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 classical serum markers
- Minimally invasive technique that avoids unnecessary diagnostic surgeries
- Potential reduction of radiation exposure during follow-up and long-term monitoring
- High sensitivity and specificity in primary diagnosis as well as in follow-up monitoring
- For professional *in vitro* diagnostic use
- CE_{2797}-IVDR certified

GOLD STANDARD DIAGNOSTICS

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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. Preoperative elevation has been reported in 80-90% of both SGCT and NSGCT with higher levels in metastatic compared to localised disease. A number of studies suggest higher discriminatory accuracy for micro-RNA (miRNAs) (particularly miR-371a-3p) compared to conventional GCT markers in diagnosis, clinical staging, treatment monitoring, and predicting of residual or recurrent viable disease." **(EAU Guidelines on Testicular Cancer, March 2026)**

The marker miR-371a-3p (M371) is not expressed by other tumors and can help to differentiate reliably between malignant germ cell tumors and other testicle diseases. The marker falls to 2,6% of the pre-surgical value within 24h after orchiectomy.

Clinical and Scientific Evidence

Marker	Classical serum markers[1]		M371-Test	
Setting	Primary diagnosis[2]	Follow-up[3]	Primary diagnosis[2]	Follow-up[3]
Sensitivity[4]	cSI: 51 % cSII/III: 85 %	45 %	cSI: 89 % cSII/III: 99 %	100 %
Specificity	82 %	92 %	96 %	96 %

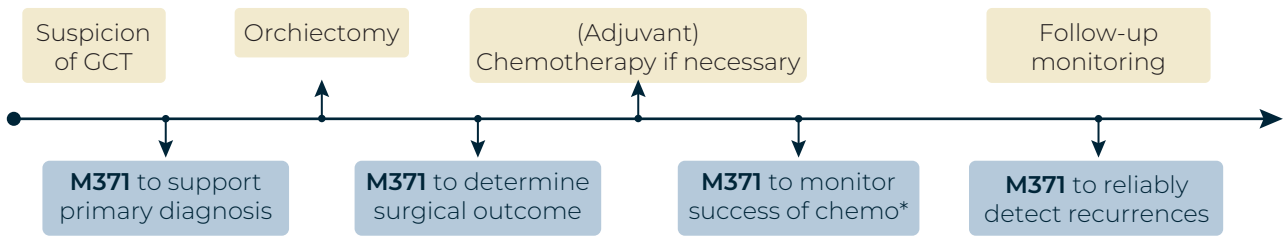
[1] AFP, ß-hCG, LDH. LDH was not considered in the follow-up setting.
[2] Dieckmann et al., 2019, doi: 10.1200/JCO.18.01480.
[3] Belge et al., 2024, doi: 10.1158/1078-0432.CCR-23-0730.
[4] The sensitivity in the primary diagnosis is reported separately for clinical stage I and stages II and III.

The M371-Test allows a more accurate and earlier detection of relapses in comparison to the classical markers: In the most comprehensive follow-up study to date, the M371-Test detected recurrences with a sensitivity of 100% and a specificity of 96%.

Validated on the following thermocyclers (as of May 2026):

- LightCycler® PRO, LightCycler® 480 II and cobas® z 480 (Roche)
- AriaDx (Agilent)
- QuantStudio™ 5 and QuantStudio™ 5 Dx (Thermo Fisher)
- CFX96™ (Bio-Rad)

Article number	Article	Format
HW/MCS0105	M371-Test	5 tests
HW/MCS0115	M371-Test	15 tests



*ongoing studies

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Not available in the U.S. Contact your local representative for more details.
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