

Certificate of Analysis

A. Product Name: SERATEC PSA Semiquant (Cat. No.: PSM400F)

B. Contents of ingredients

Component	Raw materials	Amount
Test region, first line (Ingredients of main reaction)	anti-human PSA IgG, monoclonal	>1µg
Reference region, second line (Ingredients of reference reaction)	anti-mouse IgG, polyclonal adjusted in the line intensity to 4 ng PSA/ml	>1µg
Control region, third line (Ingredients of main reaction)	anti-mouse IgG, polyclonal	>1.8 µg
Solid phase	Cellulose membrane	2 cm ²
Glass fibre tissue with gold labelled antibodies	glass fiber anti-human PSA IgG, monoclonal gold	0.5 cm ² >2 µg >1 ng
Further reagents	Tris Detergents and Blocking Reagents	app. 250 ng app. 670 ng
Backing Plate	PE	app. 4 cm ²
2 cellulose filters	cellulose	app. 1cm ²
Housing	PE	
Further components	Extraction buffer containing TRIS and SodiumAzide	

C. Indications

The SERATEC PSA Semiquant allows the detection of total PSA with a sensitivity of less than 1 ng/ml and a cut-off of 4 ng/ml.

D. Precautions for use

For forensic use only. Do not use the test beyond expiration date. All ingredients are non infectious and especially tested to be HIV and Hepatitis free.

E. Storage and expiry date

The test can be stored in the closed pouch two years after production at ambient temperature (4-30 °C). Do not freeze the product!

F. Package unit

40 Test and 50 mL extraction buffer

This certificate of Analysis is computer-produced and valid unsigned.