



M371-Test

Optimizing Testicular Cancer Diagnostics

The M371-Test is a qPCR-based assay intended as an **aid for primary diagnosis and follow-up monitoring of testicular germ cell tumors (TGCT)**. It measures the relative quantity of the tumor marker miR-371a-3p from a blood sample with outstanding diagnostic accuracy.

- Unique and innovative product based on patented technology
- Faster, substantially more precise, and reliable diagnosis than current biomarker standards
- Minimally invasive technique that avoids unnecessary diagnostic surgeries
- Potential reduction of radiation exposure during follow-up and long-term monitoring
- High sensitivity (90,1%) and specificity (94%)
- For professional *in vitro* diagnostic use. CE-IVD

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Background

Testicular germ cell tumors (TGCT) are the most common cancer type in men aged 20-45 years with 25.000 new cases per year in Europe (Source: Globocan 2020).

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

New Biomarker for Testicular Cancer (TC)

"Micro RNAs (miRNAs) are emerging as potential new biomarkers for TC. A number of studies suggest higher discriminatory accuracy for miRNAs (particularly miR-371a-3p) compared to conventional GCT markers in diagnosis, treatment monitoring, and predicting of residual or recurrent viable disease" - **European Association of Urology (EAU) Guidelines on Testicular Cancer (TC)**.

Our Solution

- Product: **M371-Test**
- Order No.: **HW/MCS0105**
- Format: **5 Reactions**
- Thermocycler: Lightcycler® LC480 II (Roche). Ongoing validations for AriaDx (Agilent Technologies) and QuantStudio™ 5 (Applied Biosystems)

Clinical & Scientific Evidence

Dieckmann KP, *et. al.*, 2019. Serum Levels of MicroRNA-371a-3p (M371-Test) as a New Biomarker of Testicular Germ Cell Tumors: Results of a Prospective Multicentric Study. *J Clin Oncol.* 2019 Jun 1;37(16):1412-1423. doi: 10.1200/JCO.18.01480.

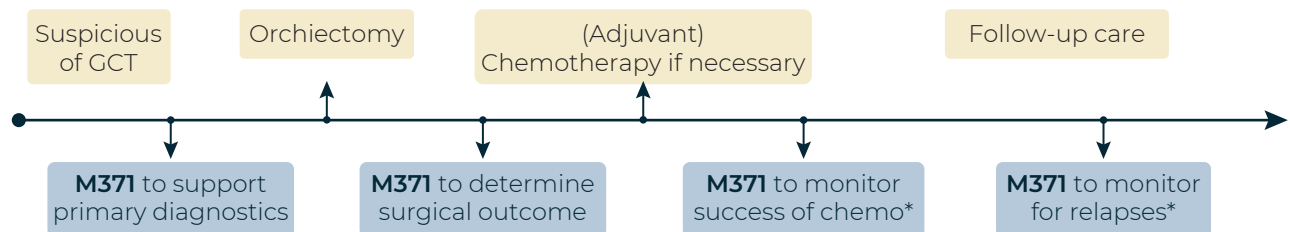
Clinical Stage	Classical Markers*		M371-Test	
	1	2/3	1	2/3
Sensitivity	51%	85%	87%	99%
Specificity	82%		94%	

*AFP, bHCG, LDH

By measuring 616 GCT patients and 258 controls in a large European clinical study it was established that tumor size as well as therapy success are highly correlated with the expression of miR371a.



- 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)
- miR371 drops to 2,6% of the pre-surgical value within 24h after orchiectomy. (Radtke *et al.* 2018)
- miR371 allows a more accurate and earlier detection of relapses in comparison to the classical markers. (Lobo *et al.* 2020; Fankhauser *et. al.*, 2021)



*ongoing studies

MANUFACTURED by mir|detect GmbH. DISTRIBUTED by Gold Standard Diagnostics Frankfurt
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Not available in the U.S. Contact your local representative for more details.

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