VIROTECH RF-SorboTech

(RF-SorboTech - 2ml)

Order no.: 161101

(RF-SorboTech - 10ml)

Order no.: 161102

(RF-SorboTech - 80x)

Order no.: B/300.00

FOR IN VITRO DIAGNOSIS ONLY

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REV 17 / VIROTECH RF-SorboTech 2 ml & 10 ml & 80x EN

Contents

RF-SorboTech for the pre-absorption of IgM rheumatoid factors in serum, plasma and CSF

1. Intended Use

RF-SorboTech is intended for pre-absorption of serum (or plasma) and cerebrospinal fluid samples in the VIROTECH IgM ELISA as well as in Virotech ELISA tests with anti-human IgA+M mixed conjugate and in selected VIROTECH IgA ELISA tests. RF-SorboTech contains precipitating goat antibodies against human IgG antibodies.

2. Diagnostic Relevance

Specific IgM antibodies in human serum and CSF are detected for the early serological diagnosis of infectious diseases. The detection of IgM can be disturbed by pathogen-specific IgG antibodies. The IgG antibodies are bound to VIROTECH RF-SorboTech by precipitation with goat anti-human IgG antibodies.

IgG and IgM antibodies compete for the antigen binding sites. Depending on the affinity and concentration of the two antibody classes, binding of IgG antibodies can predominate with blocking of the binding sites for any IgM antibodies present, giving a false negative result.

If the specific serum or CSF contains IgG antibodies and rheumatoid factors (RF), these bind as auto-antibodies to the IgG antibodies that have already reacted with antigen. RFs are mainly IgM antibodies and are as such identified by anti-human IgM conjugate / anti-human IgA+M conjugate. This leads to a false-positive IgM / IgA + IgM result.

3. Package Contents

3.1 RF-SorboTech 2ml

1. 1 dropper bottle containing 2 ml RF-SorboTech anti-human IgG (goat), contains <0.1% sodium azide as preservative, sufficient for 40 serum or 40 CSF tests, ready to use.

3.2 RF-SorboTech 10ml

1. 1 bottle containing 10 ml RF-SorboTech anti-human IgG (goat), contains <0.1% sodium azide as preservative, sufficient for 200 serum or 200 CSF tests, ready to use.

3.3 RF-SorboTech 80x

1. 2 dropper bottles each containing 2 ml RF-SorboTech anti-human IgG (goat), contains <0.1% sodium azide as preservative, sufficient for 80 serum or 80 CSF tests, ready to use.
2. PBS dilution buffer, blue, 50ml, pH 7,2, with preservative and Tween 20.

4. Storage and shelf life of the test kit and ready-to-use reagents

Store test kit at 2-8ºC. The expiry date of the individual components is printed on the respective labels.

Material	Status	Storage	Shelflife
RF-SorboTech	Undiluted, After Opening	+2 to +8°C	3 months
	Diluted	+2 to +8°C	1 week

5. Precautions

RF-SorboTech should be regarded as potentially infectious and used with appropriate precautions.

Caution: RF-SorboTech contains 0.1% sodium azide, which can react with lead or copper pipes to form highly explosive metal azide compounds. When disposing of these reagents through lead drainpipes, they should be flushed with a large volume of water in order to avoid azide formation in the sewerage system.

Sodium azide is harmful to health. In the event of contact, wash the affected areas of the body immediately under running water and consult a doctor if necessary.

6. Testprocedure

Caution: different dilution buffer in VZV.
When running the test for VZV, the PBS dilution buffer must be replaced by VZV dilution buffer.

6.1 Performing the test with RF-SorboTech-2ml, RF-SorboTech-10ml and RF-SorboTech-80x

Bring the dropper bottles to room temperature.
Always ensure that the bottle is held vertically when using dropper.

Suitable reaction tubes can consist of the following materials, for example.

- HDPE (High Density Polyethylen)
- LLDPE (Linear Low Density Polyethylen)
- LDPE (Low Density Polyethylen)
- PP (Polypropylen)
- PP (Highest Purity Polypropylen)

a) Serodiagnosis:

Serum measurement (1:101)

- Dilute RF-SorboTech 1:10 (1+9) in a suitable test tube with PBS dilution buffer. Dilute the serum 1:101 with this RF-SorboTech-buffer mixture; this is the working dilution.
  Example: 1 drop RF-SorboTech (approx. 50µl) + 450µl PBS dilution buffer (1:10). 5µl serum are added to this RF-SorboTech-buffer mixture (500µl), this is equivalent to a 1:101 serum dilution.
- Incubate at room temperature for 15 minutes.

b) CSF diagnosis:

Serum measurement IgM (1:101)

- Dilute RF-SorboTech 1:10 (1+9) in a suitable test tube with PBS dilution buffer. Dilute the serum 1:101 with this RF-SorboTech-buffer mixture; this is the working dilution.
  Example: 1 drop RF-SorboTech (approx.50µl) + 450µl PBS dilution buffer (1:10). 5µl serum are added to this RF-SorboTech-buffer mixture (500µl), this is equivalent to a 1:101 serum dilution.
- Incubate at room temperature for 15 minutes.

For a 1:404 dilution:

- Dilute the 1:101 diluted serum further 1:4
  Example: dilute 100µl serum/buffer/RF-SorboTech mixture with 300µl PBS dilution buffer.

CSF measurement (1:2)

- Dilute RF-SorboTech 1:5 (1+4) in a suitable test tube with PBS dilution buffer. Dilute the CSF 1:2 with this RF-SorboTech-buffer mixture; this is the working dilution.
  Example: 1 drop RF-SorboTech (approx.50µl) + 200µl PBS dilution buffer (1:5). Take 225µl RF-SorboTech-buffer mixture and add 225µl CSF, this is equivalent to a 1:2 CSF dilution.
- Incubate at room temperature for 15 minutes.

With an increased number of samples, a larger batch of RF-SorboTech+buffer can be made (caution: 1:10 for serum and 1:5 for CSF).

7. Performance Data

7.1 Binding capacity

Up to 15mg IgG per ml of undiluted sample are bound.

7.2 Repeatability

To determine the repeatability, sera were either diluted with the dilution buffer only or pre-absorbed with RF-SorboTech in 12 independent test runs. The 12 serum mixes were then tested in 48 wells in one test run. The variation coefficient was then obtained from the 48 individual results.

	without RF-SorboTech		with RF-SorboTech	
	variation coefficient	average OD	variation coefficient	average OD
sera with blue dilution buffer	6,0%	0,39	7,2%	0,36
sera with green dilution buffer	5,8%	0,32	8,5%	0,36

This shows that RF-SorboTech pre-absorption has a very high repeatability.

8. Dilution table

Serum Diagnostic (approximated)

RF-SorboTech: PBS Dilution Buffer in a 1 : 10 dilution:

Number of Patients	1	2	3	4	5	6	7	8	9	10
PBS Dilution Buffer	450µl	900µl	1,35ml	1,80ml	2,25ml	2,70ml	3,15ml	3,60ml	4,05ml	4,50ml
RF-SorboTech	50µl	100µl	150µl	200µl	250µl	300µl	350µl	400µl	450µl	500µl
Final Volume	500µl	1,0ml	1,5ml	2,0ml	2,5ml	3,0ml	3,5ml	4,0ml	4,5ml	5,0ml

Number of Patients	11	12	13	14	15	16	17	18	19	20
PBS Dilution Buffer	4,95ml	5,40ml	5,85ml	6,30ml	6,75ml	7,20ml	7,65ml	8,10ml	8,55ml	9,00ml
RF-SorboTech	550µl	600µl	650µl	700µl	750µl	800µl	850µl	900µl	950µl	1,0ml
Final Volume	5,5ml	6,0ml	6,5ml	7,0ml	7,5ml	8,0ml	8,5ml	9,0ml	9,5ml	10,0ml

Number of Patients	40	60	80	100	120	140	160	180	200	220
PBS Dilution Buffer	18,0ml	27,0ml	36,0ml	45,0ml	54,0ml	63,0ml	72,0ml	81,0ml	90,0ml	100,0ml
RF-SorboTech	2,0ml	3,0ml	4,0ml	5,0ml	6,0ml	7,0ml	8,0ml	9,0ml	10,0ml	11,0ml
Final Volume	20,0ml	30,0ml	40,0ml	50,0ml	60,0ml	70,0ml	80,0ml	90,0ml	100,0ml	110,0ml

CSF-Diagnostic (approximated)

Serum: RF-SorboTech: PBS Dilution Buffer in a 1 : 10 dilution (see above mentioned)

CSF: RF-SorboTech : PBS Dilution Buffer in a 1 : 5 dilution:

Number of Patients	1	2	3	4	5	6	7	8	9	10
PBS Dilution Buffer	200µl	400µl	600µl	800µl	1,0ml	1,2ml	1,4ml	1,6ml	1,8ml	2,0ml
RF-SorboTech	50µl	100µl	150µl	200µl	250µl	300µl	350µl	400µl	450µl	500µl
Final Volume	250µl	500µl	750µl	1,0ml	1,25ml	1,5ml	1,75ml	2,0ml	2,25ml	2,5ml

Number of Patients	11	12	13	14	15	16	17	18	19	20
PBS Dilution Buffer	2,2ml	2,4ml	2,6ml	2,8ml	3,0ml	3,2ml	3,4ml	3,6ml	3,8ml	4,0ml
RF-SorboTech	550µl	600µl	650µl	700µl	750µl	800µl	850µl	900µl	950µl	1,0ml
Final Volume	2,75ml	3,0ml	3,25ml	3,5ml	3,75ml	4,0ml	4,25ml	4,5ml	4,75ml	5,0ml

Number of Patients	40	60	80	100	120	140	160	180	200	220
PBS Dilution Buffer	8,0ml	12,0ml	16,0ml	20,0ml	24,0ml	28,0ml	32,0ml	36,0ml	40,0ml	44,0ml
RF-SorboTech	2,0ml	3,0ml	4,0ml	5,0ml	6,0ml	7,0ml	8,0ml	9,0ml	10,0ml	11,0ml
Final Volume	10,0ml	15,0ml	20,0ml	25,0ml	30,0ml	35,0ml	40,0ml	45,0ml	50,0ml	55,0ml