PRODUCT DATA SHEET – NAT-MAT®

Key technical aspects, components, materials, and functionalities

NAT-MAT® Cells

- 1 vial of ready-to-use macrophages
- 96-well plate, cell medium & assay medium included

NAT-MAT® Extraction

- Magnetic bead based extraction of DNA and RNA
- Automated extraction (e.g. KingFisher™ Flex) advised

NAT-MAT® dPCR

- Lyophilized primer/probe mix & positive control included
- Amplifies 2 cytokines and 1 housekeeping gene in a triplex PCR
- Can also be performed as duplex PCR (one cytokine and houskeeping gene)

TEST METHOD

Monocyte Activation Test based on digital PCR

INTENDED USE

- Pyrogen testing of sterile, parenteral medicinal products
- Replacement of Rabbit Pyrogen Test (RPT)

TEST PRINCIPLE

NAT-MAT® combines the established Monocyte Activation Test with modern digital PCR technology, enabling pyrogen detection in accordance with Ph. Eur. 2.6.30. In contrast to ELISA-based MATs that measure cytokine protein expression, NAT-MAT® detects cytokine gene expression.

FAST FACTS

- 2 samples in 3 dilutions and 1 standard curve can be tested per 96-well plate (semi-quantitative test)
- Designed for QIAcuity®
- LOD (IL-1β): 0.02 EU/ml
- LOD (TNF-α): 0.04 EU/ml

WORKFLOW

COMPLIANCE

- EP 5.1.13
- EP 2.6.30 (MAT as compendial method)
- USP <151> (MAT as alternative to RPT)

TARGET MARKET

Pharmaceutical industry

BENEFITS

- Rapid cell stimulation in just 4 hours
- Monocytic cell line ensures cell supply and reproducibility
- Highly automatable workflow

USPs

- Normalization of pyrogen concentration via housekeeping gene ensures highly accurate results
- Dual-cytokine detection for varying pyrogen levels
- User-friendly data analysis with NAT-MAT® software

SUPPORTING DOCUMENTS

Report on manufacturer´s validation available

REQUIRED

- QIAcuity® system
- Extraction robot
- Liquid nitrogen or ultra-freezer
- CO_2 Incubator
- Centrifuge
- Water bath
- Reference standard endotoxin

Please refer to manual for full list

GOOD TO KNOW

- ddPCR™ optimized version is currently being developed
- The individual components are also available separately