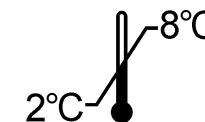


**CA 72-4**














REF

ELSA-CA72-4

IVD



<p>Trousse pour le dosage Immunoradiométrique spécifique de l'antigène TAG 72 dans le sérum ou le plasma Pour diagnostic In Vitro</p> <p>La trousse contient :</p> <table border="0"> <tr><td>ELSA</td><td>4 x 24 tubes</td></tr> <tr><td>Traceur ≤ 370 kBq</td><td>1 x 30 mL</td></tr> <tr><td>Calibrateurs 1 - 5</td><td>5 x 0,8 mL</td></tr> <tr><td>Contrôle</td><td>1 x 0,8 mL</td></tr> <tr><td>Diluant</td><td>1 x 10 mL</td></tr> <tr><td>Tampon</td><td>1 x 20 mL</td></tr> <tr><td>Sachet plastique</td><td>1</td></tr> <tr><td>Notice d'utilisation</td><td>1</td></tr> </table> <p>Attention : Certains réactifs contiennent de l'azoture de sodium</p>	ELSA	4 x 24 tubes	Traceur ≤ 370 kBq	1 x 30 mL	Calibrateurs 1 - 5	5 x 0,8 mL	Contrôle	1 x 0,8 mL	Diluant	1 x 10 mL	Tampon	1 x 20 mL	Sachet plastique	1	Notice d'utilisation	1	<p>Kit for the immunoradiometric assay for the quantitative determination of TAG 72 antigen in human serum or plasma For In Vitro diagnostic use</p> <p>Kit content :</p> <table border="0"> <tr><td>ELSA</td><td>4 x 24 tubes</td></tr> <tr><td>Tracer ≤ 370 kBq</td><td>1 x 30 mL</td></tr> <tr><td>Calibrators 1 - 5</td><td>5 x 0.8 mL</td></tr> <tr><td>Control</td><td>1 x 0.8 mL</td></tr> <tr><td>Diluent</td><td>1 x 10 mL</td></tr> <tr><td>Buffer</td><td>1 x 20 mL</td></tr> <tr><td>Plastic bag</td><td>1</td></tr> <tr><td>Instruction for use</td><td>1</td></tr> </table> <p>Warning : Some reagents contain sodium azide</p>	ELSA	4 x 24 tubes	Tracer ≤ 370 kBq	1 x 30 mL	Calibrators 1 - 5	5 x 0.8 mL	Control	1 x 0.8 mL	Diluent	1 x 10 mL	Buffer	1 x 20 mL	Plastic bag	1	Instruction for use	1	<p>Immunoradiometrischer Test zur spezifischen Bestimmung des TAG 72-Antigens in Serum oder Plasma Zur In Vitro-Diagnostik</p> <p>Inhalt des kits :</p> <table border="0"> <tr><td>ELSA</td><td>4 x 24 Röhrenchen</td></tr> <tr><td>Tracer ≤ 370 kBq</td><td>1 x 30 mL</td></tr> <tr><td>Kalibratoren 1 – 5</td><td>5 x 0,8 mL</td></tr> <tr><td>Kontrolle</td><td>1 x 0,8 mL</td></tr> <tr><td>Diluent</td><td>1 x 10 mL</td></tr> <tr><td>Puffer</td><td>1 x 20 mL</td></tr> <tr><td>Plastikbeutel</td><td>1</td></tr> <tr><td>Gebrauchsinformation</td><td>1</td></tr> </table> <p>Achtung : Einige Reagenzien enthalten Natriumazid</p>	ELSA	4 x 24 Röhrenchen	Tracer ≤ 370 kBq	1 x 30 mL	Kalibratoren 1 – 5	5 x 0,8 mL	Kontrolle	1 x 0,8 mL	Diluent	1 x 10 mL	Puffer	1 x 20 mL	Plastikbeutel	1	Gebrauchsinformation	1
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	FRA	ENG	DEU	ITA	SPA	ELL	HUN	RUS	TUR	SRB	SVK	BUL
	Explication des symboles	Explanation of symbols	Erläuterung der Symbole	Spiegazione dei simboli	Significado de los símbolos	Επεξήγηση των συμβόλων που	Jelmagyarázat	Объяснение символов	Sembollerin açıklaması	Objašnjenje simbola	Vysvetlenie symbolov	Обяснение на символите
	Conforme aux normes européennes	European conformity	CE-Konformitätskennzeichnung	Conformita europea	Conformidad europea	European conformity	Megfelel az európai szabványoknak	Европейский соответствия	Avrupa'ya uyum	Evropska usaglašenost	Európska zhoda	Европейско съответствие
	T° limite de stockage	Storage temperature limitation	Limitierung der Lagertemperatur	Limiti per la temperatura di conservazione	Limites de temperatura de almacenamiento	Περιορισμός θερμοκρασίας φύλαξης	Tárolási hőmérséklet határ	Ограничение температуры хранения	Depolama sıcaklığı sınırlaması	Ograničenje temperature za čuvanje	Limity teploty skladovania	Температурни ограничения при съхранение
	N° de lot	Batch code	Chargencode	codice lotto	Código de lote	Κωδικός παρτίδας	Gyártási szám	код партии	Parti kodu	Šifra serije	Kód šarže	Партиден номер
	Utiliser jusqu'au	Use by	Verwendbar bis	utilizzare entro	Consumir antes de	Ημερομ. λήξης	Felhasználható az alábbi dátumig :	Используйте по	Son kullanım tarihi	Upotrebiti do	Použitelné do	Използвайте до
	Consulter la notice d'utilisation	Consult operating instructions	Das Handbuch zu Rate ziehen	consultare le istruzioni per l'USO	Consultar las instrucciones de manejo o funcionamiento	Ανατρέξτε στις οδηγίες λειτουργίας	Olvassa el a használati utasítást	Соблюдать инструкцию по эксплуатации	İşletim talimatlarına danişin	Pogledajte uputstvo za upotrebu	Prečítajte si návod na použitie	Консултирайте се с инструкциите за работа
	Diagnostic In Vitro	In Vitro Diagnostic device	In-VitroDiagnostische Anwendung	Dispositivo Diagnostico In Vitro	Dispositivo de diagnóstico In Vitro	διαγνωστική συσκευή In Vitro	In vitro diagnosztika	В устройстве Vitro диагностики	In Vitro Tanılama cihazı	Uređaj za dijagnostiku <i>in vitro</i>	In vitro diagnostická pomôcka	Ин Витро Диагностично изделие
	Fabriqué par	Manufactured by	Hergestellt von	Prodotto da	Fabricado por	Κατασκευάζεται από την	Gyártja:	Производитель	Üretici	Proizveo	Výrobca	Произведено от
	Référence	Catalogue number	Katalog Nr.	N. catalogo	Número de catálogo	Αριθμός καταλόγου	Referenciakészít mény	номер по каталогу	Katalog numarası	Kataloški broj	Katalógové číslo	Каталожен номер
	Nombre de tubes	Number of determinations	Anzahl der Bestimmungen	Numero di determinazioni	Número de determinaciones	Αριθμός προσδιορισμών	A kémcsövek száma	Количество определений	Saptama sayısı	Broj određivanja	Počet stanovení	Брой на определянията
	Tubes revêtus	Coated tubes	beschichtete Röhrchen	Provette coattate	Tubos recubiertos	Επιστρωμένα σωληνάκια	Bevont kémcsövek	Покрытые трубы	Tüpler	Obložene epruvete	Potiahnuté skúmavky	Покрити епруветки
	Traceur radioactif	Radioactive tracer	Radioactiver Tracer	Tracciante radioattivo	Trazador radiactivo	Ραδιενεργός ιχνηθέτης	Nyomjelző izotóp	радиоактивного индикатора	Radyoaktif izleyici	Radioaktivni indikator	Rádioaktívny značkováč	Радиоактивен трейсър
	Calibrateur	Calibrator	Kalibrator	Calibratore	Calibrador	Βαθμονομητής	Kalibrátor	калибратор	Kalibratör	Kalibrator	Kalibrátor	Калибратор
	Contrôle	Control	Kontrolle	Controllo	Control	Ορός ελέγχου	Kontroll	контроль	Kontrol	Kontrola	Kontrolný roztok	Контрол

FRA **Modifications par rapport à la version précédente :**

Ajout de la langue Bulgare.

ENG **Changes from the previous version:**

Added Bulgarian language.

DEU **Änderungen gegenüber der Vorgängerversion:**

Bulgarische Sprache hinzugefügt.

ITA **Modifiche rispetto alla versione precedente:**

Aggiunta la lingua bulgara.

SPA **Cambios desde la versión anterior:**

Se agregó el idioma búlgaro.

ELL **Αλλαγές από την προηγούμενη έκδοση:**

Προστέθηκε βουλγαρική γλώσσα.

HUN **Változások az előző verzióhoz képest:**

Hozzáadott bolgár nyelv.

RUS **Изменения по сравнению с предыдущей версией:**

Добавлен болгарский язык.

TUR **Bir önceki sürüm üzerinde yapılan değişiklikler:**

Bulgar dili eklendi.

SRB **Promene od prethodne verzije:**

Dodan je bugarski jezik.

SVK **Zmeny oproti predchádzajúcej verzii:**

Pridaný bulharský jazyk.

BUL **Промени от предишната версия:**

Добавен български език.

1. NAME AND INTENDED USE

ELSA-CA72-4 is an immunoradiometric assay for the quantitative determination of TAG 72 antigen in human serum or plasma. The kit is intended for professional use.

2. INTRODUCTION

TAG 72 is a high molecular weight glycoprotein associated with tumors, and recognized by B 72-3* and CC 49 monoclonal antibodies*.

The B 72-3 antibody was obtained by immunizing a mouse with a metastatic human breast cancer-enriched membrane fraction. In immunohistochemistry, it shows good affinity for gastro-intestinal and human mammary carcinomas, as opposed to the corresponding benign or normal tissues. The CC 49 antibody was generated after immunizing a mouse with TAG 72 previously purified by affinity chromatography. It recognizes a different epitope from that recognized by B 72-3.

This assay system was used in numerous clinical studies, which demonstrated its good level of sensitivity to gastric cancers (70% for the metastatic stages and 20% for the non-metastatic) and its outstanding specificity.

The assay also enables the follow-up of gastric cancer cases under treatment or in remission.

3. PRINCIPLE

ELSA-CA72-4 is a solid phase two-site immunoradiometric assay. Two monoclonal antibodies were prepared against sterically remote antigenic sites on the TAG 72 molecule : the first is coated on the ELSA solid phase, the second, radiolabeled with iodine 125, is used as a tracer.

TAG 72 molecules present in the calibrators or the samples to be tested are "sandwiched" between the two antibodies. Following the formation of the coated antibody/antigen/iodinated antibody sandwich, the unbound tracer is easily removed by a washing step.

The radioactivity bound to the ELSA is proportional to the concentration of TAG 72 present in the sample.

4. REAGENTS

Each kit contains enough reagents for 96 tubes. The expiry date is marked on the external label.

REAGENTS	SYMBOLS	QUANTITY	STORAGE
ELSA: ready for use. Monoclonal anti-CA 72-4 antibody coated on ELSA fixed to the bottom of the tube.	CT	4 traypacks of 24 tubes	2-8°C until the expiry date. Tubes removed from their packs must be stored in the bag supplied with the kit.
ANTI-CA 72-4 ¹²⁵I: ready for use. Monoclonal anti CA 72-4 ¹²⁵ I antibody, buffer, bovine albumin, preservative, red dye, non immunized mice immunoglobulins. ≤ 370 kBq (≤ 10 μCi).	TRACER	1 30 mL vial	2-8°C until the expiry date. After opening, 15 days at 2-8°C within the limits of the expiry date.
CALIBRATORS: ready for use. Human serum, human TAG 72, sodium azide, 3 - 10 - 25 - 50 - 100 U/mL*.	CAL	5 0.8 mL vials	
CONTROL: ready for use. Human serum, human TAG 72**, sodium azide.	CONTROL	1 0.8 mL vial	
DILUENT: ready for use. Buffer, bovine albumin, human TAG 72, sodium azide, 3 U/mL*.	DIL	1 10 mL vial	2-8°C until the expiry date.
BUFFER: ready for use. Buffer, bovine albumin, sodium azide.	BUF	1 20 mL vial	2-8°C until the expiry date.
PLASTIC BAG		1	

(*) CA 72-4 concentration is expressed in units/ml (arbitrary system based on a reference preparation).

The values shown above are only target values ; the true value of each calibrator is shown on its label.

(**) The acceptance range true values are printed on the vial label.

5. PRECAUTIONS FOR USE

5.1. Safety measures

Raw materials of human origin contained in the reagents of this kit have been tested with licensed kits and found negative for the anti-HIV 1, anti-HIV 2, anti-HCV antibodies and the HBs antigen. However as it is impossible to strictly guarantee that such products will not transmit hepatitis, the HIV virus, or any other viral infection, all raw materials of human origin including the samples to be assayed must be treated as potentially infectious.

Do not pipette by mouth.

Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.

Wear disposable gloves while handling kit reagents or specimens and wash hands thoroughly afterwards.

Avoid splashing.

Decontaminate and dispose of specimens and all potentially contaminated materials as if they contained infectious agents. The recommended method of doing this is autoclaving for a minimum of one hour at 121.5°C.

Sodium azide may react with lead or copper piping to form highly explosive metal azides. During waste disposal, flush the drains thoroughly to prevent a build-up of these products.

5.2. Basic radioprotection rules

This radioactive product may only be received, purchased, stored or used by persons so authorized, and by laboratories covered by such authorization. The solution should under no circumstances be administered to humans or to animals.

The purchase, storage, use or exchange of radioactive products are subject to the laws in force in the user's country.

The enforcement of the basic rules for handling radioactive products ensures adequate security.

A summary of these is given below :

Radioactive products must be stored in their original containers in a suitable area.

A record of the reception and storage of radioactive products must be kept up to date.

Handling of radioactive products should take place in a suitably-equipped area with restricted access (controlled zone).

Do not eat, drink, smoke or apply cosmetics in a controlled zone.

Do not mouth-pipette radioactive solutions.

Avoid any direct contact with all radioactive products by using laboratory coats and protective gloves.

Contaminated laboratory equipment and glassware must be disposed of immediately after contamination to prevent cross-contamination of different isotopes.

Any contamination or radioactive substance loss should be dealt with in accordance with the established procedures.

All radioactive waste disposal must be carried out according to the regulations in force.

5.3. Handling precautions

Do not use kit components beyond their expiry date.

Do not mix reagents from different batches.

Avoid any microbic contamination of the reagents or of the water used for washing.

Fully respect the incubation conditions and the washing instructions indicated.

6. SPECIMEN COLLECTION AND PREPARATION

The assay is performed directly on serum or plasma. If the test is to be carried out within 24 hours, the samples may be stored at 2-8°C. Otherwise, they should be divided into aliquots and deep frozen (-20°C) until needed.

Dilutions

Should elevated CA 72-4 levels be suspected, dilution is performed with the diluent found in the kit.

It is recommended that disposable plastic tubes be used when carrying out dilutions.

7. ASSAY PROCEDURE

7.1. Material required

Precision micropipettes or similar, with disposable tips, capable of dispensing 100 µL, 200 µL and 300 µL. Their calibration should be checked regularly.

Distilled water. Disposable plastic tubes. Vortex-type mixer. Circular horizontal shaker. Gamma scintillation counter calibrated for 125 iodine measurement.

7.2. Protocol

All reagents except the ¹²⁵I anti CA 72-4 monoclonal antibody must be brought to room temperature (18-25°C) at least 30 minutes before their use. Dispensing of the reagent into the ELSA tubes is also carried out at room temperature.

The assay requires the following groups of tubes:

Calibrator groups to establish the calibrator curve.

Control group for the control.

Sx groups for the test samples.

It is recommended that the assay be performed in duplicate for the calibrators, the control and the samples.

Respect the order in which reagents are to be added:

Dispense 200 µL of buffer into all the ELSA tubes.

Add 100 µL of calibrators, control or samples to the corresponding groups of tubes.

Gently mix each tube with a Vortex-type mixer.

Incubate 4 hours ± 5 mn at room temperature (18-25°C) under continuous shaking (400 rpm).

Wash the ELSA tubes as follows:

Aspirate the contents of the tubes as completely as possible.

Add 3.0 mL of distilled water to each tube, and re-empty.

Repeat this process twice.

To obtain reliable and reproducible results, the different washing steps have to be correctly performed. As much as possible of the incubation and washing solutions must be removed. If the washing is carried out manually, the tip of the aspirating device must be placed right at the bottom of the ELSA tube.

Add 300 µL of anti-CA 72-4 ¹²⁵I monoclonal antibody to all the tubes.

Gently mix each tube with a Vortex-type mixer.

Incubate overnight (16-20 h) at 2-6°C.

The incubation temperature should not exceed 6°C.

Wash the ELSA tubes as previously described.

Measure the remaining radioactivity bound to the ELSA with a gamma scintillation counter.

8. QUALITY CONTROL

Good laboratory practices require that quality control samples be used in each series of assays to check the quality of the results obtained. All specimens should be treated identically, and result analysis using the appropriate statistical methods is recommended.

9. RESULTS

For each group of tubes, calculate the mean counts after subtracting the background.

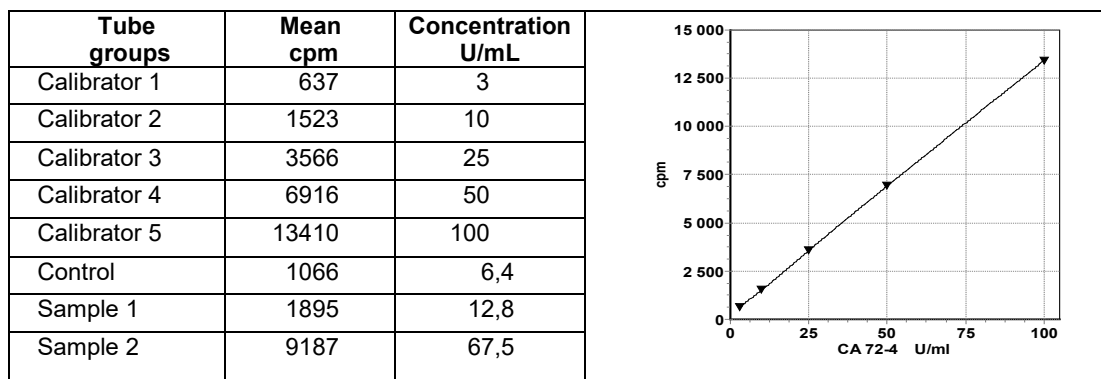
Draw up the calibrator curve by plotting the calibrator's cpm against their concentrations.

Read the sample values directly from the curve, correcting the read value for the dilution factor if necessary.

Do not forget to subtract the diluent CA 72-4 concentration to obtain the final concentration of the specimens.

The spline mathematical fitting model is recommended for calibration curve. Other fitting model may give slightly different results.

Typical calibrator curve (example only) : this data must not be substituted for results obtained in the laboratory.



10. PROCEDURAL LIMITATIONS

Samples which show turbidity, haemolysis, hyperlipemia or contain fibrin may give misleading results.

Do not extrapolate sample values beyond the last calibrator. Dilute the samples concerned and re-assay.

11. EXPECTED VALUES

Each laboratory should establish its own range of normal values.

A study measuring the level of CA 72-4 in 200 presumably healthy, smoker or non smoker subjects from both sexes has shown that 98.5% of the values were below 4 U/mL.

12. SPECIFIC CHARACTERISTICS OF THE ASSAY

12.1. Imprecision

This has been assessed using 2 samples with different concentrations. They were tested either 30 times in the same series of assays, or in duplicate in 10 different series.

Sample	Mean U/mL	Within-run CV %	Between-run CV %
1	9	9.3	11.7
2	83	5.1	5.7

12.2. Recovery test

Known quantities of CA 72-4 were added to human sera. The recovery percentages of CA 72-4 in the samples ranged from 90 to 110%.

12.3. Dilution test

Ten samples with high levels were diluted, with the recovery percentages ranging from 90 to 110%.

12.4. Specificity

The antibodies used in this assay guarantee a measurement which is completely specific for TAG 72.

12.5. Detection limit

It has been assessed as being 0.8 U/mL.

12.6. Interferences

No interference with bilirubin, haemoglobin and triglycerides, measured up to respective concentrations of equal to 250 mg/L, 5 g/L et 5g/L, has been observed.

ASSAY FLOW CHART

Tubes	Buffer μ L	Calibrators Control or Samples μ L	Mix gently. Incubate 4 hours at 18-25°C under agitation (400 rpm) Wash 3 times.	125 I anti CA 72-4 μ L	Mix gently. Incubate overnight (16-20 h) at 2-6°C. Wash 3 times.	Count
Calibrators	200	100		300		
Control	200	100		300		
Samples	200	100		300		

BIBLIOGRAPHY :

Brandt B, Liffers E, Sasse W, Assmann G. CA 72-4 : the tumor marker for gastric carcinoma. Dans : Klapdor R, ed. Tumor associated antigens, oncogenes, receptors, cytokines in tumor diagnosis and therapy at the beginning of the nineties. Cancer of the breast. State and trends in diagnosis and therapy. München, Bern, Wien, New-York : W. Zuckschwerdt Verlag. 1992:10-2.

Byrne DJ, Browning MCK, Cuschieri A. CA 72-4 : a new tumor marker for gastric cancer. Br J Surg. 1990;77:1010-3.

Colcher D, Paterson A, Sears H, Schlom J. Use of monoclonal antibody b72.3 to detect a circulating tumor-associated glycoprotein (TAG 72) in the serum of colon carcinoma patients. Hybridoma.1985;4(1):71.

Gero EG, Colcher D, Ferroni P et al. CA 72-4 radioimmunoassay for the detection of the TAG 72 carcinoma-associated antigen in serum of patients. J Clin Lab Anal.1989;3:360-9.

Guadagni F, Roselli M, Amato T et al. CA 72-4 measurement of tumor-associated glycoprotein 72 (TAG 72) as a serum marker in the management of gastric carcinoma. Cancer Res. 1992;52:1222-7.

Johnson VG, Schlom J, Paterson AJ, Bennet J, Magnani JL, Colcher D. Analysis of human tumor-associated glycoprotein (TAG 72) identified by monoclonal antibody B72.3. Cancer Res. 1986;46:850-7.

Ohuchi N, Gero E, Mori S et al. Clinical evaluation of CA 72-4 immunoradiometric assay for serum TAG 72 antigen in patients with carcinoma. J of Tumor Marker Oncol. 1990;5(1):1-10.