MIKROGEN DIAGNOSTIK

CE 0483

Automated Strip Interpretation recomScan

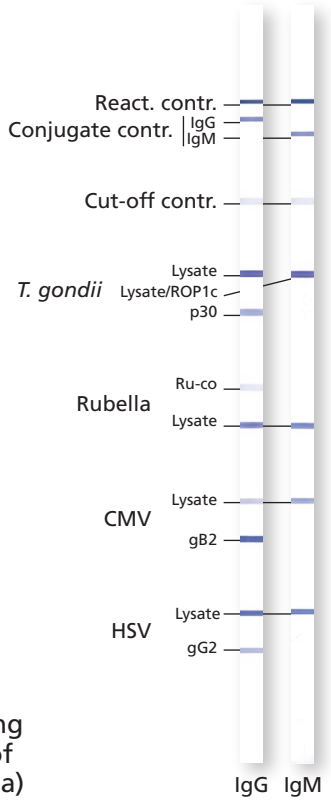
*recom*Line TORCH Screening IgG
*recom*Line TORCH Screening IgM

Strip-Immunoassay for the detection of IgG and IgM antibodies against *Toxoplasma gondii*, rubella virus, cytomegalovirus (CMV), and herpes simplex virus type 1 and 2 (HSV-1/2)

For the determination of the immune status for *Toxoplasma gondii*, rubella virus, CMV, and HSV-1/2, whole cell lysate antigens are used in the IgG and IgM assays.

***recom*Line TORCH Screening IgG**
The antigens enable differentiated diagnosis in the first step analysis (screening). Interpretation of the *recom*Line TORCH Screening IgG test follows a two-band strategy. The major band (lysate antigen) shows the presence or the absence of specific antibodies to an infectious agent and the ancillary band (e.g. recombinant antigen) is specific for each pathogen and allows further determination (see Table below).

***recom*Line TORCH Screening IgM**
The diagnostic information presented by the *recom*Line TORCH Screening IgG assay is supported by the *recom*Line TORCH Screening IgM assay. The test strips contain one band per infectious agent (four pathogen-specific lysate antigen bands per test strip), which enables the identification of specific IgM class antibodies to *T. gondii*, rubella virus, CMV, and HSV type 1 and 2, respectively. Sensitivity of the *T. gondii*-specific cell lysate antigen band is enhanced by an early phase antigen ROP1c.



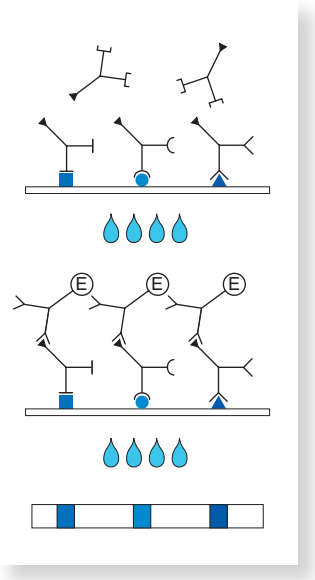
Product Advantages

- The *recom*Line TORCH Screening IgG and IgM is unique on the market allowing screening of 4 pathogens on one stripe as well as determination of the time of infection (CMV, T. gondii), protective or non-protective immune status (Rubella) and type differentiation (HSV-2)
- Fast and easy test procedure
- Well defined interpretation of bands and pattern due to easy to read bands
- No automation necessary and especially suitable for small laboratories with low sample throughput
- Easy test procedure; automation possible
- Easy and objective evaluation and documentation by *recom*Scan software
- Safe evaluation due to strip specific controls (cut-off and conjugate control)
- Separate detection of IgG and IgM antibodies possible
- Test procedure and reagents identical in all MIKROGEN strip tests - reagents exchangeable
- CE label: The *recom*Line TORCH Screening tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

Pathogen Specific Antigens used in *recom*Line TORCH Screening IgG

Antigen	Characteristics
Toxoplasma gondii lysate and recombinant antigen p30	Enables exclusion of a primary infection during the last 3 months if a positive reactivity is detectable for lysate and p30
CMV lysate and recombinant antigen gB2	Enables exclusion of a primary infection during the last 6 – 8 weeks if a positive reactivity is detectable for lysate and gB2
Rubella lysate and vaccination band	enables the assessment of protective or non-protective immunity. This band is adjusted according to the guidelines of the World Health Organization (WHO) and it nearly corresponds with an anti-rubella virus IgG antibody titer of ≥15 IU/ml.
HSV-1/2 lysate and recombinant antigen gG2 for HSV-2	allows identification of infections caused by the HSV type 2 (the most common causative agent of genital herpes).

Test Principle and Procedure



1st Incubation — A test strip loaded with TORCH antigens is incubated with diluted serum or plasma in a dish for **1 hour**.

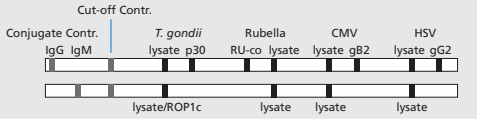
wash 3 times

2nd Incubation — Peroxidase conjugated anti-human antibodies (IgG or IgM specific) are added. Incubate for **45 minutes**.

wash 3 times

Color reaction — **8 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies.

Sample Strips



			IgG	T. gondii lysate	T. gondii p30	Rubella lysate	CMV lysate	CMV gB2	HSV 1/2 lysate	HSV 2 gG2	Interpretation
			IgM	lysate/ ROP 1c	/	lysate	lysate	/	lysate	-	
1	Rubella seronegative	IgG		-	-	neg.	2+	1+	2+	-	No immunity for Rubella
2		IgM		-	/	neg.	-	/	-	/	
3	Rubella acute infection	IgG		2+	2+	+/-	+/-	-	2+	-	No protective immunity for Rubella: Suspicious of primary infection
4		IgM		-	/	2+	+/-	/	-	/	
5	Rubella past infection	IgG		-	-	2+	2+	2+	2+	-	Protective immunity for Rubella: Suspicious of past infection
6		IgM		-	/	neg.	-	/	-	/	
7	Toxoplasma seronegative	IgG		neg.	neg.	2+	2+	2+	2+	2+	No immunity for Toxoplasma
8		IgM		neg.	/	-	-	/	-	/	
9	Toxoplasma acute infection	IgG		2+	neg.	2+	2+	2+	2+	-	Suspicious of recent Toxoplasma infection
10		IgM		2+	/	-	-	/	-	/	
11	Toxoplasma past infection	IgG		2+	1+	1+	-	-	2+	-	Suspicious of past Toxoplasma infection (p30 positive: > 3 month p.i.)
12		IgM		neg.	/	-	-	/	-	/	
13	CMV seronegative	IgG		2+	1+	1+	neg.	neg.	2+	-	No immunity for CMV
14		IgM		-	/	-	neg.	/	-	/	
15	CMV acute infection	IgG		2+	+/-	2+	2+	neg.	2+	-	Suspicious of recent CMV infection
16		IgM		-	/	-	2+	/	-	/	
17	CMV past infection	IgG		-	-	1+	2+	2+	2+	-	Suspicious of past CMV infection (gB2 positive: > 6-8 weeks p.i.)
18		IgM		-	/	-	neg.	/	-	/	
19	HSV Type 2 infection	IgG		-	-	1+	-	-	2+	1+	Suspicious of HSV type 2 infection
20		IgM		-	/	-	-	/	+/-	/	

Article-No

6472 — ***recom*Line TORCH Screening IgG**
Reagents for 20 determinations

6473 — ***recom*Line TORCH Screening IgM**
Reagents for 20 determinations

Storage and Shelf Life

At +2°C - +8°C
12 months from the date of production

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