M371
Tumor Test

THE LIQUID BIOPSY TEST FOR TESTICULAR CANCER DIAGNOSTICS

BACKGROUND

Testicular germ cell tumors (GCT) are the most common cancer type in men aged 20-45 years old with 22,000 new cases per year in Europe. Although the survival rate is very high early detection is key.

The current gold standard for diagnosis and monitoring, based on serological testing, CT and MRT, is unspecific, radiation-intensive and leaves the patient often in doubt.

M371 is a state-of-the-art liquid biopsy molecular diagnostic test that optimizes therapy for GCT patients through a very high sensitivity and specificity for GCT while being minimally invasive for the patient.

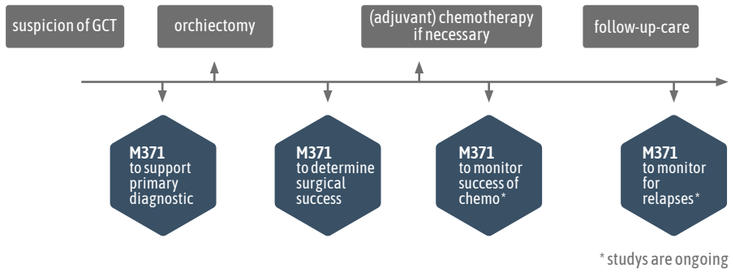
PRINCIPLE

Micro RNAs are short, non-coding RNAs which often circulate in the bloodstream and take part in the regulation of gene expression.

The expression of the microRNA 371a-3p (miR371) and its presence in blood serum is highly correlated with testicular tumors.

By measuring miR371 in patient samples through quantitative polymerase chain reaction (qPCR), M371 makes use of this correlation to support the diagnosis and treatment decisions of GCT patients.

M371 IN USE



*studys are ongoing

OPTIMIZING THERAPY FOR GCT PATIENTS

- faster diagnosis
- less exposure to radiation
- more personalized therapy
- avoiding unnecessary surgery
- earlier detection of relapses

SPECIFICATIONS

- 90% sensitivity and 94% specificity
- ready-to-use reagents
- easy storage at -25°C to -15°C
- specimen type: 200µl serum
- easy workflow

WORKFLOW

- miRNA extraction
- cDNA synthesis
- preamplification
- qPCR
- 01100011 10001100 data analysis

REQUIRED EQUIPMENT

- RNA extraction kit
  (validated for Qiagen GmbH miRNeasy Serum/Plasma Kit)
- standard thermal PCR cycler
- qPCR cycler
  (validated for Roche Diagnostics Lightcycler 480 II)

CLINICAL & SCIENTIFIC EVIDENCE

- By measuring 522 patients and 258 controls in a large European clinical study a sensitivity of 90% and a specificity of 94% of miR371 for the detection of GCT was established. Tumor size as well as therapy success are highly correlated with the expression of miR371. (Dieckmann et al., 2019)
- miR371 drops to 2,6% of the pre-surgical value within 24h after orchiectomy. (Radtke et al. 2018)
- The origin of increased biomarker levels is located in the tumor tissue. (Belge et al., 2020)
- miR371 is not expressed by other tumors and can help to differentiate reliably between malignant germ cell tumors and other testicle diseases. (Belge et al., 2021)

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