

ELISA

test kits



BIOGEMA





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BIOGEMA



Biogema, production cooperative, Košice

a stable partner in diagnostics

Company Biogema, production cooperative, Košice **builds on strong foundations** of long-term partnership in the field of production and distribution of in vitro diagnostics. As the only Slovak manufacturer of ELISA diagnostic kits, we have been striving to exceed client expectations and needs for more than 35 years. We use the knowledge, that we have acquired through many years of experience and try to make use of it in our daily practice.

We are aware of the responsibility of being a strong and stable partner in medical diagnostics and therefore offer a **strong pro-client approach** combined with high flexibility. Our expert team of employees solves everyday challenges in the production and innovation of diagnostics and their implementation in the dynamic environment of modern laboratories.

We understand the need for quality, which is why we offer our clients **only certified diagnostics**, that meet all the strictest standards and legislative requirements. Since 2004 we have had a **quality management system** in place according to STN EN ISO 9001 and STN EN ISO 13485 in the current version, which, together with internal and external control forms a process quality guarantee.





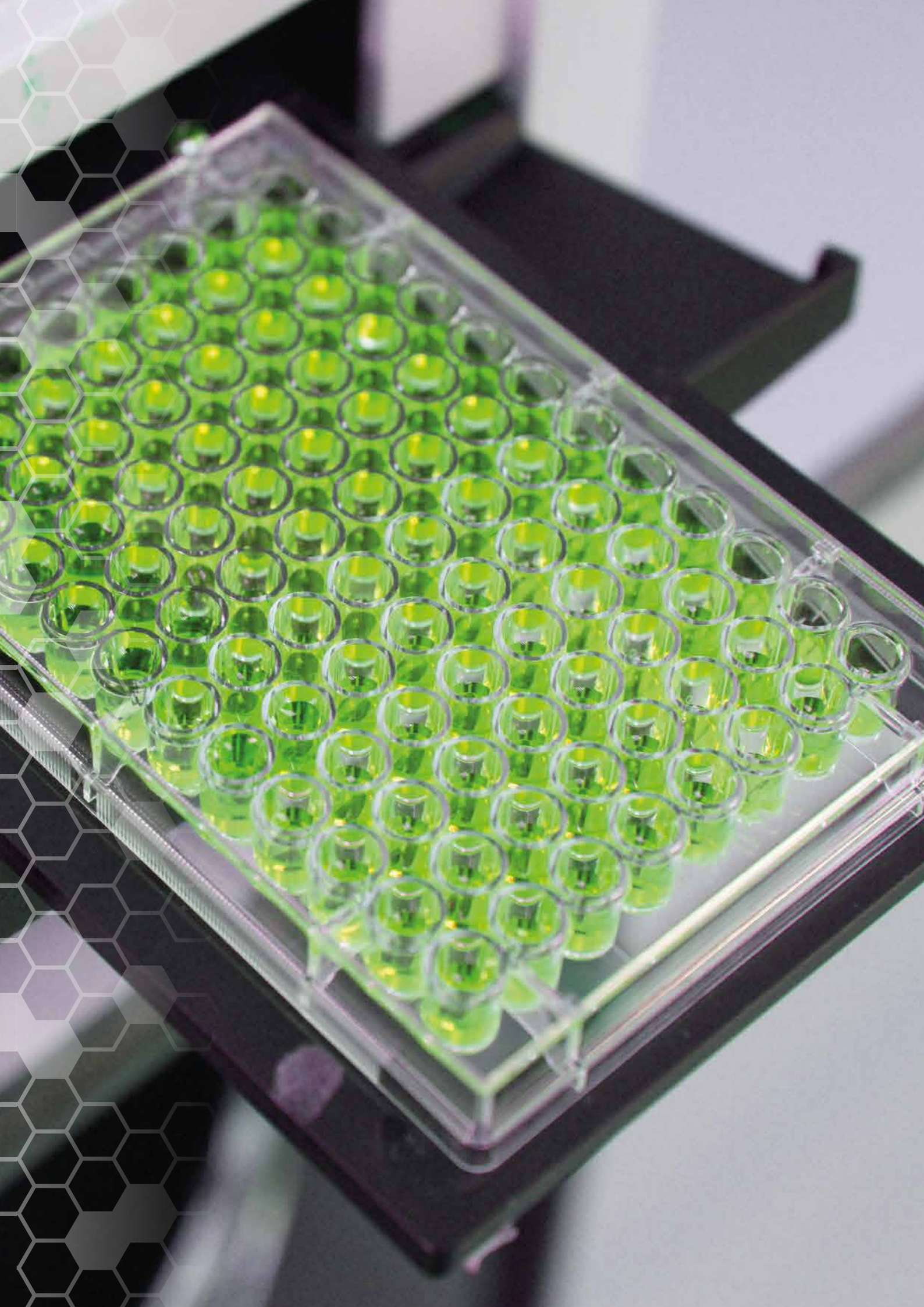


Methodology

ELISA (Enzyme-Linked Immuno Sorbent Assay) is one of the most common used analytical methodology in immunological and clinical laboratories and it is possible to determine even very low concentrations with relatively high specificity and sensitivity.

Determination of specific antibodies in our kits is based on the indirect (sandwich) ELISA method, where a known antigen is bound to a solid carrier - a microtiter plate. The kit processing process itself takes place in several steps, between which unreacted components are removed by washing. After the binding of the antigen-antibody-conjugate complex, the TMS substrate is added to the reaction, which in a positive case is cleaved by an enzyme bound to the secondary antibody and thus a colored product is formed. The reaction is subsequently stopped after a precisely determined time by adding sulfuric acid. The intensity of the resulting staining is proportional to the concentration of the determined antibody.

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Contents of ELISA test kits



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PLATE	8 wells break-apart strips coated with antigen
CAL	Calibrators * 1
CONTROL +	Control sample positive 1
CONTROL -	Control sample negative 1
CONTROL CO	Control sample cut off ** 1
CONJUGATE	Conjugate HRP 2
SUBSTRATE	TMB substrate
SAMPLEBUF	Sample diluent
WASHBUF	Wash buffer
STOP	Stop solution

* only for quantitative determination

** only for semi-quantitative determination



ELISA test kits

- quantitative determination of specific antibodies


REF	Test kit	Σ	Class	Range [U.ml ⁻¹]	Limit values [U.ml ⁻¹]
E-211	anti-DNP-G	48	IgG	6,25 - 100	< 17-22 >
E-411	anti-DNP-II-G	96	IgG	6,25 - 100	<17 - 22>
E-230	anti-GLIADIN-deam.-II-A,G	96	IgA	5 - 80	< 13-15 >
E-231	anti-GLIADIN-deam.-II-A	96	IgG	5 - 80	< 13-15 >
E-232	anti-GLIADIN-deam.-II-G	48/48	IgA/IgG	5 - 80	< 13-15 >
E-233	anti-GLIADIN-native-II-A	96	IgA	5 - 80	< 11-14 >
E-234	anti-GLIADIN-native-II-G	96	IgG	5 - 80	< 11-14 >
E-235	anti-GLIADIN-native-II-A,G	48/48	IgA/IgG	5 - 80	< 11-14 >
E-243	anti-MILK-II-M	96	IgM	6,25 - 100	< 14-17 >
E-244	anti-MILK-II-A	96	IgA	6,25 - 100	< 11-14 >
E-245	anti-MILK-II-G	96	IgG	6,25 - 100	< 15-20 >
E-246	anti-MILK-II-A,G	48/48	IgA/IgG	6,25 - 100	
E-241	anti-MILK-III-A,G,M	48/48/48	IgA/IgG/IgM	6,25 - 100	
E-244/200	anti-MILK-II-A/200	96	IgA	6,25 - 200	< 11-14 >
E-245/200	anti-MILK-II-G/200	96	IgG	6,25 - 200	< 15-20 >
E-346	anti-ASCA-II-A	96	IgA	6,25 - 100	<17 - 22>
E-347	anti-ASCA-II-G	96	IgG	6,25 - 100	<22 - 28>
E-348	anti-ASCA-II-A,G	48/48	IgA	6,25 - 100	< 17-22 >
			IgG	6,25 - 100	< 22-28 >
E-351	anti-CANDIDA-II-A	96	IgA	6,25 - 100	< 8-20 >
E-352	anti-CANDIDA-II-G	96	IgG	6,25 - 100	< 12-30 >
E-353	anti-CANDIDA-II-M	96	IgM	6,25 - 100	< 12-30 >
E-354	anti-CANDIDA-III-A,G,M	48/48/48	IgA/IgG/IgM	6,25 - 100	

Calibrators in the test kits are calibrated against an internal reference standard.

We recommend evaluation using limit values of individual kits.

ELISA test kits

- semi-quantitative determination of specific antibodies

REF	Test kit		Class
E-250/E-450	anti-CASEIN-A/-II-A	48/96	IgA
E-251/E-451	anti-CASEIN-G/-II-G	48/96	IgG
E-260/E-460	anti- β -LACTOGLOBULIN-A/-II-A	48/96	IgA
E-261/E-461	anti- β -LACTOGLOBULIN-G/-II-G	48/96	IgG
E-280/E-480	anti- α -LACTALBUMIN-A/-II-A	48/96	IgA
E-281/E-481	anti- α -LACTALBUMIN-G/-II-G	48/96	IgG
E-270/E-470	anti-LACTOSE-A/-II-A	48/96	IgA
E-271/E-471	anti-LACTOSE-G/-II-G	48/96	IgG
E-380/E-440	anti-OVALBUMIN-A/-II-A	48/96	IgA
E-381/E-441	anti-OVALBUMIN-G/-II-G	48/96	IgG
E-390/E-490	anti-SOYBEAN-A/-II-A	48/96	IgA
E-391/E-491	anti-SOYBEAN-G/-II-G	48/96	IgG
E-243 SE	anti-MILK-II-M-semiquantitative	96	IgM
E-244 SE	anti-MILK-II-A-semiquantitative	96	IgA
E-245 SE	anti-MILK-II-G-semiquantitative	96	IgG

We recommend evaluation using calculated positivity indexes IP:

- Positivity index of negative values < 1
- Positivity index of cut off values 1 - 1,3
- Positivity index of positive values > 1,3

A
M
E
G
B
I
O





Preferences

Product preferences

- ✔ CE certified diagnostic test kits
- ✔ Short incubation times
- ✔ Test kits are optimised to automatic processing on EUROLab Workstation ELISA automat
- ✔ High analytical sensitivity
- ✔ High analytical specificity
- ✔ Elimination of processing mistakes
- ✔ Possibility of customisation of test kits of client's requirements

Cooperation preferences

- ✔ Strong pro-client approach - stable customer service.
- ✔ Quick response to client requests
- ✔ The only Slovak manufacturer of ELISA test kits - possibility of export outside the EÚ
- ✔ More than 35 years of experience in in vitro diagnostics
- ✔ Possibility of consultations and assistance in setting up the processing process



A STABLE PARTNER IN DIAGNOSTICS

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