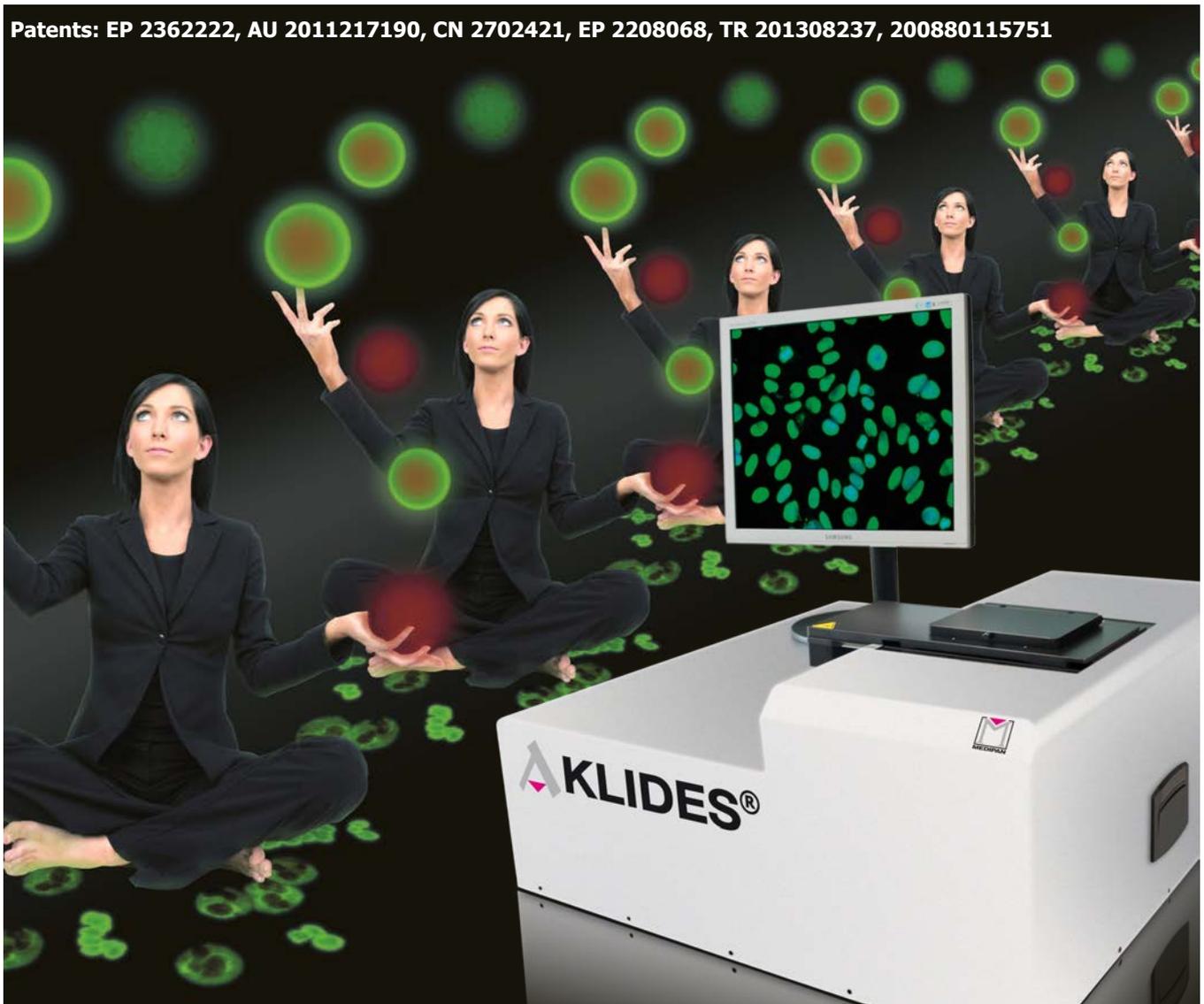


AKLIDES[®] CytoBead[®] Assays

The Automated Way of CytoBead[®]

Patents: EP 2362222, AU 2011217190, CN 2702421, EP 2208068, TR 201308237, 200880115751

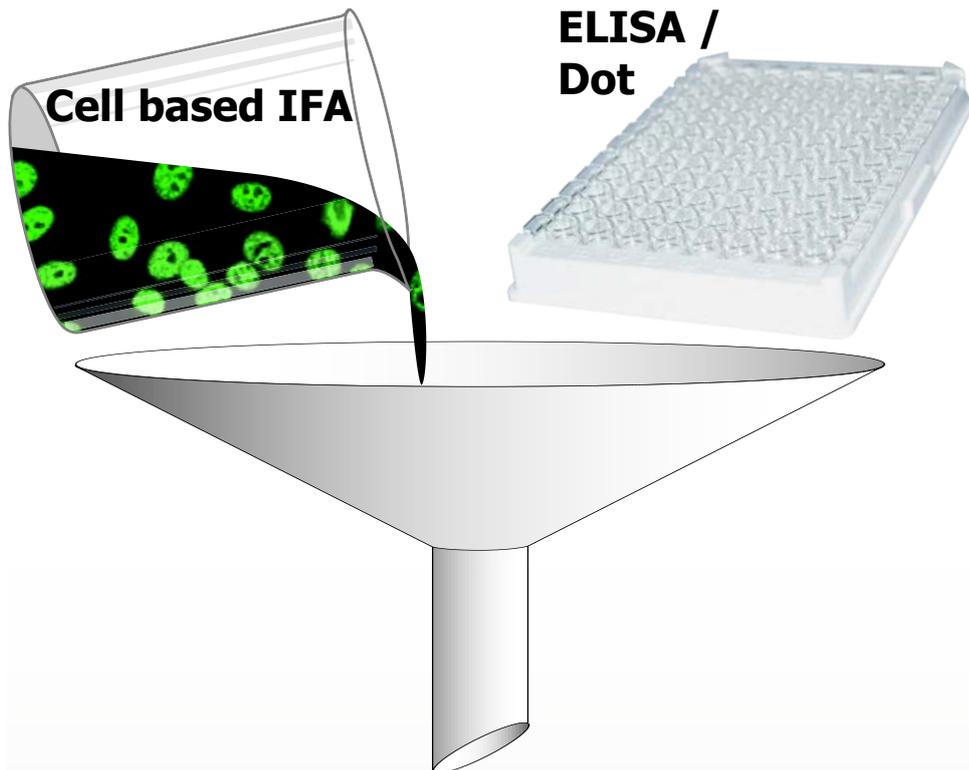


Classical Handling of Autoimmune Diagnostics

2-Step
Diagnostics

1st Screening

2nd Confirmation



1-Step
Diagnostics

Next Generation IFA

CytoBead[®]
Technology

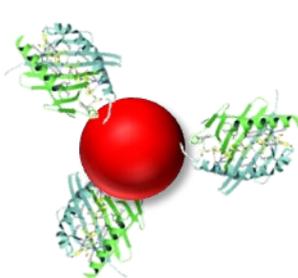
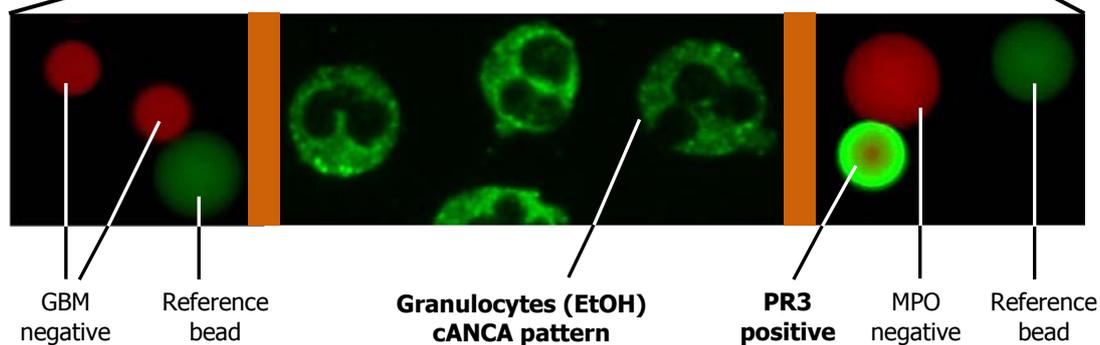
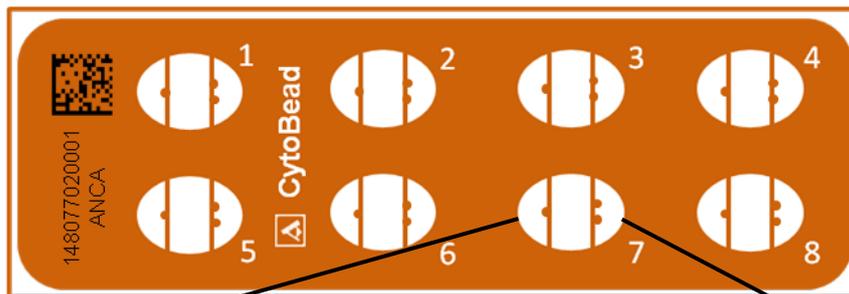
- ANA / ANA 2
- ANCA / RPGN
- CeliAK



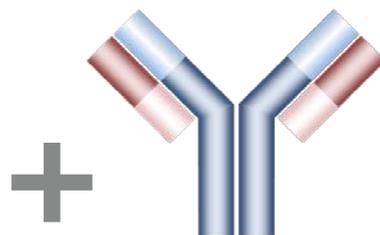
Automated evaluation with the AKLIDES[®] system.

Screening and Confirmation at once! One Well - One Step - One Assay

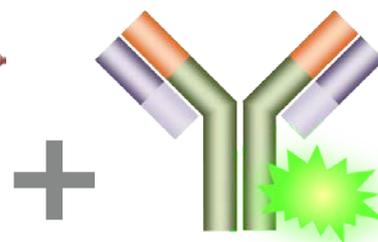
Example AKLIDES[®] CytoBead[®] ANCA



**Antigen coated
bead (e.g. PR3)**



**Primary antibody
(patient sera)**



**Secondary antibody
fluorochrome labeled**

**AKLIDES[®] CytoBead[®] is time saving and economical.
Quantitative determination of autoantibodies with AKLIDES[®].**

Evaluation with the Platform Technology AKLIDES®

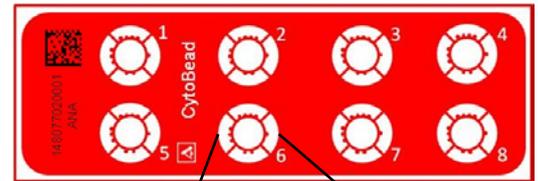
- Fully automated screening and objective evaluation of cells and tissues as well as automated microbead identification and measurement of ligand fluorescence intensity of the beads
- Standardized and reliable results between different instruments due to intensity calibration
- ELISA typical quantification of antibodies in U/ml or IU/ml with lot specific standard curves using 4 point calibration
- Automatic titer prediction → only one sample dilution is required
- Overall report of all relevant quantitative results in pdf- and xls-format
- Single well report in pdf-format (including cell images)

Slide Report

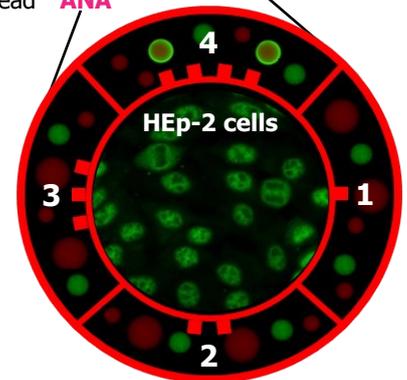
	OT: 652 Project: 15427001		Lot: 15427001		1 / 1	
	Test: 4270 CytoBeadANCA quant 08 Data measured: 2015-05-28 12:10:59 (qc) Data confirmed: 2015-05-28 12:18:03 (qc) Institute: MEDIPAN AKLIDES Nr. 91 Login: qc Design:	5 ID: MPO Dilution: 1/160 Cells + Intensity 569.00 Pattern + pANCA Titer 640 Beads + PR3 - 1.4 IU/ml MPO + 70.2 IU/ml GBM - 4.6 U/ml	1 ID: Control (CII) Dilution: Cells + Intensity 579.00 Pattern + pANCA Titer 2560 Beads + PR3 + >100.0 IU/ml MPO + >100.0 IU/ml GBM + 20.9 U/ml			
		6 ID: dsDNA Dilution: 1/20 Cells + Intensity 489.00 Pattern + nuclear Titer 80 Beads - PR3 - 1.4 IU/ml MPO - 2.8 IU/ml GBM - 2.2 U/ml	2 ID: Control (CIII) Dilution: Cells + Intensity 560.00 Pattern + cANCA Titer 2560 Beads + PR3 + >100.0 IU/ml MPO - 2.2 IU/ml GBM - 3.0 U/ml			
		7 ID: Dilution:	3 ID: Dilution:			
						

Fast and easy ANA Diagnostics

ANA (**A**nti-**N**uclear **A**ntibodies) are autoantibodies (AAB) which recognize conserved nuclear antigens. ANA show a characteristic staining of nuclear structures with indirect immunofluorescence on human epithelial cells (HEp-2). The confirmation of ANA is done in accordance to the target antigens.



CytoBead[®] ANA



Unique Combination of HEp-2 Cells with antigen coated Microbeads

Advantages of the CytoBead[®] ANA / ANA 2

- **Screening** with standardized HEp-2 cells
- **Confirmation** of 8 ANA specificities with microbeads

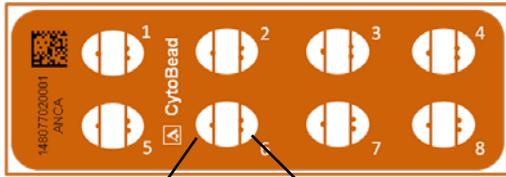
CytoBead[®] ANA / ANA 2

HEp-2 cell pattern	Com-part-ment	Bead (positive)	Quantification	Antigen	Clinical relevance
Homogeneous	3		IU/ml	dsDNA	Systemic lupus erythematosus (SLE)
			U/ml	Scl-70	Marker for progressive systemic sclerosis (PSS)
Speckled	2		U/ml	Sm	Sm antibodies highly specific for SLE; high anti-nRNP titers specific for mixed connective tissue disease (MCTD) together with other ANAs in rheumatoid arthritis (RA), SLE, PSS
			U/ml	nRNP	
	4		U/ml	Ro60/SS-A	Often in primary Sjögren's syndrome, anti-SS-A often in neonatal lupus
			U/ml	Ro52/SS-A	
	1		U/ml	La/SS-B	
Centromere	1		U/ml	CENP-B	Marker for CREST syndrome, rarely in diffuse scleroderma and Raynaud's phenomenon

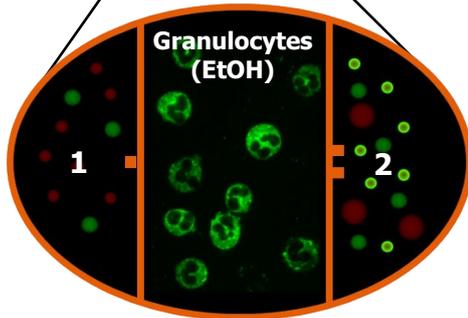
CytoBead[®] ANA 2, Jo-1 microbead replaces CENP-B microbead

Cytoplasmic	1		U/ml	Jo-1	Polymyositis, dermatomyositis
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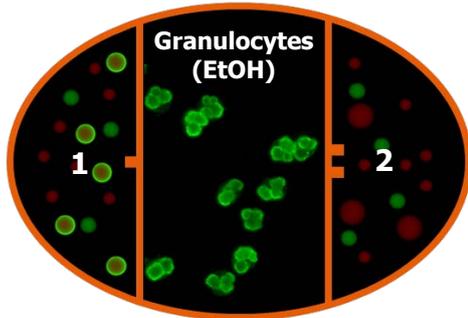
- Small bead: negative
 ● Large bead: negative
 ● Reference bead in each compartment



CytoBead® ANCA



CytoBead® RPGN



Fast and easy ANCA Diagnostics

ANCAs (Anti-Neutrophil Cytoplasmic Antibodies) play an important role in the diagnosis of ANCA associated vasculitides (AAV). According to international guidelines ANCA screening is performed using indirect immunofluorescence (IIF) with ethanol fixed granulocytes, whereby cytoplasmic (cANCA; antigen PR3) and perinuclear (pANCA; antigen MPO) IIF patterns can be differentiated.

Unique Combination of Ethanol fixed Granulocytes with antigen coated Microbeads

Advantages of the CytoBead® ANCA

- **Screening** with standardized ethanol fixed granulocytes
- **Confirmation** of 3 antibody specificities with microbeads

RPGN (Rapidly Progressive Glomerulo-Nephritis)

Especially for Use in Emergency Situations

Advantages of the CytoBead® RPGN

- **Screening** with standardized ethanol fixed granulocytes
- **Confirmation** of 4 antibody specificities with microbeads

CytoBead® ANCA / RPGN

Cell pattern	Compartment	Bead (positive)	Quantification	Antigen	Clinical relevance
negative	1		U/ml	GBM	Goodpasture syndrome
cytoplasmic	2		IU/ml	PR3	Granulomatosis with polyangiitis
perinuclear	2		IU/ml	MPO	Microscopic polyangiitis, eosinophilic granulomatosis with polyangiitis, polyarteritis nodosa

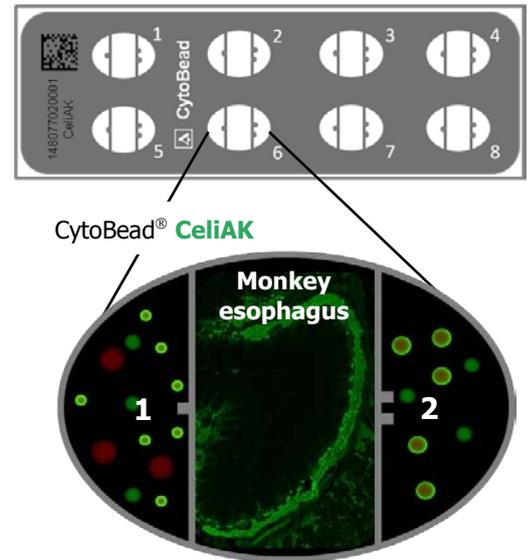
Additionally in CytoBead® RPGN

nuclear	1		IU/ml	dsDNA	Lupus nephritis
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● Small bead: negative ● Large bead: negative ● Reference bead in each compartment

Fast and easy Diagnostics of Celiac Disease or Dermatitis Herpetiformis and Detection of IgA Deficiency

Celiac disease (gluten induced enteropathy) is an intolerance to gluten. This intolerance leads to extended lesions of the mucous membranes, which manifests as a "flat" mucosa. Gliadin, the alcohol-soluble fraction of gluten, is responsible for the emergence of celiac disease. Gliadin induces inflammatory processes in the small intestinal mucosa as part of the humoral and cellular immune processes. The diagnosis of celiac disease is characterized through highly specific autoantibodies (AAB) against transglutaminase 2 (tissue transglutaminase, tTG) and deamidated gliadin (DG). Endomysial antibodies (EmA) are directed against extracellular tTG. Celiac specific antibodies are typically of IgA class. In celiac patients with IgA deficiency, antibodies of the IgG type form the basis of diagnostics.



Unique Combination of esophageal Tissue with antigen coated Microbeads

Advantages of the CytoBead[®] CeliAK

- **Screening** with standardized monkey esophageal tissue
- **Confirmation** of 3 antibody specificities with microbeads

CytoBead[®] CeliAK

Pattern Tissue	Com-part-ment	Bead (positive)	Quantification	Antigen	Clinical relevance
honeycomb pattern of muscularis mucosa	1		U/ml	tTG	Celiac disease, Dermatitis herpetiformis
	1		U/ml	DG	
	2		U/ml	IgA	IgA deficiency

-  **Small bead: negative**
  **Large bead: negative**
  **Reference bead in each compartment**

Order information

AKLIDES[®] CytoBead[®] ANA	Order no. 4272	€ €
AKLIDES[®] CytoBead[®] ANA 2	Order no. 4277	€ €
AKLIDES[®] CytoBead[®] ANCA	Order no. 4270	€ €
AKLIDES[®] CytoBead[®] RPGN	Order no. 4281	€ €
AKLIDES[®] CytoBead[®] CeliAK	Order no. 4271	€ €

Literature

Simultaneous detection of celiac disease-specific IgA antibodies and total IgA.

Grossmann K, Röber N, Hiemann R, Rödiger S, Schierack P, Reinhold D, Laass M.-W., Conrad K, Roggenbuck, D.
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Scholz J, Grossmann K, Knütter I, Hiemann R, Sowa M, Röber N, Rödiger S, Schierack P, Reinhold D, Bogdanos DP, Meroni PL, Radice A, Conrad K, Roggenbuck D.
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Sowa M, Grossmann K, Scholz J, Röber N, Rödiger S, Schierack P, Conrad K, Roggenbuck D, Hiemann R.
J Med Lab 2014; 38:309-17.



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