

Mentype[®] DigitalScreen

Handbook

RUO

For research use only. Not for use in diagnostic procedures.

DGSHB01v3en

11.04.2025

REF

45-64610-0004

LOT

Batch code



BIOTYPE GmbH
Moritzburger Weg 67
01109 DRESDEN
GERMANY

Website: www.biotype.de
Email: support@biotype.de
Ordering: sales@biotype.de



Notice of Change

Please note the following adaptations compared to the previous handbook version:

| Document code | Changes | Date |
|--------------------|---|------------|
| DGSHB01v1en | Initial version | 09.03.2023 |
| DGSHB01v2en | Layout change | 13.02.2025 |
| DGSHB01v3en | New article number DIP Positive Control | 11.04.2025 |

For any further questions, please contact us
at +49 351 8838 400 or
support@biotype.de

Content

| | |
|---|-----------|
| Product Description | 4 |
| Summary and Explanation..... | 4 |
| Materials provided | 5 |
| Reagent storage and handling | 6 |
| Material and devices required but not provided..... | 6 |
| General laboratory equipment..... | 6 |
| Reagents, kits and consumables | 7 |
| Instruments and software | 8 |
| Specimen and test samples | 8 |
| Warnings and Precautions | 8 |
| Procedure | 9 |
| Overview of the experimental workflow | 9 |
| Sample preparation | 10 |
| Sampling and DNA extraction | 10 |
| DNA storage | 11 |
| Preparation of control samples | 11 |
| Positive Control (PC) | 11 |
| No Template Control (NTC)..... | 11 |
| PCR Master mix setup | 11 |
| Restriction digestion | 13 |
| Droplet digital™ PCR – droplet generation | 13 |
| PCR amplification..... | 14 |
| Droplet reading..... | 15 |
| Data Analysis | 16 |
| General evaluation | 16 |
| Identification of informative loci | 18 |
| Characteristics and availability of Mentype® DigitalQuant assays | 18 |
| Quality Control | 20 |

Technical Assistance 20

References..... 21

Limitations of Use..... 21

Ordering information..... 22

Trademarks and Disclaimers..... 24

Explanation of Symbols 25

Product Description

The Mentype® DigitalScreen test kit is designed to determine the allele distribution of insertion-deletion polymorphisms in unmixed DNA samples qualitatively. A quantification using the Mentype® DigitalScreen kit is not possible.

The test kit is only intended to be used for research purposes, a use for diagnostic purposes is not permitted.

The test kit should only be used by professional users trained in molecular biological techniques in general and in performing digital PCR in particular.

Summary and Explanation

The Mentype® Digital approach deploys the highly sensitive digital PCR technology that allows absolute quantification of chimerism samples. Specific for digital PCR is the sample-partitioning into a plethora of nano droplets. Each droplet represents a separate compartment containing nano liters of the sample of interest. During thermal cycling each compartment functions as a separate PCR amplification chamber. Depending on how many copies of the target DNA molecules have been dispensed into the droplets (zero, one or more copies) a multitude of replicates is generated per single PCR run. Using Poisson statistics, the absolute number of starting copies can be determined very accurately. After thermal cycling each droplet is automatically analyzed and determined as positive or negative fraction. Because the digital PCR uses end-point detection of the amplification product, efficiency of the amplification is much less of a concern and calibration curves are not necessary.

Mentype® DigitalScreen represent a screening plate and allows the fast identification of biallelic short insertion/deletion polymorphisms (INDELs). The thereby identified markers can be used for subsequent DNA quantification with the kit Mentype® DigitalQuant.

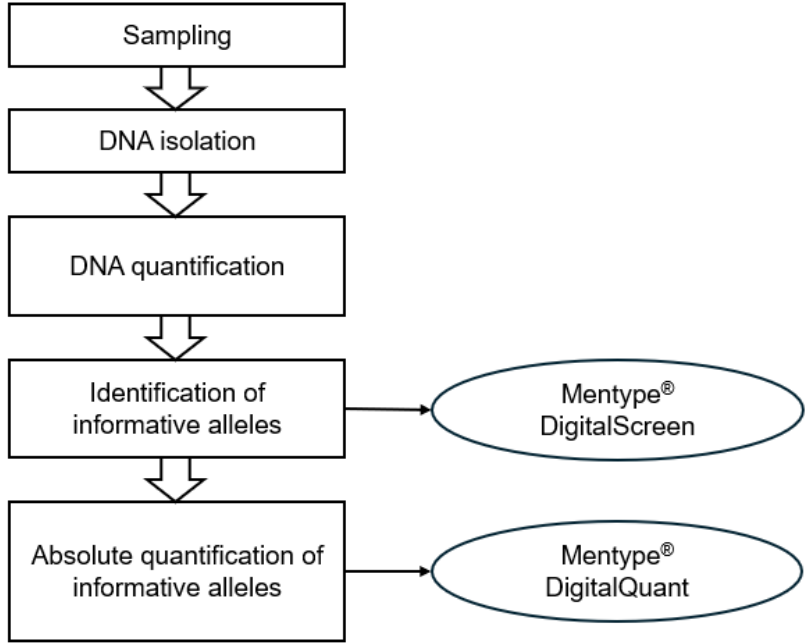


Figure 1 From sample to result with Mentype® DigitalScreen and Mentype® DigitalQuant

All specific DIP markers (see [Table 7](#)) are labeled with FAM, the active reference (REF) is labeled with HEX.

Materials provided

The following reagents for running the Mentype® DigitalScreen kit are included:

Table 1 Content of the Mentype® DigitalScreen kit

| Component | Cap color | Number per kit | Storage |
|--|------------|----------------|------------------------------------|
| Nuclease-Free Water | Light blue | 2 x 1.5 mL | -25 °C to -15 °C |
| Mentype® DigitalScreen screening plate | - | 4 | 2 °C to 8 °C, protected from light |

NOTE



The kit contains reagents to perform test of 4 DNA pairs (8 samples).

Reagent storage and handling

The kit is shipped cooled.

Please check for the completeness of the kit upon receipt. Please immediately contact BIOTYPE GmbH if one or more components are not frozen, or if tubes or the packaging have been compromised during the shipment.

Store all components according to the conditions stated on the labeling without light exposure and avoid repeated thawing and freezing.

The expiry date of the kit is indicated on the kit box label.

Material and devices required but not provided

General laboratory equipment

- Desktop centrifuge with a rotor for 2 mL reaction tubes
- Centrifuge with a rotor for microtiter plates
- Vortex mixer
- Calibrated adjustable pipettes with disposal aerosol tight filter tips
- Appropriate 200 µL 96-well reaction plates (depending on the device manufacturer) with proper optical foil, PCR grade
- Suitable racks for 2 mL tubes
- Cooling rack suitable for 2 mL tubes
- Disposable powder-free gloves
- NanoDrop™ Spectrophotometer or Qubit Fluorometer
- PCR Workstation or Clean Bench

NOTE

All material to be used for PCR shall have appropriate quality (DNA free and for molecular biology). Please ensure that all instruments used have been installed, calibrated, checked and maintained according to the manufacturers' instructions and recommendations.

Reagents, kits and consumables

Table 2 Reagents required, but not provided

| Reagent | Supplier | Order number |
|---|-------------------------|---------------|
| DIP Positive Control, 20 reactions | BIOTYPE GmbH | 27-13201-0100 |
| 2x ddPCR™ Supermix for Probes (No dUTP), 5 x 1 mL | Bio-Rad Laboratories | 1863024 |
| FastDigest EcoRI, 800 reactions | ThermoFisher Scientific | FD0274 |
| QIAamp DNA Blood Mini Kit, 50 Preps | Qiagen | 51104 |
| NucleoSpin Blood L Kit, 20 Preps | Macherey-Nagel | 740954.20 |

Table 3 specific instruments and consumables for the droplet digital™ PCR

| Consumable | Supplier | Order number |
|---|----------------------|--------------|
| QX200™ Droplet Generator | Bio-Rad Laboratories | 17005227 |
| PX1 PCR Plate Sealer | Bio-Rad Laboratories | 17005226 |
| QX200™ Droplet Reader | Bio-Rad Laboratories | 17005228 |
| Droplet Generation Oil for Probes, 10 x 7 mL | Bio-Rad Laboratories | 1863005 |
| ddPCR™ Droplet Reader Oil, 2 x 1 L | Bio-Rad Laboratories | 17005221 |
| DG8™ Cartridge Holder, 1 x | Bio-Rad Laboratories | 1863051 |
| DG8™ Cartridges for QX200™/QX100™ Droplet Generator, 24 x | Bio-Rad Laboratories | 17005222 |
| DG8™ Gaskets for QX200™/QX100™ Droplet Generator, 24 x | Bio-Rad Laboratories | 17005223 |
| Pierceable Foil Heat Seals, 100 x | Bio-Rad Laboratories | 17005225 |

| Consumable | Supplier | Order number |
|--|----------------------|--------------|
| ddPCR™ 96-Well Plates, semi-skirted, 25 x | Bio-Rad Laboratories | 17005224 |
| ddPCR™ Buffer Control for Probes, 2 x 4,5 mL | Bio-Rad Laboratories | 1863052 |
| 96-well PCR foil | Several | Varying |

Instruments and software

The test kit was validated using the Bio-Rad QX100™ and QX200™ Droplet Digital™ PCR System and the following thermocycler:

- Applied Biosystem GeneAmp® PCR System 9700 Aluminium and GeneAmp® PCR System 9700 Silber
- Eppendorf Mastercycler ep-S und Mastercycler nexus
- Biometra T1
- Bio-Rad DNA Engine PTC-200.

NOTE



The application of Mentype® DigitalScreen on other instruments than the above-mentioned one needs to be verified in the user responsibility.

Specimen and test samples

The following specimen has been verified with the Mentype® DigitalScreen kit:

- DNA extracted from peripheral venous blood samples
- DNA extracted from bone marrow.

Warnings and Precautions

- Read the instructions carefully before using the product.
- Read the safety data sheets (SDS) for all BIOTYPE products, which are available via <https://www.biotype.de/en/sicherheitsdatenblatter> or on

request. Please contact the respective manufacturers for copies of the SDS for any additionally needed reagents.

- Kit components of different kit lots must not be mixed.
- Aliquoting the kit components into other reaction vessels is not permitted.
- The use of this product is limited to personnel specially instructed and trained in PCR techniques.
- Before the first use, check the product and its components for:
 - Integrity
 - Completeness with respect to number, type and filling (see chapter Materials provided)
 - Correct labelling
 - Condition upon arrival.
- Do not use a kit that has passed its expiration date.
- Discard sample and assay waste according to your local safety regulations.
- All instruments used have been installed, calibrated, checked and maintained according to the manufacturer's instructions and recommendations.

Procedure

Overview of the experimental workflow

Analysis of DNA ratios starts with Mentype® DigitalScreen to determine which Mentype® DigitalQuant assays can be applied for quantification.

The Mentype® DigitalScreen plate contains dehydrated locus-specific primer mixes and the active reference (REF). Two DNA samples (e.g. recipient and donor) can be screened against the panel of 30 assays in one run. The layout is shown below (see Figure 2).

NOTE



Take care to use the plate in the right direction, with the letters at the left-hand site.

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|-------|-------|-------|-------|-------|-------|-------|-------|---|----|----|----|
| A | 67-D | 104-D | 131-I | 301-I | 67-D | 104-D | 131-I | 301-I | | | | |
| B | 70-D | 104-I | 133-I | 304-D | 70-D | 104-I | 133-I | 304-D | | | | |
| C | 70-I | 105-D | 134-I | 304-I | 70-I | 105-D | 134-I | 304-I | | | | |
| D | 88-D | 105-I | 140-I | 307-I | 88-D | 105-I | 140-I | 307-I | | | | |
| E | 88-I | 106-I | 152-D | 310-I | 88-I | 106-I | 152-D | 310-I | | | | |
| F | 97-I | 114-D | 163-D | SRY | 97-I | 114-D | 163-D | SRY | | | | |
| G | 101-D | 114-I | 163-I | PTC | 101-D | 114-I | 163-I | PTC | | | | |
| H | 101-I | 128-D | 301-D | NTC | 101-I | 128-D | 301-D | NTC | | | | |

DNA 1
DNA 2

Figure 2 Plate layout for the Mentype® DigitalScreen plate

Sample preparation

Sampling and DNA extraction

This test is intended for the use of DNA extracted from peripheral blood samples as well as bone marrow. The use of other samples (e. g. sorted cells) must be independently validated by the user.

For DNA extraction, commercially available kits for isolating of genomic DNA should be used. The following kits are recommended for the DNA extraction:

- QIAamp DNA Blood Mini Kit (Qiagen)
- NucleoSpin Blood L Kit (Macherey-Nagel)

The DNA should be quantified directly after the extraction with the NanoDrop spectrophotometer or Qubit fluorometer. Concentrated DNA can be adjusted to the required concentration of 2 – 4 ng/μL by dilution with 1 x TE buffer.

DNA storage

Store the DNA samples at - 25 °C to - 15 °C. Undiluted DNA samples can be stored for 4 weeks at 2 °C to 8 °C or at - 25 °C to - 15 °C for long-term storage.

Preparation of control samples

Positive Control (PC)

Thaw the DIP Positive Control (DPC, sold separately), homogenize it by gentle vortexing followed by briefly centrifugation.

Apply the undiluted DPC instead of a sample.

No Template Control (NTC)

Apply the Nuclease-Free Water included in the kit as no template control (NTC) instead of a sample.

PCR Master mix setup

Prepare the following components and thaw the reagents as required and homogenized them. The reagents should be then briefly centrifuged (approx. 10 s). Keep the enzyme on a cooling rack during usage.

- Nuclease-Free Water (light blue cap, included in the kit)
- EcoRI enzyme
- 2x ddPCR™ Supermix for Probes (No dUTP)

NOTE



Please note the shelf life of the 2x ddPCR™ Supermix for Probes (No dUTP) after opening. This should be stored and used for a maximum of 2 weeks at 4 °C after thawing.

Prepare the PCR master mix according to [Table 4](#).

Table 4 PCR master mix setup

| Component | Final Concentration | Volumen per reaction | |
|---|---------------------|----------------------|---------------------|
| | | # 1 | # 66 (1 plate) |
| 2x ddPCR™ Supermix for Probes (No dUTP) | 1 x | 10.0 µL | 660.0 µL |
| FastDigest EcoRI Enzym | | 0.5 µL | 33.0 µL |
| Nuclease-Free Water | | 4.5 µL | 297.0 µL |
| Volume master mix/well | - | 15.0 µL | 15.0 µL/well |
| DNA template (2 - 4 ng/µL) or control samples | 10 – 20 ng/well | 5.0 µL | 5.0 µL/well |

NOTE

The minimum DNA concentration for each sample per well should be 10 – 20 ng in a maximum volume of 9.5 µL. All wells for a given sample have to contain the same amount of DNA.

Gently mix the PCR master mix without generating bubbles followed by brief centrifugation. Aliquot 15.0 µL of the PCR master mixes in the plate, add the appropriate samples. Seal the plate with a PCR foil and mix the plate thoroughly (vortexing), so that the dried primers completely dissolve. Centrifuge the plate briefly.

Application of DNA templates and controls

Add 5.0 µL of the following sample types to the prepared PCR plate containing the PCR master mixes.

NTC: add 5.0 µL of Nuclease-Free Water instead of a sample to wells H4 and H8.

DNA sample: add 5.0 µL of the prepared, diluted DNA samples (2 - 4 ng/µL).

PC: add 5.0 µL of undiluted DIP Positive Control (DPC) instead of a sample to wells G4 and G8.

Restriction digestion

The BIOTYPE Mentype® Digital assays are specific for EcoRI restriction digestion.

Restriction digestion of the DNA to be analyzed prior to droplet generation is recommended. The digestion can be carried out directly in the PCR reaction vessel. Use max. 1 µL of FastDigest EcoRI enzyme (see [Table 4](#)) to digest up to 1 µg of genomic DNA in a total volume of 20 µL. For the use of Non-FastDigest EcoRI enzyme 2 units per 20 µL reaction are recommended.

After preparing the screening plate with PCR master mix, sample DNA and controls, cover the plate with a PCR tube (not supplied), mix thoroughly and centrifuge briefly.

Then incubate the screening plate in a thermocycler for 10 min at 37 °C for restriction digestion.

Droplet digital™ PCR – droplet generation

For optimal results freshly mix samples dispensed in the Mentype® DigitalScreen plate before droplet generation. Place the DG8 cartridge into the cartridge holder. Pipette each sample (20 µL of the digested PCR mix) up and down for 3 times before transferring the sample to the sample-wells of the DG8 cartridge (also see the general guidelines from Bio-Rad for droplet generation).

Start with pipetting row A1 – H1 of the digested PCR mix. Transfer samples in the DG8 cartridge from left to right. All 8 sample wells in the DG8 cartridge must be filled either with sample or 1x ddPCR™ Buffer Control for Probes (not provided).

After transferring all 8 samples, fill 70 µL of Droplet Generation (DG) Oil in the bottom-line wells. All 8 oil wells have to contain DG oil.

Hook the gasket over the cartridge holder by using the holes on both sides.

NOTE

When filling the DG8 Cartridge, always use the holder provided. The DG oil must first be distributed into the 8 wells of the DG8 cartridge when all 8 wells have been filled with sample.

Place the filled DG8 cartridge into the QX100/QX200 Droplet Generator and start the droplet generation.

After droplet generation, the top wells of the cartridge contain droplet-samples. Transfer 40 μ L of the droplet-samples into a 96-well PCR plate. Use an 8-channel pipette to save time.

Proceed the same way with samples of row A2 – H2 to A8 – H8.

NOTE

Upon droplet generation handle sample gently (no vortex, no spin-down).

Seal the 96-well PCR plate with Pierceable Foil Heat Seal and place the plate into the PX1 PCR Plate Sealer. Also see the Bio-Rad instructions in the PX1 PCR Plate Sealer Instruction Manual.

PCR amplification

When heat sealing is completed, place the 96-well PCR plate into a thermal cycler and start the program according to [Table 5](#). Use a heated lid and set to 105 °C. Set sample volume to 40 μ L.

*ramp rate depends on the PCR cycler and the block material:

- For PCR cycler with aluminium block use a ramp rate of 2 °C/s.
- For PCR cycler with silver block use 1 °C/s;
- If you cannot determine the block-material use a ramp rate of 1 °C/s.

Table 5 PCR protocol for Mentype® DigitalScreen

| Temperature | Time | Cycles | Ramping* |
|-------------|--------|--------|----------|
| 95 °C | 10 min | 1 x | 2 °C/s |
| 94 °C | 30 s | 40 x | |
| 62 °C | 60 s | | |
| 98 °C | 10 min | 1 x | 1 °C/s |
| 4 °C | ∞ | 1 x | |

Droplet reading

After the thermal cycling is finished, place the PCR plate containing the amplified sample-droplets into the holder of the QX100/QX200 droplet reader.

NOTE



The plate should be handled with care. The plate must not be vortexed or centrifuged.

Open the software Quanta™Soft from Bio-Rad. Create the plate layout for your experiment (see [Figure 2](#)). Open the editor (Applied Well Settings) by double-clicking on a well in the plate layout. Assign the sample name, the type of experiment, and determine which assay corresponds to which fluorescence channel. Then you assign the sample names of both DNA samples.

For Mentype® DigitalScreen, please define the settings according to [Table 6](#).

Table 6 Settings to be determined for analyzing the Mentype® DigitalScreen Kit in the Quanta™Soft

| Sample and experiment types | Settings |
|-----------------------------|-------------------------------------|
| Sample | |
| Name | Give a name |
| Experiment | Absolute Quantification (ABS) |
| Supermix | ddPCR Supermix for Probes (no dUTP) |

| Sample and experiment types | Settings |
|-----------------------------|------------------------|
| Target 1 | |
| Name | Marker name e. g. DP67 |
| Type | e. g. Ch 1 Unknown |
| Target 2 | |
| Name | REF |
| Type | e. g. Ch 2 Unknown |

NOTE

All specific DIP-Markers (see [Table 7](#)) are labeled with FAM. The reference (REF) is labelled with HEX accordingly.

After definition of the experiment click **Run**.

The droplet reader counts fluorescence-positive and negative droplets for absolute quantification of target DNA. Each sample-containing droplet is individually processed and verified for both FAM and HEX fluorescence. Data from at least 10,000 accepted droplets are used for the concentration calculations.

Data Analysis

General evaluation

Load the plate in the **Setup** window of the Quanta™Soft Software (Bio-Rad). Click **Analyze** to open and analyze the data. Review the data in the 2D Amplitude channel to verify whether the automated threshold and the cluster separation is correct (see [Figure 3](#)).

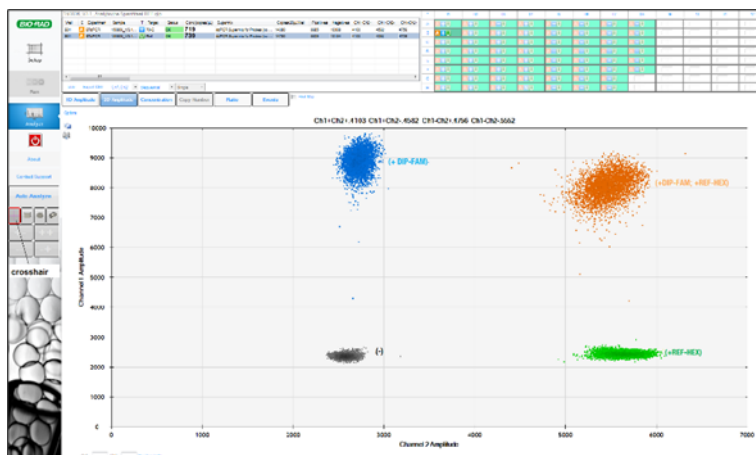


Figure 3 2D amplitude view (scatter plot) of the droplet fluorescence

All 4 cluster (grey, green, brown, blue) need to appear fully separated (see [Figure 3](#)). If clusters are not accurately separated or the automated threshold is not correct you have to draw corrections manually. Therefore, use the threshold adjustment tools (crosshair). The droplets are interpreted as follows:

- double negative (gray),
- FAM positive (blue),
- HEX positive (green) and
- double positive (orange - positive for FAM and HEX in the same droplet).

Manual correction was successful when the color of the cluster or individual droplets changes and the crosshairs are displayed in pink.

Then select the wells to analyze and click on **Table**. Then open the **Result Table** to see the results.

NOTE

i

The detection limit for a successful experiment is five FAM-positive droplets. A result with less than five droplets is defined as negative, the FAM cluster was not recognized.

Identification of informative loci

Review results and compare FAM cluster, outlining DIP loci, between the initial samples to identify specific loci. DNA 1 positive loci, which are negative in DNA 2 sample (see [Figure 2](#)), are recommended to be used for the absolute quantification and analysis with Mentype® DigitalQuant duplex assays. DNA 2 positive loci, that are negative in DNA 1 sample, can however likewise be used to analyse mixes samples.

To determine if the identified DIP allele (AOI) is homozygous or heterozygous, use the following formula:

$$\text{Ratio in percent} = (100 * \text{conc AOI}) / \text{conc REF}$$

If the percentage of copies/μL of AOI to copies/μL of reference (REF) is less than 65 %, the AOI in the marker is heterozygous.

If the ratio is greater than 65 %, the marker is homozygous.

This information must be taken into account when calculating the quantification with Mentype® DigitalQuant (see handbook Mentype® DigitalQuant).

For a statistically reliable and robust DNA analysis, the analysis of at least 2 and optimally 3 informative loci is recommended. After selecting the specific loci, you can order the corresponding Mentype® DigitalQuant assays (see [Table 10](#), [Table 11](#))

Characteristics and availability of Mentype® DigitalQuant assays

Table 7 chromosomal location of the specific loci

| Locus | Chromosomal Location | Locus | Chromosomal Location |
|-------|----------------------|-------|----------------------|
| 67 | 5q33.3 | 133 | 3p22.1 |
| 70 | 6q16.1 | 134 | 5q11.2 |
| 88 | 9q22.33 | 140 | 3q23 |
| 97 | 13q13.1 | 152 | 16p13.2 |
| 101 | 15q26.1 | 163 | 12q24.31 |

| Locus | Chromosomal Location | Locus | Chromosomal Location |
|-------|----------------------|-------|----------------------|
| 104 | 13q32.1 | 301 | 17q21.32 |
| 105 | 14q24.3 | 304 | 9q34.3 |
| 106 | 16q13 | 307 | Xp11.23 |
| 114 | 17p13.2 | 310 | 2p22.3 |
| 128 | 1q31.3 | SRY | Yp11.2 |
| 131 | 7q36.2 | | |

Table 8 available Mentype® DigitalQuant Assays

| Loci | Deletion (- Allel) | Insertion (+ Allel) | Allele specific duplex assay with Reference (REF) | Allele specific duplex assay with marker for Y chromosomal region (SRY) |
|------|-----------------------|------------------------|---|--|
| 67 | 67-D | | DP67-D+REF | DP67-D+SRY |
| 70 | 70-D | | DP70-D+REF | DP70-D+SRY |
| | | 70-I | DP70-I+REF | DP70-I+SRY |
| 88 | 88-D | | DP88-D+REF | DP88-D+SRY |
| | | 88-I | DP88-I+REF | DP88-I+SRY |
| 97 | | 97-I | DP97-I+REF | DP97-I+SRY |
| 101 | 101-D | | DP101-D+REF | DP101-D+SRY |
| | | 101-I | DP101-I+REF | DP101-I+SRY |
| 104 | 104-D | | DP104-D+REF | DP104-D+SRY |
| | | 104-I | DP104-I+REF | DP104-I+SRY |
| 105 | 105-D | | DP105-D+REF | DP105-D+SRY |
| | | 105-I | DP105-I+REF | DP105-I+SRY |
| 106 | | 106-I | DP106-I+REF | DP106-I+SRY |
| 114 | 114-D | | DP114-D+REF | DP114-D+SRY |
| | | 114-I | DP114-I+REF | DP114-I+SRY |
| 128 | 128-D | | DP128-D+REF | DP128-D+SRY |
| 131 | | 131-I | DP131-I+REF | DP131-I+SRY |
| 133 | | 133-I | DP133-I+REF | DP133-I+SRY |
| 134 | | 134-I | DP134-I+REF | DP134-I+SRY |

| Loci | Deletion (- Allel) | Insertion (+ Allel) | Allele specific duplex assay with Reference (REF) | Allele specific duplex assay with marker for Y chromosomal region (SRY) |
|------|-----------------------|------------------------|---|--|
| 140 | | 140-I | DP140-I+REF | DP140-I+SRY |
| 152 | 152-D | | DP152-D+REF | DP152-D+SRY |
| 163 | 163-D | | DP163-D+REF | DP163-D+SRY |
| | | 163-I | DP163-I+REF | DP163-I+SRY |
| 301 | 301-D | | DP301-D+REF | DP301-D+SRY |
| | | 301-I | DP301-I+REF | DP301-I+SRY |
| 304 | 304-D | | DP304-D+REF | DP304-D+SRY |
| | | 304-I | DP304-I+REF | DP304-I+SRY |
| 307 | | 307-I | DP307-I+REF | DP307-I+SRY |
| 310 | | 310-I | DP310-I+REF | DP310-I+SRY |
| SRY | | SRY | DPSRY+REF | |

Quality Control

All kit components undergo an intensive quality assurance process at BIOTYPE GmbH. Quality of the test kits is permanently monitored to ensure unrestricted usability. Please contact us if you have any questions regarding quality assurance.

Technical Assistance

For technical advice, please contact our Customer Support Team:

E-mail: support@biotype.de

Phone: +49 (0)351 8838 400

References

Alizadeh M, Bernard M, Danic B, Dauriac C, Birebent B, Lapart C, Lamy T, Le Prise PY, Beauplet A, Bories D, Semana G, Quelvennec E. (2002) Quantitative assessment of hematopoietic chimerism after bone marrow transplantation by real-time quantitative polymerase chain reaction. *Blood* 99, 4618-4625.

Vogelstein B, Kinzler KW (1999) Digital PCR. *Proc Natl Acad Sci USA* 96:9236-9241.

George D, Czech J, John B, Yu M, Jennings LJ (2013) Detection and quantification of chimerism by droplet digital PCR. *Chimerism*, 4:102-108.

Manoj P (2014) Droplet digital PCR technology promises new applications and research areas. *Mitochondrial DNA* 2014, e-published ahead of print [doi: 10.3109/19401736.2014.913168].

Jim F. Huggett, Carole A. Foy, Vladimir Benes, Kerry Emslie, Jeremy A. Garson, Ross Haynes, Jan Helleman, Mikael Kubista, Reinhold D. Mueller, Tania Nolan, Michael W. Pfaffl, Gregory L. Shipley, Jo Vandesompele, Carl T. Wittwer, and Stephen A. Bustin¹³ (2013) Guidelines for Minimum Information for Publication of Quantitative Digital PCR Experiments. *Clinical Chemistry* 2013.206375.

Limitations of Use

- The procedures in this handbook must be followed, as described. Any deviations may result in assay failure or cause erroneous results.
- Use of this product is limited to personnel specially instructed and trained in ddPCR techniques.
- Appropriate specimen collection, transport, storage and processing procedures are required for the optimal performance of this test.
- This assay must not be used on the specimen directly. Appropriate nucleic acid extraction methods have to be conducted prior to using this assay.
- The kit was only verified using the kits and procedures described.
- Good laboratory practice is required to ensure the performance of the kit.

- Results must be interpreted by a trained professional user.
- Interpretation of results must account for the possibility of false negative and false positive results.
- Do not use expired or incorrectly stored components.

Ordering information

Direct your orders via email to sales@biotype.de.

Table 9 General ordering information

| Product | Packaging size | Order number |
|------------------------|-------------------------------|---------------|
| Mentype® DigitalScreen | 4 plates (4 x 2 DNA pairs) | 45-64610-0004 |
| DIP Positive Control | 20 reactions | 27-13201-0100 |

Table 10 Ordering information for allele specific Mentype® DigitalQuant assays, these assays are available to you anytime (warehousing)

| Assay | 25 reactions |
|-------------|---------------|
| DP67-D+REF | 45-02011-0025 |
| DP70-D+REF | 45-02021-0025 |
| DP70-I+REF | 45-02031-0025 |
| DP88-D+REF | 45-02041-0025 |
| DP88-I+REF | 45-02051-0025 |
| DP97-I+REF | 45-02061-0025 |
| DP101-D+REF | 45-02071-0025 |
| DP101-I+REF | 45-02081-0025 |
| DP104-D+REF | 45-02091-0025 |
| DP104-I+REF | 45-02101-0025 |
| DP105-D+REF | 45-02111-0025 |
| DP105-I+REF | 45-02121-0025 |
| DP106-I+REF | 45-02131-0025 |
| DP114-D+REF | 45-02141-0025 |

| Assay | 25 reactions |
|-------------|---------------|
| DP114-I+REF | 45-02151-0025 |
| DP128-D+REF | 45-02161-0025 |
| DP131-I+REF | 45-02171-0025 |
| DP133-I+REF | 45-02181-0025 |
| DP134-I+REF | 45-02191-0025 |
| DP140-I+REF | 45-02201-0025 |
| DP152-D+REF | 45-02211-0025 |
| DP163-D+REF | 45-02221-0025 |
| DP163-I+REF | 45-02231-0025 |
| DP301-D+REF | 45-02241-0025 |
| DP301-I+REF | 45-02251-0025 |
| DP304-D+REF | 45-02261-0025 |
| DP304-I+REF | 45-02271-0025 |
| DP307-I+REF | 45-02281-0025 |
| DP310-I+REF | 45-02291-0025 |
| DPSRY+REF | 45-02301-0025 |

Table 11 Ordering information for the allele-specific Mentype® DigitalQuant Assays, these assays are made for you upon request (on-demand ordering)

| Assay | 25 reactions |
|--------------|---------------|
| DP67-D+SR Y | 45-02311-0025 |
| DP70-D+SR Y | 45-02321-0025 |
| DP70-I+SR Y | 45-02331-0025 |
| DP88-D+SR Y | 45-02341-0025 |
| DP88-I+SR Y | 45-02351-0025 |
| DP97-I+SR Y | 45-02361-0025 |
| DP101-D+SR Y | 45-02371-0025 |
| DP101-I+SR Y | 45-02381-0025 |
| DP104-D+SR Y | 45-02391-0025 |
| DP104-I+SR Y | 45-02401-0025 |
| DP105-D+SR Y | 45-02411-0025 |
| DP105-I+SR Y | 45-02421-0025 |

| Assay | 25 reactions |
|-------------|---------------|
| DP106-I+SRY | 45-02431-0025 |
| DP114-D+SRY | 45-02441-0025 |
| DP114-I+SRY | 45-02451-0025 |
| DP128-D+SRY | 45-02461-0025 |
| DP131-I+SRY | 45-02471-0025 |
| DP133-I+SRY | 45-02481-0025 |
| DP134-I+SRY | 45-02491-0025 |
| DP140-I+SRY | 45-02501-0025 |
| DP152-D+SRY | 45-02511-0025 |
| DP163-D+SRY | 45-02521-0025 |
| DP163-I+SRY | 45-02531-0025 |
| DP301-D+SRY | 45-02541-0025 |
| DP301-I+SRY | 45-02551-0025 |
| DP304-D+SRY | 45-02561-0025 |
| DP304-I+SRY | 45-02571-0025 |
| DP307-I+SRY | 45-02581-0025 |
| DP310-I+SRY | 45-02591-0025 |

Trademarks and Disclaimers

Mentype® is a registered trademark of BIOTYPE GmbH.

Registered names, trademarks, etc. used in this document, even if not specifically marked as such, are not to be considered unprotected by law.

© 2025 BIOTYPE GmbH; all rights reserved.

Explanation of Symbols



Manufacturer



Batch code



Contains sufficient reagents for <N> tests



Consult electronic instructions for use (eIFU)



Use-by date



Temperature limit



Catalogue number



Keep away from sunlight



Keep dry

Further marking used in this handbook:

i



Attention, be sure to follow this notice!

[blue underlined text](#)

Links leading to external content like
homepages, e-mail addresses

black underlined text

Cross-links in the document for easy navigation

Black, bold, cursive
text

Fields which are to be clicked in a software

BIOTYPE GmbH

Moritzburger Weg 67
01109 DRESDEN / GERMANY

Tel.: +49 351 8838 400

Fax: +49 351 8838 403

www.biotype.de

Ordering

sales@biotype.de

Customer Service & Support

support@biotype.de

