

Purity
Check

Seramun
Diagnostica GmbH

Serazym[®] Ovalbumin (E-041a-1)

Enzyme-linked immunosorbent assay for detection of ovalbumin in biological fluids

- ▲ short incubation times
- ▲ ready-to-use reagents
- ▲ quantitative results (ng/ml)
- ▲ incubation at 37 °C

Introduction

The Serazym[®] Ovalbumin is an *in-vitro* test developed for the very sensitive determination of ovalbumin in biological fluids and can be used for example to control the purity of vaccines.

Principle of the test

The Serazym[®] Ovalbumin is a direct sandwich enzyme immunoassay using immobilized polyclonal anti-Ovalbumin-antibodies and anti-ovalbumin-HRP-conjugate as detection system. Conjugate and samples are incubated simultaneously.

Test components

- 96-well microtitration plate
- 50 ml wash buffer, 10fold concentrated
- 50 ml sample diluent
- 7 x 1.0 ml ovalbumin standards, ready-to-use
- 1.0 ml ovalbumin control sample, ready-to-use
- 15 ml HRP-conjugate, ready-to-use
- 15 ml TMB-substrate solution, ready-to-use
- 15 ml stop solution, ready-to-use

Test procedure

- Add 100 µl of HRP-conjugate to every well
- add 100 µl of the diluted samples and of the ready-to-use standards and controls
- incubate 60 min at 37 °C
- wash wells 5 x
- add 100 µl of TMB-substrate solution to every well
- incubate 10 min at 20...25 °C protected from light
- add 100 µl of stop solution to every well
- read absorbances at 450 / ≥ 620 nm

Quantification

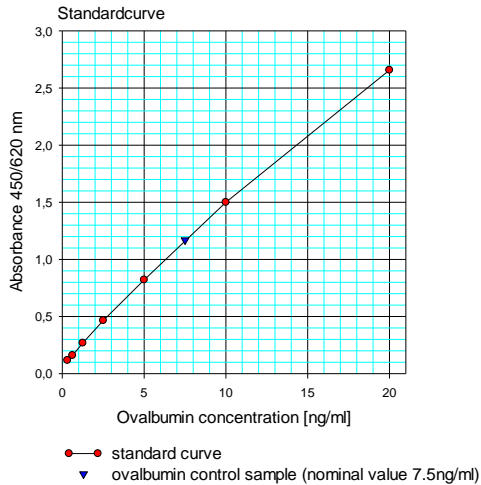
A standard curve is created by plotting the measured values of absorbance of the standards 1-7 (y-axis) against the declared ovalbumin concentration (x-axis).

Determine the ovalbumin concentration of the unknown samples by referring their absorbance to the standard curve and multiply the values with the dilution factor.

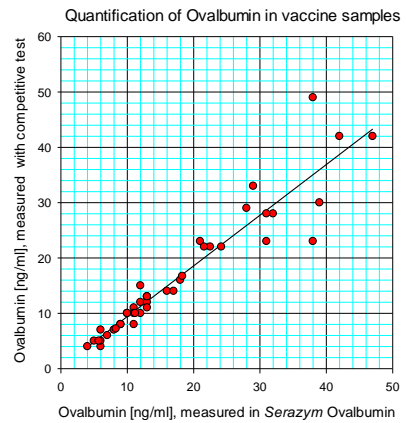
Test validity

Standard S 1	absorbance	≥ 1.50
Standard S 7	absorbance	≤ 0.50
Control sample		5.0 – 10.0 ng/ml

Typical standard curve in Serazym® Ovalbumin



Serazym® Ovalbumin vs. competitor test



Precision

Intra-assay coefficient of variation (n = 12)

Mean absorbance	Standard deviation	Coefficient of variation [%]
2.508	0.08	3.2
1.937	0.03	2.0
1.573	0.07	4.2
1.135	0.04	3.7
0.645	0.03	3.8
0.281	0.01	4.5

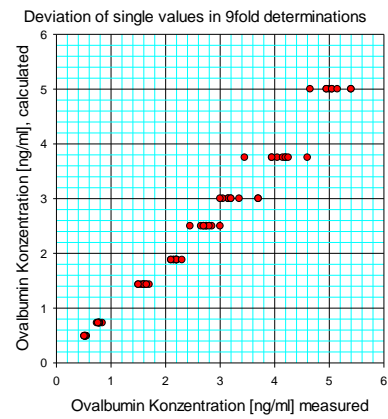
Ovalbumin concentration [ng/ml]	Standard deviation	Coefficient of variation [%]
5.07	0.23	4.6
4.09	0.31	7.6
3.28	0.26	7.9
2.18	0.06	2.8
1.59	0.07	4.6
0.78	0.03	3.5

Inter-assay coefficient of variation (n = 24)

Mean absorbance	Standard deviation	Coefficient of variation [%]
2.326	0.14	6.1
1.750	0.07	3.9
1.078	0.05	4.9
0.407	0.03	7.5

Ovalbumin concentration [ng/ml]	Standard deviation	Coefficient of variation [%]
8.83	0.73	8.2
4.55	0.29	6.4
3.04	0.21	7.0
0.82	0.05	6.6

Linearity



Purity check of vaccines

