



PRODUCT CATALOG

DNA / RNA DIAGNOSTICS

Bacterial Infections

Viral Infections

Human Genetics

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

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



Introduction

Úvod

Dear Customers,

ELISABETH PHARMACON is an innovative company developing advanced products for clinical and scientific laboratories. In our portfolio you will find plenty of unique polymerases, kits for DNA and RNA isolation, DNA diagnostics and human genetics that are presented in this catalog.

EliGene® kits satisfy not only real experts

In the catalog we present a wide range of DNA/ RNA diagnostic kits designed for bacterial and viral detection, as well as kits for human genetics and oncogenetics. The 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 diagnostic kits are quantitative. They provide beside the information about presence of detected pathogens also information about their quantity.

Vážený 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 lidskou genetiku, které vám prezentujeme v tomto katalogu.

Kity EliGene® uspokojí nejen skutečné profesionály

V katalogu vám představujeme ucelenou řadu DNA/RNA diagnostických kitů pro detekci virů a bakterií a dále soupravy určené k lékařské genetice a onkogenetice. 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

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 mikroorganismy

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

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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 %

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

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 %



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 Cyclor



Analytical specificity and sensitivity

Chlamydomphila 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® Chlamydomphila pneumoniae UNI** kit, totally 50 clinical specimens were analyzed. The **EliGene® Chlamydomphila pneumoniae UNI** kit diagnosed correctly as *Chlamydomphila pneumoniae* positive 6 specimens. Totally 44 specimens were rightly determined by **EliGene® Chlamydomphila pneumoniae UNI** kit as negative.

Sensitivity: 100 %

Specificity: 100 %

References / Zdroje

Pignanelli S, Shurghi A, Delucca F, et al. 2009. Simultaneous use of direct and indirect diagnostic techniques in atypical respiratory infections from *Chlamydomphila 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.

Analytická specifita a senzitivita

Chlamydomphila 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® Chlamydomphila pneumoniae UNI** bylo analyzováno 50 klinických vzorků. Souprava **EliGene® Chlamydomphila pneumoniae UNI** identifikovala správně všech 6 vzorků pozitivních na *Chlamydomphila pneumoniae* a 44 vzorků negativních.

Senzitivita: 100 %

Specifita: 100 %

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 %

References / Zdroje

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

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 %

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® 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 Cyclor



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 %

Specificity: 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

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 %

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 %

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 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 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 Cyclor



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: Infctious 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 the dttciton of *Neisseria gonorrhoeae* in gcnital and cxttagcnital spciimcns. Diagn Miicrobiol 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 dttciton of *Neisseria gonorrhoea*. Scx Hcalth. 5(1):17-23.

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 detrmind 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® 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 Cyclcr



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 Cyclcr



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 %

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® 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 Cyclor

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 Cyclor



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 %

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.

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 %

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* sensu lato.

Sensitivity: 100 %

Specificity: 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, Žáková 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

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, tkáň, 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* sensu lato.

Senzitivita: 100 %

Specifita: 100 %



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 Cyclor

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 Cyclor



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, tkáň, 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 %

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, tkáň 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

Kříž P, Kralík P, Sláň M, Sláň I, Svobodová J, Parmová I, Barnet V, Jurek V, Pavlík I. 2011. *Mycobacterium pinnipedii* in a captive Southern sea lion (*Otaria flavescens*): a case report. *Veterinari 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.

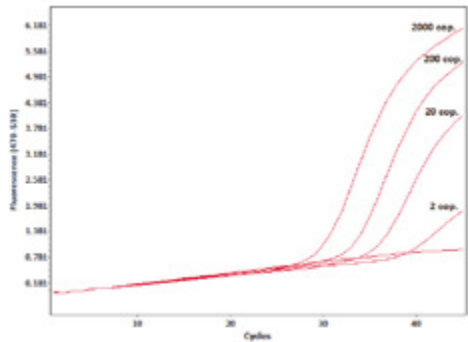


Figure: Sensitivity test of **EliGene® MTB UNI** kit on **LightCycler® 2.0** instrument shows the detection of **2 DNA copies** in reaction mix.

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

EliGene® 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® 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



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 %

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.

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, tkáň

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 %

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 %

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

Analytická specifita a senzitivita

Anaplasma phagocytophilum
1–10 kopií bakteriální DNA v amplifikovaném
vzorku

Vzorky

Krev, moč, mozkomíšní mok, synoviální
tekutiny, tkáň

Technologie detekce

Molecular Beacons

Studie funkční způsobilosti a výsledky

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

Senzitivita: 100 %

Specifita: 100 %

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

Compatible devices / Kompatibilní přístroje

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

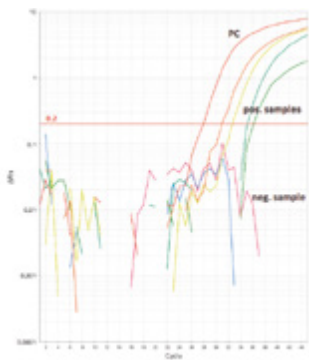
Thermofisher Scientific: QuantStudio 3 and 5

Applied Biosystems: Real-Time System ABI
7500FAST

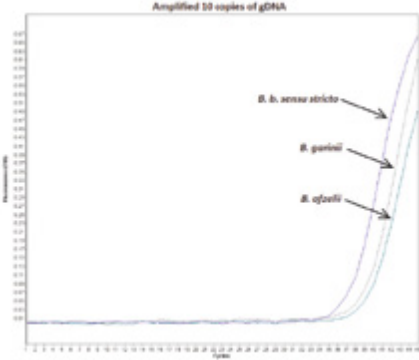
Qiagen: Rotor-Gene 6000 or Rotor-Gene Q

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

Bio Molecular Systems: MIC qPCR Cyclor



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



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

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

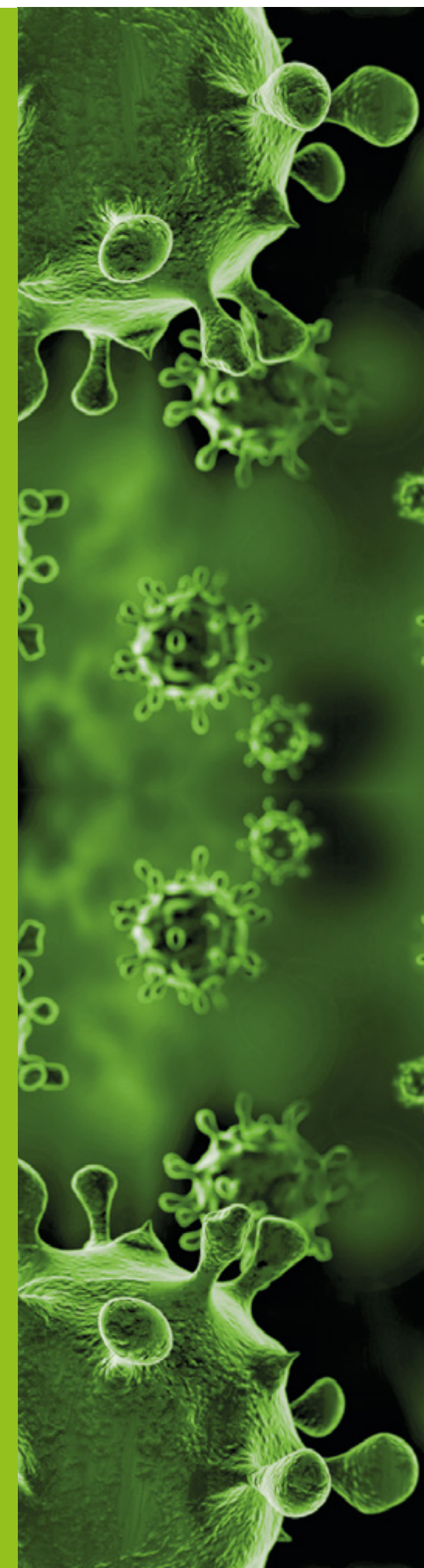
Qiagen: Rotor-Gene 6000 or Rotor-Gene Q

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

Bio Molecular Systems: MIC qPCR Cyclor

VIRAL INFECTION VIROVÉ INFEKCE

EliGene® COVID19 Triple RIC RT	23
EliGene® Influenza A/B/pandemic LC	24
EliGene® HCV LC	25
EliGene® HBV RT	26
EliGene® HSV1/HSV2 UNI	27
EliGene® VZV UNI	28
EliGene® Adenovirus RT	29
EliGene® Norovirus LC	30
EliGene® Enterovirus LC	31
EliGene® TBEV LC	32
EliGene® Monkeypox RT	33



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** vykazala 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

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 %

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

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 %

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 diagnosed 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 %

References / Zdroje

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

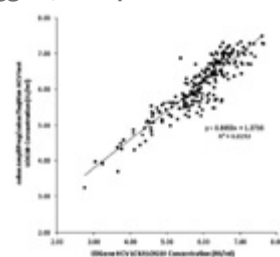


Figure: Comparison of the COBAS AMPLICOR HCV MONITOR Test (v2.0) against the **EliGene® HCV LC** Kit

Obrázek: Srovnání COBAS AMPLICOR HCV MONITOR Test (v2.0) s **EliGene® HCV LC**.

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** diagnostikovala 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 IU/ml séra)

Specifita: 100 %

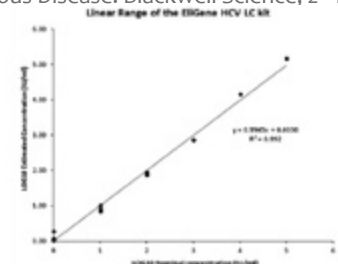


Figure: Calculation of the linear range. The equation of the regression line is included in the figure.

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

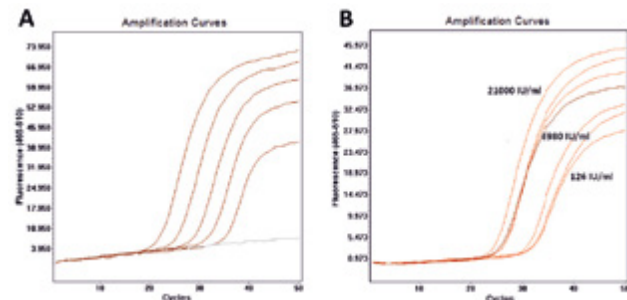


Figure: Analysis of specimens with different concentration of HCV from 126 IU/ml to 21000 IU/ml with **EliGene® HCV LC** kit. A – amplification curves for five HCV standards, B – amplification curves for HCV positive specimens.

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



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 diagnosed 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 1×10⁵ IU/μl to at least 0.1 IU/μl.

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

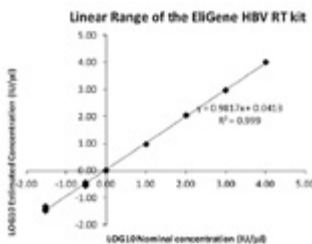
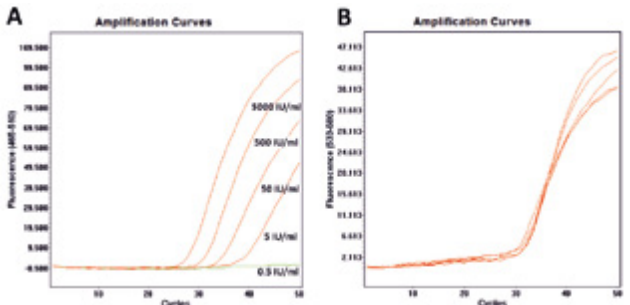


Figure: Calculation of the linear range.
Obrázek: Výpočet lineárního rozsahu.



Figures: Analysis of specimens with different concentration of HBV from 0.5 IU/ml to 5000 IU/ml with **EliGene® HBV RT** kit:
Obrázky: Analýza vzorků o různé koncentraci HBV (od 0.5 IU/ml to 5000 IU/ml séra) soupravou **EliGene® HBV RT**:
A – amplification curves for FAM channel (HBV detection) / amplifikační křivky kanálu FAM (HBV detekce),
B – amplification curves for HEX channel (Internal control) / amplifikační křivky kanálu HEX (interní kontrola).

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 diagnostikovala 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 1×10⁵ IU/μl do 0,1 IU/μl.

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

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 %

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.

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 %

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



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 %

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.

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.

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® 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® 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

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 %

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

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 %

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

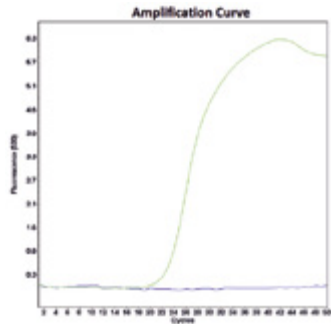
Performance study and results
Within the frame of performance study of **EliGene[®] Enterovirus LC** kit overall 100 clinical specimens were analyzed. From these specimens 100 blind specimens were verified by reference method (La Rosa et al. 2010). From these 100 samples 56 samples were Enterovirus RNA 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 %

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[®] 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[®] 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



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.

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)

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 Flaviviridae se uskutečňuje klíšťaty nebo alimentární cestou. Onemocnění může být zoonózou.

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

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

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	37
EliGene® Coeliac 3.0 RT	38
EliGene® Coeliac RT	38
EliGene® Lactose intolerance RT	39
EliGene® Spondylitis HLA-B27 RT	40

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 alleles. Totally 50 samples were determined right by EliGene[®] Celiac DQ PLUS RT.

Analytical sensitivity: 5 ng of DNA
in reaction mix

Specificity: 100 %

References / Zdroje

Bourgey M, Calcagno G, Tinto N, Gennarelli D, Margaritte-Jeannin P, Greco L, Limongelli MG, Esposito O, Marano C, Troncone R, Spampinato 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.

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 buků 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 %



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

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 %

References / Zdroje

Bourgey M, Calcagno G, Tinto N, Gennarelli D, Margaritte-Jeannin P, Greco L, Limongelli MG, Esposito O, Marano C, Troncone R, Spampinato 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.

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 bukalní 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 %

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 %

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).

Účel použití

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

Vzorky

Stěr z bukání 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 %

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[®] 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

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 bukání 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

REF / Cat. No.: 90060-C6 (COBAS 6800/8800) 192 reactions

Compatible devices / Kompatibilní přístroje

Applied Biosystems: ABI 7000, 7300, 7500FAST

Roche: LightCycler[®] 480, LightCycler[®] Nano

Qiagen: Rotor-Gene 6000 nebo Rotor-Gene Q

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® diagnostic 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 diagnostic kits. Diagnostic 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 102 to 106 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® 1.2, 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.

Product lines of EliGene® kits

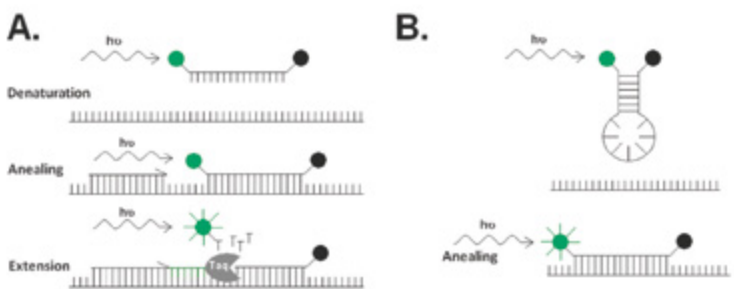
EliGene® kits for Real-Time PCR

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)

PRODUCT PORTFOLIO
of ELISABETH PHARMACON

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 (CE-IVDR)
- EliGene® Urine Isolation Kit (CE-IVDR)
- EliGene® Viral DNA/RNA Isolation Kit (CE-IVDR)
- 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

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 (CE-IVDR)
- EliGene® Urine Isolation Kit (CE-IVDR)
- EliGene® Viral DNA/RNA Isolation Kit (CE-IVDR)
- 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

ELISABETH PHARMACON holds the following quality certificates:



ČSN EN ISO 9001:2016 Quality Management System
ČSN EN ISO 9001:2016 Systémy managementu kvality

ELISABETH PHARMACON je držitelem následujících certifikátů kvality:



ČSN EN ISO 13485 ed. 2:2016 Medical devices –
Quality management systems
ČSN EN ISO 13485 ed. 2:2016 Zdravotnické prostředky –
Systémy managementu kvality

CERTIFICATES
ELISABETH PHARMACON

MEMBERS OF ELISABETH PHARMACON GROUP

Elisabeth Pharmacon Czech Republic

Elisabeth Pharmacon United Kingdom

Elisabeth Pharmacon Slovakia



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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