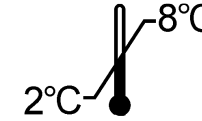




CA 15-3



ELSA-CA15-3



<p align="center">Trousse pour le dosage Immunoradiométrique du CA 15-3 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 ≤ 555 kBq</td><td>1 x 30 mL</td></tr> <tr><td>Calibrateur 0</td><td>1 x 2 mL</td></tr> <tr><td>Calibrateurs 1 - 5</td><td>5 x 2 mL</td></tr> <tr><td>Contrôle</td><td>1 x 0,2 mL</td></tr> <tr><td>Diluant</td><td>1 x 100 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 ≤ 555 kBq	1 x 30 mL	Calibrateur 0	1 x 2 mL	Calibrateurs 1 - 5	5 x 2 mL	Contrôle	1 x 0,2 mL	Diluant	1 x 100 mL	Sachet plastique	1	Notice d'utilisation	1	<p align="center">Kit for the immunoradiometric assay of the CA 15-3 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 ≤ 555 kBq</td><td>1 x 30 mL</td></tr> <tr><td>Calibrator 0</td><td>1 x 2 mL</td></tr> <tr><td>Calibrators 1 - 5</td><td>5 x 2 mL</td></tr> <tr><td>Control</td><td>1 x 0.2 mL</td></tr> <tr><td>Diluent</td><td>1 x 100 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 ≤ 555 kBq	1 x 30 mL	Calibrator 0	1 x 2 mL	Calibrators 1 - 5	5 x 2 mL	Control	1 x 0.2 mL	Diluent	1 x 100 mL	Plastic bag	1	Instruction for use	1	<p align="center">Immunoradiometrischer Test zur quantitativen Bestimmung von CA 15-3 im Serum und Plasma Zur In Vitro Diagnostik</p> <p>Inhalt des kits :</p> <table border="0"> <tr><td>ELSA</td><td>4 x 24 Rörchen</td></tr> <tr><td>Tracer ≤ 555 kBq</td><td>1 x 30 mL</td></tr> <tr><td>Kalibrator 0</td><td>1 x 2 mL</td></tr> <tr><td>Kalibratoren 1 – 5</td><td>5 x 2 mL</td></tr> <tr><td>Kontrolle</td><td>1 x 0,2 mL</td></tr> <tr><td>Diluent</td><td>1 x 100 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 Rörchen	Tracer ≤ 555 kBq	1 x 30 mL	Kalibrator 0	1 x 2 mL	Kalibratoren 1 – 5	5 x 2 mL	Kontrolle	1 x 0,2 mL	Diluent	1 x 100 mL	Plastikbeutel	1	Gebrauchsinformation	1
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	Explication des symboles	Explanation of symbols	Erläuterung der Symbole	Spiegazione dei simboli	Significado de los símbolos	Επεξήγηση των συμβόλων	Significadodo s símbolos	Wyjaśnienie symboli	Jelmagyarázat	Объяснение на символите	ОбЪяснени е символoв	Objašnjenje simbola
	Conforme aux normes européennes	European conformity	CE-Konformitätskennzeichnung	Conformita europea	Conformidad europea	European conformity	Conformidad com as normas europeias	Zgodne z normami europejskimi	Megfelel az európai szabványoknak	Европейската съответствието	Европейское соответствие	Evropska usaglašenost
	T° limite de stockage	Storage temperature limitation	Limitierung der Lagertemperatur	Limiti per la temperatura di conservazione	Limites de temperatura de almacenamiento	Περιορισμός θερμοκρασίας φύλαξης	Limite da temperatura de armazenagem	Graniczna temperatura przechowywania	Tárolási hőmérséklet határ	Ограничаване на температурата на съхранение	Ограничение температуры хранения	Ograničenje temperature za čuvanje
	N° de lot	Batch code	Chargencode	codice lotto	Código de lote	Κωδικός παρτίδας	Lote	Numer partii	Gyártási szám	номер	номер партии	Šifra serije
	Utiliser jusqu'au	Use by	Verwendbar bis	utilizzare entro	Consumir antes de	Ημερομ. λήξης	Utilizado por	Zużyć do	Felhasználható az alábbi dátumig :	Използвайте от	дата истечения срока действия	Upotrebiti do
	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 χρήσης	Consulte o manual de operações	Patrz dołączona ulotka	Olvassa el a használati utasítást	Консултирайт е се с инструкциите за употреба	Учитывать Руководство по эксплуатации	Pogledajte uputstvo za upotrebu
	Diagnostic In Vitro	In Vitro Diagnostic device	In-Vitro Diagnostisch e Anwendung	Dispositivo Diagnostico In Vitro	Dispositivo de diagnóstico In Vitro	Διαγνωστική συσκευή In Vitro	Dispositivo de diagnóstico In Vitro	Diagnostyka In Vitro	In vitro diagnosztika	За ин витро диагностика устройство	In Vitro диагностическое устройство	Uredaj za dijagnostiku <i>in vitro</i>
	Fabriqué par	Manufactured by	Hergestellt von	Prodotto da	Fabricado por	Κατασκευάζεται από την	Fabricado por	Wyprodukowane przez	Gyártja:	Произведено от	Изготовитель	Proizveo
	Référence	Catalogue number	Katalog Nr.	N. catalogo	Número de catálogo	Αριθμός καταλόγου	Número do catalogo	Wzorzec	Referenciakész ítmény	Каталожен номер	номер по каталогу	Kataloški broj
	Nombre de tests	Number of determinations	Anzahl der Bestimmungen	Numero di determinazioni	Número de determinaciones	Αριθμός προσδιορισμών	Número de determinações	Liczba próbek	A kémcsövek száma	Брой определяния	Количество определений	Broj određivanja
	Traceur radioactif	Radioactive tracer	Radioactiver Tracer	Tracciante radioattivo	Trazador radiactivo	Ραδιενεργός ιχνηθέτης	Marcador radioativo	Znacznik radioaktywny	Nyomjelző izotóp	Покритите тръби	пробирки с покрытием	Radioaktivni indikator
	Calibrateur	Calibrator	Kalibrator	Calibratore	Calibrador	Βαθμονομητής	Calibrador	Kalibrator	Kalibrátor	Калибратор	калибратор	Kalibrator
	Contrôle	Control	Kontrolle	Controllo	Control	Μάρτυρας	Controle	Kontrola	Kontroll	Контрол	Управление	Kontrola
	Diluant	Diluent	Verdünnungsmittel	Diluyente	Diluyente	Αραιωτικό	Diluyente	Rozcieńczalnik	Hígítószer	разредител	разбавитель	Razblaživač

FRA **Modifications par rapport à la version précédente :**
Modification code langue Serbe.

ENG **Changes from the previous version:**
Modification Serbian language code.

DEU **Änderungen gegenüber der Vorgängerversion:**
Änderung serbischer Sprachcode.

ITA **Modifiche rispetto alla versione precedente:**
Modifica codice lingua serba.

SPA **Cambios desde la versión anterior:**
Modificación del código de idioma serbio.

ELL **Αλλαγές από την προηγούμενη έκδοση:**
Τροποποίηση κώδικα σερβικής γλώσσας.

POR **Alterações em relação à versão anterior:**
Modificação do código de idioma sérvio.

POL **Zmiany w stosunku do poprzedniej wersji:**
Modyfikacja kodu języka serbskiego.

HUN **Változások az előző verzióhoz képest:**
Szerb nyelvkód módosítása.

BUL **Промени от предишната версия:**
Промяна на кода на сръбския език.

RUS **Изменения по сравнению с предыдущей версией:**
Модификация Сербский язык.

SRB **Promene od prethodne verzije:**
Izmjena kod srpske jezika.

1. NAME AND INTENDED USE

ELSA-CA15-3 is a kit for the immunoradiometric assay of the CA 15-3 antigen in human serum or plasma. The kit is intended for professional use.

2. INTRODUCTION

CA 15-3 is a human breast tumor-associated antigen, recognized and assayed by two monoclonal antibodies. The first, 115D8*, was raised against antigens from human milkfat globule membranes and the second, DF3*, against a membrane-enriched fraction of a human breast carcinoma. The CA 15-3 antigen recognized by both of these monoclonal antibodies is a high molecular weight glycoprotein found at elevated levels in the sera of breast cancer patients.

High pre-operative levels of CA 15-3 are associated with a poor prognosis and correlate to the tumor volume. During a remission period, repeated testing for CA 15-3 enables an early diagnosis of a relapse or metastasis. When a diagnosis of metastasis has been made and throughout the treatment period, variations in CA 15-3 level are correlated to therapeutic efficiency.

The use of CA 15-3 assays is therefore indicated at all stages in the evolution of a breast carcinoma, though it must under no circumstances be considered a screening test.

The sensitivity at the time of diagnosis of metastatic breast cancer is close to 80%.

3. PRINCIPLE

ELSA-CA15-3 is a solid phase "sandwich" immunoradiometric assay. Two monoclonal antibodies were prepared against two sterically-remote antigenic sites on the CA 15-3 molecule. The first is coated on the ELSA solid phase, and the second, radiolabeled with iodine 125, is used as a tracer.

CA 15-3 molecules present in the standards or the samples to be tested are "sandwiched" between the two antibodies. Excess tracer is easily removed during the washing step of the procedure, and only the adsorbed coated antibody/antigen/tracer antibody combination remains on the ELSA.

The amount of radioactivity bound to the ELSA is thus proportional to the amount of CA 15-3 present in the sample at the beginning of the assay.

4. REAGENTS

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

REAGENTS	SYMBOLS	QUANTITY	STORAGE
ELSA: ready for use. Monoclonal anti-CA 15-3 antibody coated on the ELSA fixed at the bottom of the tube.	CT	4 tray-packs of 24 tubes	2-8°C until the expiry date. ELSA tubes removed from their packs must be stored in the plastic bag supplied with the kit.
ANTI-CA 15-3 ¹²⁵I: ready for use. Anti-CA 15-3 ¹²⁵ I monoclonal antibody, buffer, calf serum, sodium azide, non-immunized mouse immunoglobulins, red dye. ≤ 555 kBq (≤ 15 µCi).	TRACER	1 30 mL vial	2-8°C until the expiry date.
CALIBRATORS: lyophilized*, prediluted. Human CA 15-3 antigen, buffer, horse serum, bovine albumin, sodium azide. 0 - 15 - 40 - 80 - 140 - 240 U/mL. Reconstitute with 2.0 mL of distilled water.	CAL	6 2 mL vials	2-8°C until the expiry date. After reconstitution, store 1 month at 2-8°C or 2 months frozen at -20°C.
CONTROL: lyophilized** Human CA 15-3 antigen, buffer, horse serum, sodium azide. Expected value: 30 U/mL. Reconstitute with 0.2 mL of distilled water.	CONTROL	1 0.2 mL vial	2-8°C until the expiry date. After reconstitution, store 1 month at 2-8°C or 2 months frozen at -20°C.
DILUENT: ready for use. Buffer, bovine albumin, sodium azide.	DIL	1 100 mL vial	2-8°C until the expiry date.
PLASTIC BAG		1	

(*) The values shown above are only target values; the true value of each standard is shown on its label and is expressed in units/mL (arbitrary system based on a reference preparation).

(**) 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 radiation protection 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.

Enforcement of the basic radioprotection rules will ensure 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 times and the washing instructions indicated.

6. SPECIMEN COLLECTION AND PREPARATION

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

Dilutions

When high CA 15-3 levels are suspected, dilution of the sample is performed with the diluent supplied in the kit.

The use of disposable plastic tubes is recommended for the dilution operations.

7. ASSAY PROCEDURE

7.1. Material required

Precision micropipettes or similar, with disposable tips, permitting the dispensing of 20 µL, 300 µL and 1000 µL, 2000 µL. Their calibration must be checked regularly.

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

7.2. Protocol

All reagents must be brought to room temperature (18-25°C) in their unopened packaging at least 30 minutes before use. Dispensing of the reagents into the ELSA tubes is also to be carried out at room temperature. Open the cover of the control vial with caution and carefully reconstitute its contents according to the instructions (see n° 4 REAGENTS).

The assay requires the following groups of tubes: 0 Calibrator group for the determination of non-specific binding, calibrator groups to establish the calibrator curve, control group for checks, Sx groups for the samples to be assayed. It is recommended that the assay be performed in duplicate for the calibrators, the control and the samples.

Respect the order of addition for the reagents:

Predilution of samples and control (1/51). Dispense 20 μ L of each sample or control into the plastic tubes. Add 1 000 μ L of diluent to each tube and mix.

NOTE: after reconstitution, the calibrators are ready to use; do not predilute.

Dispense 300 μ L of calibrators and control or prediluted samples into the corresponding ELSA tubes (check labels).

Gently mix each tube with a Vortex-type mixer.

Incubate for 1 hour \pm 5 minutes at room temperature (18-25°C) while continuing shaking at 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; re-empty.

Repeat the operation twice, for a total of 3 washes.

For reliable and reproducible results to be obtained, the different washing steps must be efficient: as much as possible of the different incubation and washing solutions must be removed. If they are carried out manually, the tip of the aspirating device must reach right to the bottom of the ELSA tube.

Add 300 μ L of anti-CA 15-3 ¹²⁵I monoclonal antibody to all of the tubes. Mix gently (Vortex).

Incubate 1 hour \pm 5 minutes at room temperature (18-25°C) while continuing shaking at 400 rpm.

Wash the ELSA tubes in the manner previously described.

Using a gamma scintillator, measure the radioactivity bound to the ELSA.

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.

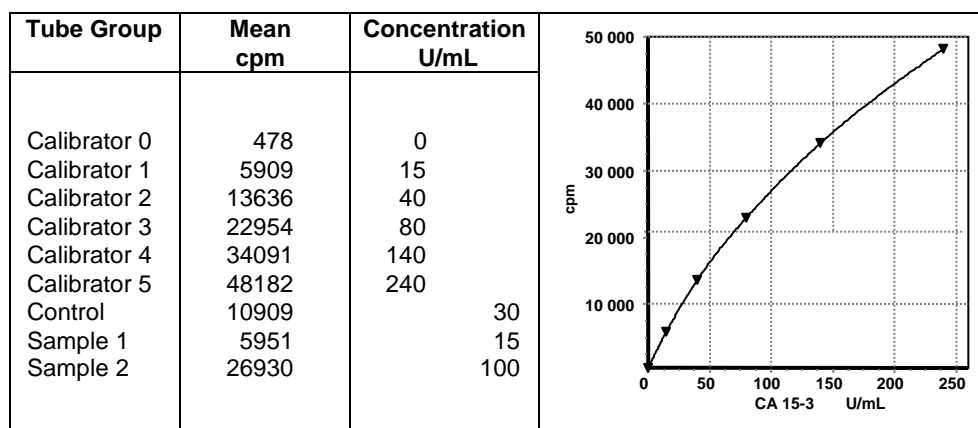
9. RESULTS

For each group of tubes compute the mean counts after subtracting the background. Draw the calibrator curve, plotting the calibrators' cpm compared to their concentrations.

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

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 under no circumstances 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 values for samples beyond the last standard. Dilute the samples concerned and re-assay.

11. EXPECTED VALUES

Each laboratory must establish its own range of normal values. The values given below must only serve as an indicator.

A study concerning 186 women unaffected by any benign or malignant pathology has shown that 98.6% of the values were below 30 U/mL.

12. SPECIFIC CHARACTERISTICS OF THE ASSAY

12.1. Imprecision

This was evaluated using 2 samples with different concentrations assayed either 30 times in the same series or in duplicate in 10 different series.

Sample	Mean U/mL	Within-run CV %	Between-run CV %
1	41.4	5.2	4.8
2	105	5.4	6.0

12.2. Recovery test

Known quantities of CA 15-3 were added to human sera. Recovery percentages of CA 15-3 obtained ranged between 95 and 105%.

12.3. Dilution test

Ten high-value samples were diluted. Recovery percentages were between 95 and 115%.

12.4. Specificity

The antibodies used in this assay guarantee a measurement which is completely specific for CA 15-3.

12.5. Detection limit

The detection limit is defined as being the smallest concentration different from 0 with a confidence interval of 95%. It has been determined as being 0.2 U/mL.

12.6. Measurement range

0.2 – 240 U/mL.

12.7. Interference

The presence of bilirubin at concentrations of up to 250 mg/L and triglycerides up to 20 g/L have no effect on the assay results. The immuno-assay is protected against heterophilic antibodies. However, we cannot guarantee that this protection is exhaustive.

ASSAY FLOW CHART

Tubes	Calibrators Control* Samples* µL	Mix. Incubate 1 hour at 18-25°C, continuing shaking.	125µl Anti-CA 15-3 µL	Mix. Incubate 1 hour at 18-25°C continuing shaking.	Measure
Calibrators	300	Wash 3 times.	300	Wash 3 times.	
Control or Samples	300		300		

(*) Control and samples must be prediluted.

BIBLIOGRAPHY :

Colomer R, Ruibal A, Salvador L. Circulating tumor marker levels in advanced breast carcinoma correlated with the extent of metastatic disease. *Cancer*. 1989;64:1674-81.

Dnistrian AM, Schwartz MK, Greenberg EJ, Smith CA, Scharz C. CA 15-3 and carcinoembryonic antigen in the clinical evaluation of breast cancer. *Clin Chem Acta*. 1991;200:81-94.

Gion M, Mione R, Nascimben O, et al. The tumor-associated antigen CA 15-3 in primary breast cancer. Evaluation of 667 cases. *Br J Cancer*. 1991;63:809-13.

Hilkins H, Buijs F, Lingtenberg M. Complexity of MAM-6, an epithelial sialomucin associated with carcinomas. *Cancer Res*. 1989;49:786-93.

Hilkins H, Buijs F, Hilgers J, et al. Monoclonal antibodies against human milk-fat globule membranes detecting differential antigens of the mammary gland and its tumors. *Int J Cancer*. 1984;34:197-206.

Kerin MJ, McAnena OJ, O'Malley VP, et al. CA 15-3 : its relationship to clinical stage and progression to metastatic disease in breast cancer. *Br J Surg*. 1989;76:838-9.

Kufe D, Inghirami G, Abe M, et al. Differential reactivity of a novel monoclonal antibody (DF3) with human malignant versus benign breast tumors. *Hybridoma*. 1984;55:567-9.

Pons-Anicet DMF, Krebs BP, Mira R, Namer M. Value of CA 15-3 in the follow-up of breast cancer patients. *Br J Cancer*. 1987;55:567-9.

Schlom J, Greiner J, Horan Hand P, et al. Monoclonal antibodies to breast cancer-associated antigens as potential reagents in the management of breast cancer. *Cancer*. 1984;54:2777-94.

SiddiquiJ, Abe M, Hayes D, et al. Isolation and sequencing of a cDNA coding for the human DF3 breast carcinoma-associated antigen. *Proc Natl Acad Sci USA*. 1988;85:2320-3.