Mentype® **DIPscreen** CE IVD

Monitoring of chimerism samples with 34 markers and a sensitivity of 2-4 %

Bio type® Diagnostic GmbH

Accurate and sensitive determination of the chimerism status is essential to detect engraftment failure, secondary graft rejection or disease relapse. Mentype® **DIPscreen** represents a multiplex-PCR application that simultaneously screens for 34 genetic markers including the gender specific locus Amelogenin for donor and recipient differentiation.

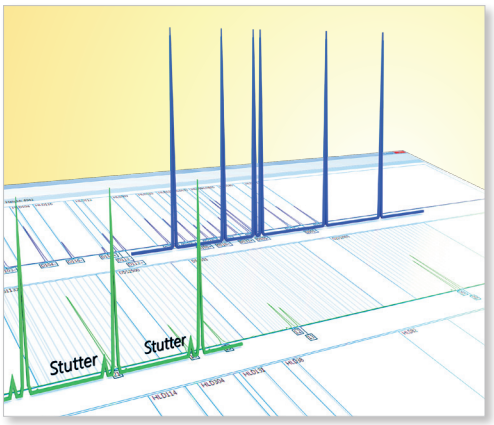
Mentype® **DIPscreen** ensures a precise investigation of chimerism in related and unrelated donor/recipient pairs. Especially for mixed chimerism samples Mentype® **DIPscreen** combines exact quantification with high reproducibility and robustness.

Sensitivity:

As a result of elaborate primer design and accurate reagent composition, Mentype® **DIPscreen** represents a very good sensitivity level. Our customers report a sensitivity level of 2-4 % which is ideally suited to monitor chimerism status over a wide measurement range.

No Stutter Artifacts:

In contrast to other multiplex-applications, Mentype® **DIPscreen** deploys Insertion/Deletion Polymorphisms (DIPs) that do not cause interfering stutter artifacts. As a result chimerism analysis with Mentype® **DIPscreen** provides a clear and unambiguous readout and is optimally suited for routine chimerism monitoring.



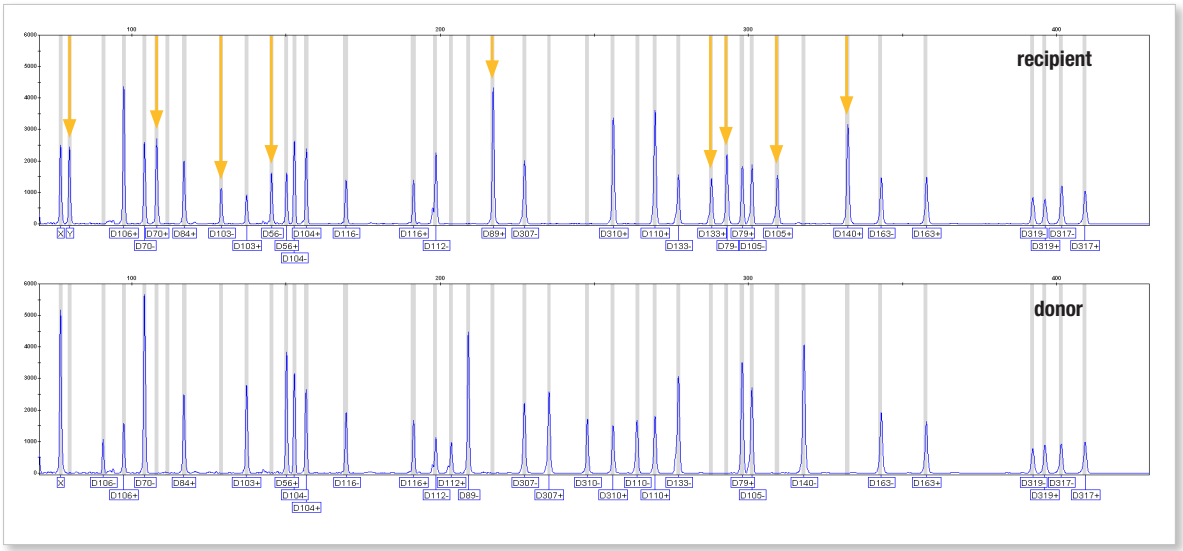
Stutter-free read-out of **DIPscreen** (blue) in comparison to stutter occurrence of conventional STR-based assays (green).

Clinical Validation:

Mentype® **DIPscreen** was validated in a clinical performance study. Chimerism samples of 98 adult patients were tested and showed a very good concordance in comparison to other CE-IVD certified methods. Mentype® **DIPscreen** can be safely applied to genotype donor and recipient for informative loci as well as it is perfectly suited to analyze chimerism samples postTx.

Power of Discrimination:

Analyzing 34 genetic markers Mentype® **DIPscreen** reveals its strength in donor and recipient differentiation. Also in closely related donor/recipients pairs the assay provides high potential to identify a convincing number of informative loci.



Arrows indicate identified recipient specific informative alleles that can be used for subsequent monitoring. Genotyping plot of only the 6-FAM panel.

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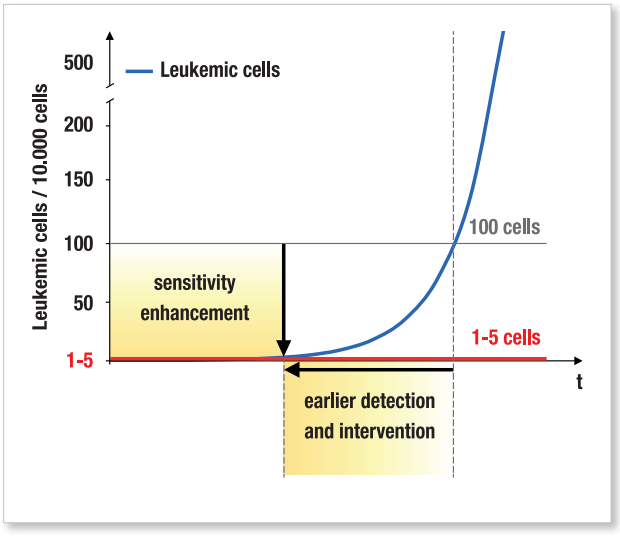
Features of Mentype® **DIPscreen**

- Validated in a Clinical Performance Study on Patient Chimerism Samples
- Quality Controlled by International Ring Trials (UKNEQAS)
- Screens 34 Genetic Markers in 1 Reaction
- Provides 2% - 4% Sensitivity
- Yields a High Number of Informative Loci
- No Stutter Artifacts due to Insertion/Deletion Polymorphisms
- Software Supported Genotyping and Chimerism Monitoring by **Chimeris**™ **Monitor 2.0**
- Possibility to be Combined with highly Sensitive qPCR Mentype® **DIPquant** Assays
- Possibility to be Combined with highly Accurate ddPCR Mentype® **DigitalQuant** Assays

Combine Mentype® DIPscreen with qPCR or ddPCR analyses to earlier detect imminent relapse though highly sensitive chimerism monitoring



Quantitative chimerism analysis supports early detection of imminent threats and enables early intervention.

For the genetic markers addressed by Mentype® **DIPscreen** corresponding Mentype® **DIPquant** qPCR assays and Mentype® **DigitalQuant** ddPCR assays are available that provide a plus in sensitivity down to 0.05-0.1 %.

The combined strategy:

- Provides a surplus to the **DIPscreen** chimerism analysis by expanding in a higher sensitivity level
- Allows thus chimerism analysis over a wide measurement range
- Features a flexible assay format making it routine fit and manageable for all laboratory pathways

Bio type®
Diagnostic GmbH

Moritzburger Weg 67
D-01109 Dresden
Tel.: +49 351 8838 400
Fax: +49 351 8838 403
info@biotype.de
www.biotype.de