Syphilis Related Reagents

Test Menu	Product name	Component	Method	Storage
RPR	Mediace RPR	R1：Buffer solution	Latex-Immunoturbidimetric method	2-8℃
		R2：Latex reagent		
	RPR Standard Serum	1mL×5conc.×1		
	RPR Control	Negative 1mL×2、Positive 1mL×2		
TPLA	Mediace TPLA	R1：Buffer solution	Latex-Immunoturbidimetric method	2-8℃
		R2：Latex reagent		
	TPLA Standard Solution	2mL×5conc.		
	TPLA Control(K)	1mL×2conc.×2		

*Please ask us about packaging sizes of each products

Precautions for Use

1. A positive antibody test should be followed by subsequent tests. The result should be evaluated along with other test results and clinical symptoms. A final diagnosis of syphilis should be made by a physician based on overall findings including other relevant tests and clinical symptoms. Do not make a diagnosis based on the Mediace test result alone.

2. Serum samples from patients in the early stage of antibody production or from those with decreased antibody production due to compromised immune function contain a small amount of antibody and may test negative.

3. A non-specific immune response may occur in serum samples from patients with autoimmune diseases.
The test result should be evaluated based on other test results and clinical symptoms.

4. Serum samples from patients receiving blood products containing immunoglobulin may test positive.
Evaluate the test result carefully.

5. Keep in mind that the prozone phenomenon (which is associated with immune response) may affect results.

References

1) Osato,Kazuhisa, et al.; Clinical Evaluation of Latex Agglutination Test Kits for Detecting Anti-syphilitic Lipoidal Antibodies and Anti-treponemal Antibodies, Japanese Journal of Sexually Transmitted Diseases, 13 (1) 124-130, 2002

2) Osato,Kazuhisa, et al.; Clinical Evaluation of Latex Agglutination Test Kits of Syphilis (TPLA) for automated analyzer, Clinical Laboratory Instrument & Reagent, 14 (4), 739-743, 1991

3) Asaka Ayabe, et al.; Comparison of automatic latex agglutination test and modified venereal disease research laboratory test in detection of syphilitic anti-lipoidal antibodies, Japanese Journal of Medicine and Pharmaceutical Science, 62(4): 781-789, 2009

4) Masashi Chiba, et al.; Measurement in the Automatic analyze device of the syphilis inspection reagent that coated it to the Latex particle and reaction characteristic analysis, Medical Technology, 53 (10), 1217-1221, 2004

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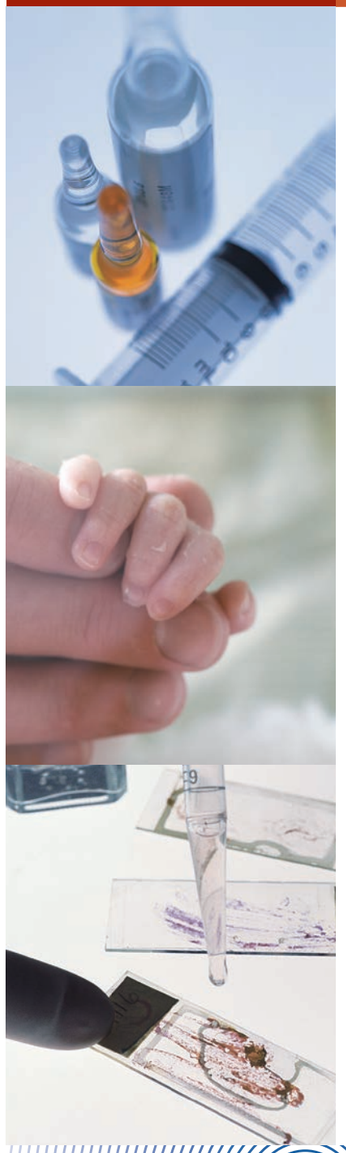
The products are not available in all countries.

Syphilis Related Reagents

In Vitro Diagnostic Reagents



- Mediace™ RPR (Non-treponemal Lipid Antibody Test Kit)
- Mediace™ TPLA™ (Treponemal Antibody Test Kit)

Features

1. Ready-to-use liquid format reagent based on latex turbidimetric immunoassay
2. Applicable to various types of automated analyzers
3. Automation allows cost and labor savings
4. Result consistency increased through automated analyzers
5. Good correlation with traditional methods (RPR card method, TPHA method)

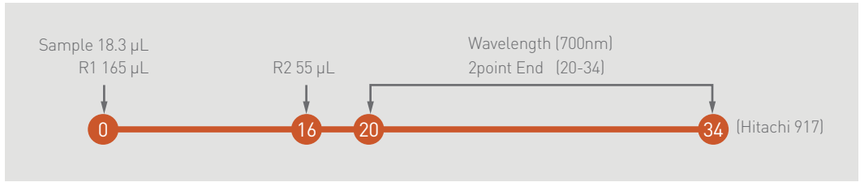
SEKISUI MEDICAL CO., LTD.

Mediace RPR

1 Measurement Principle

The formation of syphilis anti-lipid antibody and latex clumps in the sample is induced by the reaction between the polystyrene latex sensitized with lipid antigens (cardiolipin and lecithin) and the sample under given conditions. The syphilis anti-lipid antibody titer in the sample is measured based on the difference in pre- and post-reaction turbidities (turbidity changes), or the post-reaction turbidity increases, resulting from clump formation.

2 Parameter



Serum and plasma can be used.

3 Measurement Unit

R.U. (RPR Units) is based on the WHO Standard (the International Standard for Syphilitic Human Serum [1st international standard preparation], established in 1958). 1 R.U. is equal to 0.4 IU. 1 R.U. is equivalent to the reading with the RPR card method.

4 Evaluation

A measurement of 1 R.U. or higher indicates that the sample is antibody positive.
1. A positive antibody test should be followed by subsequent tests. The result should be evaluated along with other test results and clinical symptoms.
2. A final diagnosis of syphilis should be made by a physician based on overall findings including other relevant tests and clinical symptoms. Do not make a diagnosis based on the Mediace RPR test result alone.

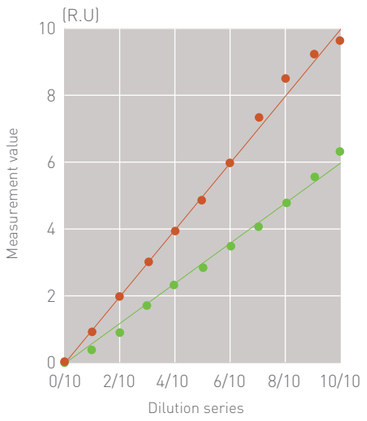
5 Basic Performance Data (Hitachi 917)

Within-run reproducibility

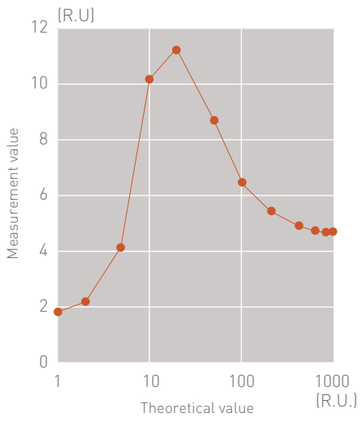
	SampleA	SampleB	SampleC
n	10	10	10
Mean	0.8	2.1	6.8
S.D.	0.06	0.07	0.13
CV(%)	8.0	3.1	1.9
Min.	0.7	2.1	6.6
Max.	0.9	2.3	6.9
Range	0.2	0.2	0.3

(R.U.)

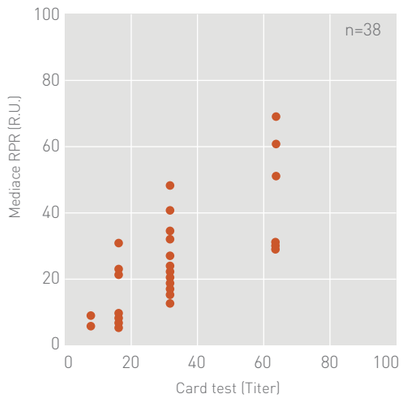
Linearity



Prozone

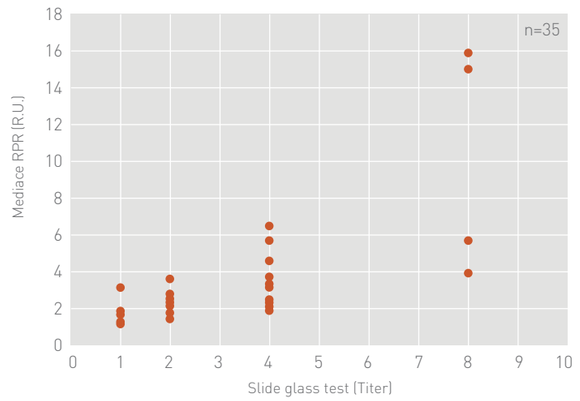


Correlation with RPR Card Test [1)]



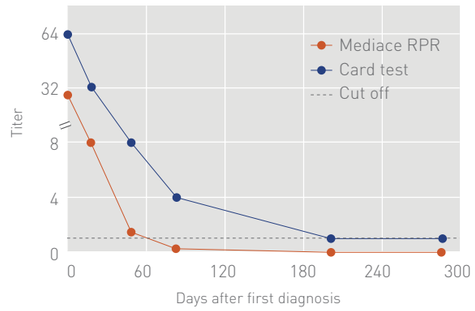
Mediace RPR has a great correlation with the RPR card test based on measurements from 38 syphilis patients at diagnosis. (First period: 7 samples, Second period; 8 samples, Early latent Syphilis; 20 samples, Late stage; 3 samples)

Correlation with Slide Glass Method [3)]

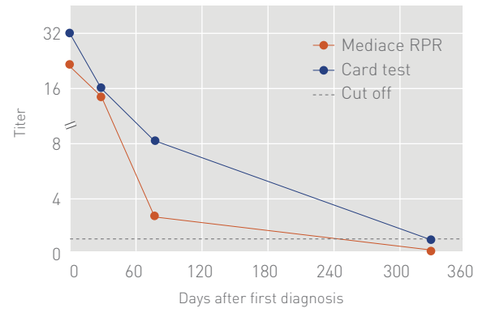


Mediace RPR has a great correlation with the RPR glass method based on measurements from 38 syphilis patients.

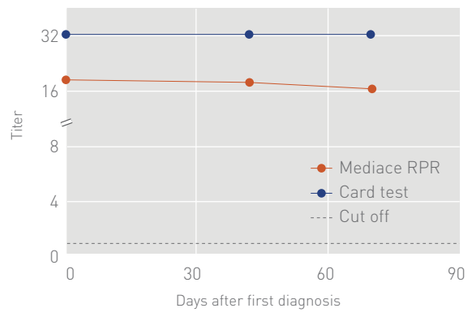
Primary Syphilis [1)]



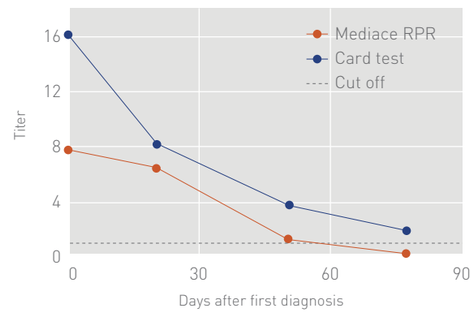
Secondary Syphilis [1)]



Late Syphilis [1)]



Early Latent Syphilis [1)]



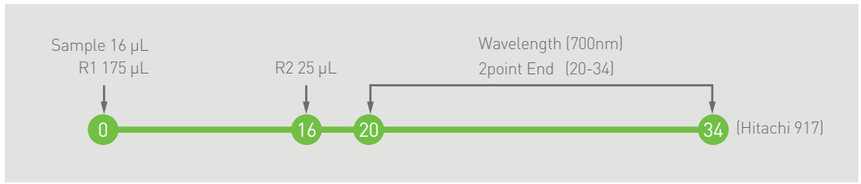
In the case of first period, second period and early latent syphilis, antibodys titer using Mediace RPR declined more quickly than RPR card test during treatment.

Mediace TPLA

1 Measurement Principle

The formation of anti-treponema antibody and latex clumps in the sample is induced by the reaction between the treponema pallidum antibody-coated latex and the sample under given conditions. The anti-treponema antibody titer in the sample is measured based on the difference in pre- and post-reaction turbidities, or the post-reaction turbidity increases, resulting from clump formation.

2 Parameter



Serum and plasma can be used

3 Measurement Unit

T.U. is the abbreviation of a unit of measure (TITER UNITS) for anti-treponema antibody used in the Mediace TPLA test. 1 T.U. in the WHO reference substance equals 2 mIU. (The International Standard for Syphilitic Human Serum [1st international standard preparation] established in 1958)

4 Evaluation

A measurement of 10 T.U. or higher indicates that the sample is antibody positive.
1. A positive antibody test should be followed by subsequent tests. The result should be evaluated along with other test results and clinical symptoms.
2. A final diagnosis of syphilis should be made by a physician based on overall findings including other relevant tests and clinical symptoms. Do not make a diagnosis based on the Mediace TPLA test result alone.

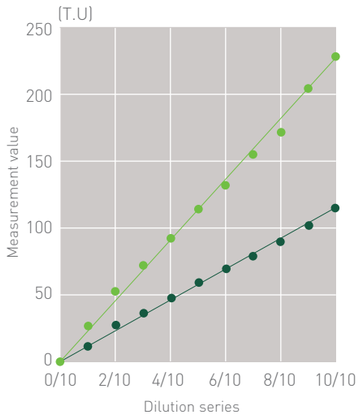
5 Basic Performance Data (Hitachi 917)

Within-run reproducibility

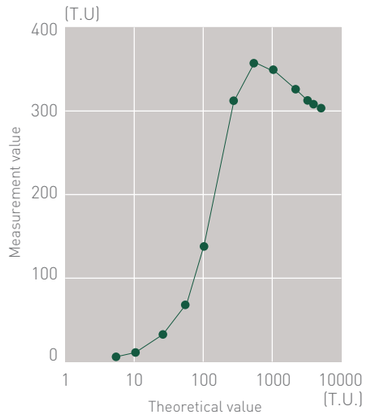
	SampleA	SampleB	SampleC
n	10	10	10
Mean	23.3	72.7	124.8
S.D.	0.30	0.58	1.00
CV(%)	1.3	0.8	0.8
Min.	22.9	71.7	123.1
Max.	23.8	73.5	126.3
Range	0.9	1.8	3.2

(T.U)

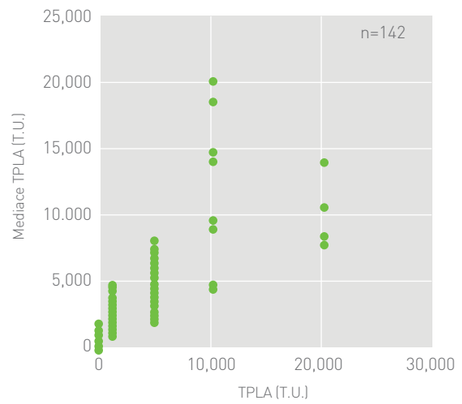
Linearity



Prozone



Correlation with TPHA [1)]



Mediace TPLA has a great correlation with TPHA based on 142 tests using 38 syphilis patients during the period from the initial treatment to the post treatment. (First period: 7 samples, Second period; 8 samples, Early latent Syphilis; 20 samples, Late stage; 3 samples)

Correlation with FTA-ABS [2)]

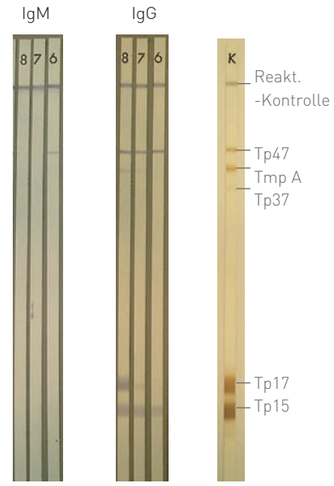
(T.U.)

FTA-ABS Titer	n	Range Min.	Range Max.
5	2	46.5	139.7
20	26	27.0	421.9
80	38	30.5	644.8
160	1	-	190.5
320	17	60.8	628.8
>1,280	18	169.3	611.2

FTA-ABS and Mediace TPLA for syphilis patients gave results of 10 T.U.(Cut off value) or more.

Sensitivity in the early stages after infection [1)]

	TPHA (Titer)	Mediace TPLA (T.U.)	Western blotting method				
			IgM		IgG		Lane
			Anti Tp47k	Anti Tp15,17k	Anti Tp47k	Anti Tp15,17k	
First diagnosis	0	99	(+)	(-)	(+)	(+)	6
One month after initiation of therapy	0	35	(-)	(-)	(+)	(+)	7
Three months after initiation of therapy	80	95	(-)	(-)	(+)	(+)	8



Mediace TPLA can detect syphilis antibody "IgM" in the early stages after infection.

Correlation with Chemiluminescent Method [4)]

		Mediace TPLA +	Mediace TPLA ±	Mediace TPLA -	Total
CLEIA	+	12	0	1	13
	±	0	0	0	0
	-	3	1	749	753
Total		15	1	750	766

Total consistent rate: (12+749)/766=99.3%

Mediace TPLA has a great correlation with the chemiluminescent method based on measurements from 766 samples.

Memo

Memo