Dermatology Profile ELISA (IgG)

- **ELISA for the detection of the six most important autoantibodies in bullous autoimmune dermatoses**
- **Simultaneous investigation in a single test run**
- **Cost-effective and simple interpretation of results due to the use of a universal calibrator**

Technical data

Antigens	BP180, BP230, desmoglein 1 and desmoglein 3, envoplakin, collagen type VII
Calibration	Semiquantitative; calculation of a ratio from the extinction of the sample and the extinction of the antigen-specific factor x extinction of the calibrator
Result interpretation	EUROIMMUN recommends interpreting results as follows: Ratio < 1.0: negative Ratio ≥ 1.0: positive
Sample dilution	Serum or plasma, 1 : 101 in sample buffer
Reagents	Ready for use, with the exception of the wash buffer (10x)
Test procedure	30 min / 30 min / 15 min at room temperature
Measurement	450 nm, reference wavelength between 620 nm and 650 nm
Test kit format	12 microplate strips each containing 8 wells; kit includes all necessary reagents
Order no.	**EA 1490-1208-1 G**

Clinical significance

Bullous autoimmune dermatoses belong to the organ-specific autoimmune diseases. They are characterised by the formation of autoantibodies against structural proteins of the skin. These structural proteins establish the cell-to-cell contact in keratinocytes within the epidermis and the adhesion of the epidermis to the dermis. Bullous autoimmune dermatoses are divided in four main groups by means of their target antigens and the localisation of the blisters: pemphigoid diseases, pemphigus diseases, including paraneoplastic pemphigus, epidermolysis bullosa acquisita (EBA) and dermatitis herpetiformis (DH). In pemphigus diseases the blisters are formed intraepidermally, whereas in pemphigoid diseases, EBA and DH they occur subepidermally. The diagnosis of bullous autoimmune dermatoses is based on a combination of the clinical picture with the detection of autoantibodies against structural proteins of the skin or against recombinant, biochemically purified antigens. In addition to the Dermatology Profile ELISA (IgG) with the most important and indicative autoantigens, ELISA single tests and, as a different test method, various dermatology mosaics (IIFT) are available. With the aid of these procedures a previously unattained diagnostic certainty can be achieved for pemphigoid and pemphigus diseases (pemphigus foliaceus, pemphigus vulgaris), EBA and DH. Morevoer, the disease activity, disease course and indications for paraneoplastic pemphigus can be monitored.

Diagnostic application

The Dermatology Profile ELISA (IgG) comprises the six most important structural proteins of the skin, against which autoantibodies produced in bullous autoimmune dermatoses are directed. This allows multiparameter analysis in a single test run.

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Detection limit

The lower detection limit is defined as the mean value of an analyte-free sample plus three times the standard deviation and is the smallest clearly detectable antibody titer. The lower detection limit of the Dermatology Profile ELISA (IgG) is, on average, ratio 0.1 for all parameters.

Reference range

The levels of autoantibodies against the skin proteins used in the Dermatology Profile ELISA (IgG) were determined in sera from 100 healthy blood donors. With a cut-off of ratio 1.0 the prevalences were as follows (see table).

Antibodies against	Prevalence (%)
BP180	3.0
BP230	1.0
Desmoglein 1	1.0
Desmoglein 3	1.0
Evoplakin	2.0
Collagen type VII	0.0

Reproducibility

The reproducibility was investigated by determining the intra- and inter-assay coefficients of variation using at least three sera. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on four determinations performed in six different test runs. The mean coefficients of variation (CVs) are shown in the table.

	Intra-assay variation n = 20	Inter-assay variation n = 4 x 6
Antigen	CV (%)	CV (%)
BP180	2.3	2.8
BP230	3.6	7.2
Desmoglein 1	3.4	6.8
Desmoglein 3	4.2	4.8
Envoplakin	2.3	3.5
Collagen type VII	5.7	6.1

Sensitivity and specificity

The specificities of the Dermatology Profile ELISA (IgG) based on the data of the monospecific EUROIMMUN ELISAs, from which the profile is configured, are between 97.4 % and 99.6 % in patients with rheumatic diseases, bullous autoimmune dermatoses and in healthy blood donors.

Antigen	Panel	n	Positive
BP180	Bullous pemphigoid	118	106 (89.88 %)
	Pemphigus gestationes	20	20 (100 %)
BP230	Bullous pemphigoid	118	67 (56 %)
	Pemphigus gestationes	20	1 (5.0 %)
Desmoglein 1	Pemphigus foliaceus	50	48 (96 %)
	Pemphigus vulgaris	71	33 (46.5 %)
Desmoglein 3	Pemphigus vulgaris	71	71 (100 %)
	Pemphigus foliaceus	50	0 (0 %)
Envoplakin	Paraneoplastic pemphigus	28	24 (85.7 %)
Collagen type VII	EBA patients	70	65 (92.9 %)

Literature references

1. Hertl M, Jedlickova H, Karpati S, Marinovic B, Uzun S, Yayli S, Mimouni D, Borradori L, Feliciani C, Ioannides D, Joly P, Kowalewski C, Zambruno G, Zillikens D, Jonkman MF. Pemphigus. S2 Guideline for diagnosis and treatment - guided by the European Dermatology Forum (EDF) in cooperation with the European Academy of Dermatology and Venerology (EADV) J Eur Acad Dermatol Venereol (2014 Oct 22) 1-10.
2. Probst* C, Komorowski* L, Dähnrich* C, Rosemann* A, Schlumberger* W, Wandinger* KP, Mothes T, Stöcker* W. (*EUROIMMUN AG). Designer antigens as diagnostic targets for (auto)antibody determination. In: Conrad K et al. (Hrsg.). From Etiopathogenesis to the Prediction of Autoimmune Diseases: Relevance of Autoantibodies. Pabst Science Publishers 5 (2007) 619-632
3. Schmidt E, Zillikens D. The diagnosis and treatment of autoimmune blistering skin diseases. Dtsch Arztebl Int 108 (2011) 399-405

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EA_1490_D_UK_A01, 10/2015