and 42 samples were correctly determined as HLA-B27 negative

Analytical sensitivity: 1 ng/µl
Specificity: 100 %

Účel použití
Genotypizace alely HLA-B27 (subtypy B*2701-2759).

Kit je optimalizován pro přístroj cobas® 6800/8800 Systems (Roche).

Vzorky
Nesrážlivá plná krev

Technologie detekce
TaqMan

Studie funkční způsobilosti a výsledky
V rámci funkčního ověření soupravy **EliGene® Spondylitis HLA-B27 C6** bylo analyzováno 166 vzorků, z toho 124 pozitivních. DNA z klinických vzorků byla izolována automatickou izolací pomocí přístroje **cobas® 6800 (Roche)**, kdy následně souprava **EliGene® Spondylitis HLA-B27 C6** zachytila správně 124 vzorků jako HLA-B27 pozitivních ve srovnání s výsledky zjištěnými pomocí referenční metody EliGene® Spondylitis HLA-B27 RT a 42 vzorků bylo správně určeno jako HLA-B27 negativních.

Analytická citlivost: 1 ng/µl
Specifita: 100 %

References / Zdroje
Khan MA. Remarkable Polymorphism of HLA-B27: An Ongoing Saga. Curr Rheumatol Report. 2010; 12: 337-41

Robinson PC, Brown MA. 2012. The genetics of ankylosing spondylitis and axial spondyloarthritis. Rheum Dis Clin North Am. 38(3):539-53

Thomas GP, Brown MA. Genetics and Genomics of Ankylosing Spondylitis. Immunol Rev. 2010; 233:162-180.

EliGene® Spondylitis HLA-B27 C6
REF/Cat. No.: 90060-C6
(COBAS 6800/8800) 192 reactions

Compatible devices / Kompatibilní přístroje
Roche: cobas® 6800/8800 Systems

RUO

Product guarantee policy

Product quality is our highest priority at **ELISABETH PHARMACON**. Clinical studies are available for all CE certified kits. As manufacturing, testing, packaging and delivery are carried out under the **EN ISO 13485:2016** quality system, we guarantee batch-to-batch consistency. All **EliGene®** products are supplied with a Certificate of Analysis, summarizing the conditions and results of quality assurance tests.

Shipping

EliGene® detection kits must be shipped frozen on dry ice, for short journeys, kits can be shipped packed on blue ice. Freeze-thaw cycles lower the sensitivity of detection kits. Detection kits are packed in polystyrene boxes to protect them from thawing during shipment and laboratory work.

Advantages of EliGene® detection kits

- The usage of the Internal Control allows to monitor the extraction procedure and to check possible PCR inhibition
- Kits are supplied with positive control allowing quality control of the analysis
- Simultaneous amplification (multiplex) of DNA/RNA from pathogen and internal control in one PCR tube
- The usage of Hot-Start technology minimizes the risk of non-specific reaction and provide ultimate sensitivity 1–10 copies of nucleic acid/reaction
- The usage of Ready to use Mastermixes containing all reaction components for easier reaction setup and handling
- To ensure the highest quality of our kits, the raw material from the leading providers is used
- Quantitative Standards in specific kits enables to precisely determine the NA load from 10^2 to 10^6 copies/reaction
- High stability of used reagents
- The usage of EliGene® UNI kits enables a complete detection in 50 minutes
- Kits are CE certified IVD
- Kits are validated on LightCycler® 2.0, Nano and 480, ABI® 7300, 7500, 7500FAST, QuantStudio 3 and QuantStudio 5, Rotor-Gene Q (Rotor-Gene 6000), MIC qPCR Cycler, CFX96
- Compatibility of the kits with a broad range of instruments capable to detect dyes in FAM, HEX, TexasRed and Cy5 spectra

Sample processing

The amplification success depends mostly on the quality of the purified NA. The highest sensitivity in PCR detection can only be achieved when you have first-rate sample preparation. The quality of sample preparation depends not only on isolation procedure but also on timing of collection (clinical relevancy), transport and storage conditions. The presence of conservation agents in transport media could lead to PCR inhibition as well. Taking together all these facts, the isolation procedure must be rigorously tested to avoid false negative results.

EliGene® TECHNOLOGY

Product lines of EliGene® kits

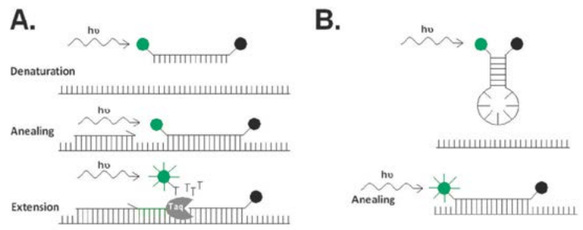
EliGene® kits for Real-Time PCR

EliGene® kits for real-time PCR analysis are divided according to detection chemistry to basic lines RT, UNI and LC virus, respectively.
In RT line, the TaqMan chemistry using hydrolyzing fluorescence probes is used in the combination with hot-start polymerase and ROX dye as a passive reference as an optional additive (see Figure 1A). The total reaction volume is 20/25 ul when 5 ul of isolated DNA is added directly to ready to use mastermix containing all necessary components for reaction. In RT kits, the fluorescence dyes FAM and HEX and in particular products also TexasRed and Cy5 in combination with non-fluorescent quenchers are used. These kits are designed for Applied Biosystems (ABI 7300, 7500, 7500FAST), Thermofisher Scientific (QS3 and QS5), Roche (LightCycler® Nano, LightCycler® 480), Bio-Rad (CFX96) instruments, however, can be used with the other instruments that meet the spectral characteristics of used fluorescence dyes. The typical time of the run for RT kits is about 105 minutes.

In **UNI line**, the Molecular Beacons using hybridization fluorescence probes or TaqMan chemistry using hydrolyzing fluorescence probes are used in combination with hot-start polymerase (see Figure 1). The total reaction volume is 20 ul when 5 ul of isolated DNA is added directly to ready-to use mastermix containing all necessary components for reaction. In UNI kits the fluorescence dyes FAM and HEX in combination with non-fluorescent quenchers are used. These kits are designed for almost all real-time PCR instruments on the market. The typical time of run for UNI kits is about 60 minutes.

In **LC virus line**, the Molecular Beacons using hybridization fluorescence probes or TaqMan chemistry using hydrolyzing fluorescence probes are used in combination with one-step master mix for reverse transcription with consequent qPCR analysis (see Figure 1). The total reaction volume is 20/30 ul when 5/10 ul of isolated RNA is added to mastermix created by mixing of reverse transcriptase with reaction mix containing all necessary components for the reaction. The fluorescence dyes FAM, HEX, TexasRed and Cy5 together with non-fluorescence quenchers are used. The LC kits are designed for the majority of real-time instruments on the market that meet the spectral characteristics of used fluorescence dyes in particular kits. The typical time of run for LC kits is about 70 minutes.

Figure 1. *Basic principle of TaqMan hydrolization probes (A) and Molecular Beacons hybridization probes (B) action.*



The TaqMan probe hybridizes between the primers in annealing step and during elongation step probe is cleaved by exonuclease activity of Taq Polymerase. The Molecular Beacon probe forms beacon-like structure that opens to specific sequence during the hybridization in annealing step (B).
"TaqMan" is registered trademark of Roche Molecular Systems Inc., "Molecular Beacon" is registered trademark of Public Health Research Institute Properties, Inc. (PHRI)

RUO

ELISABETH PHARMACON is a leading Czech provider of comprehensive solutions for PCR applications and related technologies. Our proprietary product line, which includes next-generation polymerases and kits, is recognized under the name **EliZyme™**.

End-point PCR
- EliZyme™ FAST Taq
- EliZyme™ HS FAST
- EliZyme™ HS Robust
- EliZyme™ HIFI
- EliZyme™ HS HIFI MIX
- EliZyme™ ProofRead
- EliZyme™ ProofRead HS
- EliZyme™ OneS Kit

qPCR
- EliZyme™ Green MIX
- EliZyme™ Probe MIX
- EliZyme™ Super HRM MIX
- EliZyme™ Super Probe MIX
- EliZyme™ Lyo Super Probe MIX

qRT-PCR
- EliZyme™ OneS Green Kit
- EliZyme™ OneS Probe Kit
- EliZyme™ OneS Super Probe MIX
- EliZyme™ OneS Viral Probe Kit
- EliZyme™ Air OneS Super Probe MIX
- EliZyme™ Lyo OneS Super Probe Kit

NGS
- EliZyme™ Library Quantification Kit

Isothermal amplification
- EliZyme™ LAMP
- EliZyme™ LAMP OneS MIX

PCR accessories
- EliZyme™ Reverse Transcriptase
- EliZyme™ Reverse Transcriptase 2.0
- EliZyme™ RiboProtect
- EliZyme™ dNTP MIX
- EliZyme™ Ladder

ELISABETH PHARMACON je předním českým dodavatelem komplexních řešení pro PCR aplikace a související technologie. Naše vlastní produktová řada, která zahrnuje polymerázy a kity nové generace, je známá pod názvem **EliZyme™**.

End-point PCR
- EliZyme™ FAST Taq
- EliZyme™ HS FAST
- EliZyme™ HS Robust
- EliZyme™ HIFI
- EliZyme™ HS HIFI MIX
- EliZyme™ ProofRead
- EliZyme™ ProofRead HS
- EliZyme™ OneS Kit

qPCR
- EliZyme™ Green MIX
- EliZyme™ Probe MIX
- EliZyme™ Super HRM MIX
- EliZyme™ Super Probe MIX
- EliZyme™ Lyo Super Probe MIX

qRT-PCR
- EliZyme™ OneS Green Kit
- EliZyme™ OneS Probe Kit
- EliZyme™ OneS Super Probe MIX
- EliZyme™ OneS Viral Probe Kit
- EliZyme™ Air OneS Super Probe MIX
- EliZyme™ Lyo OneS Super Probe Kit

NGS
- EliZyme™ Library Quantification Kit

Izotermická amplifikace
- EliZyme™ LAMP
- EliZyme™ LAMP OneS MIX

PCR doplňky
- EliZyme™ Reverse Transcriptase
- EliZyme™ Reverse Transcriptase 2.0
- EliZyme™ RiboProtect
- EliZyme™ dNTP MIX
- EliZyme™ Ladder

EliGene® isolation kits are available in the version for research only or certified for clinical use. In our portfolio there are kits for manual DNA and RNA isolation on column from different materials. The EliGene® product line also includes LabCleaner decontamination solutions designed to degrade or remove nucleic acids, proteins and lipids from laboratory surfaces.

- EliGene® MTB Isolation Kit
- EliGene® Urine Isolation Kit
- EliGene® Viral DNA/RNA Isolation Kit
- EliGene® Blood DNA Isolation Kit
- EliGene® Tissue DNA Isolation Kit
- EliGene® FFPE Tissue DNA Isolation Kit
- EliGene® Soil DNA Isolation Kit
- EliGene® Plant DNA Isolation Kit
- EliGene® Gel DNA MiniPrep Kit
- EliGene® Plasmid DNA MiniPrep Kit

- EliGene® Lab Cleaner A
- EliGene® Lab Cleaner B

Wide range of plastic laboratory consumables under the **αPlastic™** brand are primarily used in molecular biology research experiments in PCR and are suitable for liquid handling, storage and sealing. αPlastic™ is tested by experienced specialists in our laboratory on a daily basis, so we can guarantee the first-class quality and we are sure that our PCR plastic will meet the demanding expectations of our clients.

- PCR microtubes
- Microcentrifuge tubes with Safe-Lock cap
- Centrifuge tubes
- Screw-cap storage tubes
- Cryogenic tubes
- PCR/qPCR 8-Well strips
- PCR/qPCR 96-Well plates
- Sealing membranes and silicone sealing films
- Pipette tips with / without filter
- Tube opener

EliGene® izolační soupravy jsou dostupné ve verzi pro výzkum nebo certifikované pro klinické využití. V našem portfoliu jsou soupravy pro manuální kolonkovou izolaci DNA a RNA z různých materiálů. Produktová řada EliGene® zahrnuje také dekontaminační roztoky LabCleaner určené k degradaci či odstranění nukleových kyselin, proteinů a lipidů z laboratorních povrchů.

- EliGene® MTB Isolation Kit
- EliGene® Urine Isolation Kit
- EliGene® Viral DNA/RNA Isolation Kit
- EliGene® Blood DNA Isolation Kit
- EliGene® Tissue DNA Isolation Kit
- EliGene® FFPE Tissue DNA Isolation Kit
- EliGene® Soil DNA Isolation Kit
- EliGene® Plant DNA Isolation Kit
- EliGene® Gel DNA MiniPrep Kit
- EliGene® Plasmid DNA MiniPrep Kit

- EliGene® Lab Cleaner A
- EliGene® Lab Cleaner B

Široký sortiment spotřebních laboratorních plastů pod značkou **αPlastic™** má své využití především ve výzkumných experimentech a klinické diagnostice v oblasti molekulární biologie a je vhodný pro manipulaci s kapalinami, skladování a utěsňování. αPlastic™ je testován zkušenými odborníky v naší laboratoři na denní bázi, takže můžeme zaručit prvotřídní kvalitu a jsme si jisti, že náš plast pro PCR bude splňovat náročná očekávání našich zákazníků.

- PCR mikrozkumavky
- Mikrocentrifugační zkumavky se zavíráním Safe-Lock
- Centrifugační zkumavky
- Šroubovací skladovací zkumavky
- Kryogenní zkumavky
- PCR/qPCR 8místné stripy
- PCR/qPCR 96jamkové destičky
- Těsnicí fólie, silikonové fólie
- Pipetovací špičky s filtrem /bez filtru
- Otvírák na zkumavky

LABORATORY PLASTICS FOR EVERY NEED

New in the αPlastic™ range

αPlastic™
Labware ELISABETH PHARMACON

Wide Range • Fast Delivery • Trusted Quality

Elisabeth Pharmacon offers a **comprehensive portfolio of plastic consumables** for **molecular diagnostics and life sciences.**

An overview of the plastic material portfolio can be found on page 45 of this catalog.

Discover new products designed for precision, reliability, and comfort in your daily laboratory work:

- **Non-filter pipette tips** – available in bags or racks
- **Microcentrifuge tubes with Safe-Lock cap** – volumes 1.5 ml and 2 ml
- **Centrifuge tubes** – volumes 15 ml and 50 ml
- **Screw-cap storage tubes** – volumes 1.5 ml and 2 ml
- **Cryogenic tubes** – volume 1.5 ml, ideal for low-temperature storage
- **Silicone sealing films**
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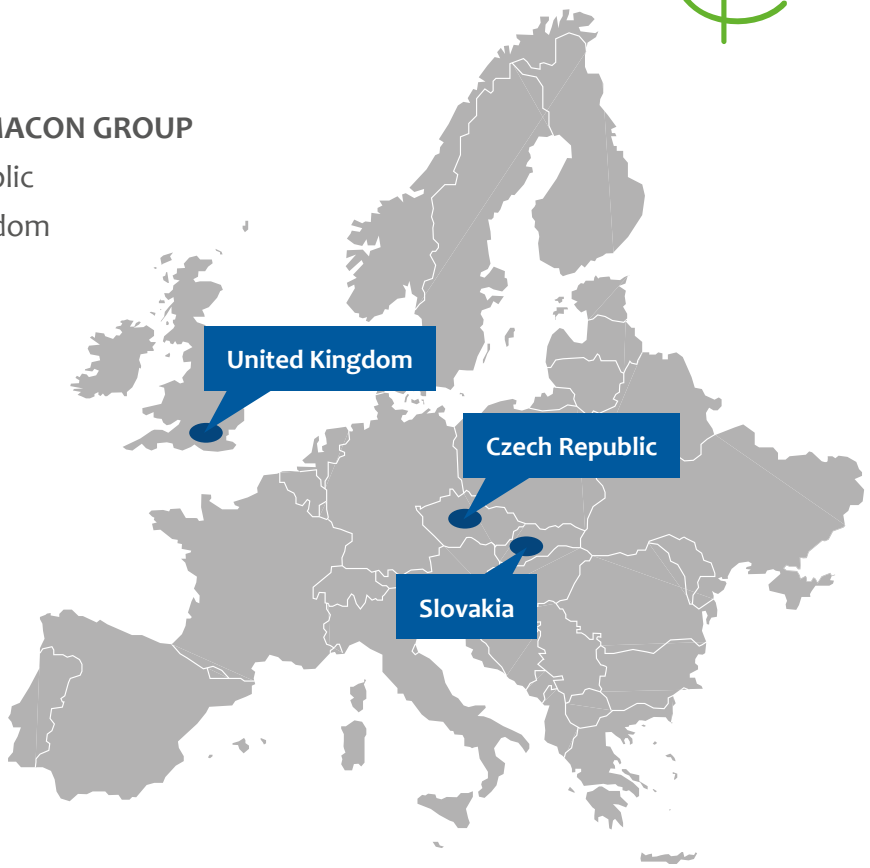

ELISABETH PHARMACON, founded in 2001 and headquartered in Brno, Czech Republic, is an innovative biotech company specializing in the development, manufacturing, and distribution of *in vitro* diagnostic medical devices and products. Our diverse portfolio includes advanced DNA diagnostic solutions, high-quality DNA polymerases, and nucleic acid isolation kits. We also offer a comprehensive range of PCR plastic consumables, laboratory equipment, and instruments designed to meet the needs of research, medical, veterinary, and food-related sectors.

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