



LZ TEST 'EIKEN'

Reagent List

LZ TEST 'EIKEN' series are based on the principle of latex agglutination immuno-turbidimetry.

LZ TEST 'EIKEN' series

► Reagents for automated clinical chemistry analyzer

LZ TEST 'EIKEN' reagents are applicable to most automated clinical chemistry analyzers on the market

► Method

Latex-enhanced turbidimetric immunoassay

► Reagents

Ready-to-use: no reconstitution error

► Calibrators

Multi point calibration for accuracy

Ready-to-use: no reconstitution error

CE registered

Gastric diseases

H.pylori Antibody

Helicobacter pylori, identified and isolated by Warren and Marshall in the gastric mucosa, is gram-negative microaerophilic bacillus known to cause chronic inflammation of the gastric mucosal epithelium. In 1995, the World Health Organization (WHO) classified *Helicobacter pylori* into the class I carcinogen with a strong relationship with cancer. Thus, it is considered a risk factor for gastric carcinogenesis. One of the diagnostic methods for *Helicobacter pylori* infection is serum antibody test to detect specific antibodies in blood of infected hosts. The test, which detects *Helicobacter pylori* without the need for endoscopy, provides a useful indicator in infection diagnosis.

Specimen	Serum, Plasma
Calibrators	6 point (0, 10, 20, 40, 70, 100 U/mL)
Measurement range	3 - 100 U/mL
Expected reference values	Negative < 10 U/mL, Positive ≥ 10 U/mL

Japanese regulation approved

Rheumatoid arthritis

RF

Rheumatoid factor is an autoantibody that appears in the blood of most persons suffering from rheumatoid arthritis (RA). Although it is not specific to rheumatic arthritis and also appears with other ailments, RF is essential for diagnosis and treatment of RA.

Specimen	Serum, Plasma
Calibrators	6 point (0, 5, 25, 50, 150, 500 IU/mL)
Measurement range	5 - 500 IU/mL
Reference range	≤ 15 IU/mL (Adult)

Pepsinogen I, Pepsinogen II

Pepsinogen in blood is receiving attention as a tool for diagnosis of gastric disorders. Pepsinogen serology is useful non-invasive test to explore the gastric mucosa status (non-atrophic vs atrophic). Also, combined serological tests with *H. pylori* antibody are usually applied in panels of multiple tests (ABC classification) which is useful for identifying individuals at increased risk for gastric cancer.

	PG I	PG II
Specimen	Serum, Plasma	Serum, Plasma
Calibrators	6 point (0, 10, 25, 70, 130, 200 ng/mL)	6 point (0, 5, 15, 30, 60, 100 ng/mL)
Measurement range	2 - 200 ng/mL	1 - 100 ng/mL
Expected reference values	Positive: PG I ≤ 70 ng/mL and PG I / II ratio ≤ 3 Strong positive: PG I ≤ 30 ng/mL and PG I / II ratio ≤ 2	

MMP-3

Matrix metalloproteinase-3 (MMP-3) is a proteolytic enzyme secreted from synovial and chondrocytic cells when stimulated by IL-1 or other factors. MMP-3 is known to play a major clinical role in joint destruction by degrading proteoglycan to cause cartilage destruction and activating other proteolytic enzymes. Because this proteolytic enzyme is considered to have the strongest association with pathological condition of rheumatoid arthritis, it is widely used to evaluate the condition of patients with rheumatoid arthritis as a useful indicator of evaluation for disease activity, prognosis, and treatment response.

Specimen	Serum, Plasma
Calibrators	6 point (0, 100, 300, 600, 900, 1,200 ng/mL)
Measurement range	10.0 - 1,200 ng/mL
Reference range	male : 35.2 - 123.8 ng/mL female : 16.1 - 56.8 ng/mL

Inflammation

SAA

Serum amyloid A (SAA) is an apolipoprotein associated in HDL. It has 11.4 kDa molecular weight and its amino acid sequence has high homology between animals. SAA has been considered as one of the most sensitive acute-phase protein as CRP. Serum SAA level rises dramatically by bacterial infection, viral infection, stress, trauma, inflammation, surgery, tumors, autoimmune diseases and tissue necrosis. Also, level of SAA is considered to reflect healing of the inflammation. The increase occurs within 12 hrs after induction and the level may increase 1000 times of normal concentration.

Specimen	Serum, Plasma
Calibrators	6 point (0, 10, 50, 150, 300, 500 µg/mL)
Measurement range	5 - 500 µg/mL
Reference range	≤ 8 µg/mL

CRP

C-reactive protein (CRP) is widely used inflammatory marker. However, it is not only an inflammatory marker, in recent years high-sensitivity CRP for low concentration level is also gaining attention as a predictive factor for atherosclerotic cardiovascular disease.

Specimen	Serum, Plasma
	6 point ① 0, 0.5, 2, 4, 15, 30 mg/dL (H6 Type) ② 0, 1, 2, 4, 15, 30 mg/dL (B6 Type)
Calibrators	7 point 0, 0.5, 2, 4, 15, 22, 30 mg/dL (AT7 Type)
Measurement range	0.01 - 30 mg/dL
Reference range	≤ 0.18 mg/dL

Kidney function

CYSTATIN C

Cystatin C is produced at a constant rate. After it is filtered out by the renal glomerulus, nearly all of it is reabsorbed and catabolized by the kidney tubules. As a result, its concentration in blood depends upon Glomerular Filtration Rate (GFR). Cys-C is also gaining attention as a marker for early-stage renal function disorders.

Specimen	Serum, Plasma
Calibrators	6 point (0, 0.45, 0.9, 2.7, 5.4, 8.1 mg/L)
Measurement range	0.1 - 8.1 mg/L
Reference range	male : 0.63 - 0.94 mg/L female : 0.52 - 0.85 mg/L

β₂-M

β₂-microglobulin (β₂-M) is a low-molecular protein that is reabsorbed and catabolized by the kidney tubules after being filtered out by the renal glomerulus. For this reason, β₂-m in blood is used as an indicator of the renal glomerulus filtering function, while β₂-m in urine is used as an indicator for kidney tubule disorders.

Specimen	Serum, Plasma	Urine
Calibrators	6 point (0, 1, 5, 20, 40, 60 mg/L)	6 point (0, 0.2, 1, 4, 8, 12 mg/L)
Measurement range	0.25 - 60 mg/L	0.05 - 12 mg/L
Reference range	0.9 - 2.0 mg/L (Adult)	≤ 0.289 mg/L (Adult)

α₁-M

α₁-microglobulin (α₁-M) is used as an indicator of the renal glomerulus filtering function and kidney tubule disorders in the same way as β₂-m. Because α₁-M has better stability in urine than β₂-m, measurement of α₁-M in urine is used as an indicator of kidney tubule disorders.

Specimen	Serum, Plasma	Urine
Calibrators	6 point (0, 9, 22.5, 45, 90, 180 mg/L)	6 point (0, 3, 7.5, 15, 30, 60 mg/L)
Measurement range	1.2 - 180 mg/L	0.4 - 60 mg/L
Reference range	9.7 - 19.9 mg/L (Adult)	male : 0.8 - 14.1 mg/L (Adult) female : 0.5 - 7.0 mg/L (Adult)

Urin-ALB

Patients with early diabetic nephropathy (stage 2) have increased urinary albumin excretion and show a condition called microalbuminuria. The albumin level detected in microalbuminuria is in the range from 30 to 300 mg/day, which is below detection limit of dipstick. In this stage, however, vascular lesions in the body including those in the renal glomeruli may already be in a progressive state. Thus, attention is given to urine albumin level as a predictive and risk factor marker in early diagnosis of diabetic nephropathy and evaluation of cardiovascular disorders in the context of lifestyle-related diseases.

Specimen	Urine
Calibrators	6 point (0, 25, 100, 200, 400, 800 mg/L)
Measurement range	5 - 800 mg/L
Reference range	< 30 mg/gCr

Prostate cancer

PSA

Prostate-specific antigen (PSA) is a type of proteolytic enzyme composed of 237 amino acids with a molecular weight of 34 kDa, and is a bioactive substance secreted from the prostate gland into semen. It migrates into blood from the tissue affected by prostate cancer more easily than from the healthy tissue, resulting in an elevated blood PSA level. Thus, it is used as a marker in early detection, treatment and follow-up of prostate cancer.

Specimen	Serum, Plasma
Calibrators	6 point (0, 2, 4, 10, 25, 50 ng/mL)
Measurement range	0.5 - 50 ng/mL
Reference range	≤ 4 ng/mL

Interstitial pneumonia

KL-6

Krebs von den Lungen-6 (KL-6), an aggregate of glycoproteins with a molecular weight of at least 200,000, is a type of sialoglycoprotein antigens of MUC1 mucin. KL-6 is expressed on type II alveolar epithelial cells with potential primary functions of cell protection, regulation of cell adhesion, and suppression of inflammatory reaction. When the alveolar epithelium is damaged, increased KL-6 production in the type II alveolar epithelium with regeneration-induced hyperplasia and enhanced vascular permeability in the alveolar region are believed to result in the release of KL-6 from the alveolar lumens into blood, which elevates its serum level. KL-6 is one of the diagnostic criteria for idiopathic interstitial pneumonia in Japan, and is widely used to diagnose different types of interstitial pneumonia and to discriminate it from other lung diseases as well as to evaluate its disease activity and prognosis.

Specimen	Serum, Plasma
Calibrators	6 point (0, 500, 1000, 2000, 4000, 6000 U/mL)
Measurement range	50 - 6,000 U/mL
Reference range	123 - 384 U/mL

Anemia

FERITIN

The concentration of Feritin in blood reflects iron levels in the body. Clinically, it decreases in cases such as iron-deficiency anemia, and increases in cases such as iron excess, tissue damage caused by acute liver inflammation or pancreatitis and malignant tumors.

Specimen	Serum, Plasma
Calibrators	6 point (0, 25, 250, 500, 750, 1000 ng/mL)
Measurement range	5 - 1,000 ng/mL
Reference range	male : 13 - 277 ng/mL female : 5 - 152 ng/mL

Hemolytic streptococcus

ASO

Antibody for streptolysin O (ASO) is a hemolysin produced by hemolytic streptococci.

ASO measurement is used as a method of screening for hemolytic streptococci infection.

Specimen	Serum, Plasma
Calibrators	6 point (0, 62.5, 125, 250, 500, 1000 IU/mL)
Measurement range	10 - 1,000 IU/mL
Reference range	≤ 160 IU/mL (Adult) ≤ 250 IU/mL (Child)

