GP

CE IVD

Osteocalcin Fast Test Kit (Immunofluorescence Assay)

IF1112 for Getein 1100
IF5112 for Getein 1160
IF3112 for Getein 1180
REF IF4112 for Getein 1200
IF2112 for Getein 1600

Instructions for Use

INTENDED USE

Osteocalcin Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of Osteocalcin in serum or plasma samples. This test is mainly used for the auxiliary diagnosis of various osteoporosis and early bone synthesis after bone injury. For professional and laboratory use.

SUMMARY

Osteocalcin, also known as bone gamma-carboxyglutamic acid protein (BGP), is a highly abundant non-collagenous protein in the bone. Osteocalcin is an active polypeptide synthesized and secreted by osteoblasts, with approximately 50% deposited in bone matrix and the other 50% entering the bloodstream. Its primary physiological function is to maintain the normal mineralization rate of the bone. As a specific and sensitive biochemical indicator reflecting the status of bone metabolism, serum osteocalcin levels can essentially reflect the recent situation of osteoblasts and bone formation. It plays an indispensable role in the auxiliary diagnosis and monitoring of skeletal diseases such as fractures, osteomyelitis, bone tumors, etc. At the same time, various other diseases or physiological conditions such as renal insufficiency, thyroid dysfunction, parathyroid dysfunction, diabetes, and pregnancy can also cause changes in the level of osteocalcin.

PRINCIPLE

Osteocalcin Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test card, the fluorescence latex-labelled osteocalcin monoclonal antibody I binds with osteocalcin in sample and forms a marked antigen-antibody complex. The complex moves to the detection area by capillary action, then it is captured by osteocalcin monoclonal antibody II coated on the detection area of nitrocellulose membrane, forming a double-antibody complex. The complex generates a fluorescent signal and the intensity increases in proportion to the amount of osteocalcin in sample. Subsequently, the fluorescently labeled antigen-antibody complex is measured and analyzed by the accompanying instrument, enabling the quantitative detection of the levels of osteocalcin in human blood.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/Getein 1160 /Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
Osteocalcin test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10*0.2 mL/tube	25*0.2 mL/tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

*Osteocalcin test card
A test card consists of: Fluorescence latex-labelled Osteocalcin monoclonal antibody, Osteocalcin monoclonal antibody and goat anti-mouse IgG antibody.
** Sample diluent
(1) Sample diluent for Getein 1100/ Getein 1160/ Getein 1180 is 0.2 mL contained in each tube consists of:
- Sample diluent main contains phosphate buffer (20 mmol/L), NaN3 (＜0.1%).

(2) Sample diluent for Getein 1200/ Getein 1600 is an independent packing box consists of:
- Sample diluent main contains phosphate buffer (20 mmol/L), NaN3 (＜0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),
- Box with pipette tips (96 tips/box),
- Mixing plate (1 piece/box).

Note:
1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.
Use the test card for Getein 1100/Getein 1160/Getein 1180 within 1 hour once the foil pouch is opened.
For test card of Getein 1200/Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. Please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches or the cartridge until ready to perform the test.
5. Do not reuse the test card or pipet.
6. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
7. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. Serum and plasma can be used as samples in the assay.
2. Heparin, sodium citrate and EDTA can be used as the anticoagulants for plasma. Do not use hemolysis specimens.
3. This assay is designed and validated for use with human blood, other specimens or body fluids may not get accurate results.
4. It is recommended to test the sample within 4 hours after collection. Serum and plasma are stable for 5 days when stored at 2~8°C and 6 months when stored at -20°C.
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:
1. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
2. Select the corresponding “Sample” on the analyzer according to the sample type (see the instructions of analyzer for details).
3. Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4. Using disposable pipet, deliver 100 uL (reach the black scale line of the pipette) of sample into one tube of sample diluent and blow 3-5 times repeatedly. Then drop 100 uL (reach the black scale line of the pipette) of sample mixture into sample well on the test card.
5. Reaction time: **15 minutes.** Insert the test card into Getein 1100 and click on “Start” icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:
1. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
2. Select the corresponding “Sample” on the analyzer according to the sample type (see the instructions of analyzer for details).
3. Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4. Using disposable pipet, deliver 100 uL (reach the black scale line of the pipette) of sample into one tube of sample diluent and blow 3-5 times repeatedly. Then drop 100 uL (reach the black scale line of the pipette) of sample mixture into sample well on the test card.
5. Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 1200/Getein 1600:
1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
2. Put the sample diluent at the correct position in Getein 1200/Getein 1600.
3. Place samples in the designed area of the sample holder,

insert the holder and select the right test item, Getein 1200/Getein 1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein 1100/Getein 1160/Getein 1180.
3. Make sure the insertion of test card and the sample are correct and complete.

LIMITATIONS

1. The test results of this reagent are for clinical reference only, and cannot be used as the basis for diagnosis or exclusion of cases alone additional tests should be performed accordingly.
2. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Concentration (Max)
Triglyceride	18 g/L
Bilirubin	0.2 g/L

EXPECTED VALUE

The expected normal value for Osteocalcin was determined by testing blood samples from apparently healthy individuals and the reference range of Osteocalcin is shown in the figure:

Group		n	95% Reference range(ng/mL)
Healthy women	Premenopausal women (>20 years old)	182	11~43
	Post menopause	160	15~46
	Patients with osteoporosis	165	13~48
Healthy men	18-30 years old	180	24~70
	30-50 years old	177	14~42
	50-70 years old	181	14~46

The reference ranges for plasma are the same as those for serum samples. It is recommended that each laboratory determine the applicability of the reference ranges through experimentation and establish their own laboratory-specific reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Measuring Range	1.5~300.0 ng/mL
Lower Detection Limit	≤1.5 ng/mL
Within-Run Precision	≤10%
Between-Run Precision	≤15%

REFERENCES

1. Ando, E., et al. "Osteocalcin promotes proliferation, differentiation, and survival of PC12 cells." Biochemical and Biophysical Research Communications 557(2021):174-179.
2. Tauer, J. M. Ferron, and S. Komarova. "Osteocalcin deficiency in a mouse model of severe dominant osteogenesis imperfecta rescues metabolic but not bone phenotype." Bone Reports 14(2021):100864.
3. Pittas, A. G., et al. "Association between serum osteocalcin and markers of metabolic phenotype. " J Clin Endocrinol Metab 3(2009):827-832.
4. Ferron, M., et al. "Osteocalcin differentially regulates beta cell and adipocyte gene expression and affects the development of metabolic diseases in wild-type mice." Proceedings of the National Academy of Sciences 105. 13(2008):5266-5270.
5. Sykaa, M, et al. "Assessment of Clinical Utility of Assaying FGF-23, Klotho Protein, Osteocalcin, NTX, and Sclerostin in Patients with Primary Hyperparathyroidism." Journal of Clinical Medicine 10.14(2021).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Osteocalcin Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for using Osteocalcin Fast Test Kit (Immunofluorescence Assay). Please read this instructions for use carefully before operating to ensure proper use.

Version: WIF132-S-03

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054