

**Automated
Genetic
Toxicology
Tests**

Metafer
Toxicology
Application Packages



Versatile Applicability

With Metafer, all major microscope-based preclinical tests in genetic toxicology can be automated. Our application packages comply with the OECD guidelines of the respective tests and can be designed to be fully GLP-compliant.



Established Sensitivity

Many laboratories worldwide benefit from Metafer imaging automation in genetic toxicology. Together with our long-term users, the parameter sets for all tests could be developed and optimized in a practice-oriented way.









High Specificity

Standardization is key to genetic toxicology testing. The often very subtle effects can only be reliably detected if all aspects of the test, including the scoring, are performed on the basis of standardized parameters.

META TOXICO AUTOM

Portfolio - Overview:

Application Package	Guideline	GLP	Main Functionality
 Chromosomal Aberration Assay	#473	Yes	Automated imaging; manual on-screen analysis.
 Cytokinesis-Block Micronucleus Test	#487	Yes	Unattended MN scoring in bi-nucleates.
 Proliferation Index (CBPI)			Automated CBPI calculation.
 Rodent Erythrocyte Micronucleus Test	#474	Yes	MN scoring in PCE; PCE/NCE ratio.
 Single Cell Gel Electrophoresis	#489	Yes	Fully automated analysis (TM, OTM, more).
 Ames II / Ames MPF Test	#471	Yes	Colorimetric readout and colony detection.

METAFER IMAGING TECHNOLOGY INFORMATION

Outstanding Speed

MetaSystems offers hardware extensions that work seamlessly with the Metafer software allowing for high scanning speed and excellent image quality. For instance, a typical cytokinesis block micronucleus slide is scanned in less than 4 minutes.



Adaptive Scalability

An imaging system operated by Metafer has a modular design and is easy to adapt to individual needs. Application packages can be combined with each other as desired, and the slide capacity ranges from 8 to 800 preparations per run.

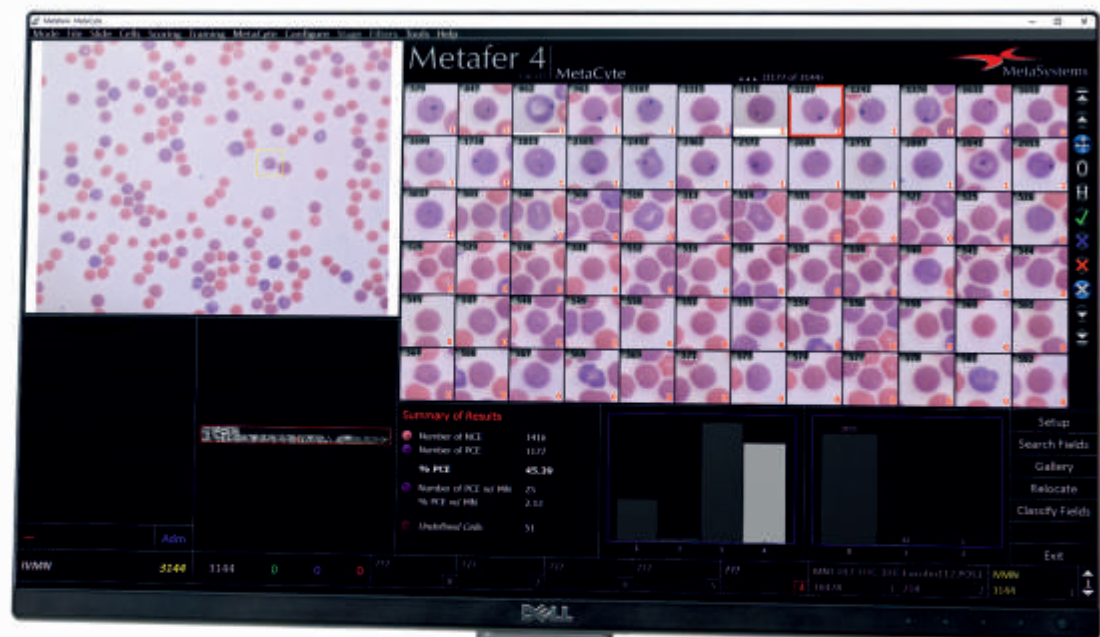


Seamless Integration

Each Metafer installation comes with Neon, a study and image management tool that provides users with a clear overview of all results. Data, images, and statistical results can be exchanged manually or automatically with other databases.



→ Metafer screen with the readout of the Rodent Erythrocyte Microcnucleus Test. Gallery shows the single objects detected. Histogram and figures summarize the measurement results and the distribution of PCE and NCE cell populations.



CONVENTIONAL

↓ The evaluation of the chromosome aberration test can be greatly simplified and accelerated with Metafer's many tools.

Chromosomal Aberration Assay



The Gold Standard

Although the test for chromosomal aberrations appears complex and manual analysis is tedious, it is still referred to as the "Gold Standard" for the evaluation of DNA damage.

With Metafer, users of this test benefit from many helpful tools to speed up, and to standardize the analysis.

Benefits

- Automated metaphase finder and high-resolution imaging of metaphases,
- On-screen aberration analysis with customizable scoring sheets,
- Digital reporting and data export,
- Offline review installations for work-sharing evaluation,
- Comprehensive Documentation of all findings and audit trails,
- High-volume scanning with up to 800 slides per run.

DNA TESTS

Single-Cell Gel Electrophoresis



The Comet Assay

The Comet assay quantifies DNA fragmentation in single cells. The assay has the advantage of being rapid, relatively inexpensive, and highly sensitive. Yet, it is still vulnerable to factors that can affect reproducibility.

Standardization through automation is the key to improving the reliability and significance of the test.

Benefits

- Automated selection of target cells based on morphology criteria,
- Assessment of all relevant cell features (e.g., tail moment, tail moment Olive, %DNA in tail, etc.),
- Documentation of all cells with graphical display of the results,
- Optionally: detection and separate assessment of 'Hedgehog' cells.

Ames II and Ames MPF Test



Modernizing an Established Test

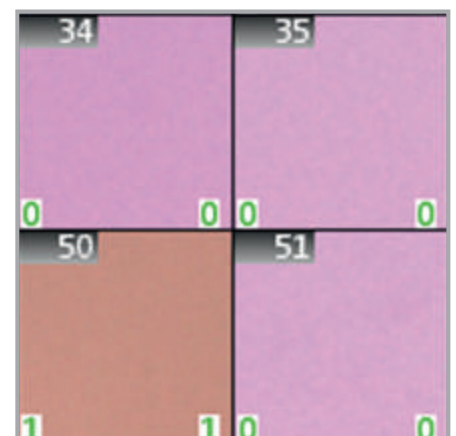
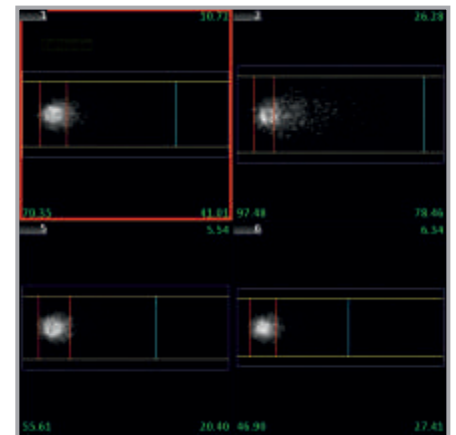
The Ames test is one of the oldest recognized tests for genetic toxicology. Ames II and Ames MPF are modernized versions of the test that use liquid cultures instead of agar plates. The assays are performed on 384-well plates (MWP) and have a colorimetric readout.

Metafer uses its rapid imaging capabilities to identify positive cultures based on their color. Results can then be summarized in a report according to the test manufacturer's specifications.

Benefits

- Fast evaluation of individual wells (only one image per well required),
- Identification of positive cultures based on color values ,
- Documentation according to the manufacturer's specifications as a report,
- Normal preparations and MWP can be scanned on the same device w/o conversion.

↓ Gallery of Comet assay results. Red and blue lines show the boundaries between head and tail, and the tail end, respectively. Numbers in the image corners are the measurement results.



↑ Ames test gallery with one positive culture (bottom left).

MICRONUC

Rod. Erythrocytes Micronucleus Test



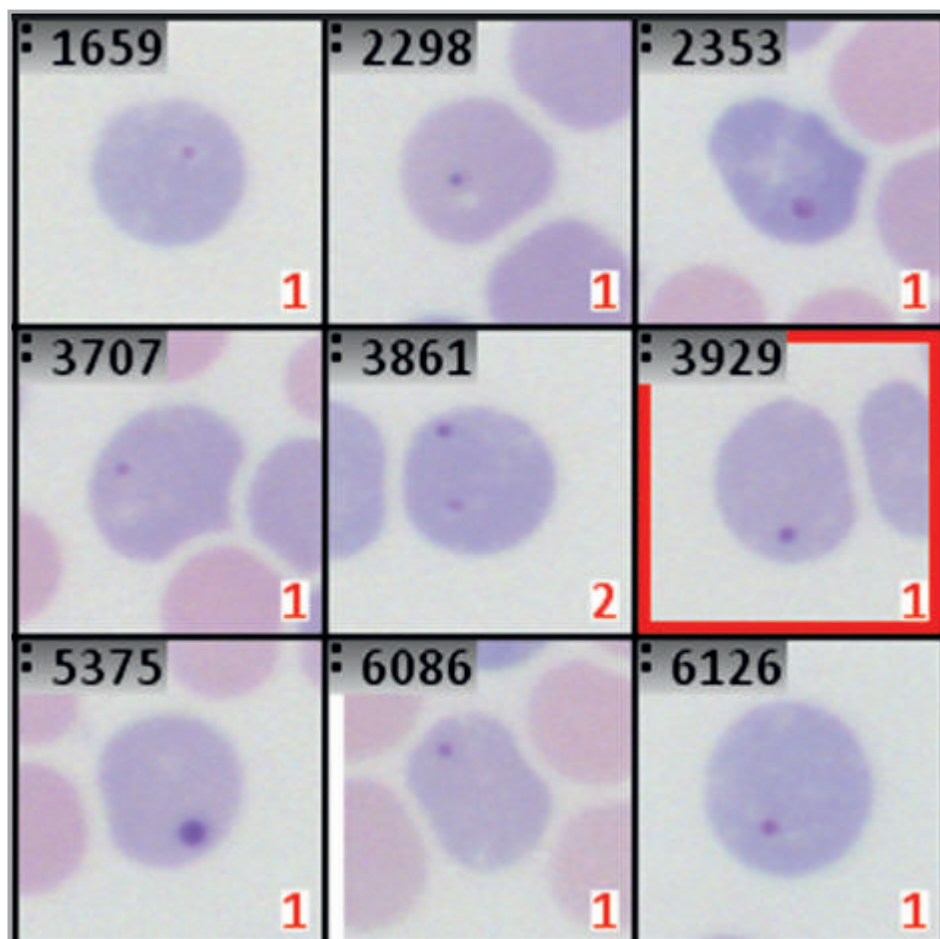
In Vivo Micronucleus Test

The Rodent Erythrocyte Micronucleus Test is routinely used for in vivo evaluation of chemicals. The target cells of the test are immature erythrocytes (PCE) from the bone marrow of animals. Furthermore, the test allows an assessment of cytotoxicity based on the ratio between PCE and mature erythrocytes (NCE).

With Metafer, the entire evaluation of the test can be automated in an OECD-compliant manner and under GLP conditions.

Benefits

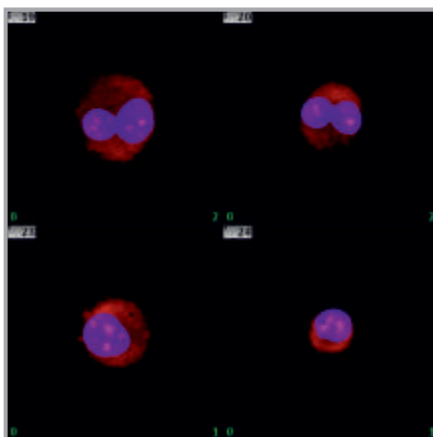
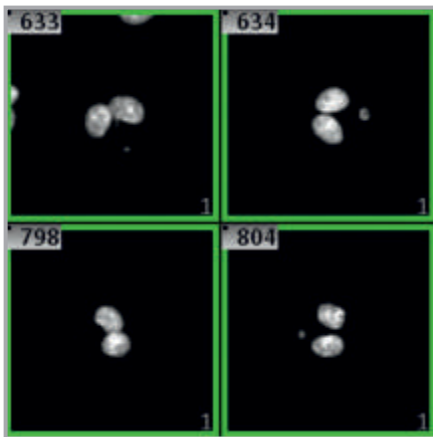
- Fully automated analysis of the test in May-Gruenwald-stained, purified erythrocyte samples,
- Automated calculation of micronucleus rates and PCE/NCE ratio,
- Documentation of each erythrocyte as gallery image,
- Automatic adjustment to staining variations.



↑ Metafer image gallery of PCE with micronuclei.

LEUS TESTS

↓ Micronuclei detection in bi-nucleated cells is considered one of the most reliable and rapid methods in the genetic toxicology portfolio.



Cytokinesis-Block Micronucleus Test



Complete Automation

Scoring of micronuclei in bi-nucleated cells has been established as a fast and easy alternative to the aberration assay. Due to the relatively easy analysis, it is the perfect test to achieve full automation.

Benefits

- Ultra-fast imaging of DAPI stained micronucleus assay samples,
- Automated scoring of micronuclei in bi-nucleates or mono-nucleates,
- Digital reporting and data export
- Smart review workflow with option to correct automated scoring proposals,
- Image gallery and quick relocation of all cells.

Proliferation Index (CBPI)



Cytotoxicity

The OECD guideline #487 for the mammalian cell micronucleus test recommends evaluation of the Cytokinesis-Block Proliferation Index (CBPI) to assess the level of cytotoxicity.

With the help of an application package for Metafer, also this step can be automated.

Benefits

- Automated assessment of mono-, bi-, and multinucleates,
- Automated calculation of the CBPI,
- Quick filter for the different cell classes,
- Image gallery and quick relocation of all cells.

↑ Cytotoxicity can be assessed with the help of the CBPI application package.



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The described functions refer to the following software versions: **Metafer 4.3**

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MetaSystems products are used in many countries worldwide. Depending on the regulations of the respective country or region, some products may not be used for clinical diagnostics.

Some hardware components supplied by other manufacturers are not included in MetaSystems IVD products and are therefore not IVD medical devices.

The application packages presented here are application-specific adaptations of the Metafer software. It is possible that further adaptations to specific specimen conditions are necessary.

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