

Purity
check

Seramun
Diagnostica GmbH

Serazym[®] Ovalbumin (E-041c-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 room temperature

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
- 6 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 control
- incubate 60 min at 20...25 °C
- wash wells 5 x
- add 100 µl of TMB-/substrate solution to every well
- incubate 15 min at 20...25 °C protected from light
- add 100 µl of stop solution to every well
- read absorbances at 450 / \geq 620 nm

Quantification

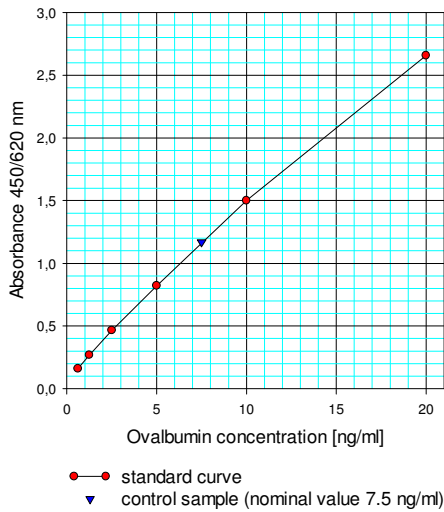
A standard curve is created by plotting the measured values of absorbance of the standards 1-6 (y-axis) against the declared ovalbumin concentration (x-axis).

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

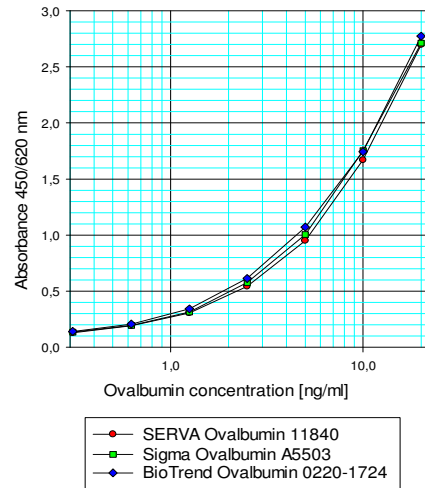
Test validity

Standard S 1	absorbance	\geq 1.50
Standard S 6	absorbance	\leq 0.50
Control sample		5.0 – 10.0 ng/ml

Typical standard curve in Serazym® Ovalbumin



Titration of different Ovalbumin preparations



Precision

Intra-assay coefficient of variation (n = 12)

Mean absorbance	Standard deviation	Coefficient of variation [%]
2.494	0.06	2.3
1.513	0.04	2.3
0.867	0.02	2.6
0.509	0.02	3.1
0.303	0.01	2.9
0.199	0.01	4.2

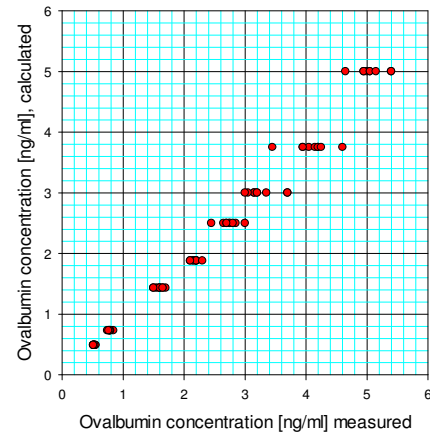
Ovalbumin concentration [ng/ml]	Standard deviation	Coefficient of variation [%]
19.9	0.65	3.3
10.1	0.31	3.1
4.90	0.16	3.3
2.50	0.10	3.9
1.27	0.05	3.0
0.68	0.05	6.7

Inter-assay coefficient of variation (n = 12)

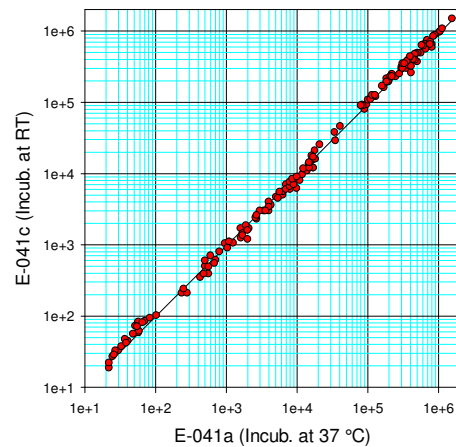
Mean absorbance	Standard deviation	Coefficient of variation [%]
2.319	0.13	5.6
1.387	0.11	8.0
0.781	0.06	8.1
0.407	0.03	7.5

Ovalbumin concentration [ng/ml]	Standard deviation	Coefficient of variation [%]
10.07	1.02	10.1
4.99	0.47	9.5
2.40	0.19	8.1
1.24	0.10	8.1

Linearity



Correlation of Serazym® Ovalbumin E-041a and E-041c



Catalogue-No. E-041c-1



Management System
 EN ISO 13485:2012
 ISO 9001:2008
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