

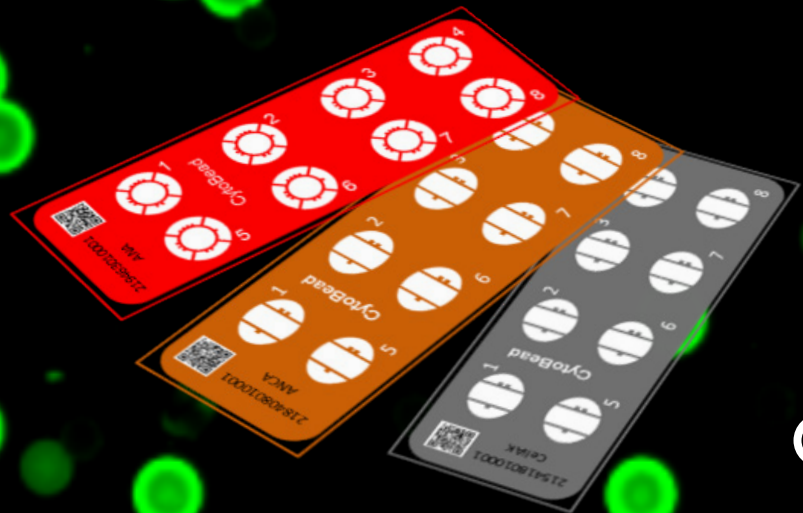
IFA

**BytoBead**<sup>®</sup>

For manual and automated assessment



# Multiparameter IFA Technology



## Product Highlights

- Second generation IFA by combining of screening and confirmation
- Integration with automated evaluation systems
- Multiplex analysis capability

# YOUR RELIABLE PARTNER IN AUTOIMMUNE DIAGNOSTICS

20 Years of Experience, 150 Partners in more than 100 Countries

## CytoBead® Technology

### Next Generation Multiparameter IFA Technology

#### CytoBead® Technology

The CytoBead® technology is an innovative approach in the analysis of autoantibodies (AAb) associated with autoimmune diseases. It facilitates the interpretation of indirect immunofluorescence (IFA) on cellular and tissue substrates and quantitative multiplex analysis of AAb using addressable microbead immunoassays within a single reaction environment. Fundamentally, the CytoBead® technology integrates two crucial components of autoantibody analysis:

**1. Screening of Autoantibodies:** By employing cell- or tissue-based immunofluorescence tests (IFA), the CytoBead® technology allows for the screening of AAb in patient samples. This initial screening phase enables the identification of potentially positive samples containing autoantibodies targeting various cellular components.

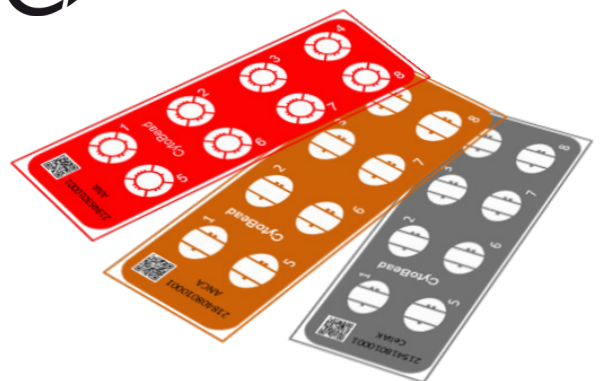
**2. Confirmation of Autoantibodies:** Through the use of microbead immunoassays, the CytoBead® technology facilitates the differentiation of AAb and determination of their specificity.

By combining screening and confirmation into a single step, the CytoBead® technology significantly enhances the efficiency and accuracy of autoimmune disease diagnosis. Moreover, it enables multiplex analysis, allowing for the simultaneous detection of multiple AAb within a single sample.

The utilization of specialized automated platforms such as AKLIDES® or akiron® systems complements the CytoBead® technology by facilitating the automated interpretation of results. These systems leverage advanced algorithms and software to interpret fluorescence patterns and quantify the presence of AAb in patient samples.

With the CytoBead® technology, laboratories can streamline their analysis processes, resulting in faster turnaround times, increased accuracy, and reduced variability in result interpretation. Ultimately, this integration enhances the efficiency and reliability of autoimmune disease diagnosis and management.<sup>1,2</sup>

**CytoBead®**



Available for:  
ANA/ANA 2 | ANCA | CeliAK

<sup>1</sup> Sowa M., Hiemann R., Schierack P., Reinhold D., Conrad K., Roggenbuck D.: Next-Generation Autoantibody Testing by Combination of Screening and Confirmation—the CytoBead® Technology Clin Rev Allerg Immunol 2017, 53:87–104.

<sup>2</sup> 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. The CytoBead assay - a novel approach of multiparametric autoantibody analysis in the diagnostics of systemic autoimmune diseases.

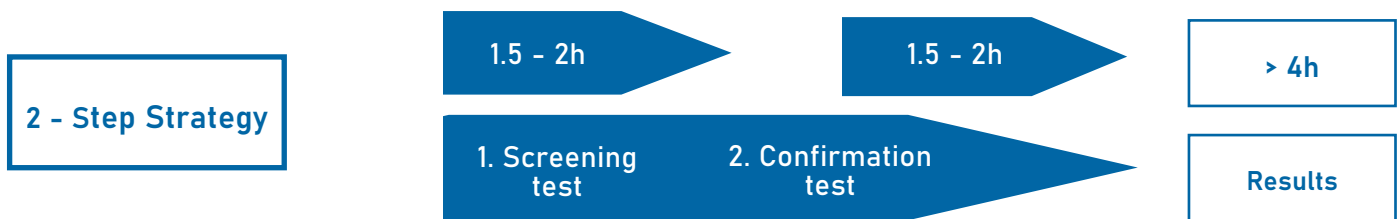
# CytoBead® Technology



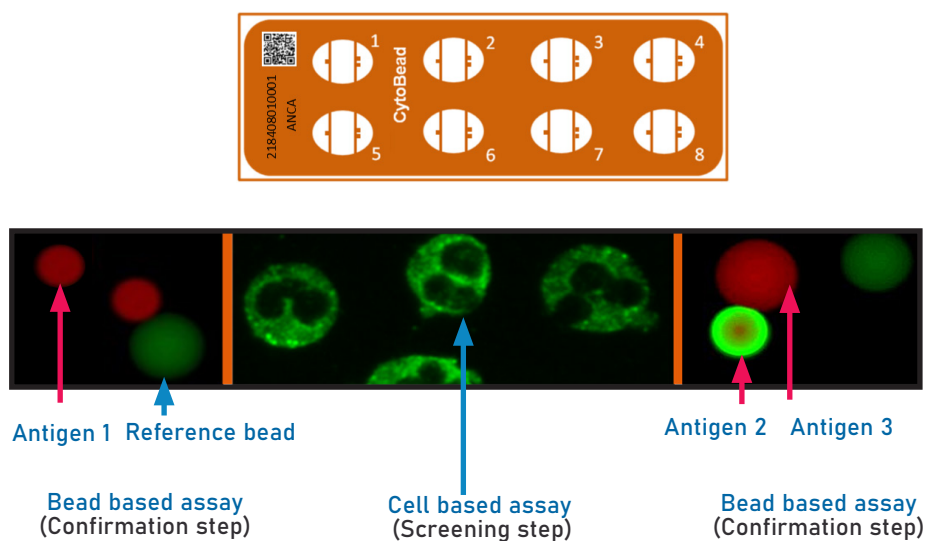
## CytoBead® Technology



## Standard workflow in Autoimmune Diagnostics



## How do CytoBead® assays work?



### Compartmented slide well:

- Screening on cells (classic IFA) in the central compartment
- Confirmation with a bead based assay in the side compartments

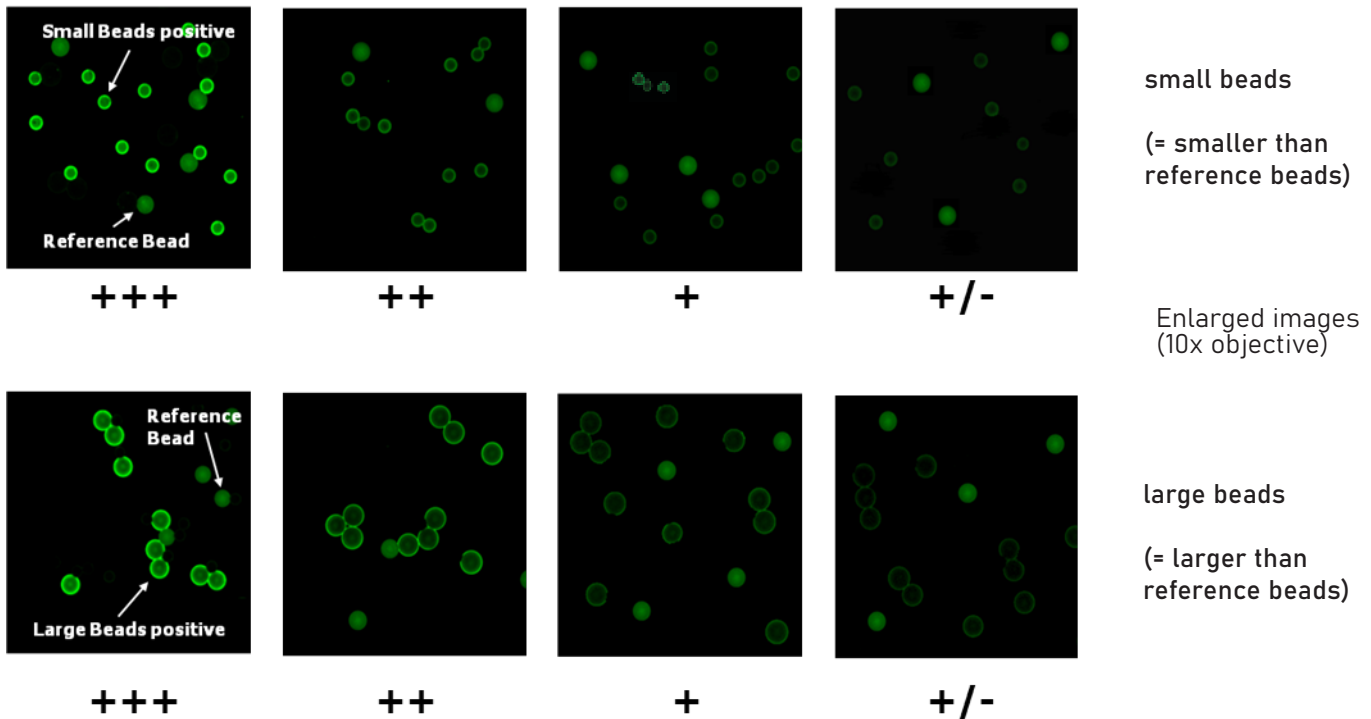
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## Manual CytoBead® Evaluation

Manual Evaluation using the CytoBead® Technology

Semi-quantitative evaluation of fluorescence intensity

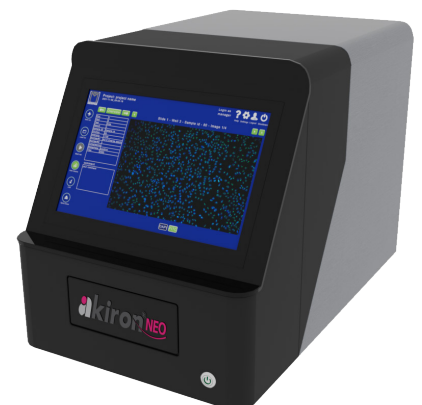


## Automatic CytoBead® Evaluation

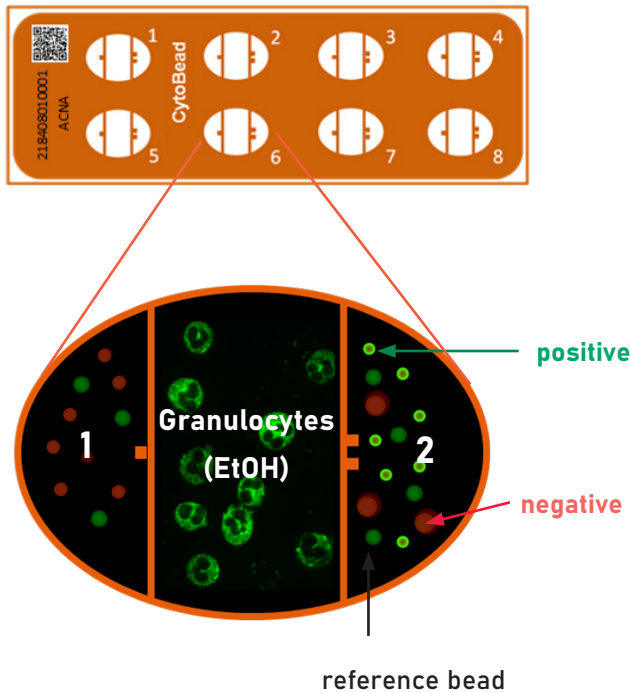
Evaluation by akiron® NEO

The akiron® NEO is a compact benchtop IFA analyzer for automated digital imaging of immunofluorescence slides to support the diagnosis of autoimmune diseases. Its AI-based software allows for objective ANA/ANCA pattern recognition and intensity evaluation in about 35 seconds and supports standardized evaluation of other immunofluorescence assays, including antibodies *Crithidia luciliae* (CLIFT, dsDNA), various tissues sections (e.g. EmA). In addition, the use of CytoBead® technology in conjunction with Akiron® NEO allows the quantification of antibody activity in U/mL or IU/mL based on a standard curve.

**akiron®** NEO



# CytoBead® ANCA






## 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 immunofluorescence (IFA) with ethanol-fixed granulocytes, whereby cytoplasmic (cANCA; antigen PR3) and perinuclear (pANCA; antigen MPO) IFA patterns can be differentiated.

Unique combination of granulocytes with antigen coated microbeads
<b>Advantages of CytoBead® ANCA</b> <ul style="list-style-type: none"> <li>• Screening with standardized ethanol fixed granulocytes</li> <li>• Confirmation of 3 ANCA-specific antigens</li> </ul>

## CytoBead® ANCA

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

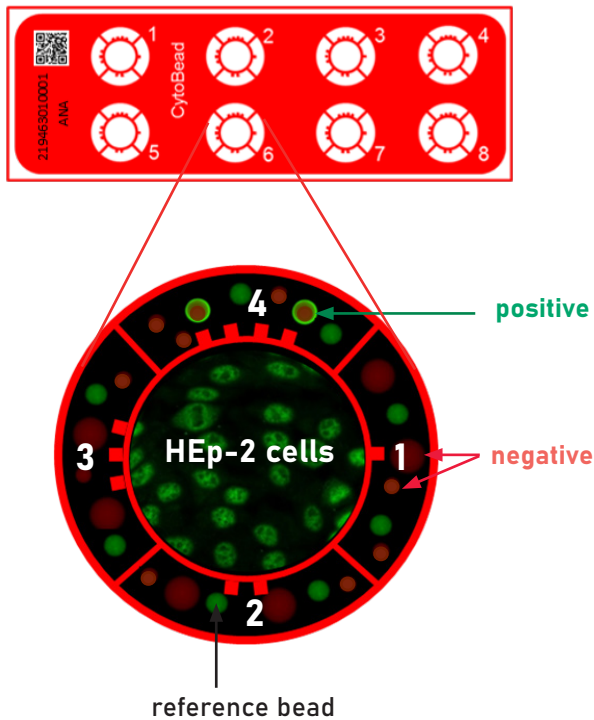
Romero-Sánchez C, Benavides-Solarte M, Galindo-Ibáñez I, Ospina-Caicedo AI, Parra-Izquierdo V, Chila-Moreno L, Villa Amanda, Casas-Gómez MC, Angarita I, Bautista-Molano W, Romero-Álvarez V, Bello-Gualteroa JM. Reumatología Clínica 2020, 473-479. Frequency of positive ANCA test in a population with clinical symptoms suggestive of autoimmune disease and the interference of ANA in its interpretation.

Sowa M, Grossmann K, Knütter I, Hiemann R, Röber N, Anderer U, Csernok E, Bogdanos DP, Borghi MO, Meroni PL, Schierack P, Reinhold D, Conrad K, Roggenbuck D. PLoS One 2014, 16;9(9). Simultaneous automated screening and confirmatory testing for vasculitis-specific ANCA

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## CytoBead® ANA / ANA 2



### Fast and easy ANA diagnostics

ANA (Anti-Nuclear Antibodies) are autoantibodies 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.

Unique combination of HEp-2 cells with antigen coated microbeads

#### Advantages of CytoBead® ANA / ANA 2

- Screening with standardized HEp-2 cells
- Confirmation of 8 ANA-specific antigens

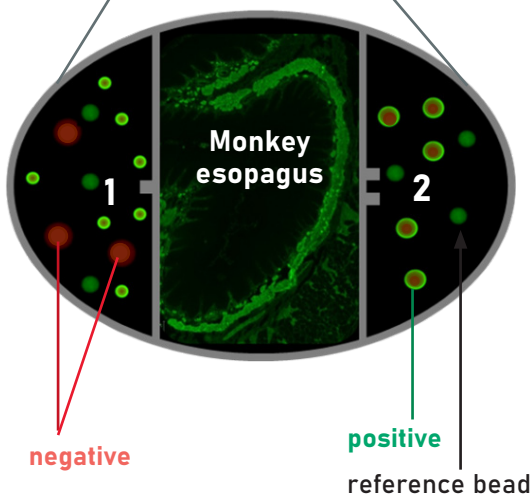
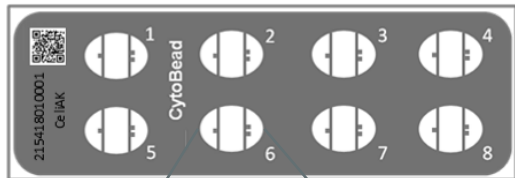
### CytoBead® ANA / ANA 2

HEp-2 cell pattern	Compartment	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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# CytoBead® CeliAK



**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 against transglutaminase 2 (tissue transglutaminase, tTG) and deamidated gliadin (DG). Endomysial antibodies (EmA) are directed against extracellular tTG. Celiac specific antibodies are usually of IgA class but in patients with IgA deficiency the IgG class is of diagnostic significance.

Unique combination of esophageal tissue with antigen coated microbeads

### Advantages of CytoBead® CeliAK

- Screening with standardized monkey esophageal tissue
- Confirmation of 3 celiac-specific antigens

## CytoBead® CeliAK

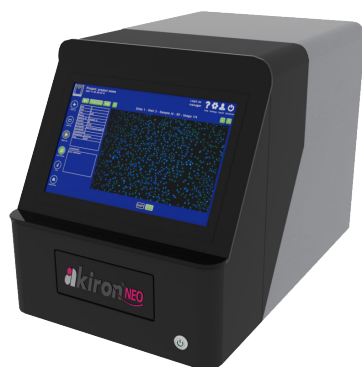
Tissue pattern	Compartment	Bead (positive)	Quantification	Antigen	Clinical relevance
honeycomb pattern of muscularis mucosa	1		U/mL	tTG	Celiac disease, dermatitis herpetiformis
	1		U/mL	DG	
	2		U/mL	Anti-IgA	IgA deficiency

Abdukhakimova D, Dossybayeva K, Grechka A, Almukhamedova Z, Boltanova A, Kozina L, Nurgaliyeva K, Hasanova L, Tanko MN, Poddighe D. Front. Med. 2021, 8:731067. Reliability of the Multiplex CytoBead CeliAK Immunoassay to Assess Anti-tTG IgA for Celiac Disease Screening.

Grossmann K, Röber N, Hiemann R, Rödiger S, Schierack P, Reinhold D, Laass M.-W., Conrad K, Roggenbuck, D. Auto Immun Highlights 2016, 7:2. Simultaneous detection of celiac disease-specific IgA antibodies and total IgA.

# CytoBead Assays® - Order Information

## Automated



## Automated CytoBead® Assays for akiron® NEO

Test	Reference	Determinations
AKLIDES® CytoBead® ANA	4272	80 (10 x 8)
AKLIDES® CytoBead® ANA 2	4277	80 (10 x 8)
AKLIDES® CytoBead® ANCA	4270	48 (6 x 8)
AKLIDES® CytoBead® CeliAK	4271	48 (6 x 8)
CE certified		

## Manual



## Manual CytoBead® Assays

Test	Reference	Determinations
CytoBead® ANA	8065	80 (10 x 8)
CytoBead® ANA 2	8220	80 (10 x 8)
CytoBead® ANCA	8063	48 (6 x 8)
CytoBead® CeliAK	8064	48 (6 x 8)
CE certified		

## Contact

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