Product information

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User´s Manual

PMN Elastase ELISA

Enzyme immunoassay for the measurement of PMN elastase in EDTA or citrated plasma, exudate, bronchoalveolar lavage fluid, cerebrospinal fluid and seminal plasma

REF **IB79187**

Σ **96 Wells**

RUO **For Research Use Only – Not for Use in Diagnostic Procedures**

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1 INTRODUCTION

1.1 INTENDED USE

The IBL-America PMN Elastase ELISA is an enzyme immunoassay for the measurement of PMN elastase in EDTA or citrated plasma, exudate, bronchoalveolar lavage fluid, cerebrospinal fluid and seminal plasma. **For research use only – Not for use in diagnostic procedures.**

2 PRINCIPLE

The test kit is a solid phase enzyme immunometric assay (ELISA) in the microplate format, designed for the measurement of the complex of human PMN elastase and α_1 proteinase inhibitor (α_1-PI) in plasma.The microplate is coated with a first polyclonal antibody against human PMN elastase (antigen). Calibrators, controls and samples are pipetted into the antibody coated microplate. During a 60 minutes incubation present antigens in the sample bind to the antibodies fixed on the inner surface of the wells. Non-reactive sample components are removed by a washing step.
Afterwards, a second polyclonal antibody against α_1-PI, which is labeled with horseradish peroxidase, is added. During a 60 minutes incubation, the PMN elastase/α_1-PI complex bound to the first antibody is specifically recognized by the enzyme labeled antibodies, and a sandwich complex is formed. An excess of enzyme conjugate is washed out.
A chromogenic substrate, TMB (3,3',5,5'-Tetra-Methyl-Benzidine), is added. During a 20 minutes incubation, the substrate is converted to a colored endproduct (blue) by the fixed enzyme. Enzyme reaction is stopped by dispensing of hydrochloric acid as stop solution (change from blue to yellow). The color intensitiy is direct proportional to the concentration of PMN elastase present in the sample.
The optical density of the color solution is measured with a microplate reader at 450 nm. Bi-chromatic measurement with a 600 - 690 nm reference filter is recommended.

3 WARNINGS AND PRECAUTIONS

1. This kit is for research use only. For professional use only.
2. Before starting the assay, read the instructions completely and carefully. Use the valid version of the package insert provided with the kit. Be sure that everything is understood.
3. The microplate contains snap-off strips. Unused wells must be stored at 2 °C to 8 °C in the sealed foil pouch and used in the frame provided.
4. Pipetting of samples and reagents must be done as quickly as possible and in the same sequence for each step.
5. Use reservoirs only for single reagents. This especially applies to the substrate reservoirs. Using a reservoir for dispensing a substrate solution that had previously been used for the conjugate solution may turn solution colored. Do not pour reagents back into vials as reagent contamination may occur.
6. Mix the contents of the microplate wells thoroughly to ensure good test results. Do not reuse microwells.
7. Do not let wells dry during assay; add reagents immediately after completing the rinsing steps.
8. Allow the reagents to reach room temperature (21-26°C) before starting the test. Temperature will affect the absorbance readings of the assay. However, values for the samples will not be affected.
9. Never pipet by mouth and avoid contact of reagents and samples with skin and mucous membranes.
10. Do not smoke, eat, drink or apply cosmetics in areas where samples or kit reagents are handled.
11. Wear disposable latex gloves when handling samples and reagents. Microbial contamination of reagents or samples may give false results.
12. Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.
13. Do not use reagents beyond expiry date as shown on the kit labels.
14. All indicated volumes have to be performed according to the protocol. Optimal test results are only obtained when using calibrated pipettes and microtiterplate readers.
15. Do not mix or use components from kits with different lot numbers. It is advised not to exchange wells of different plates even of the same lot. The kits may have been shipped or stored under different conditions and the binding characteristics of the plates may result slightly different.
16. Avoid contact with Stop Solution. It may cause skin irritation and burns.

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17. Chemicals and prepared or used reagents have to be treated as hazardous waste according to the national biohazard safety guideline or regulation.
18. For information please refer to Material Safety Data Sheets. Safety Data Sheets for this product are available upon request directly from IBL-America.

4 REAGENTS

4.1 REAGENTS PROVIDED

1. **SORB | MT Microtiterplate**, 12x8 (break apart) strips, 96 wells;
   Wells coated with polyclonal antibodies against PMN elastase.
2. **CAL PMN Elastase Master Calibrator,** 1 vial (2 µg), lyophilized;
   in serum/buffer matrix containing PMN elastase/ α1-PI complex
   Concentrations: 1,000 - 500 - 250 - 125 - 62.5 - 31.3 and 15.6 ng/ml
   For reconstitution see “Reagent preparation”.
3. **CONTROL | 1-2 PMN Elastase Controls** in serum/buffer matrix, 2 vials, lyophilized;
   For control values and ranges please refer to QC-Datasheet.
   For reconstitution see “Reagent preparation”.
4. **ENZ | CONJ Enzyme Conjugate**, 1 vial, 16 ml, ready to use;
   Enzyme labeled anti-α_1 PI antibody, containing polyclonal antibodies labeled with horseradish peroxidase;
5. **SAM | DIL Calibrator/Sample Diluent,** 1 vial, 50 ml, ready to use
6. **SUB | TMB Substrate Solution**, 1 vial, 22 ml, ready to use;
   Tetramethylbenzidine (TMB).
7. **STOP | SOLN Stop Solution**, 1 vial, 7 ml, ready to use;
   contains 2 M hydrochloric acid.
   Avoid contact with the stop solution. It may cause skin irritations and burns.
8. **WASH | SOLN | 10x Wash Solution**, 1 vial, 50 ml (**10X** concentrated);
   see „Preparation of Reagents“.

4.2 MATERIALS REQUIRED BUT NOT PROVIDED

- Microplate reader capable for endpoint measurements at 450 nm (optional reference filter in the range of 600 - 690 nm)
- Vortex mixer
- Microplate mixer operating at 350 – 400 rpm
- Distilled water
- Graduated cylinders for 100 and 1000 ml
- Plastic containers for storage of the wash solution
- Pipets for 10 and 100 µl
- Adjustable pipette for up to 1000 µl
- Dispenser or repeatable pipet for 10 µl, 50 µl, 100 µl and 1000 µl

4.3 REAGENT PREPARATION

Master Calibrators:
Reconstitute lyophilized Master Calibrator with **2 ml Calibrator/Sample Diluent** 30 min. before use (end concentration of 1,000 ng/ml). Make a dilution serie with Calibrator/Sample Diluent to get calibrators with 1,000; 500; 250; 125; 62.5; 31.3 and 15.6 ng/ml.

PMN Elastase Controls:
Reconstitute with **1 ml Calibrator/Sample Diluent** 30 min before use.

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Wash Buffer:
Dilute with 450 ml dist. water to a final volume of 500 ml.

Attention: For the determination of PMN Elastase in seminal plasma, please find detailed information about the reagent preparation in chapter 13 (see page 14).

4.4 STORAGE CONDITIONS

When stored at 2-8 °C unopened reagents will be stable until expiration date. Do not use reagents beyond this date. Opened reagents must be stored at 2°-8°C. After first opening the reagents are stable for 30 days if performed and stored properly.
The Wash Buffer is stable for 12 weeks after dilution.
Store Calibrators and Controls at -20 °C or below (in aliquots), it will be stable for 30 days after reconstitution.
Microtiter wells must be stored at 2-8 °C. Once the foil bag has been opened, care should be taken to close it tightly again.
Protect TMB-Substrate Solution from light.

5 SAMPLE COLLECTION AND PREPARATION

For determination of PMN elastase EDTA or citrated plasma are the preferred sample matrixes. Exsudate, bronchoalveolar lavage fluid, cerebrospinal fluid and seminal plasma can be used.
For determination of PMN Elastase in seminal plasma please find a separate protocol in chapter 13 (see page 14).
Serum is not suitable, because during clotting PMN elastase can be released *in vitro*. Culture supernatants are as well not suitable; the reason is that the assay detects only the PMN elastase/α_1-PI complex and α_1 PI is normally not present in culture medium.
All samples are prediluted 1:100 with Calibrator/Sample Diluent. Therefore 10 µL of sample may be diluted with 990 µL of Calibrator/Sample diluent.
The subjects need not to be fasting, and no special preparations are necessary. Collect blood by venipuncture into vacutainers and separate plasma from the cells by centrifugation. Plasma samples can be stored at 2 - 8 °C up to 5 days. For longer storage samples should be stored frozen at -20°C. To avoid repeated thawing and freezing the samples should be aliquoted. Samples expected to contain higher PMN elastase concentrations than the highest calibrator (1000 ng/mL) should be diluted in the Calibrator/Sample Diluent before further assaying. The additional dilution step has to be taken into account for the calculation of the results.

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6 ASSAY PROCEDURE

6.1 GENERAL REMARKS

- Do not interchange components of different lots.
- All components should be at room temperature (18 – 28 °C) before use.
- All components of these test kits, supplied as concentrate should be diluted to their final concentration at least 30 minutes prior to use. Mix well, but prevent of foam formation.
- Use a disposable-tip micropipette to dispense plasma samples. Pipet directly to the bottom of the wells. Change the tip between samples, to avoid carryover contamination.

6.2 ASSAY PROCEDURE

1. **Preparation of calibrators**:
   Label six tubes: G (500 ng/ml), F (250 ng/ml), E (125 ng/ml), D (62.5 ng/ml), C (31.3 ng/ml), and B (15.6 ng/ml). Pipet **0.5 ml** of the Calibrator/Sample Diluent into all tubes. Pipet 0.5 ml of the reconstituted PMN Elastase Master Calibrator into tube G (500 ng/ml) and mix thoroughly. Transfer 0.5 ml from tube G (500 ng/ml) to tube F (250 ng/ml) and mix thoroughly. Repeat this process successively to complete the 2-fold dilution series. The reconstituted PMN Elastase Master Calibrator will serve as the highest calibrator H (1,000 ng/ml). Use the PMN Elastase Calibrator/Sample Diluent as the zero calibrator A (0 ng/ml).
2. Dilute all samples 1:100 with Calibrator/Sample Diluent before assay. Therefore combine 10 µl of sample with 990 µl of Calibrator/Sample Diluent in a polystyrene tube. Mix well. Calibrators and controls are ready to use and need **not** to be diluted.
3. Prepare a sufficient number of microplate wells to accomodate calibrators, controls and prediluted samples in duplicates.

	1	2	3	4	5	6	7	8	9	10	11	12
a	A	E	C1	P..								
b	A	E	C1	P..								
c	B	F	C2									
d	B	F	C2									
e	C	G	P1									
f	C	G	P1									
g	D	H	P2									
h	D	H	P2									

4. For determination of PMN Elastase pipet **100 µl** of calibrators, controls and prediluted samples into the wells according to the template.
5. Incubate for **60 minutes** at room temperature (18 - 28 °C) on a plate mixer (350 – 400 rpm).
6. Discard the content of the wells and wash **4 times** with **300 µl** buffered wash solution. Remove as much wash solution as possible by beating the microplate carefully.
7. Pipet **150 µl** of enzyme conjugate into each well.
8. Incubate for **60 minutes** at room temperature (18 - 28 °C) on a plate mixer (350 – 400 rpm).
9. Again discard the content of all wells and wash **4 times** with **300 µl** buffered wash solution. Remove as much wash solution as possible by beating the microplate carefully.
10. Dispense **200 µl** of TMB substrate solution into each well.
11. Incubate for **20 minutes** at room temperature (18 - 28 °C) in the dark.
12. Add **50 µl** of stop solution to each well and mix carefully.
13. Read the optical density at **450 nm**.

The developed color is stable for at least 15 minutes. Read optical densities during this time.

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6.3 CALCULATION OF RESULTS

For evaluation of PMN Elastase a 4-Parameter-Fit with lin-log coordinates for optical density (linear scale) and concentration (logarithmic scale) is recommended.

7 PERFORMANCE CHARACTERISTICS

7.1 ANALYTICAL SENSITIVITY

The lower detection limit for PMN Elastase was 0.2 ng/ml.

7.2 SPECIFICITY

The IBL-America PMN Elastase test is specific human PMN elastase only, respectively the PMN elastase/α_1-PI complex.

7.3 REPRODUCIBILITY

Statistics for Coefficients of variation (CV) were calculated for each of three samples from the results of 10 determinations in a single run for Intra-Assay precision and the Inter-Assay precision was calculated from the results of 10 different runs of four samples:

Intra-Assay		
Sample No.	Mean (ng/ml)	CV (%)
1	80	5.2
2	241	4.7
3	358	4.6

Inter-Assay		
Sample No.	Mean (ng/ml)	CV (%)
1	128	5.7
2	216	6.4
3	346	4.4
4	681	5.7

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7.4 RECOVERY

Three spiking solutions were prepared using the Calibrator/Sample Diluent (922, 615 and 478 ng/ml). A 50 µl aliquot of each solution (A,B,C) was spiked into 950 µl aliquots of three different plasma samples, for a spiking ratio of 1 to 20, leaving the plasma matrix of the spiked samples relatively intact. All samples were then assayed by the IBL-America PMN Elastase procedure.

Sample No.	Diluted Solution	measured Concentration	expected Concentration	Recovery [%]
		[ng/ml]	**[ng/ml]**	
1	-	23.2	-	-
	A	72.4	69.4	104
	B	59.3	54.1	109
	C	49.6	47.2	101
2	-	30.6	-	-
	A	73.4	76.7	96
	B	59.3	61.4	97
	C	56.8	54.4	104
3	-	61.7	-	-
	A	118.0	107.8	109
	B	100.8	92.5	109
	C	94.8	85.6	110

7.5 LINEARITY

In dilution experiments sera with high PMN elastase concentrations were diluted with Calibrator/Sample Diluent and assayed in the IBL-America PMN Elastase test. The assay showed linearity over the full measuring range.

Sample No.	Dilution Factor	measured Concentration	expected Concentration	Recovery [%]
		[ng/ml]	**[ng/ml]**	
1	1:1	250.1	-	-
	1:2	145.2	125.1	116
	1:4	75.3	62.5	120
	1:8	37.1	31.3	119
2	1:1	465.5	-	-
	1:2	209.2	232.8	90
	1:4	111.1	116.4	95
	1:8	58.7	58.2	101

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8 EFFECTS OF BILIRUBIN AND HEMOLYSIS

To simulate moderate and severe icterus, four samples were spiked with 100 and 200 milligrams of bilirubin per liter. All samples were assayed, both spiked and unspiked, by the IBL-America PMN Elastase procedure, with the following results (ng/ml):

Sample No.	Unspiked	100 mg/l Bilirubin	200 mg/l Bilirubin
		[ng/ml]	**[ng/ml]**
1	100	106	104
2	249	245	261
3	572	575	534
4	903	964	910

The results show that severe icterus (bilirubin up to 200 mg/l) has no significant effect on the IBL-America PMN Elastase procedure.
Samples with hemolysis normally show no effect on the IBL-America PMN Elastase procedure. In single cases hemolysis can lead to an increase due to the decay of granulocytes *in vitro*.

9 LEGAL ASPECTS

9.1 RELIABILITY OF RESULTS

The test must be performed exactly as per the manufacturer's instructions for use. Moreover the user must strictly adhere to the rules of GLP (Good Laboratory Practice) or other applicable national standards and/or laws. This is especially relevant for the use of control reagents. It is important to always include, within the test procedure, a sufficient number of controls for validating the accuracy and precision of the test.
The test results are valid only if all controls are within the specified ranges and if all other test parameters are also within the given assay specifications. In case of any doubt or concern please contact IBL-America.

9.2 LIABILITY

Any modification of the test kit and/or exchange or mixture of any components of different lots from one test kit to another could negatively affect the intended results and validity of the overall test. Such modification and/or exchanges invalidate any claim for replacement.
In the event of any claim, the manufacturer's liability is not to exceed the value of the test kit. Any damage caused to the test kit during transportation is not subject to the liability of the manufacturer.

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10 REFERENCES

1. Jochum M., Machleidt, W., Neuhof, H., and Fritz, H.
   Proteinases. In: Schlag G, Redl H (eds), Pathophysiology of Shock, Sepsis, and Organ Failure.
   Springer-Verlag Berlin Heidelberg, 1993: 46-60.
2. Jochum M., Machleidt, W., and Fritz, H.
   Proteolytic Enzyme Systems. In: Schlag G, Redl H (eds), Pathophysiology of Shock, Sepsis, and Organ Failure.
   Springer-Verlag Berlin Heidelberg, 1993: 531-548.
3. Elastase
   In: Thomas, L. (Hrsg.) Labor und Diagnose
   Die Medizinische Verlagsgesellschaft, 4. Auflage, 1992: 795 - 801
4. Elastase, Elastase-α1-Proteinase Inhibitor Complex
   In: Friedman, R.B., Young, D.S (Eds.) Effects of Disease on Clinical Laboratory Tests
   AACC Press, Washington, 3rd Edition, 1997: 3-161
5. Reinhardt, A., Haidl, G., and Schill, W-B.
   Granulocyte elastase indicates silent male genital tract inflammation and appropriate anti-inflammatory treatment.
   Andrologia 29, 1996: 187 - 192

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11 SHORT INSTRUCTION

(all sample sizes given in µl)

MP Well / Steps		A	B	C	D	E	F	G	H	Control 1/2	Sample
	ng/ml	0	15.6	31.3	62.5	125	250	500	1000		
Steps	**Solution**										
Pipet	Calibrator	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**-**	**-**
Pipet	Control	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**100**	**-**
Pipet	Prediluted sample	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**100**
Incubate for **60 min** at RT on a plate mixer											
Decant Wash **4x with 300 µl** of buffered wash solution											
Pipet	Enzyme conjugate	**150**	**150**	**150**	**150**	**150**	**150**	**150**	**150**	**150**	**150**
Incubate for **60 min** at RT on a plate mixer											
Decant Wash **4x with 300 µl** of buffered wash solution											
Pipet	Substrate Solution	**200**	**200**	**200**	**200**	**200**	**200**	**200**	**200**	**200**	**200**
Incubate for **20 min** at RT **in the dark**											
Pipet	Stop Solution	**50**	**50**	**50**	**50**	**50**	**50**	**50**	**50**	**50**	**50**
Read at **λ = 450 nm**											

For a detailed description of the procedure see also page 6.

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12 PROTOCOL FOR SEMINAL PLASMA

Separate the seminal plasma by centrifugation (5 min).
Take the supernatant and freeze the seminal plasma at –20°C for longer storage.

Preparation of the Calibrators and Controls

1. Reconstitute PMN Elastase Calibrator with **1 ml Calibrator/Sample Diluent** 30 min. before use (Calibrator H: end concentration of 2,000 ng/ml). Make a dilution serie with Calibrator/Sample Diluent to get calibrators with 1,000; 500; 250; 125; 62.5 and 31.3 ng/ml.
   Store these calibrators in aliquots at –20°C.
   Please label six tubes, A-G. Then pipet 0.5 ml Calibrator/Sample Diluent into each tube and add 0.5 ml Calibrator H into G (1,000 ng/ml). Mix well and continue the dilution serie as follows:
   G = 1.000 ng/ml
   F = 500 ng/ml
   E = 250 ng/ml
   D = 125 ng/ml
   C = 62,5 ng/ml
   B = 31,3 ng/ml
   A = 0 ng/ml (Calibrator-/Sample Diluent)
2. Reconstitute controls with **1 ml** Calibrator-/Sample Diluent 30 min. before use and mix well. For storage keep the controls frozen in aliquots at -20°C.
3. Dilute seminal plasma **1:100** with Calibrator-/Sample Diluent (e.g. 10 µl seminal plasma + 990 µl Calibrator-/Sample Diluent)
4. Pipet **100 µl** Calibrators, Controls and diluted seminal plasma into the wells according to the template.
5. Incubate for **60 minutes** at room temperature (18 - 28 °C) on a plate mixer (350 – 400 rpm).
6. Discard the content of the wells and wash **4 times** with **300 µl** buffered wash solution. Remove as much wash solution as possible by beating the microplate carefully.
7. Pipet **150 µl** of enzyme conjugate into each well.
8. Incubate for **60 minutes** at room temperature (18 - 28 °C) on a plate mixer (350 – 400 rpm).
9. Again discard the content of all wells and wash **4 times** with **300 µl** buffered wash solution. Remove as much wash solution as possible by beating the microplate carefully.
10. Dispense **200 µl** of TMB substrate solution into each well.
11. Incubate for **20 minutes** at room temperature (18 - 28 °C) in the dark.
12. Add **50 µl** of stop solution to each well and mix carefully.
13. Read the optical density at **450 nm**.

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SYMBOLS USED WITH IBL-AMERICA ELISAS

Symbol	English	Deutsch	Francais	Espanol	Italiano
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conforme aux normes européennes	Conformidad europea	Conformità europea
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las Instrucciones	Consultare le istruzioni per l'uso
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Ussage Diagnostic in vitro	Diagnóstico in vitro	Per uso Diagnostica in vitro
RUO	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
REF	Catalogue number	Katalog-Nr.	Référence	Número de catálogo	No. di Cat.
LOT	Lot. No. / Batch code	Chargen-Nr.	No. de lot	Número de lote	Lotto no
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Note warnings and precautions	Warnhinweise und Vorsichtsmaßnahmen beachten	Avertissements et mesures de précaution font attention	Tiene en cuenta advertencias y precauciones	Annoti avvisi e le precauzioni
	Storage Temperature	Lagerungstemperatur	Temperature de conservation	Temperatura de conservacion	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distribuidor	Distributtore