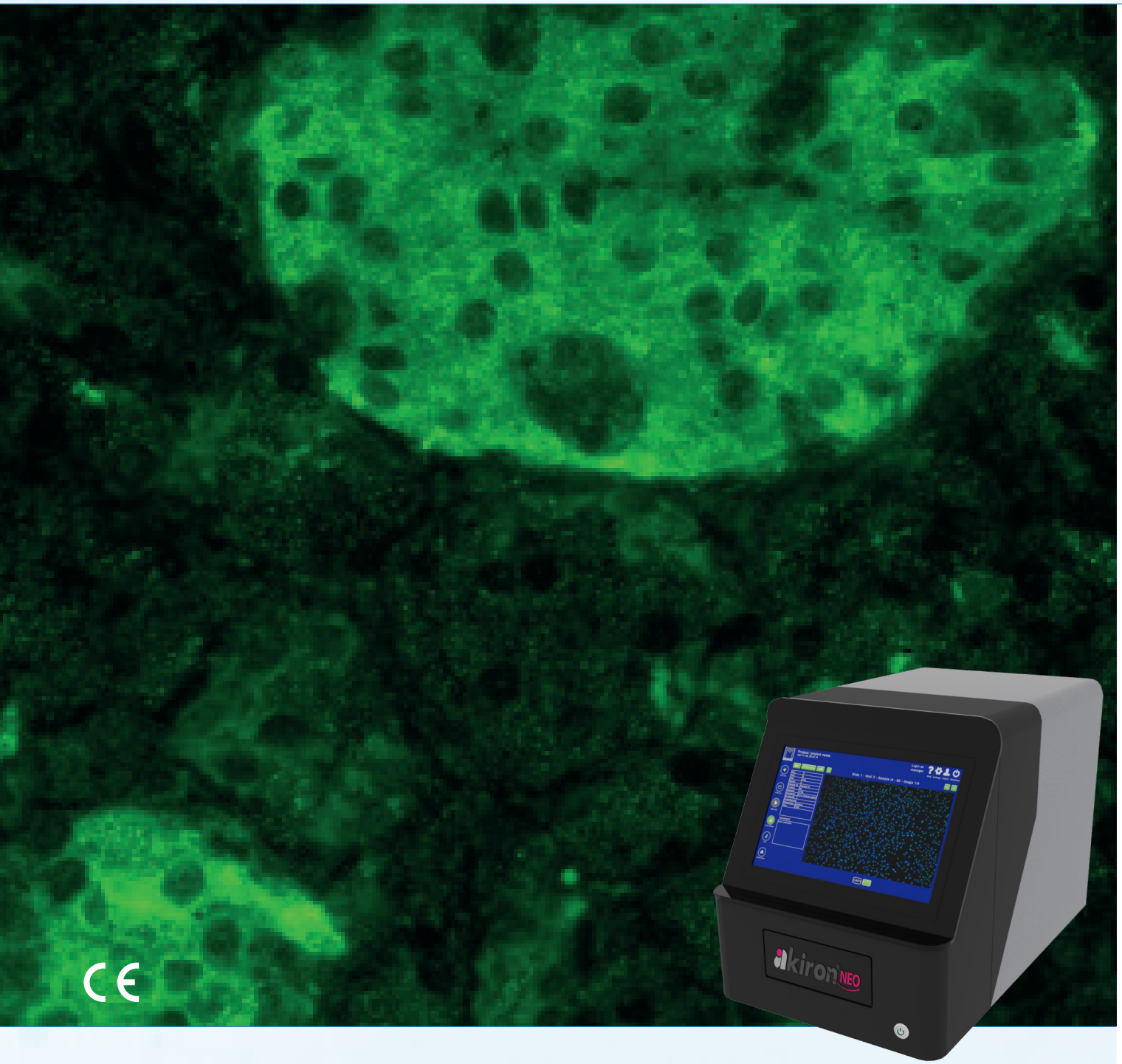
IFA

AKLIDES® ICA

Immunofluorescence assay (IFA) for the determination of IgG antibodies against antigens of islet cells

MEDIPAN



CE

Product Highlights

- Sensitive detection of IgG antibodies against islet cells
- Serological marker for autoimmune diabetes mellitus type 1
- Imaging with AKLIDES® or akiron® systems

Antibodies against Antigens of Islet Cells

and their Importance in the Diagnosis of Diabetes mellitus Type 1

Diabetes mellitus Type 1

Diabetes mellitus type 1 is a chronic autoimmune disease in which the insulin-producing beta cells of the islets of Langerhans in the pancreas are destroyed. The consequence of this destruction is a reduced insulin production, which results in high blood sugar levels as diabetes mellitus. Genetic predispositions and viral infections are considered risk factors, but the exact causes have not yet been fully clarified.

Islet Cell Antibodies

The destruction of the insulin-producing beta cells of the pancreas is based on the presence of islet cell antibodies (ICA), which are directed against different antigens of the pancreatic islet cells, such as glutamic acid decarboxylase (GAD_{65}), tyrosine phosphatase (insulinoma-associated antigen 2, IA_2), the zinc transporter 8 (ZnT8) as well as against insulin. Islet cell antibodies (ICA) can be detected in 70 – 80 % of patients with diabetes mellitus. The different antibodies usually appear months to years before the occurrence of elevated blood sugar levels and are therefore also considered important prognostic markers to identify patients with an increased risk of developing diabetes mellitus type 1. The combined detection of antibodies against GAD_{65}, IA_2, ZnT8 and insulin is considered an important method for diagnosing diabetes mellitus type 1 at the onset of the disease.

Antibodies against Glutamate Decarboxylase (GAD_{65})

Glutamic acid decarboxylase (GAD) catalyzes the synthesis of the neurotransmitter GABA in the brain and in the beta cells. Two isoforms of the enzyme are known: GAD_{65} with a molecular weight of 65 kDa and GAD_{67} with 67 kDa, respectively. Antibodies directed against GAD_{65} are observed in the majority of patients with diabetes mellitus type 1 and in a large number of individuals in the prediabetic phase. In contrast, antibodies directed against both GAD isoforms are found in patients with the very rare neuromuscular Stiff-man syndrome.

Antibodies against Tyrosine Phosphatase (IA_2)

Protein tyrosine phosphatase (insulinoma-associated antigen 2, IA_2) is localized in the granules of pancreatic beta cells. Antibodies against IA_2 can be detected in the majority of patients with diabetes mellitus type 1 and in a large number of individuals in the prediabetic phase. The appearance of antibodies against the protein tyrosine phosphatase IA_2 is correlated with rapid progression of the disease.

Antibodies against Insulin (IAA)

The appearance of antibodies against insulin (IAA) is another indication of progressive destruction of the pancreas in patients with diabetes mellitus type 1. Their prevalence is particularly increased in children and adolescents who have not yet been treated with insulin.

AKLIDES® ICA – Fluorescence Immunoassay for the Determination of IgG Antibodies against Antigens of Islet Cells of the Pancreas

Slides

The slides of the AKLIDES® ICA immunofluorescence assay are coated with tissue sections of monkey pancreas.

Test Principle

The immunofluorescence assay (IFA) is an immunoassay for the determination of specific antibodies. Tissue sections or cells containing the antigens of interest are immobilized on slides. If specific antibodies are present in the patient´s sample, they bind to the antigens. A secondary antibody conjugated with fluorescein-isothiocyanat (FITC) detects the generated immune complexes. The slides are examined using a fluorescence microscope. A specific fluorescent staining pattern based on histological distribution of the antigens in the cells or tissues demonstrates the presence of specific antibodies in the patient´s sample.

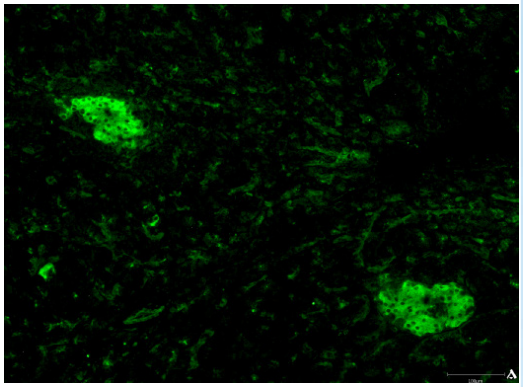
Precision

The precision of test results was assessed by the determination of the intra- and interassay variation with multiple samples of different antibody activities. No differences in the qualitative evaluation have been detected.

Diagnostic Sensitivity and Specificity

Sensitivity and specificity were assessed by the analysis of samples from patients with autoimmune diabetes mellitus type 1 and unselected blood donors.

	DIAGNOSTIC PERFORMANCE
Sensitivity	> 90 %
Specificity	> 99 %



AKLIDES® ICA

Immunofluorescence assay (IFA) for the determination of IgG antibodies against islet cells in human serum

HIGH QUALITY – MADE IN GERMANY

- Slides coated with tissue sections of monkey pancreas
- Detection of IgG antibodies against islet cells
- Support for the diagnosis of autoimmune diabetes mellitus type 1
- Ready-to-use reagents (exception: wash buffer)
- Quality assured handling in routine laboratories
- Short incubation times (30 min / 30 min) at room temperature
- Consistent processing for the parallel use of multiple AKLIDES® immunofluorescence assays
- High diagnostic sensitivity and specificity
- Imaging by use of AKLIDES® or akiron® systems
- CE marked

Product Information

AKLIDES® ICA

Order Information

AKLIDES® ICA **REF 4129**

(12 x 4 Determinations)

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