

Purity
check

Y
Seramun
Diagnostica GmbH

Serazym[®] Ovalbumin-ELISA E-041a

Enzyme immunoassay for quantitative detection of Ovalbumin

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

Introduction

The *Serazym[®]* Ovalbumin-ELISA enables the fast and sensitive quantification of Ovalbumin in vaccines and other culture supernatants won by use of chicken eggs.

Principle of the *Serazym[®]* ELISA

The *Serazym[®]* Ovalbumin-ELISA 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 kit 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 anti-Ovalbumin-HRP-conjugate, ready to use
- 15 ml TMB-/substrate solution, ready to use
- 15 ml stop solution

Test procedure

- add 100 µl of anti-Ovalbumin-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 22...25 °C protected from light
- add 100 µl of stop solution to every well
- read absorbances at 450/620 nm

Quantification

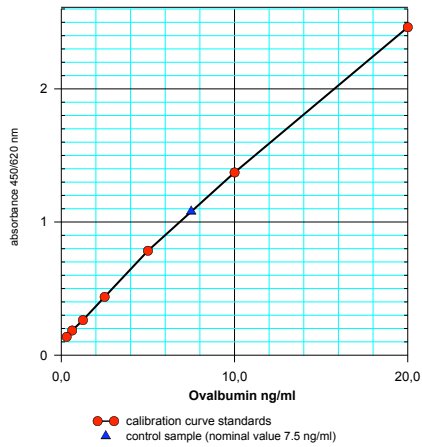
Create a calibration curve using the absorbances of the standards with ovalbumin concentrations in the range from 0.312 ng/ml to 20.0 ng/ml.

Determine the ovalbumin concentrations of the samples by referring their absorbances to the corresponding concentrations of the calibration curve.

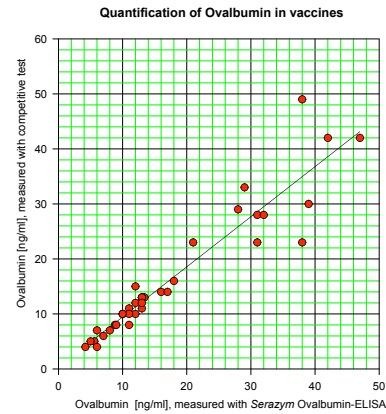
Validation

Standard S7	absorbance	< 0.5
Standard S1	absorbance	> 1.5
Control sample		5 - 10 ng/ml

Typical calibration curve in the Serazym® Ovalbumin-ELISA



Serazym® vs. competitor test



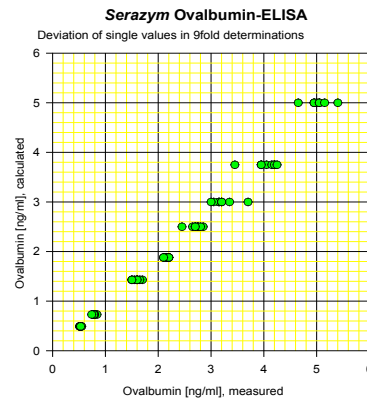
Precision of the Serazym® ELISA

Intra-assay coefficient of variation (n=12)

Mean absorbance	Standard deviation	Coefficient of variation [%]
2.508	0.081	3.21
1.937	0.034	2.03
1.573	0.066	4.16
1.135	0.042	3.73
0.645	0.025	3.83
0.281	0.013	4.49

Ovalbumin concentration [ng/ml]	Standard deviation	Coefficient of variation [%]
5.07	0.23	4.60
4.09	0.31	7.55
3.28	0.26	7.89
2.18	0.06	2.83
1.59	0.068	4.59
0.78	0.028	3.54

Linearity of the Serazym® ELISA

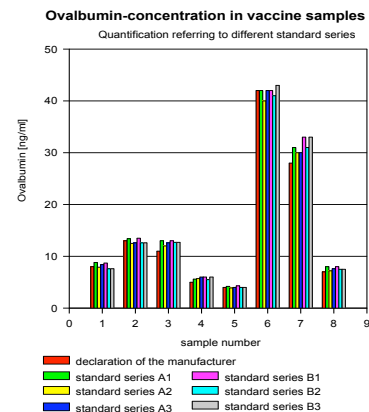


Inter-assay coefficient of variation (n = 24)

Mean absorbance	Standard deviation	Coefficient of variation [%]
2.326	0.141	6.05
1.750	0.069	3.94
1.078	0.053	4.94
0.407	0.031	7.50
0.215	0.018	8.38

Ovalbumin concentration [ng/ml]	Standard deviation	Coefficient of variation [%]
8.83	0.73	8.23
4.55	0.29	6.35
3.04	0.21	7.02
0.82	0.05	6.57

Purity check of vaccines



DIN EN ISO 13485:2003
DIN EN ISO 9001:2000

Catalogue-No. E-041a

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