

N-MID[®] Osteocalcin ELISA

For the Quantitative Determination of Osteocalcin in human serum and plasma



Immunodiagnostic Systems Limited is not responsible for any other use of the kit or consequence hereof than the one specified above. Neither for misuse, e.g. use deviating from the procedure described in this manual. Furthermore, Immunodiagnostic Systems Limited is not to be made responsible for any diagnoses or conclusions made by the user or third party based on the results obtained with the kit nor for any consequences such interpretations may cause.

INTRODUCTION

Intended use

The N-MID[®] Osteocalcin ELISA is an enzyme immunological test for the quantitative measurement of osteocalcin, an indicator of osteoblastic activity in human serum and plasma and is **intended to be used as an** *aid in the prevention of osteoporosis.*

Limitations

Osteocalcin values may vary depending upon the person's age (years post menopause), "circadian rhythm", rate of glomerular filtration and duration of treatment.

Results should be used in conjunction with information available from the clinical evaluation of the patient and other diagnostic procedures. Therefore, osteocalcin values are not recommended for use as a screening procedure to detect the presence of osteoporosis in the general population. Also, medication dosage should not be changed or stopped based solely on the osteocalcin values.

When evaluating subsequent samples, collect at the same time of day as baseline and use the same specimen type, serum or anticoagulated plasma.

Summary and explanation of the test

Osteocalcin, or bone Gla protein (BGP), is the major non-collagenous protein of bone matrix. It has a molecular weight of approximately 5800 Dalton and consists of 49 amino acids, including three residues of gamma-carboxyglutamic acid.

Osteocalcin is synthesized in bone by osteoblasts. After production, it is partly incorporated into the bone matrix and partly delivered to the circulatory system. The precise physiological function of osteocalcin is still unclear. A large number of studies have shown that the circulating level of osteocalcin reflects the rate of bone formation (1-14).

Determination of serum osteocalcin has proved to be valuable as an aid in identifying women at risk of developing osteoporosis, for monitoring bone metabolism during the perimenopause and postmenopause and during antiresorptive therapy.

Principle of the procedure

The N-MID[®] Osteocalcin ELISA is based upon the application of two highly specific monoclonal antibodies (Mabs) against human osteocalcin. An antibody recognizing the midregion (amino acids 20-29) is used as the capture antibody and for detection a peroxidase conjugated antibody recognizing the N-terminal region (amino acids 10-16) is used. In addition to intact osteocalcin (amino acid 1-49) the N-terminal-Mid fragment (amino acids 1-43) is also detected.

Standards, control and unknown samples are pipetted into the appropriate microtitre wells coated with streptavidin. Then a mixture of a biotinylated antibody and a peroxidase conjugated antibody is added. Following incubation for 2 hours at room temperature the wells are washed and a chromogenic substrate is added and the colour reaction is stopped with sulfuric acid. Finally, the absorbance is measured.

PRECAUTIONS

The following precautions should be observed in the laboratory:

- Do not eat, drink, or smoke where immunodiagnostic materials are being handled
- Do not pipette by mouth
- · Wear gloves when handling immunodiagnostic materials and wash hands thoroughly afterwards
- Cover working area with disposable absorbent paper

Storage

Store the N-MID[®] Osteocalcin ELISA kit upon receipt at 2-8°C. Under these conditions the kit is stable up to the expiry date stated on the box.

Following reconstitution the **Standards** and the **Controls** should be stored below -18°C for up to 3 months, and should only be frozen and thawed twice. When the components of the **Antibody Solution** are mixed, the remaining solution should be stored at 2-8°C for no longer than 1 month or frozen below -18°C. The remaining reagents and immunostrips should be stored at 2-8°C.

Note:

The specimens' storage and stability information stated above are general recommendations for use in a variety of settings of laboratories. Each laboratory should follow the guidelines or requirements of local, state, and/or federal regulations or accrediting organizations to establish its own specimens handling and storage stability. For guidance on appropriate practices, please refer to the CLSI GP44-A4, Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline - Fourth Edition

Warnings

For in vitro use only.

- All reagents and laboratory equipment should be handled and disposed of as if they were infectious.
- Do not use kit components beyond the expiry date and do not mix reagents from different lots.

MATERIALS

Specimen collection

Collect blood by venipuncture taking care to avoid haemolysis. Separate the serum from the cells within 3 hours after collection of blood. It is recommended to freeze (<-18°C) samples immediately. When analysing plasma, both heparin and EDTA plasma may be used.

Materials supplied

Before opening the kit, read the section on **Precautions**. The kit contains reagents sufficient for 96 determinations. For reconstitution of lyophilized material, add appropriate volume of distilled water and leave for 10 minutes before mixing. Make sure to avoid foam.

Streptavidin coated microtitre plate MICROPLAT

Microwell strips (12 x 8 wells) pre coated with streptavidin. Supplied in a plastic frame.

Osteocalcin Standard 0 CAL 0

One vial (lyophilized) containing a PBS-buffered solution with protein stabilizer and preservative. Reconstitute with 5.0 mL of distilled water. The standard must be stored below -18°C after use.

Osteocalcin Standards - CAL 1 - 5

Five vials (lyophilized) containing synthetic human osteocalcin in a PBS-buffered solution with protein stabilizer and preservative. Reconstitute with 0.5 mL of distilled water. The exact value of each Standard is printed on the QC Report. The standards must be stored below -18°C after use, and should only be frozen and thawed twice.

Controls - CTRL 1-2

Two vials (lyophilized) containing synthetic human osteocalcin in a PBS-buffered solution with protein stabilizer and preservative. Reconstitute with 0.5 mL of distilled water. Controls must be stored below -18°C, and should only be frozen and thawed twice. Please refer to enclosed QC Report for control range.

Peroxidase Conjugated Antibody ENZYMCONJ

One vial (min. 0.25 mL) of a concentrated solution of a peroxidase conjugated murine monoclonal antibody specific against the N-terminal region of osteocalcin in a TRIS-buffered solution with protein stabilizer, detergent and preservative. Prior to use, add 10 mL **Conjugate Diluent Solution**.

Biotinylated Antibody Ab BIOTIN

One vial (min. 0.25 mL) of a concentrated conjugate solution of biotinylated murine monoclonal antibody against the mid-region of osteocalcin in a TRIS-buffered solution with protein stabilizer, detergent and preservative. Prior to use, add 10 mL **Conjugate Diluent Solution**.

Conjugate Diluent Solution BUF

One vial (min. 22 mL) of a PBS-buffered solution with protein stabilizer, detergent and preservative.

Substrate Solution SUBS TMB

One vial (min. 12 mL) of a ready for use tetramethylbenzidine (TMB) substrate in an acidic buffer. Please note that the chromogenic substrate might appear slightly bluish.

Stopping Solution H2SO4

One vial (min. 12 mL) of ready for use 0.18 mol/L sulfuric acid.

Washing Solution WASHBUF 50x

One vial (min. 20 mL) of a concentrated washing buffer with detergent and preservative. Dilute 1+50 times in distilled water before use.

Sealing tape

Adhesive film for covering wells during incubation.

Materials required — not supplied

- Containers for preparing the Antibody Solution and the Washing Solution.
- Precision micropipettes to deliver 20 µL
- Distilled water
- Precision 8- or 12-channel multipipette to deliver 100 μL and 150 μL.
- Microtiter plate reader with both 450 nm and 650 nm filters

ASSAY PROCEDURE

For optimal perfomance of the assay it is important to comply with the instructions given below

Assay Procedure

Prior to use, prepare and equilibrate all solutions to room temperature. Perform the assay at 18-22°C.

Determine the number of strips needed for the assay. It is recommended to test all samples in duplicate. In addition, for each run a total of 16 wells are needed for the standards and controls. Place the appropriate number of strips in the plastic frame. Store unused immunostrips in the tightly closed foil bag with desiccant capsules.

1 Preparation of the Antibody Solution:

The Antibody Solution is prepared by 1) adding 10 mL of Conjugate Diluent Solution BUF to both the Peroxidase Conjugated Antibody Solution ENZYMCONJ and the Biotinylated Antibody Solution Ab biotin , and 2) mixing the two conjugate solutions in equal volumes.

2 Incubation in Immuno Strips

Pipette 20 μ L of either **Standards** CAL 0 - 5 -, Controls CTRL 1 - 2 - or unknown samples into appropriate wells followed by 150 μ L of the **Antibody Solution**. Cover the immunostrips with sealing tape and incubate for 120±5 minutes at 18-22°C (without any mixing).

3 Washing

Wash the immunostrips 5 times manually with 300 µL diluted **Washing Buffer** (**WASHBUF 50x** diluted 1+50 in distilled water). Using an automated plate washer, follow the instructions of the manufacturer or the guidelines of the laboratory. Usually 5 washing cycles are adequate. Make sure that the wells are **completely emptied** after each manual or automatic washing cycle.

4 Incubation with chromogenic substrate solution

Pipette 100 μ L of the **Substrate Solution SUBS TMB** into each well and incubate for 15±2 minutes at 18-22°C in the dark (without any mixing). Use sealing tape. Do not pipette directly from the vial containing TMB substrate but transfer the needed volume to a clean reservoir. Remaining substrate in the reservoir should be discarded and not returned to vial TMB.

5 Stopping of colour reaction

Pipette 100 µL of the **Stopping Solution** H2SO4 into each well.

6 Measurement of absorbance

Measure the absorbance at 450 nm with 650 nm as reference within two hours.

Limitations of the procedure

If the absorbance of a sample exceeds that of **Standard 5**, the sample should be diluted in **Standard 0** and reanalysed.

QUALITY CONTROL

Good Laboratory Practice (GLP) requires the use of quality control specimens in each series of assays in order to check the performance of the assay. Controls should be treated as unknown samples, and the results analysed with appropriate statistical methods.

RESULTS

Calculation of results

A four-parametric logistic curve fit can be used.

Alternatively, calculate the mean of the duplicate absorbance determinations. Construct a standard curve on graph paper by plotting the mean absorbances of the six standards (ordinate) against the corresponding osteocalcin concentrations (abscissa). Determine the osteocalcin concentration of the controls and each patient sample by interpolation.

Example of results obtained

Standards/ Controls/ Samples	Osteocalcin (ng/mL)	A450nm-650nm Obs 1/ Obs 2	Mean A450nm-650nm	Interpolated Osteocalcin (ng/mL)
Standard 0	0.0	0.019 / 0.020	0.020	
Standard 1	4.2	0.108 / 0.096	0.102	
Standard 2	7.6	0.183 / 0.177	0.180	
Standard 3	19.4	0.627 / 0.656	0.642	
Standard 4	35.4	1.271 / 1.278	1.275	
Standard 5	56.1	1.988 / 1.873	1.931	
Control 1		0.474 / 0.459	0.467	15.1
Control 2		1.147 / 1.132	1.140	31.8
Sample I		0.099 / 0.105	0.102	4.6
Sample II		0.899 / 0.850	0.875	25.1
Sample III		1.412 / 1.375	1.394	38.7

Please note:

The data above are for illustration only and should not be used to calculate the results of another assay.

Performance characteristics

All performance data have been established using second morning void urine samples unless otherwise indicated.

Detection limit: 0.5 ng/mL Osteocalcin

This is the concentration corresponding to three standard deviations above the mean of 21 determinations of the blank ("Osteocalcin Standard 0").

Precision

The precision of the N-MID[®] Osteocalcin ELISA was evaluated for three serum samples. The results are summarised in the table below:

InterAssay Variation (n=10)

Mean (ng/mL)	SD (ng/mL)	CV (%)
6.7	0.2	5.1
26.2	0.7	2.7
53.9	2.3	4.2

IntraAssay Variation (n=10)

Mean	SD	CV
(ng/mL)	(ng/mL)	(%)
6.7	0.1	1.3
26.2	0.4	1.8
53.9	1.2	2.2

Dilution/Linearity

It was investigated if the N-MID[®] Osteocalcin ELISA assay was sensitive to any effect of the serum matrix. Four serum samples were diluted in Standard 0, and the concentrations were determined in the N-MID[®] Osteocalcin ELISA

Sample	Dilution	Observed (ng/mL)	Expected (ng/mL)	Recovery (% of expected value)
1	1 / 1 1 / 2 1 / 4 1 / 8	12.0 5.1 2.7	12.0 6.0 3.0	100 84 88
2	1 / 1	36.1	36.1	100
	1 / 2	18.1	18.1	106
	1 / 4	9.0	9.0	105
	1 / 8	4.7	4.5	104
3	1 / 1	38.2	38.2	100
	1 / 2	20.5	19.1	107
	1 / 4	9.9	9.6	104
	1 / 8	4.3	4.8	90
4	1 / 1	48.1	48.1	100
	1 / 2	23.8	24.1	99
	1 / 4	12.2	12.0	101
	1 / 8	6.3	6.0	105

Recovery

The accuracy of the N-MID[®] Osteocalcin ELISA was determined by spiking human serum with different amounts of synthetic osteocalcin. Three serum samples were mixed in equal volumes with 4 standard solutions and assayed in the N-MID[®] Osteocalcin ELISA

Sample	Standards synthetic osteocalcin (ng/mL)	Observed (ng/mL)	Expected (ng/mL)	Recovery (% of expected value)
1	50	26.9	30.5	88
	25	16.4	18.0	91
	12.5	10.7	11.7	92
	6.3	8.4	8.6	98
2	50	30.8	35.6	87
	25	19.9	20.6	97
	12.5	14.6	14.3	102
	6.3	11.0	11.2	98
3	50	37.5	40.5	93
	25	26.6	28.0	95
	12.5	21.2	21.7	98
	6.3	18.6	18.6	100

Measuring Range

The measuring range for N-MID[®] Osteoclacin ELISA is between 0.5 ng/mL and 100 ng/mL osteocalcin.

Interference:

In the concentration listed below no interference was detected:

Lipid (IntraLipid): 15 g/L Bilirubin: 200 mg/L Hemoglobin: 5 g/L

Expected values

It is advisable for a laboratory to establish its own range of normal and pathological values. As an example, the mean values and standard deviations for various populations are given below. For further reading, please refer to the reference list.

Populations	Number of subjects	Mean Values (ng/mL)	95% Confidence Interval	
Premenopausal women	77	17.4	8.4 - 33.9	
Postmenopausal women 1)	131	26.5	12.8 – 55.0	
Males	85	19.8	9.6 - 40.8	

¹⁾ The average years after menopause is 10.3 years.

Day to Day Intra-individual Variation

The Day to Day Intra-individual Variation was assessed by analyzing serum samples (morning fasting) from 11 healthy postmenopausal women at five time points over 2 weeks

Subject	Mean (ng/mL)	SD (ng/mL)	CV (%)
1	22.0	3.5	16
2	13.4	1.0	7
3	19.6	1.3	7
4	18.0	3.1	17
5	12.9	1.1	9
6	9.9	0.9	9
7	14.4	2.2	15
8	7.5	0.4	5
9	15.3	2.2	15
10	14.5	1.6	11
11	14.8	0.6	4

CLINICAL DATA

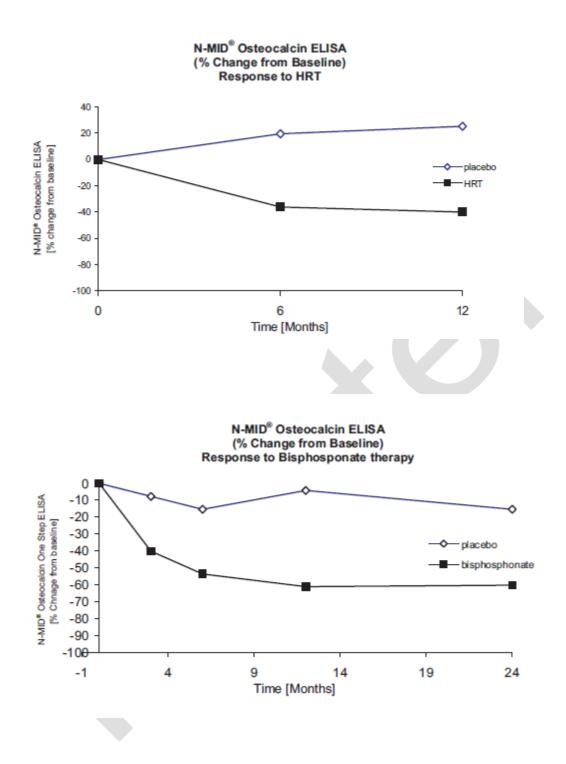
The N-MID[®] Osteocalcin ELISA has been used to monitor treatment in several clinical studies and the osteocalcin values have been compared to Bone Mineral Density (BMD^{spine}) measurements.

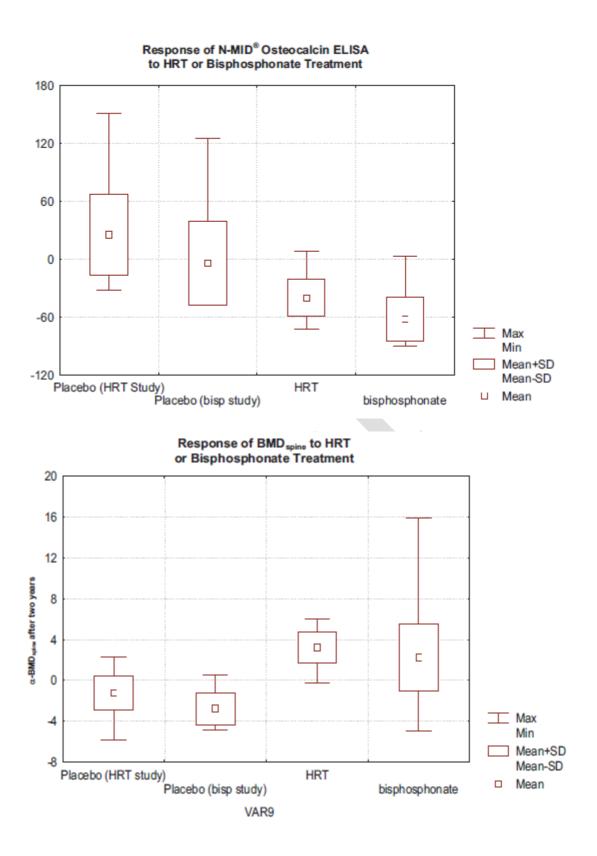
All the clinical studies presented below were performed according to the European Standard for good clinical practice (GCP and GLP).

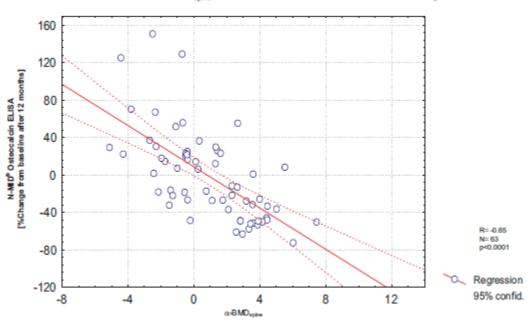
The clinical studies presented here were conducted on white Danish women. However, several studies have been published showing that other demographic groups display similar osteocalcin decrease in response to anti-resorptive therapies (7, 8, 11, 12, 14).

The Bone Mineral Density (BMD) was measured at the Lumbar spine (L1 – L4). The change in the bone mineral density presented below is α –BMD, which is defined as the slope of the linear regression line for BMD^{spine} versus time (years) for the period of treatment, i.e. α –BMD represents the % change in BMD^{spine} per year.

HRT study:	Bisphosphonate study:		
 Women more than 45 year and 1-6 years since menopause 35 participants on placebo 26 participants on active treatment 	 Women between age 40 and 59 years, and 6 months to 3 years since menopause. 12 participants on placebo 31 participants on active treatment 		

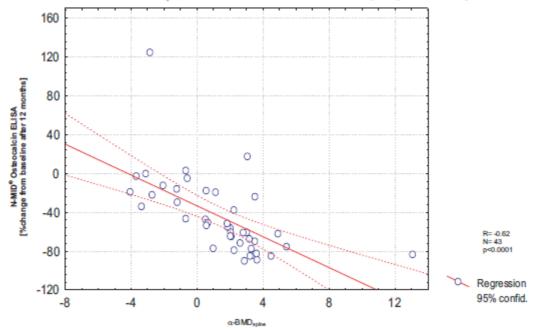






Correlation between α-BMD_{seine} and N-MID[®] Osteocalcin ELISA - HRT study





Below is summarized the specificity and sensitivity using different cut-off values of N-MID[®] Osteocalcin ELISA, change from baseline after 12 months HRT or Bisphosphonate treatment for α -BMD cut-off of 0.5%. 95% confidence intervals are indicated.

HRT study

Cut-off of change in osteocalcin	Specificity	Sensitivity
-10 [% change from baseline]	83 (64 – 94)	74 (55 – 87)
-20 [% change from baseline]	76 (56 – 90)	85 (69 – 95)
-30 [% change from baseline]	62 (42 – 79)	94 (80 – 99)
-40 [% change from baseline]	48 (29 – 67)	97 (85 – 100)

Bisphosphonate study

Specificity	Sensitivity
100 (89 – 100)	35 (14 – 62)
96 (80 – 100)	59 (33 – 82)
96 (80 – 100)	76 (50 – 93)
92 (75 –99)	82 (57 – 96)
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