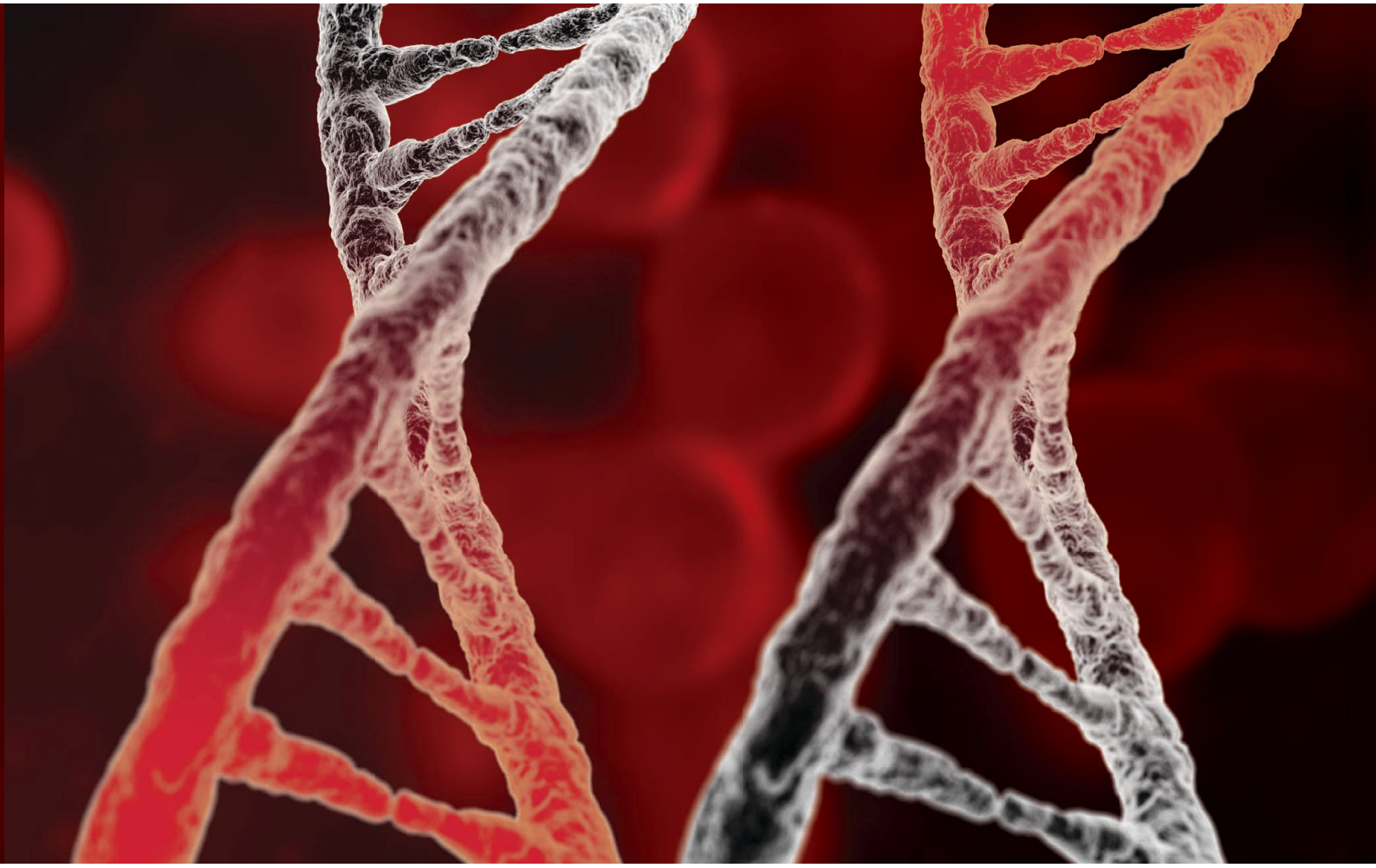
Chimerism Monitoring

Diagnostic solutions tailored to your requirements



www.biotype.de

BIOTYPE

Chimerism Monitoring

Engraftment evaluation in the era of PCR-based technologies

Allogeneic stem cell transplantation (SCT) is aimed to replace the dysfunctional hematopoietic system of the patient (recipient) with that of a healthy donor. Over the past few decades, it has become a leading treatment for high-risk blood cancers, such as acute myeloid leukemia (AML).

A key part of post-transplant care is regular diagnostics of the re-established hematopoietic system: whether it remains donor-derived or reverts to the recipient origin. This procedure is known as chimerism monitoring and it is based on detecting genetic differences between donor and recipient cells. While various techniques are available, the gold standard in the field are PCR-based assays.

Advancing Chimerism Monitoring with Tailored PCR Solutions

BIOTYPE is committed to advancing precision medicine and supports robust chimerism diagnostics. Developed in close collaboration with clinical partners and tailored to meet specific laboratory needs, our solutions offer high reliability, safety, and flexibility. Our portfolio includes:

- Assays for quantitative PCR (qPCR), digital PCR (dPCR), and capillary gel electrophoresis (CE) platforms
- Assays for qualitative genotyping and quantitative chimerism analysis
- Assays based on short tandem repeat (STR) and insertion-deletion (INDEL) assessment
- Accessories and data analysis software

With a strong focus on user-oriented design and regulatory compliance, we empower laboratories to deliver accurate and confident results, supporting effective patient monitoring in routine diagnostics.

BIOTYPE Chimerism Monitoring Solutions

Reliable tools for confident chimerism analysis

Clinically Approved & Certified

The BIOTYPE PCR Amplification kits Mentype® Chimera® (IVDR), Mentype® DIPscreen (IVDR), and Mentype® DIPquant (IVDD) as well as the software ChimerisMonitor IVD (IVDR) are registered CE-IVD products. Their value and reliability for accurate chimerism quantification have been confirmed in clinical studies, making them well-suited for routine diagnostic use.

Reliable & Accurate Results

Developed and validated using HLA-matched transplantation couples, BIOTYPE's CE-IVD kits deliver precise and reproducible results. For our Research Use Only (RUO) products, performance accuracy is supported by published data from clinical partners, demonstrating their reliability in real-world applications.

Seamless Integration into the Diagnostic Routine

BIOTYPE provides comprehensive customer support. We help you select the most suitable kit combination and integrate it smoothly into your laboratory workflow. Our experienced team provides guidance from initial setup through to routine use, ensuring a straightforward and efficient implementation process.

BIOTYPE Chimerism Monitoring Portfolio

Tailored solutions for reliable engraftment assessment

BIOTYPE provides healthcare professionals with precise and reliable tools for evaluating engraftment status. Our comprehensive portfolio features five PCR-based products tailored to various clinical and laboratory requirements. Depending on specific diagnostic priorities, users can choose from time- and cost-efficient solutions to highly sensitive, quantitative methods. Each product is designed for use with a dedicated analysis platform, such as capillary gel electrophoresis, qPCR, and dPCR.

Product Overview

- **Mentype® Chimera® (IVDR)** – chimerism analysis based on 12 STR markers + amelogenin
- **Mentype® DIPscreen (IVDR)** – chimerism analysis based on 33 INDEL markers + amelogenin
- **Mentype® DIPquant (IVDD)** – quantitative chimerism analysis using 56 INDEL assays for qPCR
- **Mentype® DigitalScreen (RUO)** – screening for 30 INDEL marker with droplet dPCR
- **Mentype® DigitalQuant (RUO)** – quantitative chimerism analysis using 59 INDEL assays for dPCR
- **ChimerisMonitor (IVDR, RUO)** – intuitive software solution for automated chimerims analysis
- **Matrix Standard BT5 multi (IVDR)** – an accessory for Mentype® multiplex PCR assays
- **DIP Positive Control DPC (RUO)** – qualitative positive control for INDEL-based assays

Chimerism Product Combinations for Optimal Performance

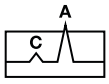
Pre-transplantation Genotyping	Post-transplantation Monitoring	Your Benefit
Mentype® Chimera® (IVDR) Mentype® DIPscreen (IVDR) ChimerisMonitor IVD (IVDR)	Mentype® Chimera® (IVDR) Mentype® DIPscreen (IVDR) ChimerisMonitor IVD (IVDR)	It detects a broad chimerism range with products suitable for samples with **low cell numbers** and **high throughput** application.
Mentype® DIPscreen (IVDR) ChimerisMonitor IVD (IVDR)	Mentype® DIPquant (IVDD) ChimerisMonitor RUO (RUO)	This combination enables a **highly sensitive** chimerism analysis by a **straightforward workflow** that reduces hands-on time to a minimum.
Mentype® DigitalScreen (RUO)	Mentype® DigitalQuant (RUO)	The digital approach enables a **highly sensitive**, quantitative detection of broad chimerism ranges, requiring **minimal sample input**.
Mentype® DIPscreen (IVDR) ChimerisMonitor IVD (IVDR)	Mentype® DigitalQuant (RUO)	This approach enables a **highly sensitive** and quantitative chimerism analysis and is applicable from low to **medium throughput** testing.

IVD - in vitro diagnostics; IVDD – CE-IVD product in grace period, certified according to IVD Directive 98/79/EC; IVDR – CE-IVD product certified according to IVD Regulation (EU) 2017/746; RUO - Research Use Only products must be validated by the customer with clinically relevant material for diagnostic purposes.

Chimerism Monitoring Tailored to Your Needs

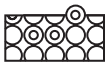
Discover the optimal BIOTYPE product combination

BIOTYPE's flexible portfolio of chimerism analysis solutions empowers you to choose the most suitable testing setup for your specific requirements. Our modular approach allows you to configure the ideal combination of products to match your daily routine based on the testing platform you use, required sensitivity, sample input and sample throughput.



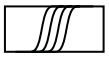
Capillary Gel Electrophoresis

Semi-quantification
Applicable for samples with low cell numbers
Capable for high throughput



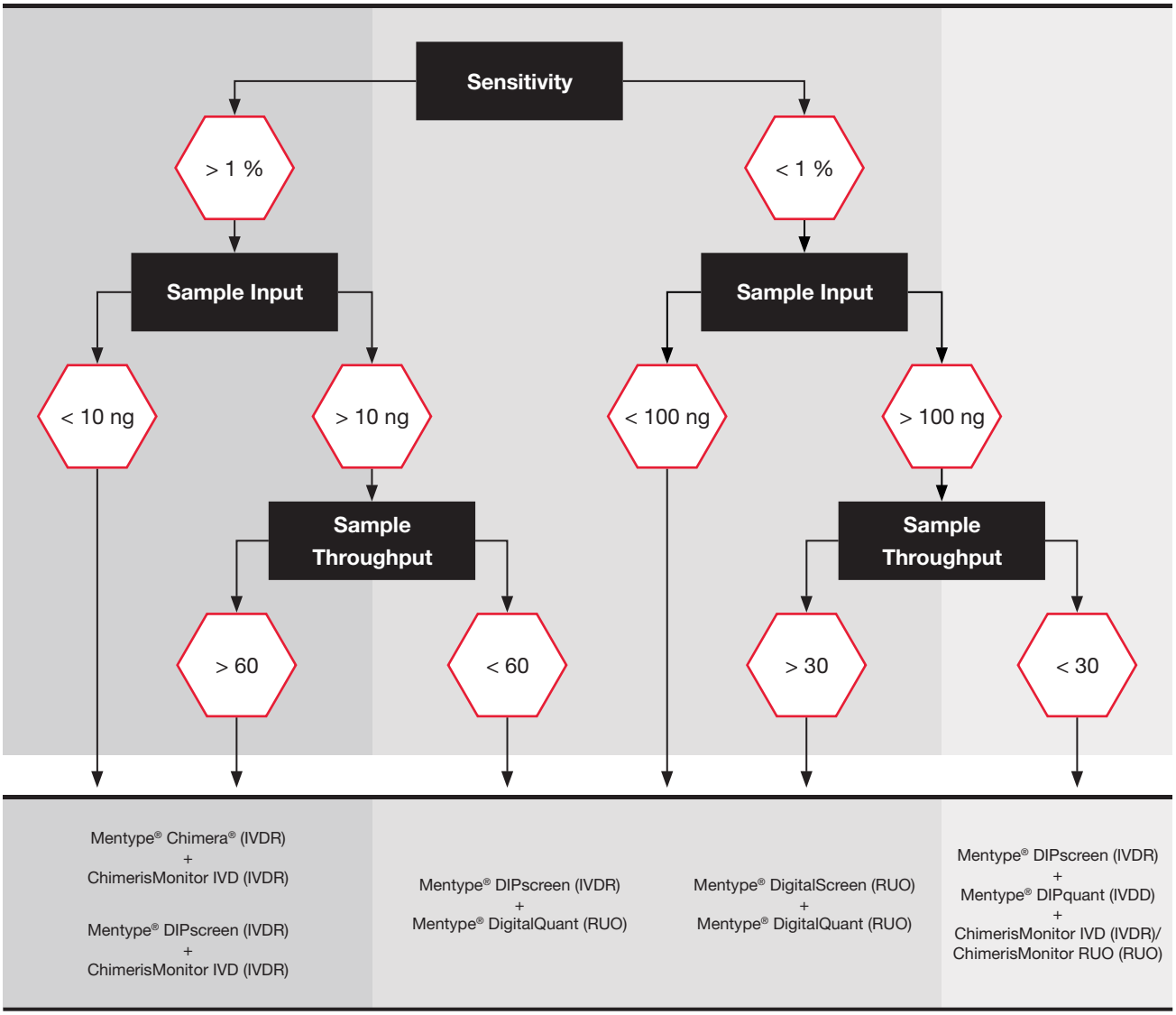
Digital PCR

Absolute quantification
High sensitivity
Wide measuring range



Quantitative PCR

Relative quantification
High sensitivity
Fast turn-around time



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Pre-Transplantation Genotyping

Precise discrimination of closely related donor-recipient pairs

Allogeneic hematopoietic stem cell transplantation in adults is preferably performed using HLA-identical related donors[1]. This makes distinguishing between the donor's and recipient's hematopoietic systems particularly challenging. A genotyping approach capable of detecting and monitoring informative genetic markers is essential.

BIOTYPE offers three specialized test kits—Mentype® Chimera® (IVDR), Mentype® DIPscreen (IVDR), and Mentype® DigitalScreen (RUO)—designed to enable precise discrimination between donor and recipient, even in closely related transplantation settings. These solutions use a combination of forensically validated STR markers and transplant-specific INDEL polymorphisms to ensure high discriminatory power.

High Discriminatory Power for Informative Marker Identification

	Mentype® Chimera® (IVDR)	**Mentype® DIPscreen (IVDR)**	**Mentype® DigitalScreen (RUO)**
Technology	Capillary gel electrophoresis	Capillary gel electrophoresis	Droplet digital™ PCR
Discrimination Power unrelated	+++	+++	++
Discrimination Power related	++	+++	++
Sample throughput	+++	+++	+
Sample Input	+++	+++	++

Suitability: +++ optimal, ++ well, + limited
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SPECIFICATIONS

	Turnaround Time	**Hands-on Time**	**DNA Input**
Mentype® Chimera®	4.5 h	15 min	0.125-2 ng
Mentype® DIPscreen	4 h	15 min	0.125-2 ng
Mentype® DigitalScreen	4.5 h	45 min	300 ng

REFERENCES:

1 LEITLINIEN zur allogenen Stammzelltransplantation von der Deutschen Arbeitsgemeinschaft für Knochenmark und Blutstammzelltransplantation (DAG-KBT), 5. Spenderauswahl zur Allogenen Stammzelltransplantation, Version 1, Stand Juni 2016.

Post-Transplantation Monitoring

Comprehensive detection of hematopoietic chimerism

Following stem cell transplantation, various forms of hematopoietic chimerism may develop[1,2]. BIOTYPE's chimerism product line is specifically designed to reliably detect and differentiate between all clinically relevant chimerism types. These insights are essential for effective post-transplant monitoring and informed patient management:

	Mentype® Chimera® (IVDR)	Mentype® DIPscreen (IVDR)	Mentype® DIPquant (IVDD)	Mentype® DigitalQuant (RUO)
	≥ 1.4 %	**≥ 1.4 %**	**0.05 %**	**0.1 %**
Complete Chimerism All hematopoietic cells are derived from donor.	+	+	+++	+++
Transient Mixed Chimerism Directly after SCT, a few recipient cells (1-5 %) are present before complete donor chimerism occurs.	++	++	+++	+++
Stable Mixed Chimerism Mixed profile with varying rates of recipient and donor hematopoiesis; the ratio remains stable.	+++	+++	++	+++
Progressive Mixed Chimerism Mixed proportion of donor and recipient hematopoiesis, with a steady decline in donor content.	+++	+++	++*	+++
Loss of Chimerism Donor chimerism is completely lost (secondary graft failure).	+++	+++	+++*	+++
Split Chimerism* Cells from one cell line come from donor while remaining cell lines originate from recipient.	++*	++*	+*	++*

Suitability: +++ ideally suited, ++ suited dependent on conditions, + limited suited, *please get in touch for further information
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SPECIFICATIONS

	Turnaround Time	Hands-on Time	DNA Input
Mentype® Chimera®	4.5 h	15 min	1 ng
Mentype® DIPscreen	4 h	15 min	2 ng
Mentype® DIPquant	1.5 h	30 min	250 ng
Mentype® DigitalQuant	2.5 h	20 min	50 ng

REFERENCES:

1 B. Fehse et al., „Real-time quantitative Y chromosome-specific PCR (QYCS-PCR) for monitoring hematopoietic chimerism after sex-mismatched allogeneic stem cell transplantation", J. Hematother. Stem Cell Res, vol. 10, p. 419-425, 2001.

2 C. Thiede et al., „Chimärismusanalysen". In: Herr W, Theobald M, Ehninger G, Einsele H, Meyer RG (eds). Hämatopoetische Stammzellen - Grundlagen und klinische Einsatzgebiete. Deutscher Ärzte Verlag: Köln, pp 157-161, 2015.

Mentype® Chimera® PCR Amplification Kit

IVD CE 0483

EU IVDR 2017/746

The gold standard for STR chimerism analysis

FEATURES

- High-throughput cost-effective solution for pre- and post-transplantation application
- 10% better chance to find highly informative, polymorphic discrimination markers
- Monitoring of a wide chimerism range with superior sensitivity of ≥ 1.4 %
- Registered CE-IVD product according to IVD Regulation (EU) 2017/746 (IVDR)

Mentype® Chimera® PCR Amplification Kit is a multiplex assay for qualitative genotyping and semi-quantitative chimerism monitoring after allogenic hematopoietic stem cell transplantation. The assay employs capillary electrophoresis technology with minimal DNA input and demonstrates a superior detection limit compared to other Short Tandem Repeat (STR) PCR methods - capable of identifying recipient fractions as low as 1.4%.

BIOMARKERS

12 tetra- / pentanucleotide STR loci, including 6 STR markers validated by European Consortium of Chimerism Analysis and 1 sex-specific INDEL:
Amelogenin (Xp22.1-22.3, Yp11.2), D2S1360 (2p24-p22), D3S1744 (3p24), D4S2366(4p16-15.2), D5S2500 (5q11.2), D6S474 (6q21-22), D7S1517 (7q31.33), D8S1132 (8q23.1), D10S2325 (10p12), D12S391 (12p13.2)

SPECIFICATIONS

Platform	Capillary gel electrophoresis
Panel	12 STRs + Amelogenin
Reactions	1 multiplex PCR reaction per sample
PCR controls	2 included (PC, NTC)
Sample input	0.125 - 1 ng gDNA from peripheral blood
Sensitivity	≥ 1.4 %
Turnaround time	~ 4.5 h after nucleic acid preparation
Detection	Qualitative genotyping Semiquantitative chimerism detection
To be used with	Standard thermal cycler + Thermo Fisher Genetic Analyzer
Data analysis	ChimerisMonitor IVD GeneMapper ID-X + specific templates

ORDER INFORMATION

Product	Size	Cat. No.	Status
Mentype® Chimera® PCR Amplification Kit	25 reactions	45-12200-0025	IVDR
Mentype® Chimera® PCR Amplification Kit	100 reactions	45-12200-0100	IVDR
Mentype® Chimera® PCR Amplification Kit	400 reactions	45-12200-0400	IVDR

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High-throughput chimerism analysis with superior performance

High Efficiency Through a Streamlined Workflow

Achieve fast and reliable results with a workflow designed to integrate seamlessly into your daily routine. With just 30 minutes of hands-on time, you can achieve same-day results, saving valuable time and resources. The multiplex assay design of the Mentype® Chimera® PCR Amplification Kit enables high-throughput analysis of clinical chimerism samples, ensuring both speed and precision in your chimerism diagnostics.

Exceptional Discriminatory Power

The Mentype® Chimera® PCR Amplification Kit combines highly polymorphic clinical markers with transplantation-specific STRs to deliver unmatched resolution. This advanced marker set provides a distinct advantage over conventional forensic STR kits, enabling more accurate and reliable detection and monitoring of chimerism.

Marker	Power of Discrimination	Donor/ Recipient (%) without Allelic Overlap[1]	Marker	Power of Discrimination	Donor/ Recipient (%) without Allelic Overlap[1]
D2S1360	0.856	22.1 %	D8S1132	0.964	23.1 %
D3S1744	0.943	20.0 %	D10S2325	0.967	24.1 %
D4S2366	0.919	20.6 %	D12S391	0.971	25.4 %
D5S2500	0.938	18.1 %	D18S51	0.964	27.7 %
D6S474	0.918	not validated	D21S2055	0.971	not validated
D7S1517	0.967	24.9 %	SE33	0.990	45.1 %

One Product for All Types of Chimerism

The Mentype® Chimera® PCR Amplification Kit enables comprehensive detection of all clinically relevant chimerism types in a single, efficient assay. While the average sensitivity of STR-PCR multiplex assays has been reported at 5% [1,2,3], the Mentype® Chimera® kit delivers a superior Limit of Detection (LoD) of ≥1.4%, ensuring reliable performance across the full spectrum of chimerism levels.

Chimerism Type	Suitability of Mentype® Chimera®
Complete chimerism	+
Transient mixed chimerism	++
Stable mixed chimerism	+++
Progressive mixed chimerism	+++
Loss of chimerism	+++

Suitability: +++ optimal, ++ well, + limited
The assay was validated in a clinical study and is intended for in vitro diagnostics.

REFERENCES:

1 C. Thiede et al., Evaluation of STR informativity for chimerism testing, Leukemia, vol. 18, no. 2, pp. 248-254, 2004.
2 Kristt et al. Quantitative platform performance on sequential samples. J. Biomol. Tech. 2005;16:380–391
3 Chia et al. Multiplex str panel for assessment of chimerism following hematopoietic stem cell transplantation (hsct) Ann. Hematol. 2019;98:1279–1291

Mentype® DIPscreen PCR Amplification Kit

IVD CE 0483

EU IVDR 2017/746

INDEL analysis for flexible application

FEATURES

- High-throughput cost-effective solution for pre- and post-transplantation application
- >99.9 % probability to find informative bi-allelic markers even in closely related transplantation couples
- Monitoring of a wide chimerism range with superior sensitivity of ≥ 1.4 %
- Registered CE-IVD product according to IVD Regulation (EU) 2017/746 (IVDR)

Mentype® DIPscreen PCR Amplification Kit is a multiplex assay for pre-transplantation genotyping and chimerism monitoring after allogenic hematopoietic stem cell transplantation. It utilizes capillary electrophoresis technology and requires little DNA input. If DNA amount is not a limiting factor, initial genotyping with Mentype® DIPscreen can be followed by chimerism analysis with Mentype® DIPquant or Mentype® DigitalQuant - for an even more sensitive quantification.

BIOMARKERS

34 INDEL markers: Amelogenin (Xp22.1-22.3, Yp11.2), 16q13, 6q16.1, 8q24.12, 12q23.1, 13q32.1, 18p11.22, 17p12, Xp11.23, 2p22.3, 16q22.1, 3p22.1, 7q31.2, 14q24.3, 3q23, 12q24.31, 11q14.1, 18p11.32, 9q22.33, 15q26.1, 5q33.3, 17q21.32, 3q22.1, 13q13.1, 16p13.2, 1q31.3, 5q11.2, 20q11.22, 2q11.2, 17p13.2, 9q34.3, 7q36.2, 1q32.2, 7q21.3

SPECIFICATIONS

Platform	Capillary gel electrophoresis
Panel	33 INDEL loci + Amelogenin
Reactions	1 multiplex PCR reaction per sample
PCR controls	2 included (PC, NTC)
Sample input	0.125-2 ng gDNA from peripheral blood
Sensitivity	≥ 1.4 %
Turnaround time	~ 4 h after nucleic acid preparation
Detection	Qualitative genotyping Semiquantitative chimerism detection
To be used with	Standard thermal cycler + Thermo Fisher Genetic Analyzer
Data analysis	ChimerisMonitor IVD GeneMapper ID-X + specific templates

ORDER INFORMATION

Product	Size	Cat. No.	Status
Mentype® DIPscreen PCR Amplification Kit	25 reactions	45-12300-0025	IVDR
Mentype® DIPscreen PCR Amplification Kit	100 reactions	45-12300-0100	IVDR

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Mentype® DIPquant

CE IVD

Next level of precision in chimerism quantification

FEATURES

- Highly sensitive solution for post-transplantation chimerism analysis
- Identification of minor target ratios down to 0.05 % up to 12.5 % chimerism
- Assay compatible with standard qPCR cyclers using FAM-specific filter sets
- Registered CE-IVD product according IVD Directive 98/79/EC (IVDD)

Following the initial genotyping, a qPCR-based assay Mentype® DIPquant can be applied for relative chimerism quantification. Fast, easy workflow and the high sensitivity make Mentype® DIPquant ideal for routine chimerism analysis, when DNA input is not a limiting factor. It indicates relapse earlier than other methods and enables earlier intervention in the patient's treatment. If the DNA amount is limited, semi-quantitative analysis with Mentype® DIPscreen is advised.

BIOMARKERS

56 allele-specific single markers: Amelogenin (Xp22.1-22.3, Yp11.2), 16q13, 6q16.1, 8q24.12, 12q23.1, 13q32.1, 18p11.22, 17p12, Xp11.23, 2p22.3, 16q22.1, 3p22.1, 7q31.2, 14q24.3, 3q23, 12q24.31, 11q14.1, 18p11.32, 9q22.33, 15q26.1, 5q33.3, 17q21.32, 3q22.1, 13q13.1, 16p13.2, 1q31.3, 5q11.2, 20q11.22, 2q11.2, 17p13.2, 9q34.3, 7q36.2, 1q32.2, 7q21.3

SPECIFICATIONS

Platform	Real-time PCR
Panel	56 allele specific singleplex assays 1 Reference assay
Reactions	3 allele specific assays + Reference assay in duplicates (8 reactions per sample)
PCR controls	2 (PC via existing samples, NTC)
Sample input	250 ng gDNA from peripheral blood
Sensitivity	≥ 0.05 %
Turnaround time	~ 1.5 h after nucleic acid preparation
Detection	Relative quantification
To be used with	Standard qPCR cycler

ORDER INFORMATION

Product	Size	Cat. No.	Status
Mentype® DIPquant (allele specific assays, Reference)	25 reactions	45-015xx*-0025	IVDD
Mentype® DIPquant Reference	100 reactions	45-01591-0100	IVDD

* xx describes the locus specific ordering number
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ChimerisMonitor

IVD CE 0483

EU IVDR 2017/746

The intuitive software for automated chimerism analysis

FEATURES

- Simplifies and speeds up data analysis for BIOTYPE chimerism kits
- Automates critical and time-consuming steps from allelic call to chimerism value calculation
- Includes an extensive control concept for run and sample validation
- Builds a patient database encompassing preTx genotypes and postTx chimerism kinetics

ChimerisMonitor is the professional software for automated chimerism analysis, which combines speed and accuracy with an intuitive and customized interface. The software mediates analysis of chimerism samples from initial genotyping to highly sensitive quantification of residual donor or recipient cells. It automatically identifies donor or recipient signals and provides a ranking of identified loci based on their informativeness. It calculates percent chimerism from various specimens and depicts the standard deviation of each analysis. The obtained results are summarized in a comprehensive report conferring clarity and providing overview in longitudinal studies.

SPECIFICATIONS

Assays analyzed	Mentype® Chimera® Mentype® DIPscreen Mentype® DIPquant
Status	IVDR, RUO
Data input	fsa/hid files, txt files
Data visualizing	Electropherogram, calculation results, overview about results in 1 sample sheet, PDF report with longitudinal chimerism kinetics
Data processing	Database included for saving of pre-transplant and post-transplant data
Turnaround time	5 min per sample

ORDER INFORMATION

Product	Licenses	Ordering	Status
ChimerisMonitor IVD	Demo, 1 year, 3 years	46-14800-0000	IVDR
ChimerisMonitor RUO	Demo, 1 year, 3 years	46-14801-0000	RUO

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Tailored Chimerism Analysis

Flexible solutions for your diagnostic needs

PRODUCT VARIANTS

- ChimerisMonitor IVD (IVDR)
- ChimerisMonitor RUO (RUO)
- ChimerisMonitor Bundle

The software is available as the IVDR-compliant ChimerisMonitor IVD application, which, in combination with the Mentype® Chimera® and Mentype® DIPscreen assays, offers a complete IVD-certified workflow from PCR set-up to data analysis. The ChimerisMonitor RUO software can additionally be used to analyze the Mentype® DIPquant assays and critical data sets with, for example, alternative sample types. By installing both applications, a synchronized database is created, which reduces effort and still provides a clear differentiation between the data from each software.

	ChimerisMonitor RUO	ChimerisMonitor CE-IVD	ChimerisMonitor Bundle
Analysis of Mentype® Chimera® and Mentype® DIPscreen	✓	✓	✓
Analysis of Mentype® DIPquants	✓	✗	✓
IVD-certified workflow for secure, robust & reliable data evaluation	✗	✓	✓
Extensive control concept for run and sample validation	✗	✓	✓
Visualization of EPGs and Size calling regressions incl. attachment (controls) to every sample	✓	✓	✓
Patient management at one glance and summary of all monitoring data in patient-specific display including report (pdf, csv)	✓	✓	✓
Synchronized database including visualization of data status (IVD/RUO)	✗	✗	✓
Reanalysis of critical data sets & reassignment of EPGs	✓	✗	✓

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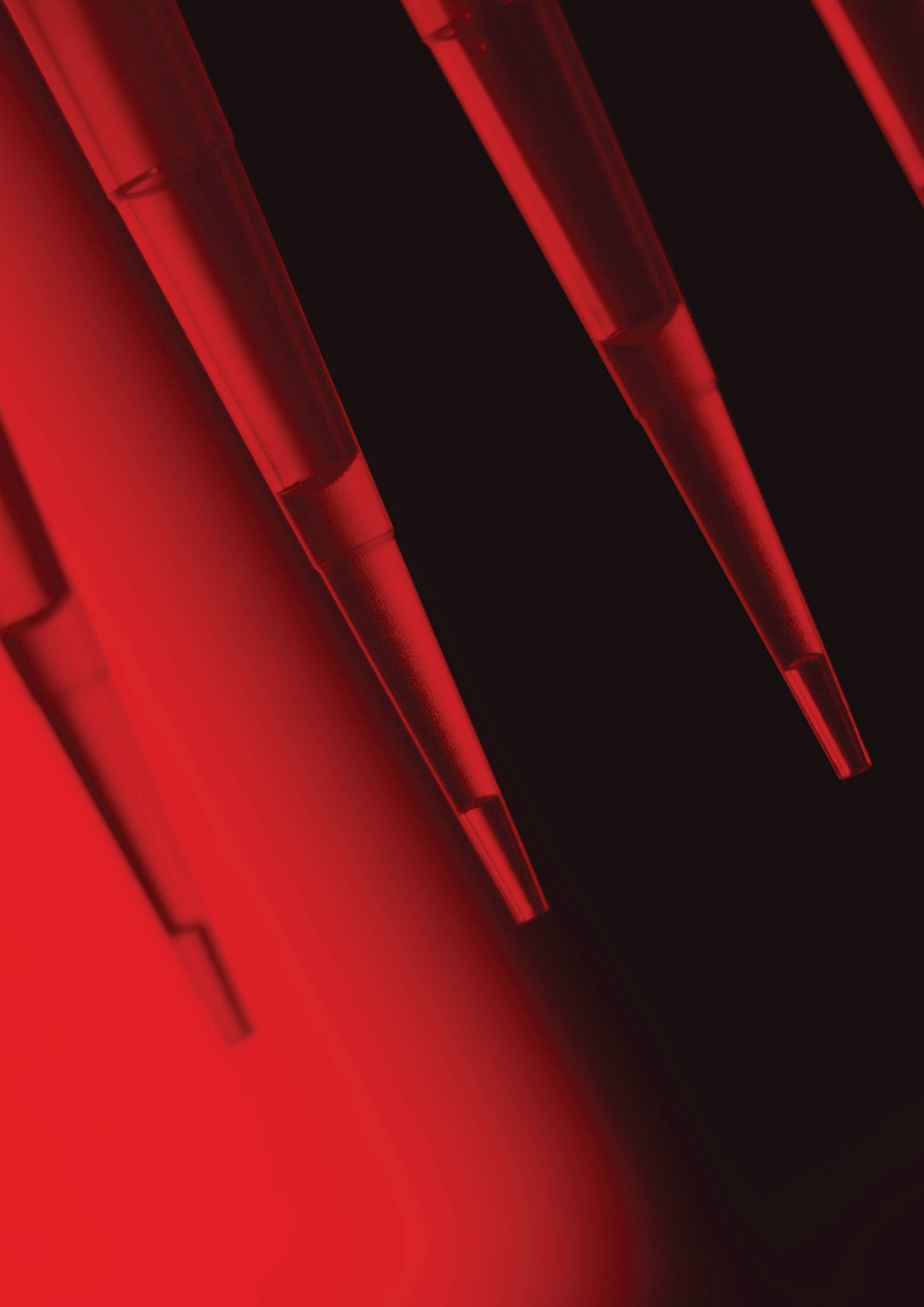

Mentype® DigitalScreen

Digital genotyping as prerequisite for clinical research

FEATURES

- Solution for straightforward initial genotyping
- Streamlined workflow of genotyping & monitoring with one platform
- Assay compatible with standard dPCR systems
- Mid-to-high throughput automation, depending on the digital PCR system

The Mentype® DigitalScreen kit serves as a research tool for initial qualitative genotype analysis of two human DNA samples. The data, provided by Mentype® DigitalScreen, enables further quantitative analysis of mixed DNA samples by Mentype® DigitalQuant - for example, for chimerism assessment. This combination of two assays consolidates both genotyping and chimerism monitoring processes onto a single platform.

BIOMARKERS

30 allele-specific INDELs in combination with a sex-independent reference gene: 5q33.3; 6q16.1; 9q22.33, 13q13.1, 15q26.1, 13q32.1, 14q24.3, 16q13, 17p13.2, 1q31.3, 7q36.2, 3p22.1, 5q11.2, 3q23, 16p13.2, 12q24.31, 17q21.32, 9q34.3, Xp11.23

SPECIFICATIONS

Platform	Digital PCR
Panel	30 allele specific duplex assays
Reactions	1 plate for 2 DNA samples
Internal controls	Reference gene
PCR controls	2 (PC extra available, NTC)
Sample input	300 ng from peripheral blood
Turnaround time	~ 4.5 h after nucleic acid preparation
Detection	Qualitative

ORDER INFORMATION

Product	Size	Cat. No.	Status
Mentype® DigitalScreen	4 Plates (8 samples)	45-64610-0004	RUO

RUO - Research Use Only products must be validated by the customer with clinically relevant material for diagnostic purposes.

Mentype® DigitalQuant

Sensitive quantification for advanced DNA ratio analysis

FEATURES

- Application e. g. for chimerism, graft rejection, or cell product research
- Absolute quantification with no need of technical replicates
- Highly sensitive quantification of target DNA ratio ≤ 0.1 %
- Assay compatible with standard dPCR systems

Following the initial genotyping, the digital PCR assay series Mentype® DigitalQuant can be applied for precise quantification of DNA ratios. The assay provides high sensitivity of detection, while requiring lower DNA input, than qPCR-based methods. In chimerism or transplantation studies Mentype® DigitalQuant can be used after the genotyping by Mentype® DIPscreen or Mentype® DigitalScreen.

BIOMARKERS

30 allele-specific INDELs: 5q33.3; 6q16.1; 9q22.33, 13q13.1, 15q26.1, 13q32.1, 14q24.3, 16q13, 17p13.2, 1q31.3, 7q36.2, 3p22.1, 5q11.2, 3q23, 16p13.2, 12q24.31, 17q21.32, 9q34.3, Xp11.23 In combination with SRY or a sex-independent reference gene

SPECIFICATIONS

Platform	Digital PCR
Panel	59 allele specific duplex assays
Reactions	3 allele specific assays per sample (3 reactions)
Internal controls	Reference gene or SRY
PCR controls	2 (PC extra available, NTC)
Sample input	50 ng gDNA from peripheral blood/ bone marrow
Sensitivity	0.1 %
Turnaround time	~ 2.5 h after nucleic acid preparation
Detection	Absolute quantification
To be used with	Bio-Rad QX100/200, Applied Biosystems QuantStudio™ Absolute Q™, QIAcuity Digital PCR System

ORDER INFORMATION

Product	Size	Cat. No.	Status
Mentype® DigitalQuant	25 reactions	45-02xx*1-0025	RUO

* xx describes the locus specific ordering number
RUO - Research Use Only products must be validated by the customer with clinically relevant material for diagnostic purposes.

Exceptional Precision in dPCR Analysis

Unmatched Reproducibility and Reliability

The Mentype® DigitalQuant Kit utilizes the power of digital PCR (dPCR) to deliver outstanding analytical precision. By partitioning each sample into thousands of individual PCR reactions, it ensures a high degree of parallelization. This results in outstanding reproducibility and consistent, highly reliable results, making Mentype® DigitalQuant Kit the ideal choice for applications that demand absolute quantification and high sensitivity.

Serial Dilution [%]	Ratio with different DigitalQuant assays [%]												Mean [%]	Standard Deviation
	70-D +REF	70-D +SRY	88-I +SRY	114-I +REF	114-I +SRY	128-D +REF	128-D +SRY	131-I +REF	131-I +SRY	133-I +REF	133-I +SRY	152-D +SRY		
0.1	0.14	0.16	0.12	0.1	0.12	0.12	0.16	0.15	0.14	0.12	0.19	0.13	0.14	0.03
1	1.2	1.2	1.2	1.2	1.1	1.3	1.1	1.0	1.1	1.2	1.2	1.2	1.2	0.08
50	50.7	52.7	51.5	50.6	45.5	51.3	52.5	46	49.7	47.2	52.9	50	50	2.65

Reliable Results from Minimal DNA Input

Compared to other quantitative PCR methods, digital PCR does not require replicates or standard curves to reliably quantify DNA targets of interest. Therefore, the Mentype® DigitalQuant assays require just 5-120 ng total DNA to identify minor DNA proportions in mixed DNA background (Figure 1).

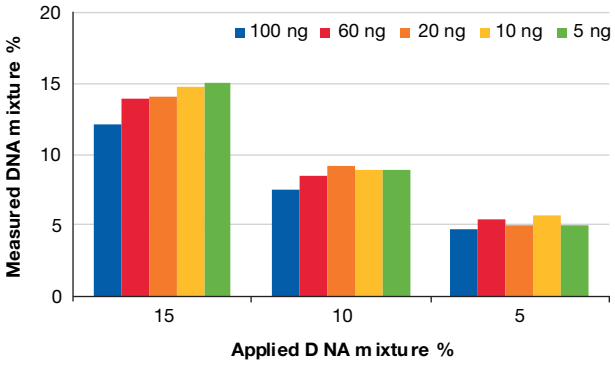

Figure 1: Analysis of a defined DNA mixture using varying DNA inputs per reaction with Mentype® DigitalQuant.

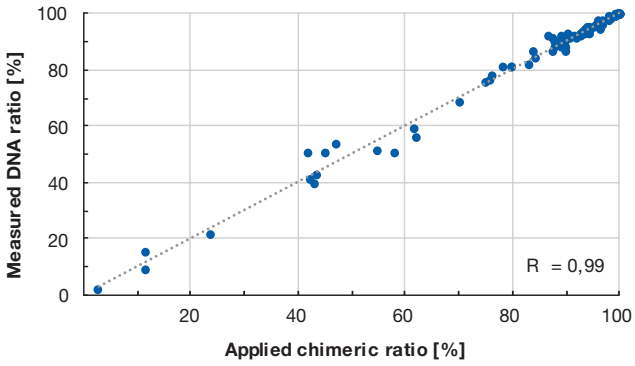

Figure 2: Analysis of defined DNA mixtures with assays of Mentype® DigitalQuant.

High Sensitivity Combined with a Large Dynamic Range

Compared to other technologies, digital PCR allows the analysis within a larger range of DNA ratios (Figure 2). The assay is optimized to reliably achieve a sensitivity of 0.1 % on the verified platforms. Mentype® DigitalScreen or Mentype® DIPscreen PCR Amplification Kit can be used for preliminary genotyping.

Mentype® DigitalQuant assays have been validated on leading dPCR platforms, including: Droplet Digital™ PCR platform (Bio-Rad Laboratories, Inc.), Applied Biosystems™ QuantStudio™ Absolute Q (Thermo Fisher Scientific), and QIAcuity Digital PCR System (Qiagen). This broad compatibility ensures accessibility for most digital PCR users across various laboratory setups.

DIP Positive Control DPC

Qualitative positive control for INDEL polymorphisms

FEATURES

- Qualitative Positive Control for INDEL-based assays
- Suitable, external material to check your PCR performance
- Compatible with, e.g., Mentype® DIPquant, Mentype® DigitalScreen, Mentype® DigitalQuant
- Universally applicable across different technologies (qPCR, dPCR)

The DIP Positive Control DPC is a DNA mixture that is positive for 35 INDEL markers, including the SRY and SMCY loci. Therefore, it is an ideal, qualitative external positive control for PCR assays, analyzing INDEL polymorphisms.

BIOMARKERS

The DIP Positive Control DPC is positive for the following insertion-deletion polymorphisms: Reference, 79-I, 105-D/-I, 134-D/-I, SRY, 82-D/-I, 106-D/-I, 140-I, SMCY, 84-D/-I, 110-I, 152-D, 23-I, 88-D/-I, 112-I, 163-D/-I, 38-I, 91-D/-I, 114-D/-I, 301-D/-I, 48-I, 97-I, 116-D/-I, 304-D, 53-D/-I, 101-D/-I, 128-D/-I, 305-D/-I, 67-D/-I, 103-D/-I, 131-D/-I, 307-D/-I, 70-D/-I, 104-D/-I, 133-I, 310-D/-I

SPECIFICATIONS

Platform	Real-time PCR, Digital PCR
Panel	35 INDEL markers
Concentration	5 ng/µL
Reactions	20 reactions
To be used with	Mentype® DIPquant, Mentype® DigitalScreen, Mentype® DigitalQuant
Data analysis	Device-specific software

ORDER INFORMATION

Product	Size	Cat. No.	Status
DIP Positive Control DPC	100 µL	27-13201-0100	RUO

RUO - Research Use Only products must be validated by the customer with clinically relevant material for diagnostic purposes.

Matrix Standard BT5 multi

The optimal spectral alignment for your Genetic Analyzer

FEATURES

- Accessory for Mentype® multiplex PCR assays
- Set-up solution for the best performance of your instrument
- Minimization of spectral overlaps and artifact formation
- Registered CE-IVD product according to IVD Regulation (EU) 2017/746 (IVDR)

The Matrix Standard BT5 multi is a tool to set up your device for a flawless application of Mentype® Chimera®, Mentype® DIPscreen, and Mentype® AMLplex^{QS} PCR amplification kits. It is a mixture of five PCR amplicons, each labeled with a different fluorophore. The preceding analysis of these amplicons allows to calculate and correct the spectral overlap between the emission spectra of the dyes. This 'spectral calibration' allows subsequent simultaneous analysis of all five dyes in one capillary, leads to a reduction of artifacts such as pull-up peaks and enables the data analysis.

SPECIFICATIONS

Platform	Capillary gel electrophoresis
Panel	6-FAM™, BTG, BTY, BTR, BTO
Reactions	1 µL per capillary
Turnaround time	~ 1 h
To be used with	Standard Thermocycler + Thermo Fisher Genetic Analyzer
Data analysis	Data Collection Software of Genetic Analyzer
Accessory for	Mentype® Chimera® Mentype® DIPscreen

ORDER INFORMATION

Product	Size	Cat. No.	Status
Matrix Standard BT5 multi	25 µL	45-15100-0025	IVDR
Matrix Standard BT5 multi	2 x 25 µL	45-15100-0050	IVDR

IVD – in vitro diagnostics; IVDD – CE-IVD product in grace period, certified according to IVD Directive 98/79/EC; IVDR – CE-IVD product certified according to IVD Regulation (EU) 2017/746.

Product	Size	Cat. No.	Status
Mentype® Chimera® PCR Amplification Kit	25 reactions	45-12200-0025	IVDR
Mentype® Chimera® PCR Amplification Kit	100 reactions	45-12200-0100	IVDR
Mentype® Chimera® PCR Amplification Kit	400 reactions	45-12200-0400	IVDR
Mentype® DIPscreen PCR Amplification Kit	25 reactions	45-12300-0025	IVDR
Mentype® DIPscreen PCR Amplification Kit	100 reactions	45-12300-0100	IVDR
Mentype® DIPquant (allele specific assays, Reference)	25 reactions	45-015xx*-0025	IVDD
Mentype® DIPquant Reference	100 reactions	45-01591-0100	IVDD
Mentype® DigitalScreen	4 Plates (8 samples)	45-64610-0004	RUO
Mentype® DigitalQuant	25 reactions	45-02xx*1-0025	RUO
DIP Positive Control DPC	100 µL	27-13201-0100	RUO
Matrix Standard BT5 multi	25 µL	45-15100-0025	IVDR
Matrix Standard BT5 multi	2 x 25 µL	45-15100-0050	IVDR
ChimerisMonitor IVD	Demo, 1 year, 3 years	46-14800-0000	IVDR
ChimerisMonitor RUO	Demo, 1 year, 3 years	46-14801-0000	RUO

* xx describes the locus specific ordering number
IVD – in vitro diagnostics; IVDD – CE-IVD product in grace period, certified according to IVD Directive 98/79/EC; IVDR – CE-IVD product certified according to IVD Regulation (EU) 2017/746; RUO - Research Use Only products must be validated by the customer with clinically relevant material for diagnostic purposes.

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BIOTYPE

Detect more. Decide better.

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