Instructions for Use

Vivafree™ Filters

Vivafree™ 2 and 500 30K and 125K device for *in vitro* diagnostic use

85037-552-88

SARTORIUS

Contents

1 Vivafree™ Filters – Introduction

1.1 Storage Conditions | Shelf Life

Vivafree™ ultrafiltration spin filters should be stored at 15 – 30°C. The devices should be used before the expiry date printed on the box.

1.2 Introduction

Vivafree™ filters are disposable ultrafiltration devices optimally suited for separating free drugs and hormones from those bound to serum proteins. For optimal sample recovery, they are equipped with a regenerated cellulose (Hydrosart®) or a cellulose triacetate membrane.

Vivafree™ 2 filters are suitable for sample volumes of 300 µl to 2 ml. They can effectively be used in rotors accepting 15 ml centrifuge tubes.

Vivafree™ 500 filters are suitable for sample volumes up to 500 µl. They can be used in rotors accepting 1.5 | 2.2 ml (11 mm) centrifuge tubes.

Vivafree™ filters are specifically designed with low internal surface and membrane area in order to achieve superior recoveries from samples with low concentrations of free drugs or hormones.

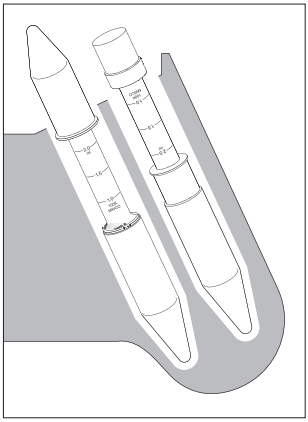
The Vivafree™ 500 & 2 product line includes 2 different cutoffs and 2 types of membranes (Molecular Weight Cutoff, MWCO):
- Vivafree™ 500: 30,000 MWCO/ Hydrosart® membrane
- Vivafree™ 2: 125,000 MWCO/ CTA membrane
- Vivafree™ 2: 30,000 MWCO/ Hydrosart® membrane
- Vivafree™ 2: 125,000 MWCO/ CTA membrane

Vivafree™ 500 & 2 30K and 125K filterdevices are for *in vitro* diagnostic use and can be used to separate free drugsand hormones from those bound to serum proteins prior to analysis. The Vivafree™ 500 & 2 devices are supplied non-sterile and are for single use only.

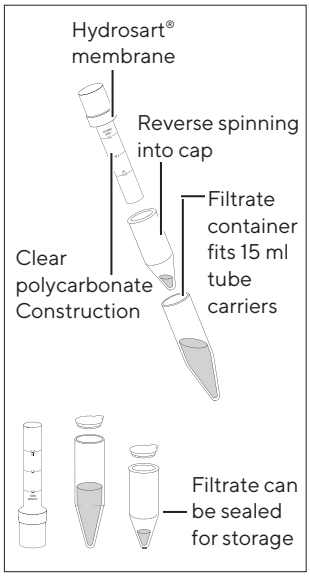
1.3 Equipment Required Vivafree™ Filters

Centrifuge	Vivafree™
Rotor type	Fixed angle or Swinging bucket*
Rotor cavity (Vivafree™ 2)	To fit 17 × 120 mm | 15 ml conical bottom tubes (recommended cavity depth 95 mm)
Rotor cavity (Vivafree™ 500)	To fit 1.5 | 2.2 ml (11 mm) conical bottom tubes

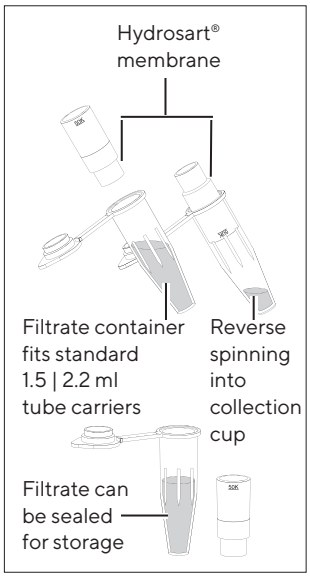
* Filtration rates for serum samples in swinging bucket rotors are typically 2 - 3 times slower compared to fixed angle rotors.



Vivafree™ 2 showing normal filtration position (Left) and reverse spinning position. Note that the backspin cap ridge must be below the top of the rotor cavity for correct support during normal centrifugation.



Vivafree™ 2 Operation



Vivafree™ 500 Operation

2 Operation

1. Select a molecular weight cut off (MWCO) which allows the free (unbound) drug or hormone to pass through the filter.
   When working with most drugs or small hormones (testosterone or cortisol), select a 30,000 MWCO. For insulin or other large hormones use a 125,000 MWCO.
2. Fill filter up to the maximum volumes (or less) shown in Table 1. (Ensure the lid is fully sealed.)
3. Insert assembled filter into centrifuge.
4. Centrifuge at speeds recommended in Table 2, taking care not to exceed the maximum g force indicated by the MWCO. Lower g force may be used but the filtration time will be longer.
5. Once the desired volume of filtrate is collected, (see Table 3 for guide to filtration times), remove the assembly and recover the free sample by removing the filtrate cup. If the concentrated protein sample is also of interest, reverse spinning may be used to collect this into the recovery cap. In this procedure remove filtrate tube, invert the concentrator body, insert concentrate recovery cap into filtrate tube and then spin at up to 2,500 g for 2 minutes. The concentrate recovery cap can be sealed for storage.

3 Technical Specifications

Table 1: Technical Specifications

	Vivafree™ 2	Vivafree™ 500
Capacity	2.0 ml	0.5 ml
Dimensions		
Total length (Filtration)	125 mm	45 mm
Total length (Back-spin)	115 mm	47.5 mm
Width	16 mm	12.4 mm
Active membrane area	0.95 cm^2	0.32 cm^2
Hold-up volume	10 µl	< 5 µl
Dead stop volume	55 µl (25° rotor)	5 µl (40° rotor)
	No Dead Stop for Swinging Bucket Rotors	

Materials of Construction

Body	Polycarbonate	Polycarbonate
Filtrate vessel	Polypropylene	Polypropylene
Back spin vial	Polypropylene	Polypropylene
Filtration cap	N/A	Polypropylene
Membrane*	CTA, Hydrosart®	CTA, Hydrosart®
O-ring	Silicone	Silicone

* CTA (cellulose triacetate) used for 125.000 MWCO only

Table 2: Recommended Maximum Spin Speed (× g)

Membrane cut off	Vivafree™ 2	Vivafree™ 500
30 kDa MWCO	5,000	5,000
125 kDa MWCO	2,500	2,500

4 Usage Tips

4.1 Flow Rate

Filtration rate is affected by several parameters, including MWCO, porosity, sample concentration, viscosity, centrifugal force and temperature. Expect longer spin times for serum samples that are lipemic.

NOTE
Serum samples in swinging bucket rotors typically have filtration rates 2 – 3 times slower than those in fixed angle rotors.

4.2 Pre-rinsing

Membranes fitted to Vivafree™ filters contain trace amounts of glycerine. Should these interfere with analysis, they can be removed by rinsing a full volume of buffer solution or deionised water through the filter. Decant filtrate and concentrate before processing sample solution. If you do not want to use the pre-rinsed device immediately, store it in a refrigerator with buffer or water covering the membrane surface. Please do not allow the membrane to dry out.

4.3 Sterilization of Vivafree™ Devices

Vivafree™ devices should not be autoclaved as high temperatures will substantially increase membrane MWCO. To sterilize, use a 70% ethanol solution or sterilizing gas mixture.

4.4 Chemical Compatibility

Vivafree™ filters are designed for use with biological fluids and aqueous solutions. For chemical compatibility details, please refer to Table 4.

4.5 Retention and Recovery

The membranes used in Vivafree™ are characterized by a molecular weight cut off (MWCO). For proteins, it corresponds to their ability to retain 90% of a molecule with this nominal molecular weight. For achieving better recovery of free drugs or hormones, use a MWCO which is at least 5 times the molecular weight of the drug or hormone in its unbound state.

5 Performance Characteristics

Table 3: Typical Performance Characteristics Vivafree™
(All data from fixed angle rotors.)

Device (MWCO)	Sample | Free Analyte	Initial Volume	Filtrate Volume	Time	Temp.	g-force
Vivafree™ 500 125,000	Serum | Insulin	500 µl	150 µl	30 min.	37°C	2,000 × g
Vivafree™ 2 30,000	Serum | Testosterone	1200 µl	600 µl	60 min.	25°C	2,000 × g

Vivafree™ 2 30,000	Serum | Phenytoin	1,000 µl	250 µl	20 min.	25°C	2,600 × g
Vivafree™ 2 30,000	Serum | Cortisol	500 µl	100 µl	20 min.	37°C	2,500 × g

NOTE
Filtration times may vary according to sample size and quality. Filtration rates for serum samples in swinging bucket rotors are typically 2 – 3 times slower compared to fixed angle rotors.

6 Chemical Compatibility

Table 4: Chemical Compatibility (2 hr contact)

	Hydrosart®	Cellulose Acetate
Compatible pH range	**pH 1–9**	**pH 4–8**
Acetic Acid (25.0%)	OK	NO
Acetone (10.0%)	NO	NO
Acetonitrile (10.0%)	NO	NO
Ammonium Hydroxide (5.0%)	OK	OK
Benzene (100%)	NO	NO
Chloroform (1%)	OK	OK
Dimethyl Formamide (10.0%)	NO	NO
Dimethyl Sulfoxide (5.0%)	NO	NO
Ethanol (70.0%)	OK	OK
Ethyl Acetate (100%)	NO	NO
Formaldehyde (30%)	OK	OK

Formic Acid (5.0%)	OK	?
Glycerine (70%)	OK	OK
Guanidine HCl (6 M)	OK	?
Hydrocarbons, aromatic	NO	NO
Hydrocarbons, chlorinated	NO	NO
Hydrochloric Acid (1 M)	OK	NO
Isopropanol (70%)	OK	OK
Lactic Acid (5.0%)	OK	NO
Mercaptoethanol (1.0 M)	OK	NO
Methanol (60%)	OK	OK
Nitric Acid (10.0%)	NO	NO
Phenol (1%)	OK	OK
Phosphate Buffer (1.0 M)	OK	OK
Sodium Dodecylsulfate (0.1 M)	OK	OK
Sodium Hydroxide (1.0 M)	NO	NO
Sodium Hypochlorite (200 ppm)	NO	NO
Sodium Nitrate (1.0%)	OK	?
Tetrahydrofuran (5.0%)	NO	NO
Toluene (1.0%)	NO	NO
Trifluoroacetic Acid (10%)	OK	NO
Tween 20 (0.1%)	OK	OK
Triton X-100 (0.1%)	OK	OK
Urea (8 M)	OK	?

OK = Acceptable
? = Questionable
NO = Not recommended

7 *In Vitro* Diagnostic Product Labeling

The following table defines the symbols found on Vivafree™ 500 & 2 30K and 125K device labels.

Symbol	Definition
	*In vitro* diagnostic medical device
	Catalogue number
	Do not reuse
	Use by
	Batch code
	Date of manufacture
	Manufacturer
	Temperature limitation
	Non-sterile product

8 Ordering Information

	Qty. per box	Prod. No.
Vivafree™ 2		
30,000 MWCO	25	VFR02H21
30,000 MWCO	100	VFR02H22
30,000 MWCO	500	VFR02H23
125,000 MWCO	25	VFR02H81
125,000 MWCO	100	VFR02H82
125,000 MWCO	500	VFR02H83
Vivafree™ 500		
30,000 MWCO	25	VFR01H21
30,000 MWCO	100	VFR01H22
30,000 MWCO	500	VFR01H23
125,000 MWCO	25	VFR01H81
125,000 MWCO	100	VFR01H82
125,000 MWCO	500	VFR01H83

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Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote the other gender as well.

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