EC CERTIFICATE

Number: 2110151CE05

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV excluding (4,6)
(List A, B and devices for self-testing)

Manufacturer:

Elitechgroup S.P.A.
Corso Svizzera 185
10149 Torino
Italy

For the product category(ies)

Nucleic acid reverse transcription and amplification assays and related components used for the detection and quantification of Hepatitis B and C virus DNA and/or RNA in human plasma and serum

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and corresponding batch release certificate(s) and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2110151CN, initially dated 26 February 2008

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit in-vitro diagnostica', the Dutch transposition of the Council Directive 98/79/EC of October 27, 1998 concerning In vitro diagnostic medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex IV of Council Directive 98/79/EC of October 27, 1998 and is subject to periodical surveillance. For placing on the market of List A devices an additional EC design examination certificate according to Annex IV (4) is mandatory.
The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2025
Issued for the first time: 15 December 2021
Revised: 19 May 2022

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

Digitally signed by Ceaicovschi Tudor
Date: 2023.03.10 16:01:46 EET
Reason: MoldSign Signature
Location: Moldova

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra.nl Company registration 09085396

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2110151DE01

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV (4)
(List A)

Manufacturer:
Elitechgroup S.P.A.
Corso Svizzera 185
10149 Torino
Italy

For the product

HBV ELITe MGB® Kit for the quantitative detection of Hepatitis B virus DNA in human serum or plasma

Documents, that form the basis of this certificate:

Certification Notice 2110151CNCN, initially dated 26 February 2008
CE Marking of Conformity 2110151CE05
Addendum, initially dated 15 December 2021

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit in-vitro diagnostica', the Dutch transposition of the Council Directive 98/79/EC of October 27, 1998 concerning In vitro diagnostic medical devices, including all subsequent amendments, based on an examination in accordance with Annex IV (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex IV (4) of Council Directive 98/79/EC of October 27, 1998 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2025
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ADDENDUM

Belonging to certificate: 2110151DE01

EC DESIGN-EXAMINATION
IN VITRO DIAGNOSTIC MEDICAL DEVICES

HBV ELITe MGB® Kit for the quantitative detection of Hepatitis B virus DNA in human serum or plasma

Issued to:

Elitechgroup S.P.A.
Corso Svizzera 185
10149 Torino
Italy

This certificate covers the following product(s):

Product variants:
HBV ELITe MGB Kit RTK602ING

Initial date: 15 December 2021

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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EC DESIGN-EXAMINATION CERTIFICATE

Number: 2110151DE02

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV (4)
(List A)

Manufacturer:
ELITechGroup S.p.A.
Corso Svizzera 185
10149 Torino
Italy

For the product

HCV ELITe MGB® Kit for the quantitative detection of HCV virus RNA in human plasma and serum

Documents, that form the basis of this certificate:

Certification Notice 2110151CN, initially dated 26 February 2008
CE Marking of Conformity 2110151CE05
Addendum, initially dated 10 February 2022

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit in-vitro diagnostica', the Dutch transposition of the Council Directive 98/79/EC of October 27, 1998 concerning In vitro diagnostic medical devices, including all subsequent amendments, based on an examination in accordance with Annex IV (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex IV (4) of Council Directive 98/79/EC of October 27, 1998 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 January 2025
Issued for the first time: 10 February 2022

DEKRA Certification B.V.

B.T.M. Holtus
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Certification Manager

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ADDENDUM

Belonging to certificate: 2110151DE02

EC DESIGN-EXAMINATION
IN VITRO DIAGNOSTIC MEDICAL DEVICES

HCV ELITe MGB® Kit for the quantitative detection of HCV virus RNA in human plasma and serum

Issued to:

ELITechGroup S.p.A.
Corso Svizzera 185
10149 Torino
Italy

This certificate covers the following product(s):

Product variants:
HCV ELITe MGB® Kit RTK601ING

Initial date: 10 February 2022

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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20122 Milano (MI) - Italia

MOD05,05-RTK601ING
Redatto da QM
Approvato da QARA
Rev. 02 del 25/05/2022, CC21-27, CC22-25

DICHIARAZIONE CE DI CONFORMITÀ
EC DECLARATION OF CONFORMITY

Nome del prodotto / *Product name*	**HCV ELITe MGB® Kit**
Codice / *Ref*	**RTK601ING**
Codice CND / *CND Code*	**W0105020307**
Codice RDM / *RDM Code*	**2213375**
Immissione sul mercato / *Placing on the market*	**23/02/2022**

Classificazione / *Classification*	**Allegato II, elenco A / *Annex II, A list***
Procedura di valutazione di conformità *Conformity assessment procedure*	**Allegato IV / *Annex IV***
Marcatura CE / *CE Marking*	**CE 0344, DEKRA Certification B.V.**
Documento di riferimento *Reference document*	**EC Certificate Number: 2110151DE02 2110151CE05**

ELITechGroup S.p.A. dichiara che il prodotto è conforme alla Direttiva Dispositivi Medico Diagnostici in vitro 98/79/CE ed al D.Lgs. 332/2000

ELITechGroup S.p.A. declares product is in conformity with in vitro Diagnostic Medical Devices Directive 98/79/EC and with Legislative Decree 332/2000

ASSOBIOMEDICA

ELITechGroup S.p.A. (con unico socio)
Società soggetta a direzione e coordinamento da parte di ELITechGroup S.a.S.
Capitale Sociale € 1.000.000,00 i.v. Iscritta nel registro delle imprese di Milano
C.F.P.IVA e n° di iscrizione 05239350969 – R.E.A. 1805944

Inviare tutta la corrispondenza alla sede Amministrativa di Torino

Management Systems ISO 9001 ISO 13485 DEKRA certified

Fabbricante / *Manufacturer*	**ELITechGroup S.p.A.** **C.so Svizzera 185 - 10149 Torino - ITALY** **Tel.: +39 011 976191 - FAX: +39 011 9367611**
Sistema di Gestione per la Qualità *Quality Management System*	**ISO 9001:2015; EN ISO 13485:2016**
Organismo di certificazione *Certification body*	**DEKRA Certification B.V.**
Norme Armonizzate *Harmonized Standard*	**EN ISO 18113-2:2011** **ISO 15223:2021** **EN 13612:2002** **EN ISO 23640:2015** **EN ISO 14971:2019**
Data e Luogo / *Date dd/mm/yyyy and Place signature* **25/05/2022, Torino**	Firma Quality Assurance Regulatory Affairs / *QARA*

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20122 Milano (MI) - Italia

MOD05,05-RTK602ING
Redatto da QM
Approvato da QARA
Rev. 01 del 25/05/2022, CC21-27, CC22-25

DICHIARAZIONE CE DI CONFORMITÀ
EC DECLARATION OF CONFORMITY

Nome del prodotto / *Product name*	**HBV ELITe MGB® Kit**
Codice / *Ref*	**RTK602ING**
Codice CND / *CND Code*	**W0105020216**
Codice RDM / *RDM Code*	**2184915**
Immissione sul mercato / *Placing on the market*	**23/12/2021**

Classificazione / *Classification*	**Allegato II, elenco A / *Annex II, A list***
Procedura di valutazione di conformità *Conformity assessment procedure*	**Allegato IV / *Annex IV***
Marcatura CE / *CE Marking*	**CE 0344, DEKRA Certification B.V.**
Documento di riferimento *Reference document*	**EC Certificate Number: 2110151DE01 and 2110151CE05**

ELITechGroup S.p.A. dichiara che il prodotto è conforme alla Direttiva Dispositivi Medico Diagnostici in vitro 98/79/CE ed al D.Lgs. 332/2000

ELITechGroup S.p.A. declares product is in conformity with in vitro Diagnostic Medical Devices Directive 98/79/EC and with Legislative Decree 332/2000

ASSOBIOMEDICA

ELITechGroup S.p.A. (con unico socio)
Società soggetta a direzione e coordinamento da parte di ELITechGroup S.a.S.
Capitale Sociale € 1.000.000,00 i.v. Iscritta nel registro delle imprese di Milano
C.F.P.IVA e n° di iscrizione 05239350969 – R.E.A. 1805944

Inviare tutta la corrispondenza alla sede Amministrativa di Torino

Management Systems ISO 9001 ISO 13485 DEKRA certified

Fabbricante / *Manufacturer*	**ELITechGroup S.p.A.** **C.so Svizzera 185 - 10149 Torino - ITALY** **Tel.: +39 011 976191 - FAX: +39 011 9367611**
Sistema di Gestione per la Qualità *Quality Management System*	**ISO 9001:2015; EN ISO 13485:2016**
Organismo di certificazione *Certification body*	**DEKRA Certification B.V.**
Norme Armonizzate *Harmonized Standard*	**EN ISO 18113-2:2011** **ISO 15223:2021** **EN 13612:2002** **EN ISO 23640:2015** **EN ISO 14971:2019**
Data e Luogo / *Date dd/mm/yyyy and Place signature* **25/05/2022, Torino**	Firma Quality Assurance Regulatory Affairs / *QARA*

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MOD05,05-IVDR- A_Instruments
Redatto da QM
Approvato da QARA
Rev.01 del 09/06/2022 RAC22-26

DICHIARAZIONE DI CONFORMITÀ UE
EU DECLARATION OF CONFORMITY

Nome prodotti / *Products name*	**Vedere lista dei prodotti allegata (Allegato Lista strumenti)** *See attached list of products (Instruments list Annex)*
Codice / *Reference*	"
Codice Basic UDI-DI/ GMN *Basic UDI-DI/ GMN Code*	"
Codice UDI-DI / *UDI-DI Code*	"
Immissione in commercio / *Placing on Market*	"
Classe di Rischio / *Risk Class*	**Vedere lista dei prodotti allegata** *See attached list of products*
Procedura di valutazione di conformità *Conformity assessment Procedure*	"
Marcatura CE / *CE Marking*	**CE**

ELITechGroup S.p.A. dichiara sotto la sua esclusiva responsabilità che i sistemi ELITe InGenius® ed ELITe BeGenius® costituiti dallo strumento, dal software e dai dispositivi ad uso esclusivo, aventi come destinazione d'uso l'estrazione di DNA e RNA da campioni liquidi umani e l'esecuzione della reazione di PCR sono conformi al Regolamento 2017/746 sui Dispositivi Medico Diagnostici in vitro e alla Direttiva (UE) 2017/2102 (RoHS2) del Parlamento Europeo sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche.

ELITechGroup S.p.A. declares under its own exclusive responsibility **the ELITe InGenius® and ELITe BeGenius®** ***systems including instruments, software and exclusive use devices listed above, which its intended use is the extraction of DNA and RNA from human body liquid samples and the performing of a PCR reaction, is in conformity with Regulation 2017/746 on In vitro Diagnostic Medical Devices and the Directive (EU) 2017/2102 on the restriction of the use of certain hazardous substances in electrical and electronical equipment.***

Fabbricante / *Manufacturer*	**ELITechGroup S.p.A.** **C.so Svizzera 185 - 10149 Torino - ITALY** **Tel.: +39 011 976191 - FAX: +39 011 9367611**
Numero di Registrazione Unico **Single Registration Number**	**IT-MF-000005919**
Sistema di Gestione per la Qualità / *Quality Management System*	**ISO 9001:2015; EN ISO 13485:2016**
Organismo di certificazione /	

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Registered Office
Sede Legale
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20122 Milano (MI) - Italia

Certification body **DEKRA Certification B.V.**

Norme Armonizzate / *Harmonized Standards*	**EN ISO 18113-2:2011**
	ISO 15223:2021
	EN 13612:2002
	EN ISO 23640:2015
	EN ISO 14971:2019
	IEC61010-1:2010/AMD1:2016
	CEI EN 61326-2-6:2012
	IEC 62304 :2015
	IEC 62366-1:2015/AMD1:2020

Luogo, Data / ***Place, Date dd/mm/yyyy***

TORINO, 25/05/2022

Firma del Quality Assurance Regulatory Affairs / ***QARA Signature***
Person Responsible for Regulatory Compliance (PRRC) Signature
Nome Cognome / Name Surname : Sergio Fazari

CODICE / CODE	NOME / NAME	Data di immissione in commercio in accordo a IVDD / Placing date on the market according to IVDD	Data di immissione in commercio in accordo a IVDR / Placing date on the market according to IVDR	Classe di Rischio / Risk Class	UDI-DI di Base / Basic UDI-DI	Codice UDI-DI / UDI-DI Code	2017/746 Allegato / Annex	Codice EMDN / EMDN Code	Descrizione EMDN / EMDN Description	Codice RDM / RDM Code
INT030	ELITe InGenius®	05/08/2015	26/05/2022	A	366154090S2R005R	03661540900013	IX	W02050116	Nucleic Acid Testing Integreted extraction/Amplification/Detection Systems	2258247
INT040	ELITe BeGenius®	12/07/2021	26/05/2022	A	366154090S2R005R	03661540900228	IX	W02050116	Nucleic Acid Testing Integreted extraction/Amplification/Detection Systems	2258248

ELITe InGenius

Combo-Panels

Assemble your syndromic test

ELITechGroup

EMPOWERING IVD

ELITe InGenius

Combo-Panels

Assemble your syndromic test

Pathogens Monitoring in Immunocompromised

CMV	PARVOVIRUS B19	HHV8
EBV	ADENOVIRUS	HEV
BKV	ENTEROVIRUS	T. GONDII
VZV	JCV	ASPERGILLUS
HSV1	HHV6	P. JIROVECII
HSV2	HHV7	WNV°

LEGEND:

Blue = ELITe MGB® Kit
Green = Third Party Kit compatible with ELITe InGenius®
° = RUO
* = under development
■ = qualitative e quantitative

Sexually Transmitted Infections

STI PLUS
C. trachomatis
N. gonorrhoeae
M. genitalium
T. vaginalis

MACROLIDE-R/MG
M. genitalium
Macrolide Resistance

C. TRACHOMATIS

HPV
16
18
Other High Risks

HSV 1/2

STI PLUS CMT
C. trachomatis
M. genitalium
T. vaginalis

Respiratory Infections

SARS-CoV-2 PLUS
SARS-CoV-2
Flu A
Flu B
RSV

SARS-CoV-2 ■

SARS-CoV-2 Variants °

MDR/MTB
MTB Complex
Rifampicin Resistance
Isoniazid Resistance

BORDETELLA
Pertussis
Parapertussis
Holmesii

ASPERGILLUS

Respiratory Viral PLUS
Flu A/ Flu B
RSV/ hMPV

BACTERIAL PANEL
M. pneumoniae
C. pneumoniae
Legionella pn.

P. JIROVECII

ELITe InGenius

Combo-Panels

Assemble your syndromic test

Meningitis & Encephalitis

VIRAL PANEL
HSV1
HSV2
VZV

VIRAL PANEL 2
Enterovirus
Parechovirus
Adenovirus

BACTERIAL PANEL
N. meningitidis
S. pneumoniae
H. influenzae
H. Influenzae type B

Viral Load

HBV *

HCV *

HEV

HIV and related assays

HIV-1 *

HHV8

P. JIROVECII

ASPERGILLUS

HLA-B57

CYP2C9-2

CYP2C9-3

Gastrointestinal Infections

NOROVIRUS PANEL
Genotypes I & II

VIRAL PANEL
Rotavirus
Adenovirus
Astrovirus

ELITe InGenius

Combo-Panels

Assemble your syndromic test

Oncohematology

- **BCR-ABL P210**
- **RNA REFERENCE**
- **BCR-ABL P190**

Healthcare Associated Infections

- **MRSA/SA**
  S. aureus
  mecA/mecC
- **CRE**
  KPC
  IMP/VIM/NDM
  OXA 48
- **ESBL**
  CTX-M-1/15
  CTX-M-9/14
- **C. difficile**
  Toxin A
  Toxin B
- **Colistin/R**
  mcr1
  mcr2
- **P. JIROVECII**

Genetics

- **COAGULATION**
  Factor V
  Factor II
  MTHFR
- **APOE**
- **BETA-FIBRINOGEN**
- **CYP2C9-2**
- **CYP2C9-3**
- **MTHFR A1298C**
- **FACTOR V H1299R**
- **FACTOR XIII – V34L**
- **HFE C282Y**
- **HFE H63D**
- **HFE S65C**
- **HPA-1 A/B**
- **HLA-B57**
- **PAI-1 4G/5G**
- **VKORC1**

Zoonosis - Other infections

- **WNV °**
- **ZIKA**
- **DENGUE**
- **CHIKUNGUNYA**
- **LEISHMANIA**
- **MALARIA**
  P. Falciparum, P. Ovale, P. Malariae, P. Viva
- **MALARIA SCREENING**
  P. Falciparum, P. Ovale, P. Malariae, P. Viva, P. Knowlesi
- **MEASLES VIRUS**

WORLDWIDE OFFICES
Please contact your sales representative for terms, conditions and product availability in your country.

ELITechGroup is certified by DEKRA and applies a quality management system in compliance with ISO 9001:2015 and EN ISO 13485:2016

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Brazil	+55 27 3025 1415
France	+33 4 83 36 10 82
Italy	+39 011 97 61 91
New Zealand	+64 800 555 611
Serbia	+381 11 2467119
The Netherlands	+31 313 430 500
UK	+44 1442 869 320
United States	+1 800 453 2725

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ELITe InGenius

EVER-GROWING menu

Fully Automated Sample-to-Result Solution

42 CE-IVD Real Time PCR assays to cover different clinical applications

Pathogens Monitoring in Immunocompromised

- **CMV** 1 2 4 5 9 11 14 19
- **EBV** 1 2
- **BKV** 2 5
- **VZV** 1 2 4
- **HSV1** 1 2 4
- **HSV2** 1 2 4
- **PARVOVIRUS B19** 1 11
- **ADENOVIRUS** 1
- **ENTEROVIRUS** 2 4
- **JCV** 2 4 5
- **HHV6** 1 2
- **HHV7** 1 2
- **HHV8** 1 2
- **HEV** 2 10
- **T. GONDII** 1 4 11
- **ASPERGILLUS** 2 9 19
- **P. JIROVECII** 9 13
- **WNV**** 1 4 5

Sexually Transmitted Infections

- **STI PLUS** 5 15 16
  - *C. trachomatis*
  - *N. gonorrhoeae*
  - *M. genitalium*
  - *T. vaginalis*
- **HSV1/2** 22
- **MACROLIDE-R/MG** 5 15* 16*
  - *M. genitalium*
  - Macrolide resistance
- **C. TRACHOMATIS** 5 15 16
- **HPV** 15 16
  - 16
  - 18
  - Other High Risks

Respiratory Infections

- **MTB EXTRA** 5 9 13 17 18 19 20
  - MTB complex
- **MDR/MTB** 5 9 13 17 18 19 20
  - MTB complex
  - Rifampicin resistance
  - Isoniazid resistance
- **BORDETELLA** 23
  - *B. pertussis*
  - *B. parapertussis*
  - *B. holmesii*
- **BACTERIAL PANEL** 9
  - *M. pneumoniae*
  - *C. pneumoniae*
  - *Legionella pn.*
- **SARS-COV-2 PLUS** 6 7 21
  - SARS-CoV-2
  - Flu A
  - Flu B
  - RSV
- **Respiratory Viral PLUS** 9 21
  - Flu A
  - Flu B
  - RSV
  - hMPV*
- **SARS-COV-2** 6 7 14 21
- **SARS-CoV-2 Variants °**
- **P. JIROVECII** 9 13
- **ASPERGILLUS** 2 9 19

Meningitis & Encephalitis

- **VIRAL PANEL** 4
  - HSV1
  - HSV2
  - VZV
- **VIRAL PANEL 2** 4
  - Enterovirus
  - Parechovirus
  - Adenovirus
- **BACTERIAL PANEL** 1 4
  - *N. meningitidis*
  - *S. pneumoniae*
  - *H. influenzae*
  - *H. influenzae* type B

Healthcare Associated Infections

- **CRE** 8 12 9* 25*
  - KPC
  - IMP-VIM-NDM
  - OXA
- **ESBL** 8 12 9* 25*
  - CTX-M-1,15
  - CTX-M-9,14
- **COLISTIN-R** 8
  - *mcr1*
  - *mcr2*
- **MRSA/SA** 6 12 9* 25*
  - *S. aureus*
  - *mecA / mecC*
- **C. DIFFICILE** 10
  - Toxin A
  - Toxin B

Gastrointestinal Infections

- **VIRAL PANEL** 10
  - Rotavirus
  - Adenovirus
  - Astrovirus
- **NOROVIRUS PANEL** 10
  - Genotypes I & II

Genetics

- **COAGULATION** 1
  - Factor II
  - Factor V
  - MTHFR

Oncohematology

- **BCR-ABL P190*** 24
- **BCR-ABL P210** 24

25 Matrices

Universal Extraction for several samples

1. Whole Blood
2. Plasma
3. Serum
4. CSF
5. Urine
6. Nasal Swabs
7. Throat Swabs
8. Rectal Swabs
9. BAL
10. Stool
11. Amniotic Fluid
12. Blood Culture
13. Sputum
14. Saliva/Buccal Swabs
15. Cervical Swabs
16. Vaginal Swabs
17. Cavitary Fluid
18. Biopsies/Tissue
19. Bronchial Aspirate (BA)
20. Gastric Aspirates
21. Nasopharyngeal Swabs
22. Cutaneous/Mucoc. Swabs
23. Nasopharyngeal Aspirate
24. White Blood Cells
25. Culture Isolates

** Under Development*
*** Available in Open Mode*
° RUO

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EMD-EverGrowing-Menu - 490-22APR21/01 EN

ELITechGroup
EMPOWERING IVD

ELITe BeGenius®

FULLY INTEGRATED SAMPLE-TO-RESULT SOLUTION FOR MOLECULAR DIAGNOSTICS

CUSTOMER PRESENTATION – ENGLISH VERSION _OCT 2021_V0.1

EMD_MP_ELITeBeGenius_100-05OCT21/01EN

Foreword

The laboratory is alive

Laboratory is an evolving environment constantly looking for new solutions

Be part of the change

© 2021 ELITechGroup – Customer presentation

Introduction

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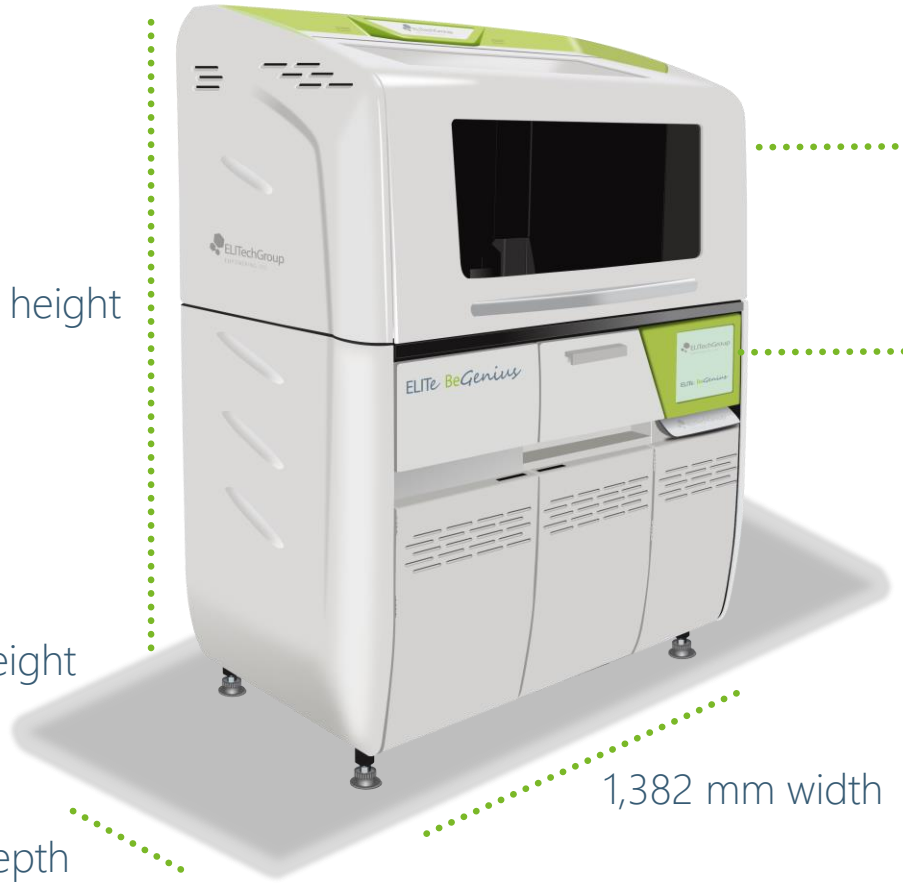
ELITe BeGenius®

Introduction



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ELITe BeGenius®

Introduction

Sliding door

Working area
- *12 extraction lines*
- *24 independent thermal cyclers*

Drawer
- *Sample and reagents caps collection*
- *Rack holder*

Cool unit
- *Samples and reagents loading*
- *Eluate storage*

Storage area
- *Consumable boxes and printer storage*

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Features & benefits

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ELITechGroup
EMPOWERING IVD

Be Smart

Tailored to your needs

- Stand alone system with compact footprint
- Cooled storage of samples, eluates, and reagents to improve their stability on-board
- Total traceability of samples, eluates and reagents with bidirectional LIS connection
- Compatibility to several different primary tubes
- Availability of a wide range of CE-IVD assays and open channel capability

CLEVER ANSWER TO ANY WORKFLOW

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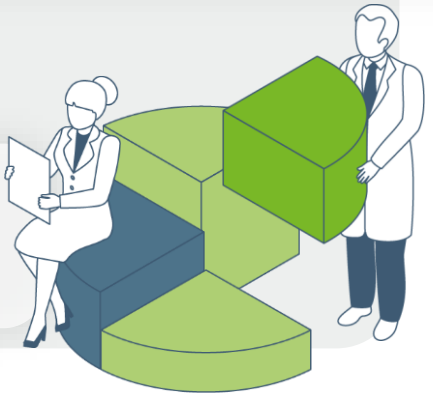
ELITechGroup
EMPOWERING IVD

Be Easy

Molecular biology becomes universally accessible

- Walk away solution: reduced hands on time, full automation and intuitive software
- Different matrices and different assays can be run simultaneously
- Capable to manage 24 independent PCR protocols
- BeGenius uses the same reagents and consumables as InGenius
- Build up your molecular corner as you wish with BeGenius

OPERATE YOUR MOLECULAR LAB ACCORDING TO YOUR NEEDS



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EMPOWERING IVD

Be Power

Boost your lab efficiency

- Run up to 72 results in a 8h shift. Up to 18.000 tests/year
- Fast mode with 2 ml primary tubes, up to 12 reports in less than 2 hours
- Run many assays from the same sample patient
- Up to 24 different samples in several kinds of matrices can be tested in parallel within the same run

FIRST RESULTS IN LESS THAN 2 HOURS AND UP TO 18.000 TESTS/YEAR

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The “Genius Way”

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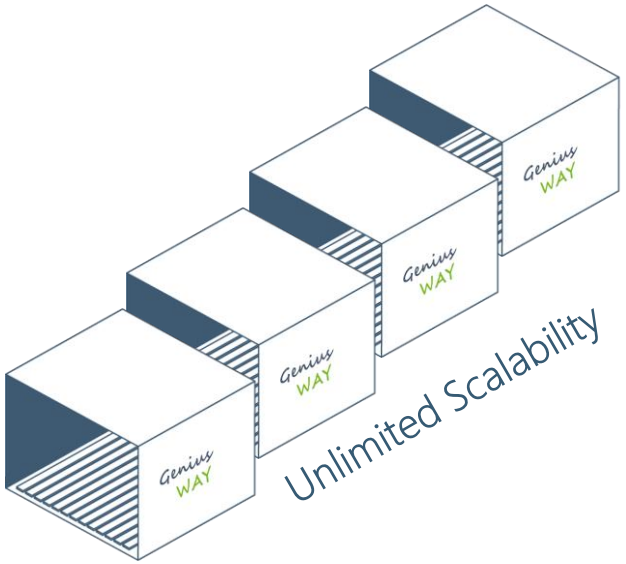
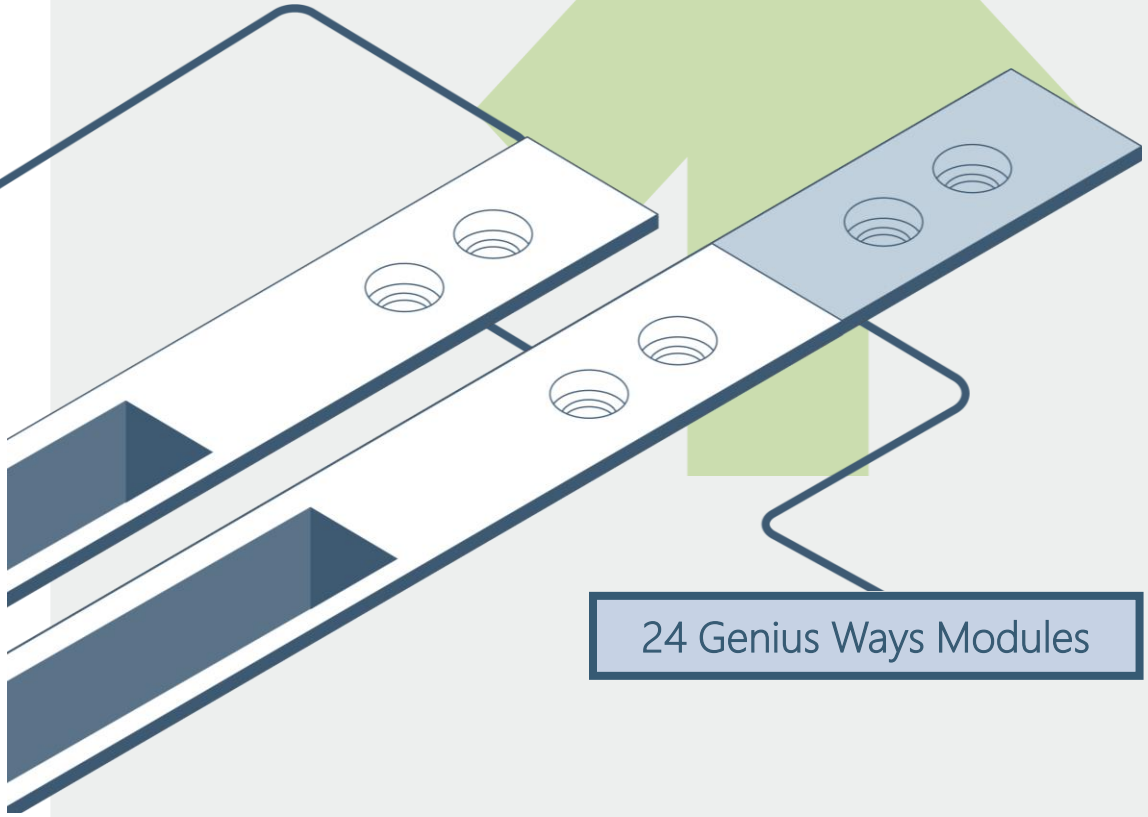
Welcome to the “Genius Way” era

BeGenius and InGenius melts into the “Genius” concept

12 Genius Ways Modules





24 Genius Ways Modules

"Genius Way“ grows with your needs

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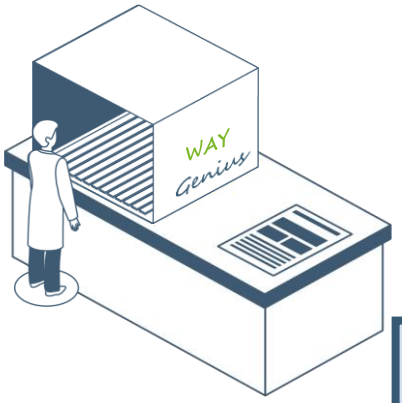
Growing with the customers

The “Genius Way” grows with your laboratory

The “Genius Way” is the solution for your laboratory today and in the future



We help you to identify your needs and offer tailored solutions for your laboratory

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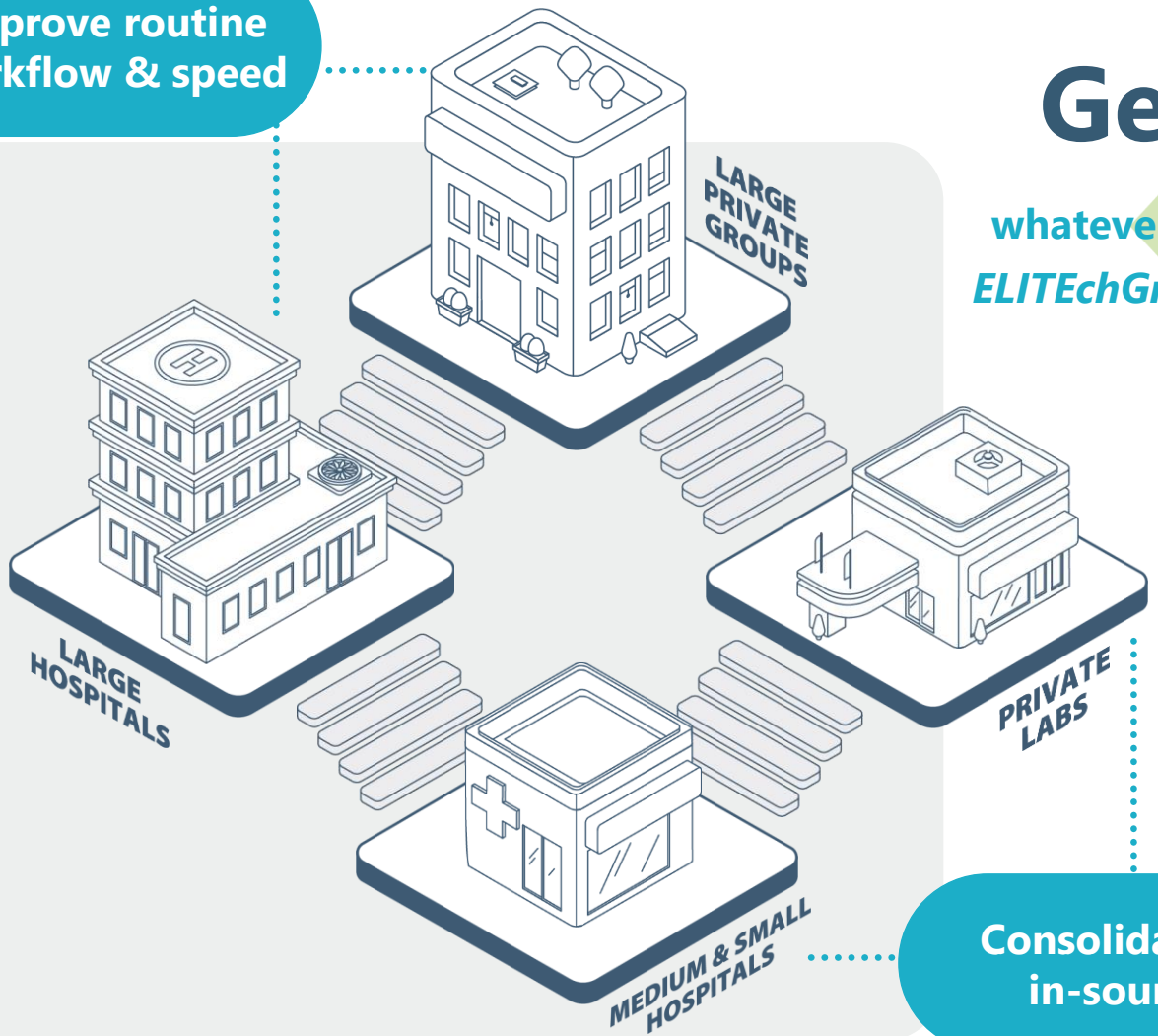
Genius Way

whatever kind of laboratory you are

ELITEchGroup has the solution for you

Improve routine workflow & speed



Consolidation & in-sourcing

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Message to Labs

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EMPOWERING IVD

Message to Labs

Be Part of the Change

Universal access to molecular biology

- Easy solution, ideal for molecular experts and beginners
- Compact and self-standing, fits into any lab

Growing with the customer

- Capable to manage 24 independent PCR protocols
- Up to 24 samples from different matrices can be tested in parallel within the same run
- Broad range of CE-IVD assays and defined IVDR roadmap

Tailored to every routine

- Easy to set up, less than two minutes hands-on-time per sample
- Walk away solution, fully automated

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Solutions rather than products

ELITechGroup
EMPOWERING IVD

elitechgroup.com

egspa.marketing@elitechgroup.com

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HIV1 ELITe MGB® Kit

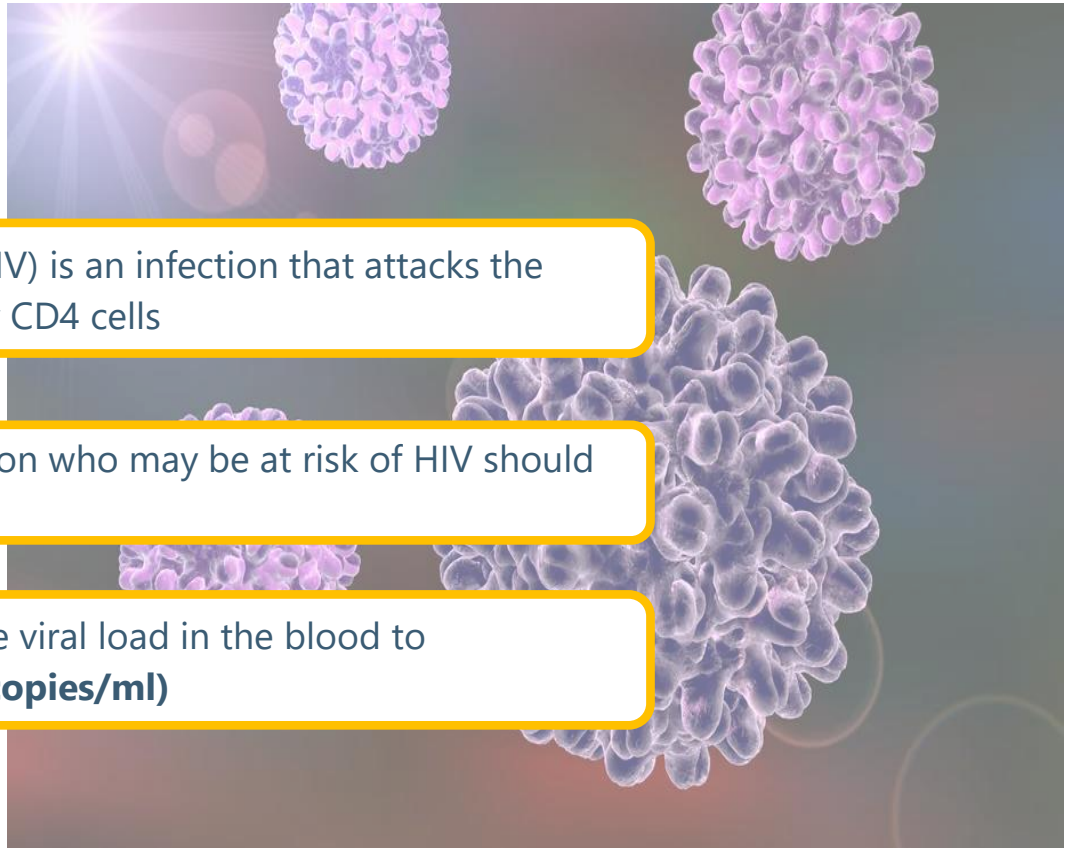
Quantitative assay for the detection and quantification of the RNA of HIV1

MARKETING PRESENTATION – ENGLISH VERSION: January 2022 – Rev. 00

EMD_MP_HIV_100-31JAN22/00EN

HIV1 RNA

Key Facts



Human immunodeficiency virus (HIV) is an infection that attacks the body's immune system, specifically CD4 cells

WHO recommends that every person who may be at risk of HIV should access testing

The treatment goal is to reduce the viral load in the blood to undetectable levels (**less than 50 copies/ml)**

https://apps.who.int/iris/bitstream/handle/10665/259638/EndAIDS-eng.pdf;sequence=1

WHO set a GLOBAL target of ending the HIV/AIDS epidemic by 2030

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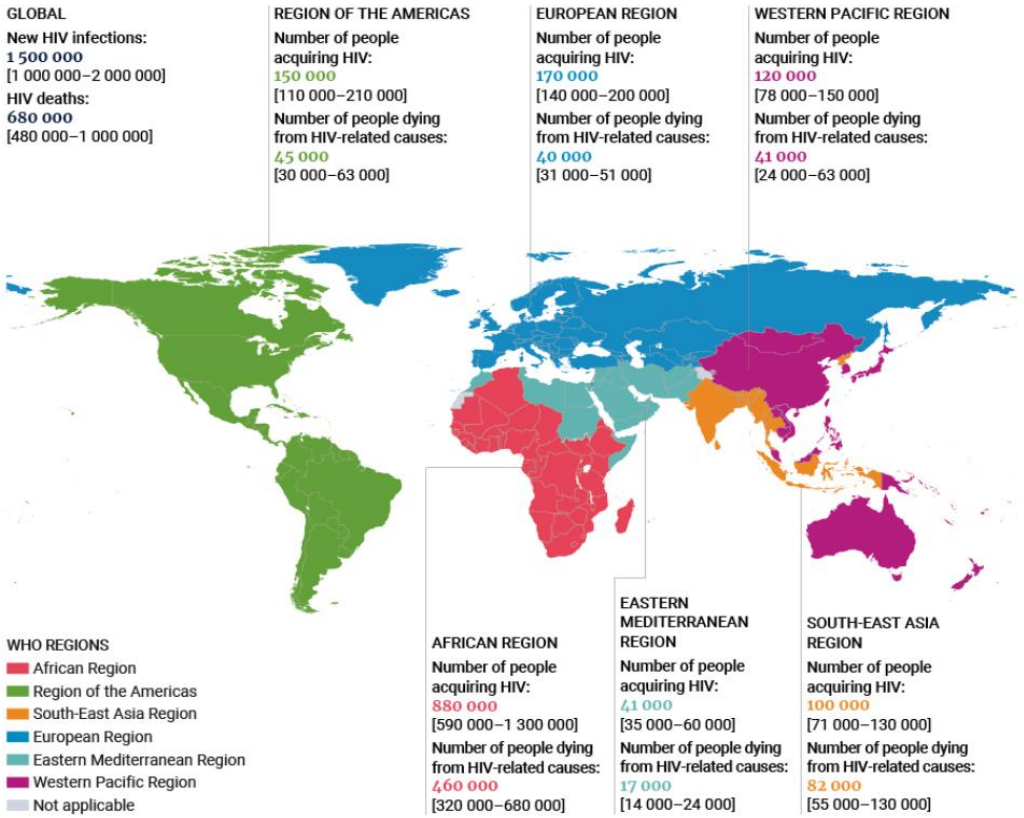
Burden of HIV Infection

WHO 2021

Number of people acquiring HIV and number of people dying from HIV-related causes, 2020



Data source: World Health Organization (2021). Global Progress Report 2021: HIV, viral hepatitis and sexually transmitted infections. Overview of the Global Health Sector Strategies, past and future.

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Monitoring for HIV-1 treatment response

WHO HIV guidelines

The guidelines state that HIV1 RNA be monitored at least two times for year during treatment

Viral load is recommended as the preferred monitoring approach to diagnose and confirm treatment failure

International guidelines suggest a value of **50 copies/ml of HIV RNA** as the threshold below which 'therapeutic success' is considered to have been achieved.

REAL-TIME PCR IS THE PREFERED METHOD FOR MONITORING HIV1 PATIENTS DURING TREATMENT

https://apps.who.int/iris/rest/bitstreams/1336192/retrieve

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Assay Presentation

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HIV1 ELITe MGB® Kit

RTK600ING – Intended Use

- Quantitative assay for the detection and quantification of the RNA of HIV1
- Detection and quantification of HIV1 group M (subtypes from A to L), group O, group N and main **CRF's (CRF03-AB)**.
- Intended for the management of HIV1-infected individuals undergoing antiviral therapy (monitoring)

INDICATED FOR MONITORING PATIENTS DURING ANTIVIRAL THERAPY

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HIV1 ELITe MGB® Kit

RTK600ING – Main characteristics

- **Specific targets:** Integrase region (pol domain)
- **Internal Control:** exogenous based on MS2 genomic RNA
- **Matrices:** Plasma in EDTA and ACD
- **Extraction:** SP1000 (600µl-50µl)
- **CE-IVD validated:** ELITe InGenius®
- **Compatibility Thermal cyclers:** 7500 Fast Dx Real-Time PCR

INDICATED FOR MONITORING PATIENTS DURING ANTIVIRAL THERAPY

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HIV1 ELITe MGB® Kit

Performances

Limit of Detection for Plasma samples	
IU/mL	**60**
Copies/mL	**26**
Diagnostic Specificity*	**99.5%**

* Vs Method Comparison. Please refer to IFU SCH mRTK600ING_02_N

Linear measuring range for Plasma samples	
Lower Limit	**Upper Limit**
60 IU / mL	3,19x108 IU / mL
26 copies / mL	1,38x108 copies / mL

WHO International Standard "4th WHO International Standard for HIV-1" (NIBSC code: 16/194) in Plasma collected in ACD.
6 dilution levels and 24 replicates for each level

OPTIMAL SENSITIVITY FOR HIV1 MONITORING

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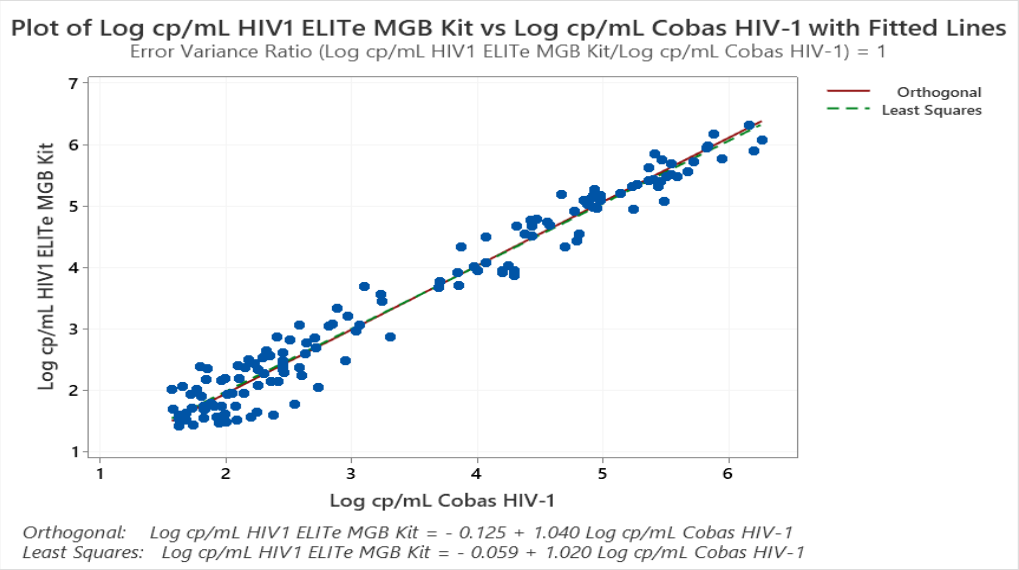
HIV1 ELITe MGB® Kit

Method correlation



Orthogonal Regression: intercept equal to -0.125 and slope equal to 1.040

Linear Regression: R equal to **0.964**

The Orthogonal and the Linear Regressions were performing by Minitab 19 statistical software (Figure 1) on the 141 samples.

EXCELLENT CORRELATION WITH REFERENCE METHOD

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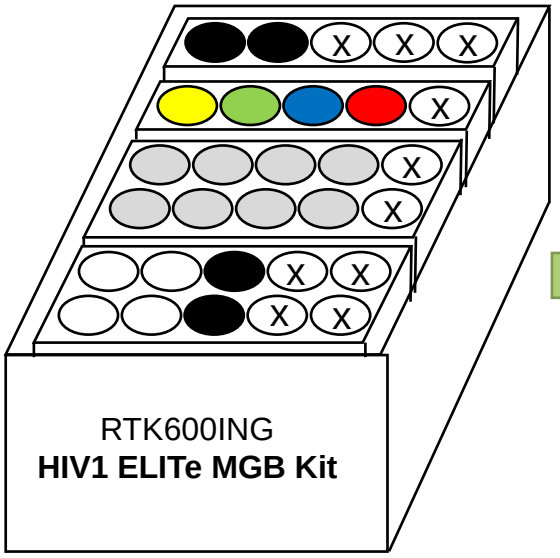
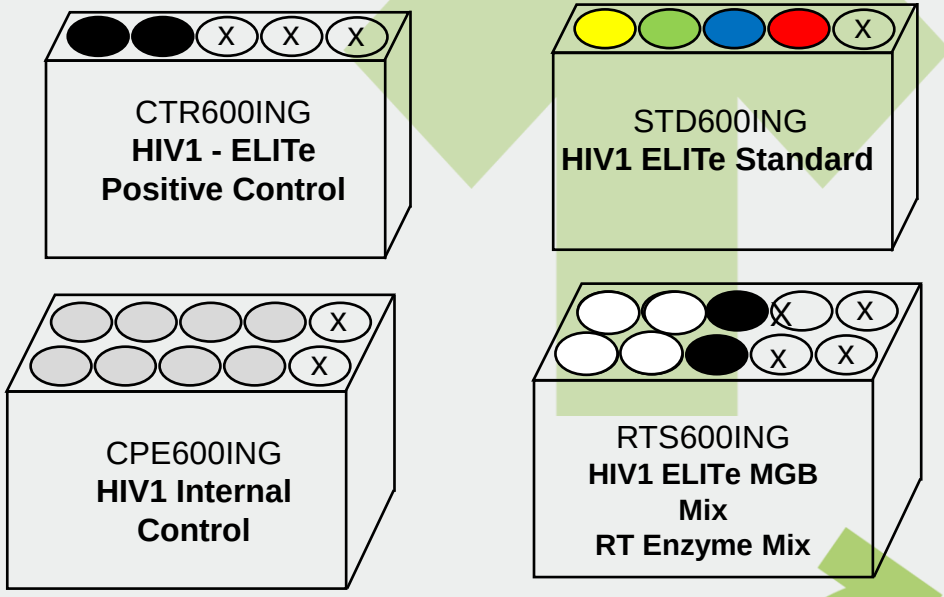
HIV1 ELITe MGB® Kit

RTK600ING – 96 tests assay





EVERYTHING YOU NEED IN ONE BOX

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HIV1 ELITe MGB® Kit

Main characteristics: MGB mix & Internal Control

HIV1 ELITe MGB Mix **600µl**

x 4

HIV1 Internal Control **160µl**

x 8

HIV1 ELITe MGB Mix (White Cap)

- 4 tube ready to use PCR MIX
- 24 test/tube
- 5 freeze-thaw cycles

HIV1 Internal Control (Grey Cap)

- 8 tubes ready to use
- 12 session / tube
- 12 freeze-thaw cycles

ASSAY

IC

THE SINGLE BOX KIT CONTAINS ALL REQUIRED READY-TO-USE REAGENTS, STANDARDS AND CONTROLS

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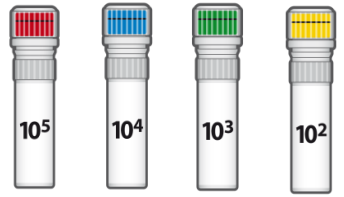
HIV1 ELITe MGB® Kit

Main characteristics: Positive Control & Standard

HIV1 ELITe MGB Mix **160µl**



HIV1 Positive Control **160µl**

x 2

HIV1 ELITe Standard

- HIV ELITe Standard 10^5 – 1 tube 160 µL (Red Cup)
- HIV ELITe Standard 10^4 – 1 tube 160 µL(Blue Cup)
- HIV ELITe Standard 10^3 – 1 tube 160 µL (Green Cup)
- HIV ELITe Standard 10^2 – 1 tube 160 µL (Yellow Cup)

- 4 tubes ready to use
- 2 session / tube
- 2 freeze – thaw cycles
- **Calibration to be performed every 60 days**

STANDARD

HIV1 - ELITe Positive Control (Black cap)

- 2 tubes ready to use
- 4 session / tube in association with ELITe InGenius®.
- 4 freeze – thaw cycles
- **Positive control to be performed every 15 days**

PC

THE SINGLE BOX KIT CONTAINS ALL REQUIRED READY-TO-USE REAGENTS, STANDARDS AND CONTROLS

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HIV1 ELITe MGB® Kit

Features

OPTIMAL SENSITIVITY: LIMIT OF DETECTION (LOD) EQUAL TO 26 COPIES/ML

OPTIMAL QUANTIFICATION OVER THE RANGE 26- 1,38x10^{8}COPIES/ML

PERFECT CORRELATION BETWEEN THE GENIUS SYSTEM AND THE REFERENCE METHOD

DIFFERENT SAMPLE TYPES TESTING (E.G. CSF)

SINGLE SAMPLE TESTING WITHOUT ANY WASTE

A NEW SOLUTION FOR THE QUANTIFICATION OF HIV1 RNA

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EMPOWERING IVD

HCV ELITe MGB® Kit

Quantitative assay for the detection and quantification of HCV RNA

MARKETING PRESENTATION – ENGLISH VERSION: MARCH 2022 – Rev. 00

EMD_MP_HCV_100-24MARC22/00EN

HCV RNA- Hepatitis C virus

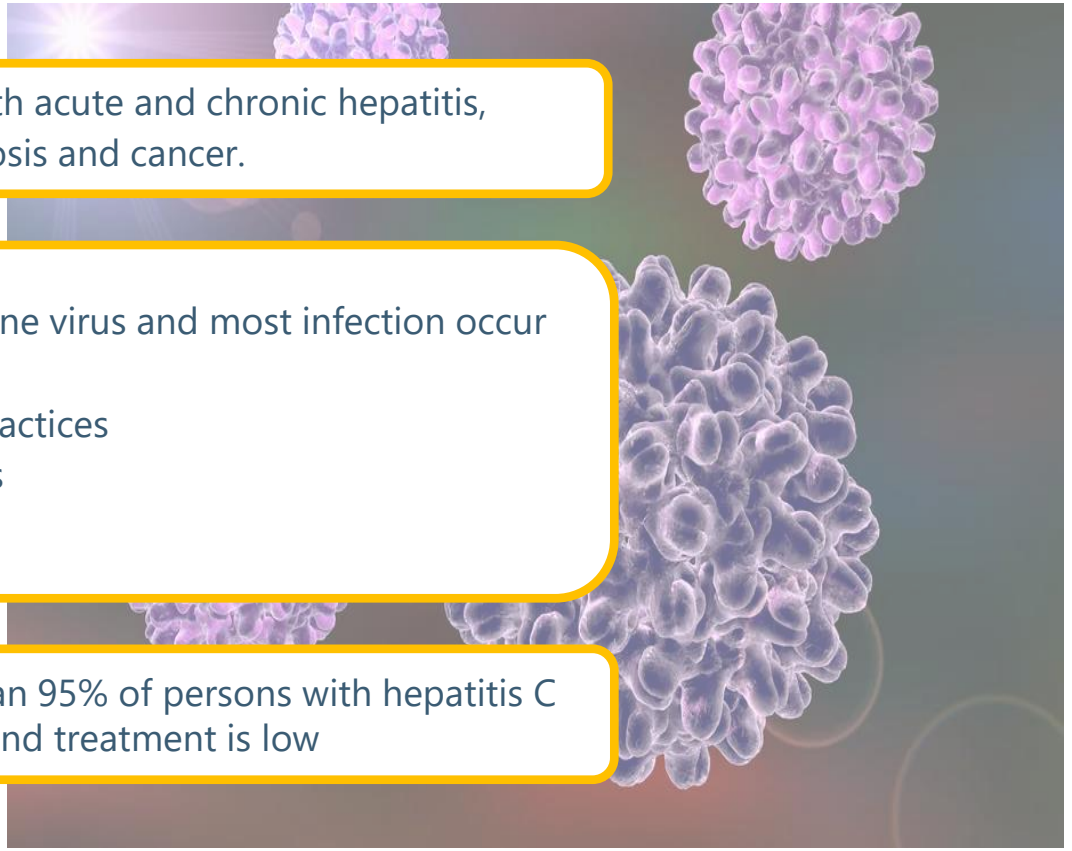
Key Facts

The Hepatitis C virus can cause both acute and chronic hepatitis, lifelong illness including liver cirrhosis and cancer.

The hepatitis C virus is a bloodborne virus and most infection occur through exposure to:

- blood from unsafe injection practices
- unscreened blood transfusions
- injection drug use

Antiviral therapy can cure more than 95% of persons with hepatitis C infection, but access to diagnosis and treatment is low



WHO GLOBAL GOAL IS TO STOP HCV BY 2030

https://www.who.int/news-room/fact-sheets/detail/hepatitis-c

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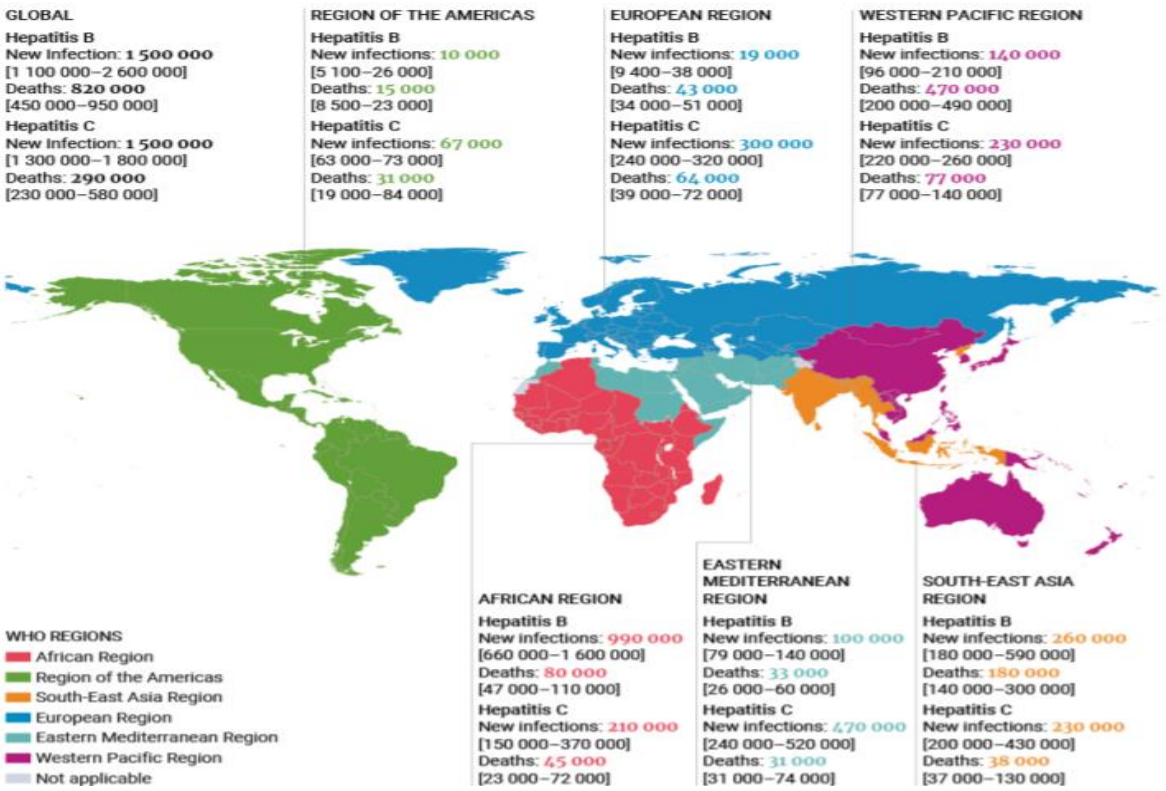
EMPOWERING IVD

Burden of HCV Infection

WHO 2021



Data source: World Health Organization (2021). Global Progress Report 2021: HIV, viral hepatitis and sexually transmitted infections. Overview of the Global Health Sector Strategies, past and future.

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Monitoring for HCV treatment response

WHO HCV guidelines

WHO recommend quantitative HCV RNA testing prior to initiating antiviral therapy and at the end of treatment after 12 or 24 weeks.

Guidelines from the AASLD* suggest testing for quantitative HCV RNA at periodic intervals during treatment (e.g. 4 weeks).

WHO recommends therapy with direct-acting antivirals (DAAs) for persons over the age of 12 years.

The goal of HCV therapy is defined as undetectable HCV RNA with a **detection limit < 25 IU/ml after therapy.**

REAL-TIME PCR IS THE PREFERRED METHOD FOR MONITORING HCV PATIENTS DURING TREATMENT

* American Association for the Study of Liver Disease

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Assay Presentation

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HCV ELITe MGB® Kit

RTK601ING – Intended Use

- Quantitative assay for the detection and quantification of the RNA of Hepatitis C virus (HCV)
- Detection and quantification of HCV genotypes **1, 2, 3, 4, 5 and 6**
- Intended for the management of HCV- infected individuals undergoing antiviral therapy (monitoring)

INDICATED FOR MONITORING PATIENTS DURING ANTIVIRAL THERAPY

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HCV ELITe MGB® Kit

RTK601ING – Main characteristics

- **Specific targets: Sequence** 5' UTR
- **Internal Control**: RNA of MS2 phage
- **Matrices:** Plasma in EDTA and ACD, Serum
- **Extraction:** SP1000 (600µl-50µl)
- **CE-IVD validated:** ELITe InGenius®
- **Compatibility Thermal cyclers:** 7500 Fast Dx Real-Time PCR

INDICATED FOR MONITORING PATIENTS DURING ANTIVIRAL THERAPY

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HCV ELITe MGB® Kit

Performances

Limit of Detection for Plasma and Serum samples	
IU/ml	**26**
Copies/ml	**11**
Diagnostic Specificity*	**100%**

* Vs Method Comparison. Please refer to IFU SCH mRTK601ING_02_N

Linear measuring range for Plasma and serum samples	
Lower Limit	**Upper Limit**
26 IU / mL	$2{,}5 \times 10^7$ IU / mL
11 copies / mL	10×10^6 copies / mL

The linearity of quantification was verified by analysis of negative Plasma collected in EDTA spiked by HCV reference material (SeraCare) for main HCV genotypes (1, 2, 3, 4, 5, 6). Each HCV genotype was tested in a panel of 6 dilution levels.

OPTIMAL QUANTIFICATION OVER THE LINARITY RANGE

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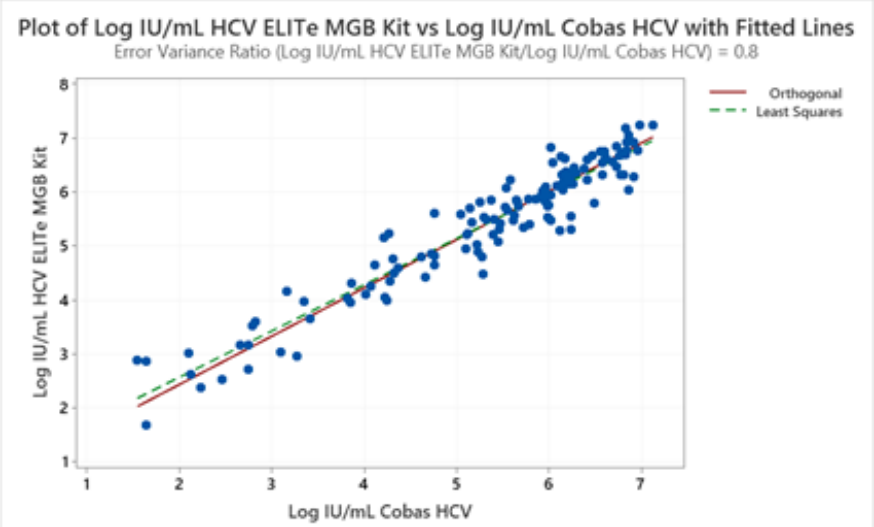
HCV ELITe MGB® Kit

Method correlation



- **Orthogonal Regression**: intercept equal to 0.651 and slope equal to **0.894**
- **Linear Regression**: R equal to **0.916**

The Orthogonal and the Linear Regressions were performing by Minitab 19 statistical software (Figure 1) on the 137 samples.

EXCELLENT CORRELATION WITH REFERENCE METHOD

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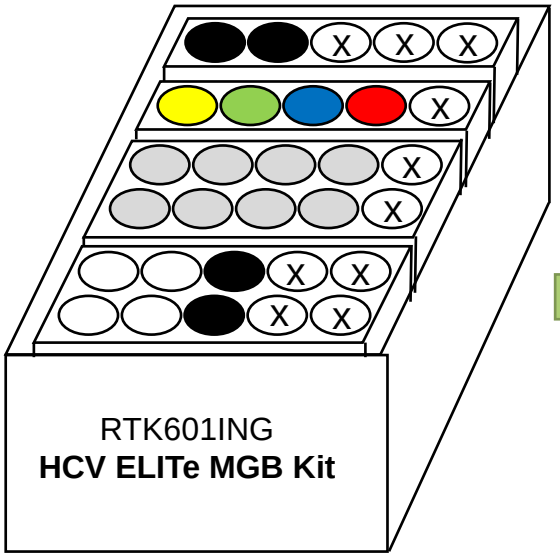
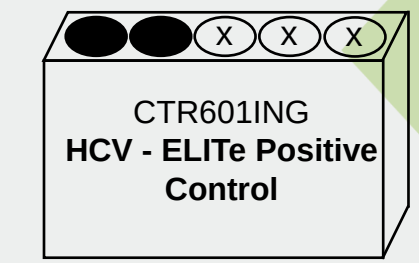
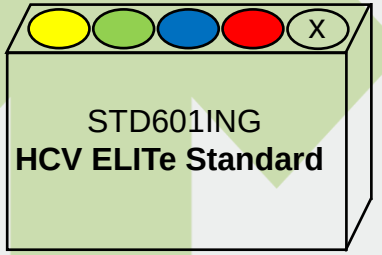
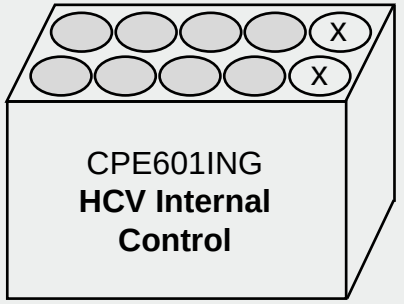
HCV ELITe MGB® Kit

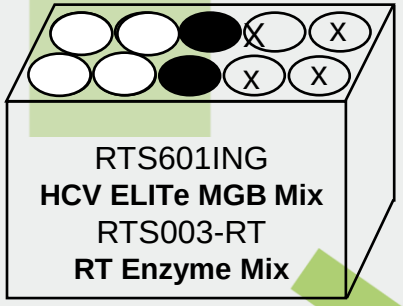
RTK601ING – 96 tests assay











ALL YOU NEED IS IN ONE BOX

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HCV ELITe MGB® Kit

Main characteristics: MGB mix & Internal Control

HCV ELITe MGB Mix	600µl
	x 4

HCV Internal Control	160µl
	x 8

HCV ELITe MGB Mix (White Cap)

- 4 tube ready to use PCR MIX
- 24 test/tube
- 5 freeze-thaw cycles

HCV Internal Control (Grey Cap)

- 8 tubes ready to use
- 12 session / tube
- 12 freeze-thaw cycles

ASSAY

IC

THE SINGLE BOX KIT CONTAINS ALL REQUIRED READY-TO-USE REAGENTS, STANDARDS AND CONTROLS

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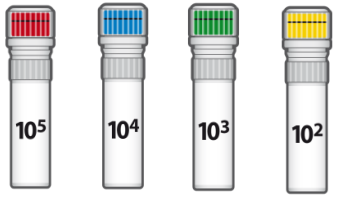
HCV ELITe MGB® Kit

Main characteristics: Positive Control & Standard

HCV ELITe Standard **160µl**



HCV ELITe Positive Control 160µl

x 2

HCV ELITe Standard

- HCV ELITe Standard 10^5 – 1 tube 160 µL (Red Cup)
- HCV ELITe Standard 10^4 – 1 tube 160 µL(Blue Cup)
- HCV ELITe Standard 10^3 – 1 tube 160 µL (Green Cup)
- HCV ELITe Standard 10^2 – 1 tube 160 µL (Yellow Cup)

- 4 tubes ready to use
- 2 session / tube
- 2 freeze – thaw cycles
- **Calibration to be performed every 60 days**

STANDARD

HCV - ELITe Positive Control (Black cap)

- 2 tubes ready to use
- 4 session / tube in association with ELITe InGenius®.
- 4 Freeze – thaw cycles
- **Control to be performed every 15 days**

PC

THE SINGLE BOX KIT CONTAINS ALL REQUIRED READY-TO-USE REAGENTS, STANDARDS AND CONTROLS

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HCV ELITe MGB® Kit

Features

- LIMIT OF DETECTION (LOD) EQUAL TO 26 COPIES/ML
- OPTIMAL QUANTIFICATION OVER THE RANGE
  26 IU / mL - 2,5 x 107 IU / mL
- PERFECT CORRELATION BETWEEN THE GENIUS SYSTEM AND THE REFERENCE METHOD
- POSSIBILIY OF ELUATE RECOVERY FOR FURTHER DIAGNOSTIC INVESTIGATIONS (I.E HCV GENOTYPING)
- SINGLE SAMPLE TESTING WITHOUT ANY WASTE

A NEW SOLUTION FOR THE QUANTIFICATION OF HCV RNA

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ELITechGroup
EMPOWERING IVD

HBV ELITe MGB® Kit

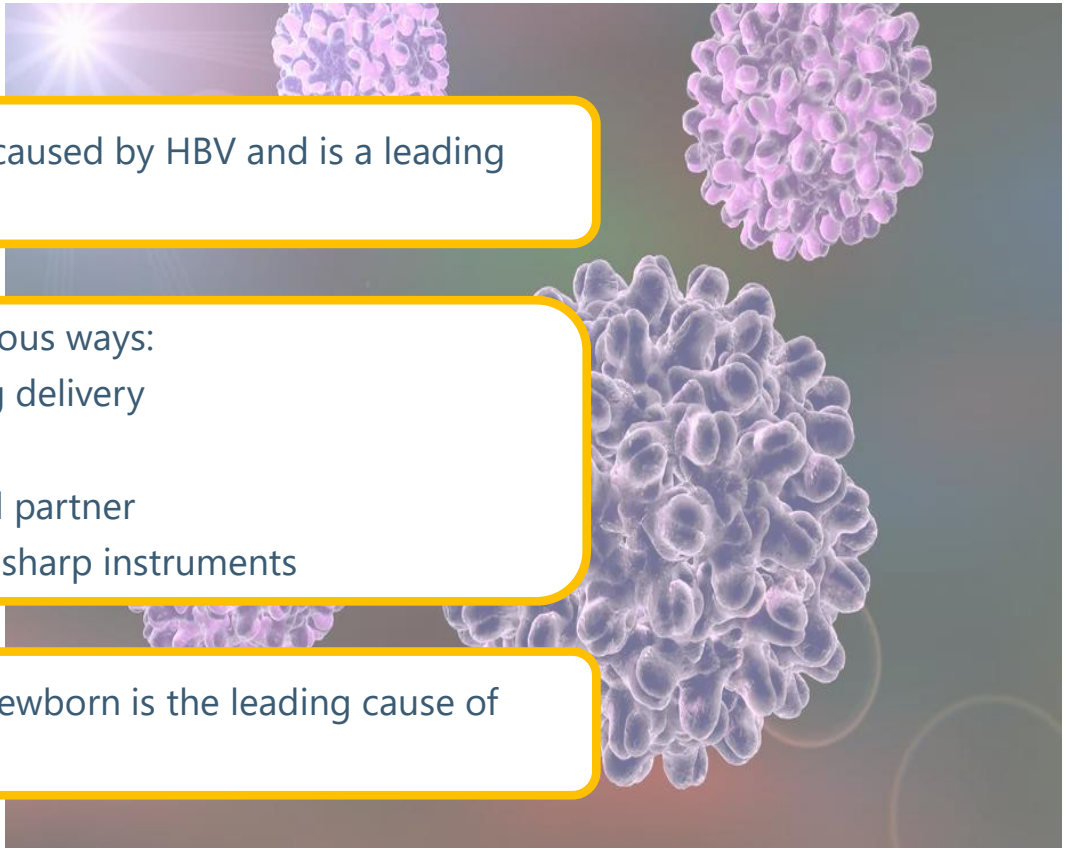
Quantitative assay for the detection and quantification of Hepatitis B virus DNA

MARKETING PRESENTATION – ENGLISH VERSION: DECEMBER 2021 – Rev. 00

EMD_MP_HBV_100-20DEC21/00EN

HBV – Hepatitis B virus

Key Facts



Hepatitis B is a contagious disease caused by HBV and is a leading cause of liver cancer

The virus can be transmitted in various ways:

- from mother to newborn during delivery
- blood contact/transfusions
- sexual relations with an infected partner
- unsafe injections and cuts from sharp instruments

HBV transmission from mother to newborn is the leading cause of chronic infection.

WHO GLOBAL GOAL IS TO STOP HEPATITIS BY 2030

https://www.who.int/news-room/fact-sheets/detail/hepatitis-b

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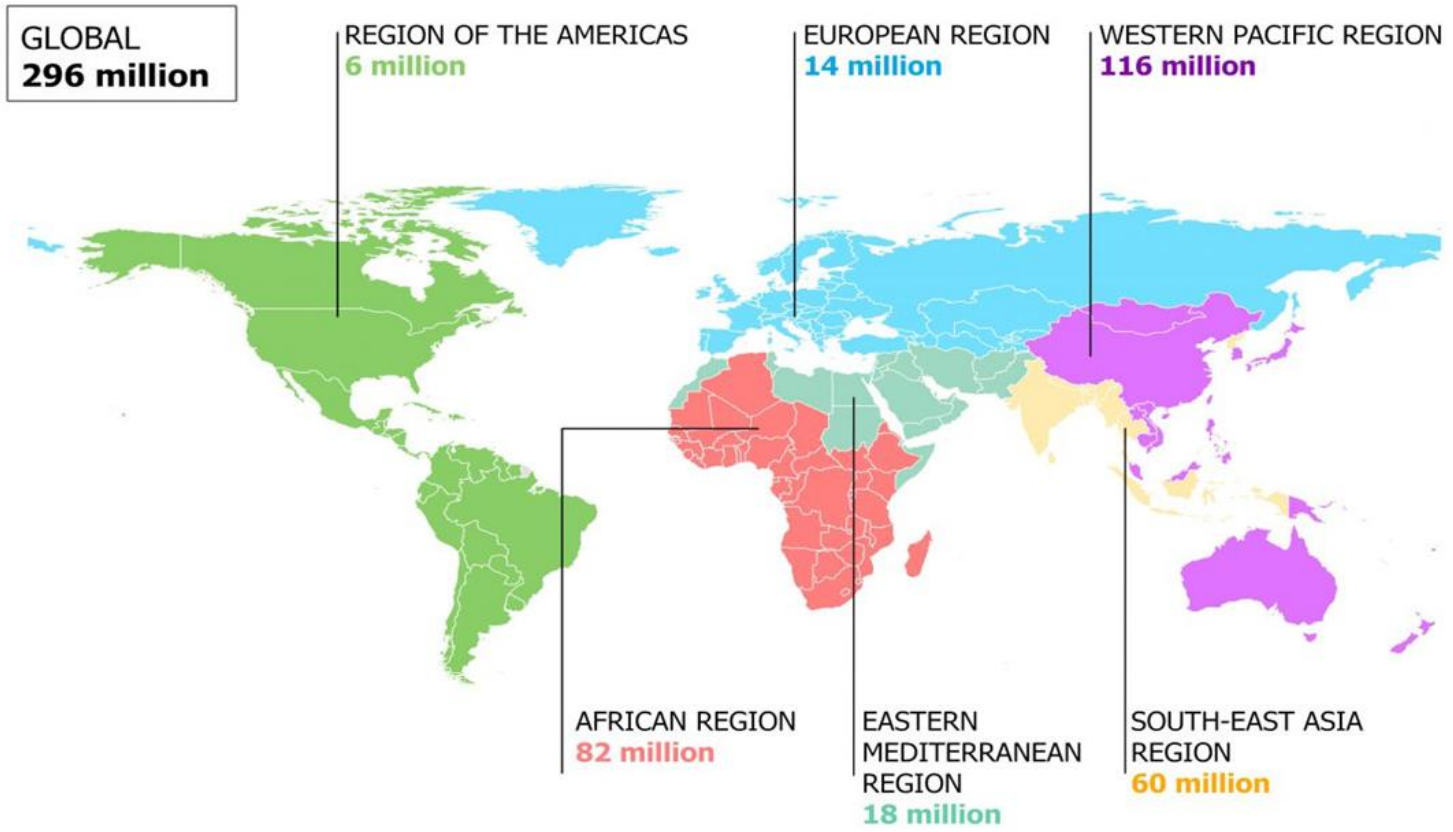
Burden of HBV infection

WHO 2021



Data source: World Health Organization (2021). Global Progress Report 2021: HIV, viral hepatitis and sexually transmitted infections. Overview of the Global Health Sector Strategies, past and future.

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Monitoring for HBV treatment response

WHO HBV 2017 guidelines

The WHO guidelines recommends monitoring HBV DNA at least annually during treatment

Quarterly monitoring is strongly recommended in the following situations:

- Patients with advanced disease
- Evaluation of therapy effectiveness during the first year of treatment
- Treatment response is not effective
- In people affected by HIV co-infection
- Follow-up after completing the treatment for 1 year

REAL-TIME PCR IS THE PREFERRED METHOD FOR MONITORING HBV PATIENTS DURING TREATMENT

GUIDELINES ON HEPATITIS B AND C TESTING, WHO, February 2017 HBVGuidance_Terrault_et_al-2018-Hepatology

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Assay Presentation

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HBV ELITe MGB® Kit

RTK602ING – Intended Use

- Quantitative assay for the detection and quantification of hepatitis B virus (HBV) DNA.
- Detection and quantification of HBV Genotypes **A to I and RF**
- Intended for the management of HBV-infected individuals undergoing antiviral therapy (monitoring)

THE PRODUCT IS INDICATED FOR MONITORING PATIENTS DURING ANTIVIRAL THERAPY

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HBV ELITe MGB® Kit

RTK602ING – Main characteristics

- **Specific targets:** Polymerase gene (TP domain)
- **Internal Control**: Plasmid DNA contains the sequence IC2
- **Matrices:** Plasma in EDTA or ACD and Serum
- **Extraction:** SP200 (200µl-50µl)
- **CE-IVD validated:** ELITe InGenius®
- **Compatibility Thermal cyclers:** 7500 Fast Dx Real-Time PCR

THE PRODUCT IS INDICATED FOR MONITORING PATIENTS DURING ANTIVIRAL THERAPY

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ELITechGroup
EMPOWERING IVD

HBV ELITe MGB® Kit

Performances

Limit of Detection for Plasma and serum samples	
IU/ml	**9**
Copies/ml	**38**
Diagnostic Specificity	**97,6%**

Linear measuring range for Plasma EDTA samples	
Lower Limit	**Upper Limit**
9 IU / mL	3,17x 10^8 IU / mL
38 copies / mL	1,3 x 10^9 copies / mL

The LoD was defined by testing a panel of HBV negative Plasma collected in ACD spiked by HBV certified reference material (4th WHO International Standard, NIBSC) at known title. Six levels of dilutions were prepared starting from 18 IU/mL to 1 IU/mL.

OPTIMAL SENSITIVITY FOR HBV MONITORING

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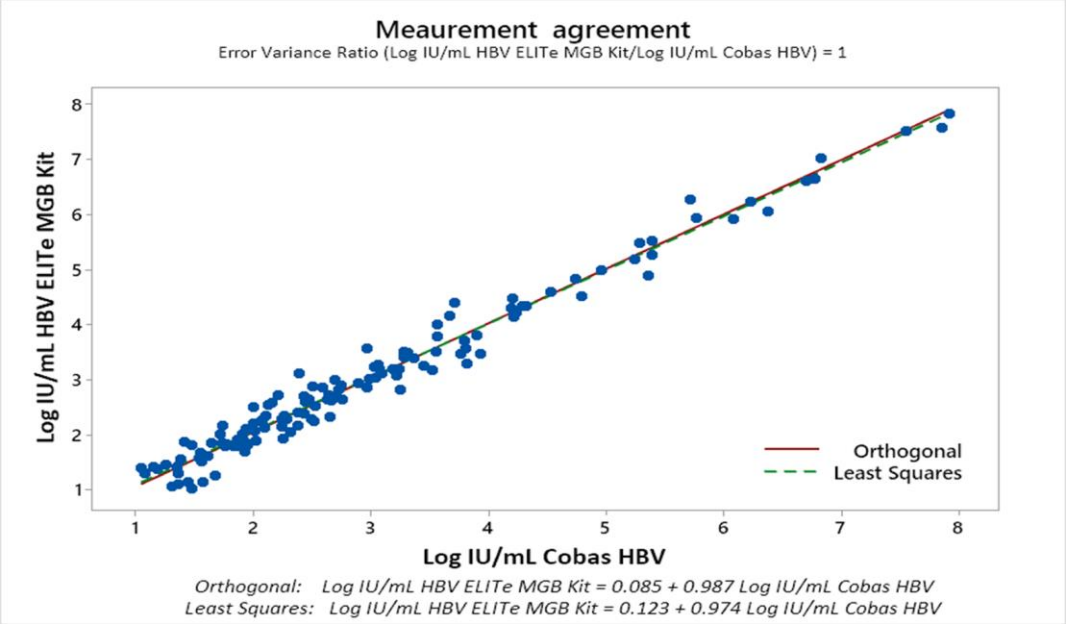
HBV ELITe MGB® Kit

Method correlation



- **Orthogonal Regression:** Intercept equal to 0.085 and slope equal to **0.987**
- **Linear Regression:** R equal to **0.974**

Over 131 plasma samples with titer within the linearity measurement range, regression analysis showed excellent correlation between HBV ELITe MGB Kit®-ELITe InGenius® and cobas® HBV kit , with an intercept equal to 0.085 (95% CI: -0.009 – 0.179), a slope equal to 0.987 (95% IC: 0.959 - 1.015) and R2 equal to 0.974.

EXCELLENT CORRELATION WITH REFERENCE METHOD

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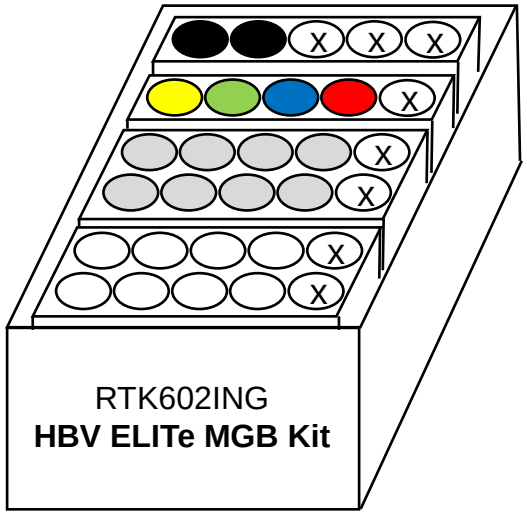
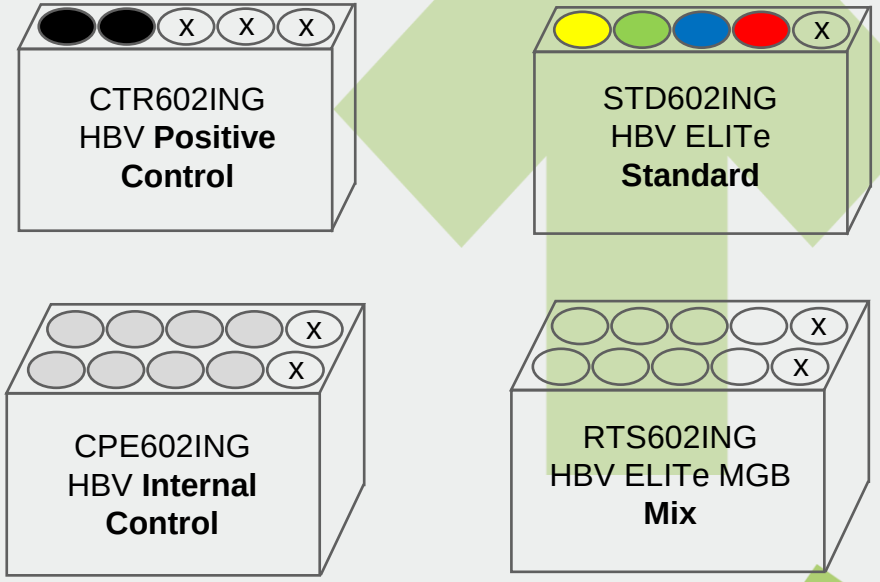
HBV ELITe MGB® Kit

RTK602ING – 96 tests assay





ALL YOU NEED IS IN ONE BOX

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HBV ELITe MGB® Kit

Main characteristics: MGB mix & Internal Control

HBV ELITe MGB Mix **280µl**

x 8

HBV Internal Control **160µl**

x 8

HBV ELITe MGB Mix (White Cap)

- 8 tubes ready to use PCR MIX
- 12 tests/tube
- 7 freeze-thaw cycles

HBV Internal Control (Grey Cap)

- 8 tubes ready to use
- 12 tests / tube
- 12 freeze-thaw cycles

ASSAY

IC

THE SINGLE BOX KIT CONTAINS ALL REQUIRED READY-TO-USE REAGENTS, STANDARDS AND CONTROLS

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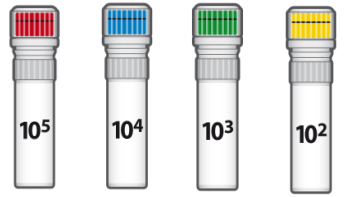
HBV ELITe MGB® Kit

Main characteristics: Positive Control & Standard

HBV ELITe Standard **160µl**



HBV ELITe Positive Control 160µl

x 2

HBV ELITe Standard

HBV ELITe Standard 105 – 1 tube 160 µL (Red Cup)
HBV ELITe Standard 104 – 1 tube 160 µL(Blue Cup)
HBV ELITe Standard 103 – 1 tube 160 µL (Green Cup)
HBV ELITe Standard 105 – 1 tube 160 µL (Yellow Cup)

- 4 tubes ready to use
- 2 session /tube
- 2 freeze – thaw cycles
- **Calibration to be performed every 60 days**

STANDARD

HBV - ELITe Positive Control (Black cap)

- 2 tubes ready to use
- 4 session / tube
- 4 Freeze – thaw cycles
- **Positive control to be performed every 15 days**

PC

THE SINGLE BOX KIT CONTAINS ALL REQUIRED READY-TO-USE REAGENTS, STANDARDS AND CONTROLS

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HBV ELITe MGB® Kit

Features

- LIMIT OF DETECTION (LOD) EQUAL TO 9 IU/ML
- OPTIMAL QUANTIFICATION OVER THE RANGE 9 IU/ML -3,17x 10^8 IU/mL
- PERFECT CORRELATION BETWEEN THE GENIUS SYSTEM AND THE REFERENCE METHOD
- POSSIBILIY OF ELUATE RECOVERY FOR FURTHER DIAGNOSTIC INVESTIGATIONS
- SINGLE SAMPLE TESTING WITHOUT ANY WASTE

A NEW SOLUTION FOR THE QUANTIFICATION OF HBV DNA

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BBV ELITe MGB® Solution Features

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ELITechGroup
EMPOWERING IVD

BBV ELITe MGB® Kit

Solution suitable to all laboratories

AVAILABLE FROM Q4 2022

- **EASE OF USE**
- **MINIMUM «HANDS ON TIME»**
- **RESULTS IN LESS THAN 3 HOURS**
- **SINGLE SAMPLE TESTING WITHOUT ANY WASTE**
- **RAPID RESULTS SUPPORT BETTER PATIENT MANAGEMENT**

WE OFFER THE BEST GENIUS WAY SOLUTION FOR YOUR LAB

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ELITechGroup
EMPOWERING IVD

Welcome to the “Genius Way” era

BeGenius and InGenius combine forces into one unified into the “Genius” concept

InGenius

Throughput**: 36/samples/8 hours**
Pos ID**: NO**
Eluate Storage**: YES**
BBV Primary Tube Loading**: NO**
Different extraction protocols: **NO**

BeGenius

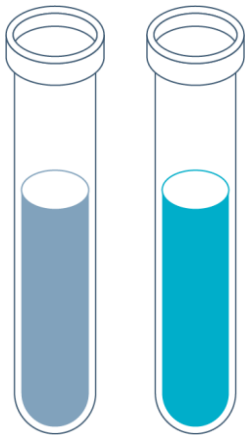
Throughput**: 72/samples/8 hours**
Pos ID**: YES**
Eluate Storage**: YES**
BBV Primary Tube Loading**: YES**
Different extraction protocols: **YES**

Genius Way unlimited the scalability that ensures a future for any laboratory

ELITechGroup
EMPOWERING IVD

Universality

Of the "Genius" series



Urgent

Routine

Results

- QUALITATIVE ASSAY
- QUANTITATIVE ASSAY
- MULTIPLEX OR SINGLEPLEX

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Genius® Menu

Complete panel for detecting and monitoring Hepatitis and HIV 1 related pathogens

Blood borne Panel

- HBV
- HCV
- HEV
- HIV1
- HAV

HIV Related Test

- HIV1
- HHV8
- P. JIROVECII
- ASPERGILLUS
- HLA-B5701

Blue = Validated Kit
Green = Compatible Kit

MEET CLINICAL NEEDS WITH OUR COMPRHENSIVE MENU

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EG Solution Positioning

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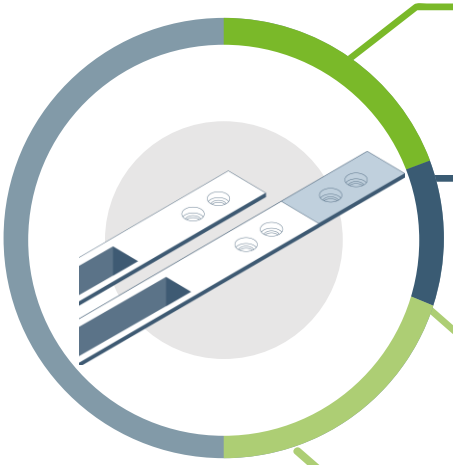
BBV ELITe MGB® Kit

Target customer



1. **InGenius Customer** not perform BBV Panel (e.g. send out, Covid)
2. Hospitals performing BBV **(every)where an InGenius is already installed** (take advantage of Load Factor or «emergency test»)
3. New Customers: **Private Laboratories** (Comprehensive MENU, unique supplier).
4. New Customers: **Reference Hospital** and **Children's Hospitals** (eluate recovery, CSF).

IDEAL TARGET : 500-5000 tests/year

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EMPOWERING IVD

POSITIONING

Target Customers

Medium realities (5000-10000 test/year)

Labs with complex dynamics seeking simplification, synergy and optimization

Small – Medium realities (500-5000 test/year)

Local facilities looking for fast response, in-sourcing and growth

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Competition

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HIV1 ELITe MGB® Kit

Competition chart

	ELITechGroup	Roche	Roche	Abbott	Abbott
KIT	HIV1 ELITe MGB® KIT	Cobas® HIV Test	Cobas® HIV Test	Real Time HIV-1	ALINITY m HIV-1 ASSAY
IVD	CE-IVD	CE IVD	CE_IVD	CE_IVD	CE_IVD
PLATFORM	ELITe InGenius®	COBAS 4800	COBAS 6800/8800	M2000sp/rt	Alinity m
TAT (min)	2h 30m	96 in 3h 30m, 192 in 5 h	96 in 3h 30m 192 in 5 h	96 in 7h 25 min.	<115 min
Genotypes	group M, group O, group N and main CRF's	Group M , Group O, Group N	Group M , Group O, Group N	Group M , Group O, Group N	Group M , Group O, Group N
Matrix Samples	Plasma EDTA and ACD	EDTA plasma	EDTA plasma	Plasma	Plasma
Sample processing volume	600µL	400uL or 200µL	500 µL or 200 µL	600µL	600µL
Amplicon Region	Integrase region (pol domain)	Gag and LTR regions	Gag and LTR regions	Integrase and LTR	Integrase and LTR
LOD	60 IU/mL plasma 26 copies / mL plasma	400 µL: 14.2 copies/mL 200 µL: 43.9 copies/mL	500 µL: 13.2 copies/mL 200 µL: 35.5 copies/mL	40 copie/mL	10 IU/mL in plasma
Linear Range	60-3,2x10^8 IU / mL	400 µL: 20 - 10^7copies/mL 200 µL: 60 - 10^7copies/mL	500 µL: 20 – 10^7 copies/mL 200 µL: 50 -10^7 copies/mL	10- 2x10^9 IU/mL	10 to 2 x10^7 Copies/mL
Specificity	99,5%	100%	100%	100%	100%





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HIV1 ELITe MGB® Kit

Competition chart

KIT	HIV1 ELITe MGB® KIT	Xpert® HIV1 Viral Load	Aptima® HIV Quant Assay kit	artus® HIV1 QS-RGQ Kit
IVD	CE-IVD	CE IVD	CE_IVD	CE_IVD
PLATFORM	ELITe InGenius®	GenXpert	Panther System	QIAsymphony® SP/AS and Rotor-Gene® Instruments
TAT (min)	2h 30m	1h 30m	120 in 2.4hrs 335 up to 500 in 8 hrs	96 samples in 9h 15m
Genotypes	group M, group N, group O and main CRF's	group M, group N, group O	group M, group N, group O	group M,
Matrix Samples	Plasma EDTA and ACD	Plasma EDTA	Plasma and Serum	Plasma
Sample processing volume	600µL	1ml	1200µL	1300µL
Amplicon Region	Integrase region (pol domain)	LTR (NC)	Polimerase and LTR gene	LTR
LOD	60 IU/mL in plasma 26 copies / mL in plasma	38 IU/mL in plasma	35 IU/ml in plasma	76,4 IU/ml in plasma
Linear Range	60-3,2x10^8 IU / mL	40-10^7 IU/ml	2,0 to 6,70 log copies/ml	31.5-2x107 IU/ml
Specificity	99,5%	98,5%	100%	100%
				

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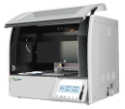
HCV ELITe MGB® Kit

Competition chart

	ELITechGroup	Roche	Roche	Abbott	Abbott
KIT	HCV ELITe MGB® KIT	Cobas® HCV Test	Cobas® HCV Test	ALINITY m HCV ASSAY	ALINITY m HCV- ASSAY
IVD	CE-IVD	CE IVD	CE_IVD	CE_IVD	CE_IVD
PLATFORM	ELITe InGenius®	COBAS 4800	COBAS 6800/8800	M2000sp/rt	Alinity m
TAT (min)	2h 30m	96 in 3h 30m, 192 in 5 h	96 in 3h 30m 192 in 5 h		
Genotypes	Genotype 1-6	Genotype 1-6	Genotype 1-6	Genotype 1-6	Genotype 1-6
Matrix Samples	Plasma EDTA and ACD and serum	EDTA plasma and serum	EDTA plasma and serum	Plasma and Serum	Plasma and Serum
Sample processing volume	600µL	400uL or 200µL	500 µL	500ul or 200ul	600ul
Amplicon Region	5' UTR	5' UTR	5' UTR	5' UTR	Dual target 5' UTR
LOD	LoD is 26 IU/mL in plasma and serum	400 µL: 9.2 IU/mL plasma 200 µL: 15.2 IU/mL plasma 400 µL: 7.6 IU/mL serum 200 µL: 15.3 IU/mL serum	500 µL: 12 IU/ml Plasma 500 µL: 13.2 IU/ml serum	500 µL: 12 IU/mL 200 µL: 30 IU/mL	600 µL: 8.46 IU/ml Plasma 600 µL: 7.47 IU/ml serum
Linear Range	26-25x10^6 IU / mL	400 µL: 15 - 10^8copies/mL 200 µL: 25 - 10^7copies/mL	500 µL: 15 - 10^8copies/mL	12- 10^8 IU/mL	7 to 2 x10^8 Copies/mL
Specificity	100%	100%	100%	100%	100%





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HCV ELITe MGB® Kit

Competition chart

KIT	HCV ELITe MGB® KIT	Xpert® HCV Viral Load	Aptima® HCV Quant Assay kit	artus® HCV QS-RGQ Kit
IVD	CE-IVD	CE IVD	CE_IVD	CE_IVD
PLATFORM	ELITe InGenius®	GenXpert	Panther System	QIAsymphony® SP/AS and Rotor-Gene® Instruments
TAT (min)	2h 30m	1h 30m	120 in 2.4hrs 335 up to 500 in 8 hrs	
Genotypes	Genotype 1-6	Genotype 1-6	Genotype 1-6	Genotype 1-6
Matrix Samples	Plasma EDTA and ACD and serum	Plasma and Serum	Plasma and Serum	Plasma and Serum
Sample processing volume	600µL	1ml	1200µL	1200µL
Amplicon Region	5' UTR		5' UTR	5' UTR
LOD	LoD is 26 IU/mL in plasma and serum	4.9 IU/ml in Plasma 6 IU/ml in serum	4.1 IU/ml in Plasma 13.2 IU/ml in serum	21 IU/ml in plasma
Linear Range	26-25x10^6 IU / mL	10-10^8 IU/ml	25-10^8 IU/ml	35-1,6x 10^8 IU/ml
Specificity	100%	100%	100%	




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HBV ELITe MGB® Kit

Competition chart

	ELITechGroup	Roche	Roche	Abbott	Abbott
KIT	HBV ELITe MGB® KIT	Cobas® HBV Test	Cobas® HBV Test	Abbott RealTime HBV	ALINITY m HBV ASSAY
IVD	CE-IVD	CE IVD	CE_IVD	CE_IVD	CE_IVD
PLATFORM	ELITe InGenius®	COBAS 4800	COBAS 6800/8800	M2000sp/rt	Alinity m
TAT (min)	2h 30m	96 in 3h 30m, 192 in 5 h	96 in 3h 30m 192 in 5 h		300 in 8h
Genotypes	A-I and RF	A-H	A-H	A-H and I	A-H and I
Matrix Samples	Plasma EDTA and ACD Serum	Plasma and Serum	Plasma and Serum	Plasma EDTA and ACD Serum	Plasma EDTA and ACD Serum
Sample processing volume	200µL	400uL or 200µL	200 µL and 500 µL	200 µL and 500 µL	300 µL
Amplicon Region	Polymerase gene (TP domain)	Pre-Core and Core Regiones	Pre-Core and Core Regiones	Surface Antigen gene	Surface Antigen gene
LOD	LoD is 9 IU/mL in plasma and serum	Plasma: 4.4 IU/mL (400 µL) Plasma: 7.6 IU/mL (200 µL) Serum: 2.8 IU/mL (400 µL) Serum: 5.5 IU/mL (200 µL)	Plasma: 6.6 IU/mL(500 µL) Plasma: 15.5 IU/mL (200 µL)	10 IU/mL (500 µL) 15 IU/mL (200 µL)	LoD is 10 IU/mL in plasma and serum
Linear Range	10-3x108 IU/ml	10- 10^9 IU/mL	25 IU/mL -10^9 IU/mL(200 µL) 10 IU/mL -10^9 IU/mL (500 µL)	10- 10^9 IU/mL	7- 2x10^9 IU/mL
Specificity	96,7%	100%	100%	100%	100%





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HBV ELITe MGB® Kit

Competition chart

KIT	HBV ELITe MGB® KIT	Xpert® HBV Viral Load	Aptima® HBV Quant Assay kit	artus® HBV QS-RGQ Kit
IVD	CE-IVD	CE IVD	CE_IVD	CE_IVD
PLATFORM	ELITe InGenius®	GenXpert	Panther System	QIAsymphony® SP/AS and Rotor-Gene® Instruments
TAT (min)	2h 30m	57m	120 in 2.4hrs 335 up to 500 in 8 hrs	
Genotypes	A-I and RF	A-H	A-H	A-H
Matrix Samples	Plasma EDTA and ACD Serum	Plasma and Serum	Plasma EDTA and ACD Serum	Pre-core region
Sample processing volume	200µL	600µL	700µL	
Amplicon Region	Polymerase gene (TP domain)		Polimerase and surface gene	
LOD	LoD is 9 IU/mL in plasma and serum	Plasma: 3,20 IU/ml Serum: 5,99IU/ml	Plasma: 5.58 IU/ml Serum: 4.29IU/ml	Plasma:10.2IU/ml
Linear Range	10-3x108 IU/ml	10-109 IU/ml	10- 109 IU/mL	31.5-2x107 IU/ml
Specificity	96,7%	100%	100%	
				

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MKT & Scientific Material

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Customer & MKT Presentation
Marketing Material

HOW SHOULD I USE IT?

- Marketing presentation: it contains confidential info. You do not have to share it with customers but keep it as reference for personal purposes.
- Customer presentation: sales tool to be used at customer's site to present BeGenius. It is not confidential, can be shared with customer in not editable format (pdf).

HOW CAN I HAVE IT? Downloadable from ELITeBoard and sent as attachment within the launch announcement by e-mail.

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Teaser
Marketing Material

WHAT IS IT? Tool used to promote the product and to circulate information about it.

HOW SHOULD I USE IT? Share it with your customers!

HOW CAN I HAVE IT? Downloadable from the Website, ELITeBoard and sent as attachment within the launch announcement by e-mail.

AVAILABLE STARTING FROM: March 2022

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Brochure
Marketing Material

WHAT IS IT? Tool used to promote the product and to circulate information about it.

HOW SHOULD I USE IT? Share it with your customers!

HOW CAN I HAVE IT? Downloadable from the Website, ELITeBoard and sent as attachment within the launch announcement by e-mail.

AVAILABLE STARTING FROM: March 2022

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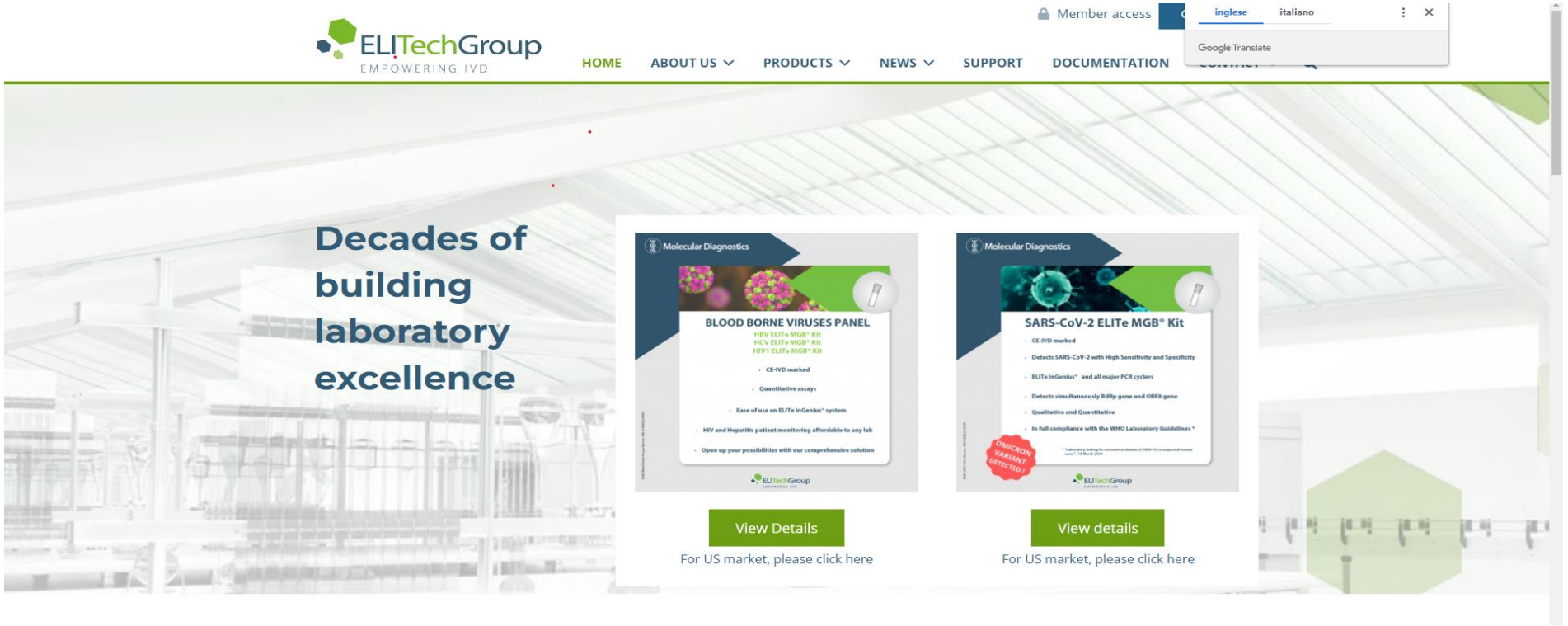
Materiale MKT

Banner web page



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Scientific Material

Poster 31st ECCMID 9-12 July 2021

31st ECCMID Online 9 – 12 July 2021

ESCMID EUROPEAN SOCIETY OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES

HBV ELITe MGB Kit ® and ELITe InGenius ®: a new system for the Quantification of HBV DNA in plasma and serum samples

G. Bovolenta, D. Barberis, C. Bittoto, S.Costa, C. Olivo, G. Stefanuto

ELITechGroup Molecular diagnostics

Poster # 4810

ELITechGroup EMPOWERING IVD

BACKGROUND

HBV viral load quantification is necessary to support clinical decisions in starting and manage anti-HBV treatments. The HBV monitoring is mainly performed at laboratories of major hospitals, with a long sample-to-result time and difficulties in reaching the care centers. This can result in delaying responses to clinicians and losing patients during the follow-up.

Integrated, easy-to-use, small-footprint platforms like ELITe InGenius® may offer a new tool in HBV monitoring.

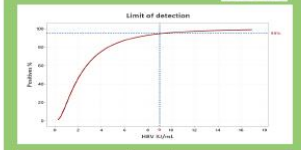
In this study, we evaluated the analytical and diagnostic performance of the new system HBV ELITe MGB Kit® and ELITe InGenius® in comparison to the cobas® HBV test and cobas® 4800 or 6800 System, for the quantification of HBV DNA in plasma and serum samples.

MATERIAL & METHODS

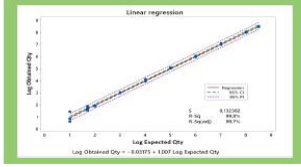
The Limit of detection (LoD) was evaluated by Probit analysis on a serial dilution of the 4th WHO International standard for HBV DNA for NAT on ACD-plasma, and confirmed on EDTA plasma and serum according to the CLSI guideline-EP17-A. The secondary reference material Hepatitis B virus Concentrate (ZeptoMetrix) was used in serial dilutions from 10^3 to about $10^{8.5}$ IU/mL in EDTA-plasma, to assess the linearity of measurement. The QCMD 2020 Hepatitis B Virus DNA EQA Programme (QCMD Ltd.) was used to asses the system reproducibility.

In the performance comparison, 127 HBV negative and 131 positive samples of EDTA-plasma were tested in parallel with HBV ELITe MGB Kit ® on ELITe InGenius ® and cobas® HBV on cobas® 4800/6800 System (Roche Diagnostics). Statistical analysis was performed with MINITAB ® (SV 19.2020.1).

RESULTS



- The LoD was equal to 9 IU/mL.



- The linearity of measurement ranged from 9 to 3.18 $10^{8.5}$ IU/mL.
- The linearity measurement within clinically relevant concentrations was confirmed for the main HBV genotypes (A, B, C, D, E, F, G) with R2 from 0.979 to 0.996 and quantitative results within ±0.5 Log IU / mL.

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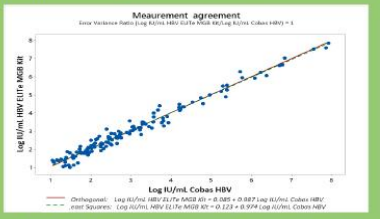
scientific.dept@elitechgroup.com

- The reproducibility of secondary reference material with titers from 1.7 to 3.8 Log IU/mL was within the expected SD range, from ±0.13 to ±0.23.

Sample ID	HBV genotype	Consensus Log UI/ml	SD Log UI/ml	ELITe InGenius Log UI/ml
HBVDNA1015-01	type A	2.823	0.130	2.695
HBVDNA1015-02	type D	2.673	0.148	2.625
HBVDNA1015-03	type D	3.642	0.155	3.579
HBVDNA1015-04	negative	-	-	-
HBVDNA1015-05	type A	1.869	0.229	1.688
HBVDNA1015-06	type A	3.803	0.156	3.781
HBVDNA1015-07	type A	2.848	0.176	2.696
HBVDNA1015-08	type D	1.724	0.227	1.422

- Evaluation over clinical samples showed 97.6% agreement on negative specimens (127) and 100% on positives (131).



- Over 131 plasma samples with titer within the linearity measurement range, regression analysis showed excellent correlation between HBV ELITe MGB Kit®-ELITe InGenius® and cobas® HBV kit , with an intercept equal to 0.085 (95% CI: -0.009 – 0.179), a slope equal to 0.987 (95% IC: 0.959 -1.015) and R2 equal to 0.974.

CONCLUSIONS

HBV ELITe MGB Kit ® and ELITe InGenius ® system showed optimal sensitivity in detecting HBV DNA genotypes A, B, C, D, E, F, G, H, I and RF accurate quantitation of HBV DNA over and extensive viral load range.

Such performances and the easiness of use make this system an interesting solution for small monitoring routines or backup of high throughput routine.

REFERENCES

1. S. Velkov et al., The Global Hepatitis B Virus Genotype Distribution Approximated from Available Genotyping Data. Genes. 2018 Oct 15;9(10):495.
2. European Association for the Study of the Liver. EASL 2017 Clinical Practice Guidelines on the management of hepatitis B virus infection. J Hepatol. 2017 Aug;67(2):370-398
3. Terrault N. et al, Update on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B: AASLD 2018 Hepatitis B Guidance, HEPATOLOGY 2018, VOL. 67, NO. 4, 2018

EG SOLUTION SHOWED OPTIMAL SENSITIVITY AND QUANTIFICATION OF HBV DNA OVER AN EXTENSEIVE VIRAL LOAD RANGE

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Take Home Message

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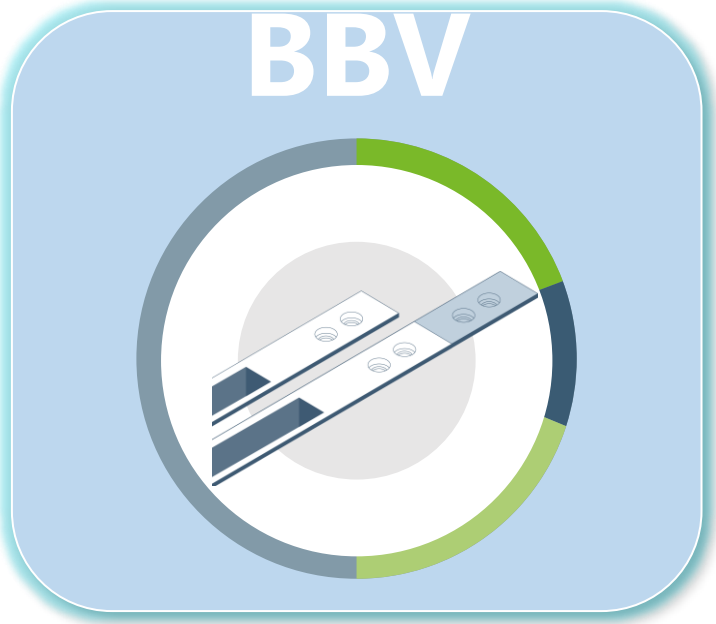
Take Home Message

BBV ELITe MGB® Kit in combination with "Genius Way"



- Complete solution for monitoring HIV+ patients (HHV8, Aspergillus, Pneumocystis, HLA B5701)
- Indicated for monitoring patients during antiviral therapy
- Possibility of eluate recovery for further diagnostic investigations (i.e. drug resistance,NGS, etc)
- Optimized management of controls and calibrators
- Can be used with different matrices (CFS)
- Extension of detected groups and subtypes for HIV (CRF)
- Single samples testing without any waste
- The extensive menu of tests on a fully automated platform (sample to results)
- Tailored for any type of Laboratory testing HIV and hepatitis

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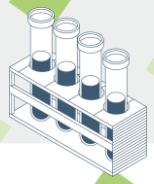
BBV ELITe MGB® Kit

Ordering Information

Reference Code	Product	Q.ty
RTK602ING	HBV ELITe MGB® Kit	96
RTK600ING	HIV1 ELITe MGB® Kit	96
RTK601ING	HCV ELITe MGB® Kit	96

THE KIT CONTAINS ALL THE READY-TO-USE REAGENTS, STANDARDS AND CONTROLS

EVERYTHING YOU NEED IN ONE BOX



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Solutions rather than products

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Molecular Diagnostics

HBV ELITe MGB® Kit

Real-Time PCR Assay for Hepatitis B Monitoring

MGB

IDEAL SOLUTION for all small and medium labs

EASE OF USE on ELITe InGenius® system

OPTIMAL SENSITIVITY for Hepatitis B patient monitoring

COMPLETE PANEL available in combination with HCV and HIV1 ELITe MGB® Kits

CE IVD 0344

In Vitro Diagnostic Medical Device
Not available in all countries.
Not available in the United States.

ELITechGroup
EMPOWERING IVD

"Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus (HBV).
Chronic hepatitis B infection can be treated with oral antiviral agents.
Treatment can slow the progression of cirrhosis, reduce incidence of liver cancer and improve long term survival.
In 2021 WHO estimated that 12% to 25% of people with chronic hepatitis B infection will require treatment.
WHO recommends the use of oral treatments as the most potent drugs to suppress hepatitis B virus.
Most people who start hepatitis B treatment must continue it for life".

World Health Organization

HBV ELITe MGB® Kit is a quantitative assay detecting the DNA of all known HBV genotypes (A-I and RF) and provides a new solution in the management of HBV-infected individuals undergoing antiviral therapy.

HBV ELITe MGB® Kit used with **ELITe InGenius®** demonstrates optimal sensitivity and quantification of HBV DNA over an extensive viral load range.

PERFORMANCES

LoD: 9 IU/ml in serum and plasma samples
LoD: 38 copies/ml in serum and plasma samples Diagnostic
Specificity: 97,6%
Perfect alignment of the result with the most common platforms

HBV ELITe MGB® Kit is calibrated with the 4th WHO International Standard, NIBSC.

ALL YOU NEED IN ONE BOX

The Kit contains ready-to-use reagents, standards and controls.

RESULTS IN LESS THAN 3 HOURS

Fast results support better disease management and better patient care

Ordering information

Reference	Product	Quantity
RTK602ING	**HBV ELITe MGB® Kit**	96 test

ELITechGroup Molecular Diagnostics, a major innovator in the molecular diagnostic market, offers a comprehensive real-time PCR range of products for diagnosis and monitoring of viral and microbiological infections.

ELITechGroup is certified by DEKRA Certification BV and applies a quality management system in compliance with ISO 9001:2015 and EN ISO 13485:2016

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Brazil	+55 27 3025 1415	The Netherlands	+31 313 430 500
France	+33 4 83 36 10 82	UK	+44 1442 869 320
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EMD HBV ELITe MGB-490-20DEC21/00EN

Molecular Diagnostics

ELITe BeGenius

TECHNICAL SPECIFICATIONS

Fully automated platform for nucleic acid extraction, PCR set-up, amplification and detection.

Performance Specifications

Time to first results	2h30 minutes (24 results)
Maximum throughput	72 results/8 hours
Walk-away time	~ 2h30 minutes
Maximum number of tests per run	24 tests
Sample capacity	24 reagent tubes
Reagent capacity	24 reagent tubes; possibility to unload during the run
Reagents	Ready-to-use, barcoded
Operational flexibility	• Integrated barcode readers for complete traceability of samples and reagents • Cooled storage of samples, eluates and reagents to improve their stability on-board and overnight runs. • Increase analytical throughput by a thermal block with 24 PCR positions • Improved single pipette module to implement high volume dispensing, multidispensing and reduce primary sample dead volume • Maximum flexibility in system placement within the laboratory • LIS connectivity
Barcode	Samples Barcode: Code 39; Code 128; Interleaved 2 of 5; Codabar; EAN 128 Reagents and Elution Tubes Barcode: DataMatrix

Physical Dimensions

Width	1,382 mm
Depth	850 mm
Height	1,843 mm
Total weight	440 kg
LCD touch panel	12.1″

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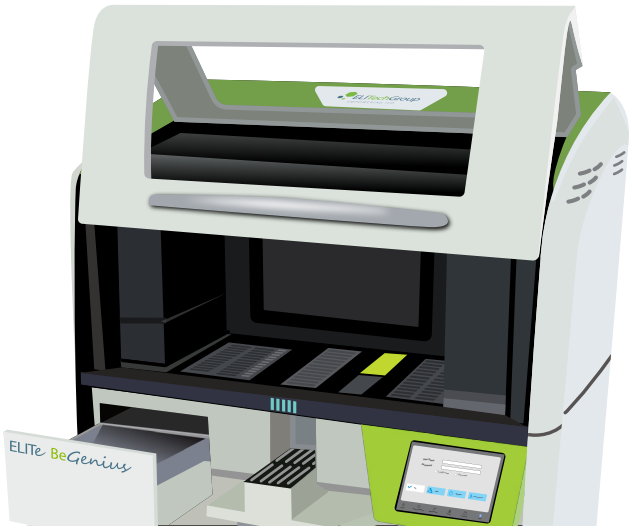
Electrical Specifications

Maximum power input	1050VA (1050W)
Input voltage	100-240V AC +/- 10%
Max current	10.5A/100V or 4.57A/230V
Frequency	50/60Hz
Installation category	Over voltage category: II
Pollution degree	2
Laser device	Class 1



Channel / Dye	Compatible Dyes	Excitation (nm)	Emission (nm)
1 FAM	FAM, SYBR green, Alexa Fluor 488	470	510
2 AP525	JOE, HEX, VIC	530	555
3 AP559	TAMRA, Alexa Flour 555, NED	560	590
4 AP593	ROX, Texas Red	590	630
5 AP642	Cy5, Alexa Fluor 647	630	670
6 AP680	Cy5.5, Alexa Flour 680, Quasar 705	670	710

Environmental Requirements

Operating temperature	+15 to 30° C
Storage temperature	+5 to 40° C
Transport temperature	-25° to 60° C
Ambient operating humidity	20-80% non-condensing
Maximum altitude	0-2,000 m (6,562 ft)
Non-operating temperature	-20–60° C
Non-operating relative humidity	20-90% non-condensing
Noise level	<70 dBA during 24 PCR amplification
Operation location	For indoor use only
Installation floor	The floor shall be level withstand the load of at least 500kg

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ELITechGroup
EMPOWERING IVD

EMD-ELITe BeGenius-Technical Specifications-02JUL21/00EN

Molecular Diagnostics

HCV ELITe MGB® Kit

Real-Time PCR Assay for HCV Monitoring

MGB

IDEAL SOLUTION for all small and medium labs

EASE OF USE on ELITe InGenius® system

OPTIMAL SENSITIVITY for HCV patient monitoring

COMPLETE PANEL in combination with HBV and HIV1 ELITe MGB® Kits

CE IVD 0344

In Vitro Diagnostic Medical Device
Not available in all countries. Not available in the United States.

ELITechGroup
EMPOWERING IVD

"Early diagnosis can prevent health problems that may result from infection and prevent transmission of the virus. WHO recommends testing people who may be at increased risk of infection.
Quantitative HCV RNA testing is recommended prior to initiating antiviral therapy and at the end of treatment after 12 or 24 weeks.
WHO Global goal is to stop HCV by 2030 increasing diagnosis and treatment."

World Health Organization

HCV ELITe MGB® Kit is a quantitative assay detecting the RNA of Hepatitis C virus (HCV), genotypes 1, 2, 3, 4, 5 and 6 providing a new solution for the management of HCV- infected individuals undergoing antiviral therapy.

HCV ELITe MGB® Kit in combination with **ELITe InGenius®** shows optimal sensitivity and quantification of HCV RNA.

PERFORMANCES

LoD: 26 IU/ml in plasma and serum samples
LoD: 11 copies/ml in plasma and serum samples
Diagnostic Specificity: 100%

ALL YOU NEED IN ONE BOX

The Kit contains ready-to-use reagents, standards and controls.

RESULTS IN LESS THAN 3 HOURS

Fast results support better disease management and better patient care

Ordering information

Reference	Product	Quantity
RTK601ING	**HCV ELITe MGB® Kit**	96 test

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EMD HCV ELITe MGB-490-31MAR22/00EN