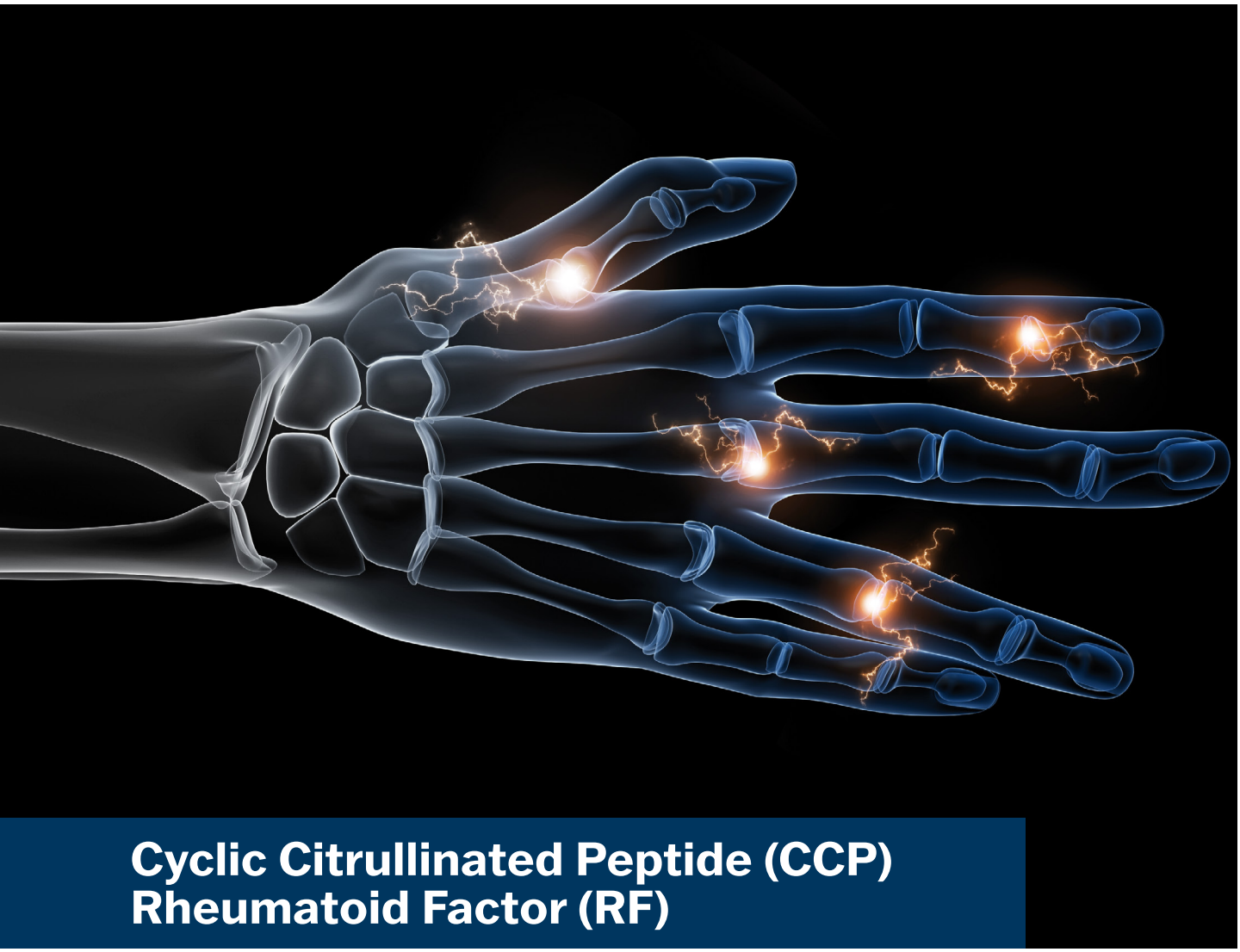


Cyclic Citrullinated Peptide (CCP) Rheumatoid Factor (RF)

Enzyme immunoassays for the diagnosis of rheumatoid arthritis

ELISA kits are optimized and validated for detection of IgA, IgG and IgM antibodies in human serum and plasma

ELISA kits are optimized and validated for detection of rheumatoid factor in human serum and plasma

CE IVD Diagnostic kits are intended for professional use in the laboratory.

BG TestLine®

Introduction

Rheumatoid arthritis (RA) is an autoimmune disorder whose typical features are chronic osteosynovitis and erosion of articular cartilage and bone followed by joint destruction. It affects more than 5 million people worldwide. Usually appearing between the ages of 30 and 50, nearly three-fourths of all sufferers are women. The aetiology of rheumatoid arthritis is not completely understood. RA is a multifactorial disease where interactions between a number of genes and external environment factors play a considerable role.

Diagnosis of Disease

The most often used laboratory assay for RA is the determination of a Rheumatoid factor (RF).

Rheumatoid factors are immunoglobulins which bind to the C-terminal portion of the constant region of human heavy chain of IgG (Fc fragment). High levels of RF are indicative of rheumatoid arthritis whereas lower concentrations can be found in cases of other diseases such as Sjögren's syndrome, SLE and bacterial endocarditis. Screening for RF is typically performed by assays based on aglutination, turbidimetry, nephelometry or ELISA. These methods are semiquantitative and detect primarily RF of the IgM antibody class and not RF of other (IgA, IgG) classes.

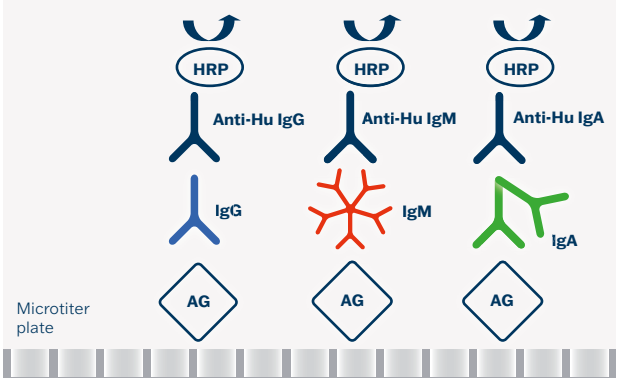
Detection of **individual IgA, IgG and IgM classes** using the ELISA method enables quantitative determination with high sensitivity and specificity. RF can be present individually as well as in various combinations depending on clinical parameters and activity of disease. There is documented correlation between RF IgA, IgG levels and disease prognosis.

Determination of antibodies to **Cyclic citrullinated peptides** (CCP) is a highly specific test enabling early diagnostics of rheumatoid arthritis. Anti-CCP antibodies can be detected several years before clinical manifestation of the disease; their presence indicating higher risk of an unfavourable disease process.

ELISA

Test Principle

The assays are based on a sandwich type ELISA method.



Summary Protocol

Step		Test steps
	1.	Dilution of samples – serum/plasma 1:101 (10 µl + 1 ml)
	2.	Pipette Controls and diluted samples 100 µl – Including blank
	3.	Incubate 30 min. at 37 °C
	4.	Aspirate and wash the wells 5 times
	5.	Add Conjugate 100 µl – Including blank
	6.	Incubate 30 min. at 37 °C
	7.	Aspirate and wash the wells 5 times
	8.	Add 100 µl Substrate (TMB-Complete) – Including blank
	9.	Incubate 30 min. at 37 °C
	10.	Add 100 µl Stopping solution – Including blank
	11.	Read colour intensity at 450 nm

Antigens

CCP – Cyclic Citrullinated Peptides of 2nd generation

RF – Purified human IgG immunoglobulin

Clinical Application

- Detection of rheumatoid arthritis and other diseases, e.g. Sjögren's syndrome, SLE or bacterial endocarditis
- Quantitative results could be used to control fertility therapy and to determine the prognosis of the disease

User Comfort

- Ready-to-use components
- Colour-coded components
- Interchangeable components
- Breakable colour-coded microplate strips
- CUT-OFF included
- Calibrators included
- Semiquantitative evaluation of results (Index of Positivity)
- Quantitative evaluation of results (U/ml)
- Easy assay procedure

Advantages

- Identical assay procedure
- High diagnostic specificity and sensitivity
- High reproducibility
- High dynamics of antibody response
- Short total assay time
- Ready for automation
- Customer support

Test Characteristics

ELISA	Diagnostic Sensitivity	Diagnostic Specificity
EIA CCP IgA	98.7%	98.8%
EIA CCP IgG	98.6%	98.6%
EIA RF IgA	93.1%	96.6%
EIA RF IgG	94.1%	93.7%
EIA RF IgM	95.1%	97.7%

Ordering Information

ELISA

Cat. No.	Product	Units
CCPA96	EIA CCP IgA	96
CCPG96	EIA CCP IgG	96
RFA096	EIA RF IgA	96
RFG096	EIA RF IgG	96
RFM096	EIA RF IgM	96
SK-CCPA96	SmartEIA CCP IgA	96
SK-CCPG96	SmartEIA CCP IgG	96
SK-RFA096	SmartEIA RF IgA	96
SK-RFG096	SmartEIA RF IgG	96
SK-RFM096	SmartEIA RF IgM	96

SmartEIA kits are designed for automated processing using the Agility® analyzer.

TestLine®

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CERTIFIED ISO 9001 · ISO 13485

Company is certified to the quality management system standards ISO 9001 and ISO 13485 for in vitro diagnostics.

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