Aout 2019 – Modèle 017

Cisbio Bioassays
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chromo@

REF ***CGA-ELISA***

Σ 96

IVD

CE

2°C – 8°C

Trousse ELISA destinée à la mesure de la chromogranine A humaine dans le sérum et le plasma.

Pour diagnostic In Vitro

La trousse contient :

Microplaque	1x 96 puits
Conjugué	2 x qsp 11 mL
Buf-conj	1 x 24 mL
Calibrateur 0 / Diluant	1 x 80 mL
Calibrateurs 1 - 5	5 x qsp 0,25 mL
Contrôle	2 x qsp 0,25 mL
Solution de lavage concentrée	1 x 10 mL
Substrat	1 x 15 mL
Solution d'arrêt	1 x 22 mL
Film adhésif pour microplaque	3
Sachet plastique	1
Notice d'utilisation	1

Attention : Certains réactifs contiennent de l'azoture de sodium

ELISA kit designed to measure the chromogranin A human in serum and plasma.

For In Vitro diagnostic use

Kit content:

Microplate	1 x 96 wells
Conjugate	2 x qsp 11 mL
Buf-conj	1 x 24 mL
Calibrator 0 / Diluent	1 x 80mL
Calibrators 1 - 5	5 x qs 0.25 mL
Control	2 x qs 0.25 mL
Concentrated washing solution	1 x 10 mL
Substrate	1 x 15 mL
Stop solution	1 x 22 mL
Adhesive for microplate	3
Plastic bag	1
Instruction for use	1

Warning: Some reagents contain sodium azide

ELISA-Kit zur Bestimmung des Human CgA im Serum oder plasma.

Zur In Vitro-Diagnostik

Inhalt des Kits:

Microtiterplatte	1 x 96 Vertiefungen
Komplex	2 x q.s 11mL
Buf-con	1 x 24mL
Kalibrierprobe 0 / Verdünnungs	1 x 80 mL
Kalibrierproben 1 - 5	5 x q.s. 0,25 mL
Kontrolle	2 x q.s. 0,25 mL
Konzentrierte waschlösung	1 x 10 mL
Substrat	1 x 15 mL
Stopplösung	1 x 22 mL
Klebefolie fûr microtiterplatte	3
Plastikbeutel	1
Gebrauchsinformation	1

Achtung: Einige Reagenzien enthalten Natriumazid

Kit ELISA destinato alla misurazione della CGA umana nel siero o plasma.

Per uso diagnostico In Vitro

Contenuto del kit:

Micropiastra	1x 96 pozetti
Coniugato	2 x q.b a 11mL
Buf-conj	1 x 24 mL
Calibratore 0 / Diluente	1 x 80 mL
Calibratori 1 - 5	5x q.b a 0,25 mL
Controllo	2 x q.b a 0,25 mL
Soluzione di lavaggio concent	1 x 10 mL
Substrato	1 x 15 mL
Soluzione d'arresto	1 x 22 mL
Film adesivo per micropiastra	3
Sacchetto di plastica	1
Istruzioni per l'uso	1

Attenzione: Alcuni reagenti contengono sodio azide

Equipo ELISA diseñado para medir la CGA humana en el suero o plasma.

Para uso de diagnóstico In Vitro

Contenido del equipo:

Microplaca	1x 96 pozos
Conjugado	2 x csp 11mL
Buf-conj	1 x 24mL
Calibrador 0 / Diluyente	1 x 80 mL
Calibradores 1 - 5	5 x csp 0,25 mL
Control	2 x csp 0,25 mL
Solución de lavado concent.	1 x 10 mL
Substrato	1 x 15 mL
Solución de parada	1 x 22 mL
Film adhesivo para microplata	3
Bolsa de plástico	1
Instrucciones de uso	1

Precauciones: Algunos reactivos contienen azida sódica

Δοκιμή ELISA που προορίζεται για τη μέτρηση της ανθρώπινης CGA στον ορό.

Για διάγνωση In Vitro

ΠΕΡΙΕΧΟΜΕΝΑ ΤΗΣ ΤΥΠΟΠΟΙΗΜΕΝΗΣ ΣΥΣΚΕΥΑΣΙΑΣ

ΜΙΚΡΟΠΛΑΚΑ	1x 96 ΦΡΕΑΤΙΑ
ΣΥΖΕΥΓΜΑ	2 x QS 11 mL
Buf-conj	1 x 24mL
ΒΑΘΜΟΝΟΜΗΤΗΣ 0 / ΑΡΑΙΩΤΙΚΟ	1 x 80 mL
ΒΑΘΜΟΝΟΜΗΤΗΣ 1 - 5	5 x QS 0,25 mL
ΜΑΡΤΥΡΑΣ	2 x QS 0,25 mL
ΣΥΜΠΥΚΝΩΜΕΝΟ ΡΥΘΜΙΣΤΙΚΟ	1 x 10 ML
ΥΠΟΣΤΡΩΜΑ	1 x 15 ML
ΔΙΑΛΥΜΑ ΤΕΡΜΑΤΙΣΜΟΥ	1 x 22 ML
ΑΥΤΟΚΟΛΛΗΤΗ ΤΑΙΝΙΑ	3
ΠΛΑΣΤΙΚΟ ΣΑΚΟΥΛΑΚΙ	1
ΟΔΗΓΙΕΣ ΧΡΗΣΕΩΣ	1

ΠΡΟΣΟΧΗ: ΟΡΙΣΜΕΝΑ ΑΝΤΙΔΡΑΣΤΗΡΙΑ ΠΕΡΙΕΧΟΥΝ ΑΖΙΔΙΟ ΝΑΤΡΙΟΥ

	FRA	ENG	DEU	ITA	SPA	ELL	POR	SWE	DAN	POL	HUN	CES	TUR
	Explication des symboles	**Explanation of symbols**	**Erläuterung der Sumbole**	**Spiegazione dei simboli**	**Significado de los simbolos**	**Επεξήγηση των συμβόλων**	**Significadodos simbolos**	**Symbol förklaring**	**Symbol forklaring**	**Wyjaśnienie symboli**	**Jelmagyarázat**	**Vysvětlení symbolů**	**Sembollerin açıklaması**
	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	T°-gräns vid förvaring	T° grænse for opbevaring	Graniczna temperatura przechowywania	Tárolási hőmérséklethatár	Mezní teplota skladování	Depolama sıcaklığı sınırlaması
	N° de lot	Batch code	Chargencode	codice lotto	Código de lote	Κωδικός παρτίδας	Lote	Lotnr.	Lot nr.	Numer partii	Gyártási szám	Č. šarže	Parti kodu
	Utiliser jusqu'au	Use by	Verwendbar bis	utilizzare entro	Consumir antes de	Ημερομ. λήξης	Utilizado por	Används senast	Udløbsdato	Zużyć do	Felhasználható az alábbi dátumig :	Použitelné do	Son kullanım tarihi
	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	Läs bruksanvisningen	Se brugsvejledningen	Patrz dołączona ulotka	Olvassa el a használati utasítást	Přečtěte si návod k použití	İşletim talimatlarına danışın
IVD	Diagnostic In Vitro	In Vitro Diagnostic device	In-VitroDiagnostische Anwendung	Dispositivo Diagnostico In Vitro	Dispositivo de diagnóstico In Vitro	Διαγνωστική συσκευή In Vitro	Dispositivo de diagnostico In Vitro	*In vitro*-diagnos	In vitro diagnose	Diagnostyka In Vitro	In vitro diagnosztika	Diagnostika in vitro	In Vitro Tanılama cihazı
	Fabriqué par	Manufactured by	Hergestellt von	Prodotto da	Fabricado por	Κατασκευάζεται από την	Fabricado por	Tillverkad av	Fremstillet af	Wyprodukowane przez	Gyártja:	Vyrobil	Üretici
REF	Référence	Catalogue number	Katalog Nr.	N. catalogo	Número de catálogo	Αριθμός καταλόγου	Número do catalogo	Referens	Reference	Wzorzec	Referenciaké szítmény	Reference	Katalog numarası
	Nombre de tests	Number of determinations	Anzahl der Bestimmungen	Numero di determinazioni	Número de determinaciones	Αριθμός προσδιορισμών	Número de determinações	Antal rör	Antal glas	Liczba probówek	A kémcsövek száma	Počet zkumavek	Saptama sayısı
CONJ	Conjugué	Conjugate	Komplex	Coniugato	Conjugado	Σύζευγμα	Conjugado	Konjugat	Kombineret	Koniugat	Kétfázisű elegy	Konjugát	Konjugat
CAL	Calibrateur	Calibrator	Kalibrator	Calibratore	Calibrador	Βαθμονομητής	Calibrador	Kalibrator	Kalibrator	Kalibrator	Kalibrátor	Kalibrátor	Kalibratör
CONTROL	Contrôle	Control	Kontrolle	Controllo	Control	Μάρτυρας	Controle	Kontroll	Kontrol	Kontrola	Kontroll	Kontrola	Kontrol
TWEEN 20	Solution concentrée	Concentrated solution	Konzentrierte Lösung	Soluzione concentrata	Solución concentrada	Συμπυκνωμένο διάλυμα	Solução concentrada	Koncentrerad lösning	Koncentreret opløsning	Roztwór skoncentrowany	Koncentrált oldat	Koncentrovaný roztok	Derişik çözelti
MICROPLATE	Microplaque	Microplate	Mikrotiterplatte	Micropiastra	Microplaca	Μικροπλάκα	Microplaca	Mikroplattan	Mikropladen	mikropłytka	mikrolemez	Mikrotitrační destička	Mikroplaka
DIL	Diluant	Diluent	Verdünnungs-mittel	Diluente	Diluyente	Αραιωτικό	Diluente	Spädningsmedel	Fortyndings middel	Rozcieńczalnik	Hígítószer	ředidlo	Seyreltici
SUBS TMB	Substrat	Substrate	Substrat	Sustrato	Substrato	Υπόστρωμα	Substrato	Substrat	Substrat	Substrat	Szubsztrátum	Substrát	Substrat
STOP SOLN	Solution d'arrêt	Stop solution	Stopplösung	Soluzione d'arresto	Solución de parada	Διάλυμα τερματισμού	Solução de paragem	Stopplösning	Stopoløsning	Roztwór hamujący reakcje	Semlegesitó oldat	Zastavovacó roztok	Durdurma çözeltisi

MISE A JOUR / UPDATING

CE

CGA-ELISA
Cisbio Bioassays – Aout 2019 - Modèle 017

FRA **Modifications par rapport à la version précédente :**
§9 - Supression du protocole long

ENG **Changes from the previous version:**
§9 -Removal of the overnight protocol

DEU **Änderungen gegenüber der Vorgängerversion:**
§9 - Übernachtprotokoll entfernt

ITA **Modifiche rispetto alla versione precedente:**
§9 - Eliminazione del protocollo notturno

SPA **Cambios desde la versión anterior:**
§9 - Eliminación del protocolo nocturno

ELL **Αλλαγές από την προηγούμενη έκδοση:**
§9 - αφαίρεση του μακριού πρωτοκόλλου

POR **Alterações em relação à versão anterior:**
§9 - Supressão do protocolo longo

SWE **Ändringar från föregående utgåva:**
§9 - Borttagning av övernatt-protokollet

DAN **Ændringer fra den tidligere version:**
§9 - Protokol for natten over fjernet

POL **Zmiany w stosunku do poprzedniej wersji:**
§9 - Usunięcie protokołu nocnego

HUN **Változások az előző verzióhoz képest:**
§9 - Egy éjszakán át végzendő protokoll törlése.

CES **Změny od předchozí verze:**
§9 - Odstranění protokolu přes noc

TUR **Bir önceki sürüm üzerinde yapılan değişiklikler:**
§9 - Gece protokolünün çıkarılması

1. NAME AND INTENDED USE

CHROMOGRANIN A is a kit for the enzymatic assay of human chromogranin A (CGA) in serum or plasma.
The kit is intended for professional use.

2. INTRODUCTION

CGA is a hydrophilic and acidic protein of 439 aa (49 kD) present in the chromaffin granules of neuroendocrine cells. It is part of the granin family.
CGA is thought to act as a pro-hormone. Its proteolysis is a key component of its physiology. This degradation releases biologically active peptides (vasostatins, chromostatin, pancreastatin, parastatin), which possess different paracrine and autocrine functions. This proteolysis is tissue-specific and fragmentation of the protein is different depending on its location. It primarily takes place in the cell, inside chromaffin granules. In immunohistochemistry, the presence of CGA in tumour cells is suggestive of a neuroendocrine origin of the tumour. Circulating CGA exists in healthy subjects and the values obtained are independent of age and gender. The value of serum assay of CGA was demonstrated first of all in pheochromocytoma, then quickly extended to other endocrine cancers with particularly significant elevations in intestinal carcinoid levels and endocrine tumours of the pancreas. Recent studies have demonstrated that circulating CGA levels were associated with neuroendocrine differentiation and linked to the tumour mass, without, however, replacing more specific secretions, such as NSE in small-cell lung cancer. Some authors have also demonstrated that the presence of CGA in prostate cancers could be a sign of an unfavourable course. These pathological levels have been associated with reduced survival independently of stage.

3. PRINCIPLE

The CHROMOGRANIN A kit is an ELISA-type immunoassay. A first monoclonal antibody, immobilized on the microplate, captures the CGA proteins contained in the calibrators and samples. After washing, the fixed proteins are then recognized by a second monoclonal antibody conjugated to HRP (Horse-Radish-Peroxidase). After a second incubation, the unfixed reagents are eliminated by washing. Then the colorimetric reaction is started by the addition of an HRP substrate, TMB (3, 3', 5, 5' Tetramethyl benzidine). After the reaction is stopped, the optical density (OD) of each well is read at 450 nm. The OD values measured are proportional to the CGA protein concentration contained in the calibrators and samples.

4. REAGENTS

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

REAGENTS	SYMBOLS	QUANTITY	STORAGE
MICROPLATE: Ready for use. Anti-CGA monoclonal mouse antibody fixed to the bottom of the well, Bovine albumin.	MICROPLATE	1 plate with 96 wells	2-8°C until the expiry date. After opening, any unused strips may be stored for 6 weeks in the plastic bag supplied, properly sealed, within the limits of the expiry date.
CONJUGATE: Lyophilized. Anti-CGA monoclonal mouse antibody coupled to HRP, Non-immunised mouse immunoglobulins, bovine proteins, sugars. Reconstitute each vial with 11 mL BUF CONJ	CONJ	2 vials	2-8°C until the expiry date. After uptake, do not store for more than 2 hours at 18-25°C or freeze at –20°C for a period of 6 weeks, within the limits of the expiry date.
CONJUGATE UPTAKE SOLUTION: Ready for use. Buffer, bovine proteins, preservative.	BUF CONJ	1 vial 24 mL	2-8°C until the expiry date.
CALIBRATORS: Lyophilized. Human recombinant CGA, human serum, EDTA, preservative. 60 – 120 – 225 – 450 – 820 ng /mL * Reconstitute with 0.25 mL distilled water.	CAL	5 vials	2-8°C until the expiry date. After reconstitution, do not store for more than one hour at room temperature, divide into aliquots and freeze at - 20°C for a period of 6 weeks, within the limits of the expiry date.
CONTROLS: Lyophilized. Human recombinant CGA, human serum, preservative. 80 – 575 ng/mL ** Reconstitute with 0.25 mL distilled water.	CONTROL	2 vials	2-8°C until the expiry date. After reconstitution, do not store for more than one hour at room temperature, divide into aliquots and freeze at - 20°C for a period of 6 weeks, within the limits of the expiry date.
BUFFER: Ready for use. This reagent is used as an incubation buffer, diluent and standard 0. Buffer, beef serum, sodium azide, EDTA.	DIL CAL	1 vial 80 mL	2-8°C until the expiry date.
TWEEN 20: Concentrated washing solution Dilute 9 mL Tween 20 in 3 L distilled water. Shake gently.	TWEEN 20	1 vial 10 mL	2-8°C until the expiry date. The diluted Tween may be stored for one week at 2-8°C, within the limits of the expiry date.
SUBSTRATE: Ready for use 3, 3', 5, 5' Tetramethyl benzidine: TMB	SUBS TMB	1 vial 15 mL	2-8°C until the expiry date.
STOP SOLUTION: Ready for use 0.5 M sulphuric acid.	STOP SOLN	1 vial 22 mL	2-8°C until the expiry date.
ADHESIVE FILM FOR MICROPLATE		3	
PLASTIC BAG		1	

(*) The values indicated above are target values, the actual values are indicated on the vial labels.
(**) The actual acceptance limit values are indicated on the vial labels.

5. PRECAUTIONS FOR USE

5.1. Safety measures

The raw materials of human origin contained in the reagents of this kit have been tested with licensed kits and have been found to be negative for anti-HIV 1, anti-HIV 2 and anti-HCV antibodies and the HBs antigen. However, as it is still impossible to strictly guarantee that such products are incapable of transmitting 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 samples or kit reagents are handled.
Wear disposable gloves while handling kit reagents or samples and wash hands thoroughly afterwards. Avoid splashing.
Decontaminate and dispose of samples and all potentially contaminated materials as if they contained infectious agents. The best decontamination method 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. When disposing of waste, dilute thoroughly to prevent the formation of such products.

5.2. Handling precautions

Do not use kit components beyond their expiry date. Do not mix reagents from different batches. Avoid any microbial contamination of the reagents and water. Comply with the incubation times.

6. SAMPLE COLLECTION AND PREPARATION

The assay is performed directly on serum or plasma. For an assay performed within 4 hours, the samples must be stored at room temperature (18-25°C). For an assay performed within 48 hours, the samples must be stored at 2-8°C following specimen collection. For an assay beyond 48 hours, they should be divided into aliquots which must be stored frozen (-20°C) up to 10 months. If the samples are taken on plasma, the values will be systematically higher.
For Taiwan: use serum protocol only

Dilution: If high CGA levels are suspected, dilution should be performed using the diluent buffer supplied with the kit.
It is recommended that dilutions be performed in disposable plastic tubes.

7. ASSAY PROCEDURE

7.1. Equipment required

Precision micropipettes or similar equipment with disposable tips for distribution of 20, 50, 100, 200 and 1000 µL. Calibration of these must be regularly checked.
Distilled water. Disposable plastic tubes.
Vortex mixer. Microplate washer (optional). Microplate reader, capable of measuring absorbance at 450 nm. As an option, the reader may be fitted with a filter capable of reading the absorbance at a wavelength of between 610 nm and 650 nm. This second reading makes it possible to correct the microplate's imperfections.

7.2 Protocol

All the reagents must be brought to room temperature (18-25°C) at least 30 minutes before their use. The reagents are taken up and distributed into wells at room temperature (18-25°C). Each calibrator, control or sample must be tested in duplicate.

Determine the number of wells required for the assay and remove any unused strips. Store at 2-8°C in the plastic bag supplied for this purpose, properly sealed.
Reconstitute the vials of calibrators and controls. Carefully check that all the lyophilisate is dissolved and **use within an hour following reconstitution**.
The conjugate should be reconstituted 10 minutes before use with the conjugate diluent.

To obtain reliable and reproducible results, it is recommended that the washing stages be performed as indicated. The residual washing solution volume must be as low as possible.

Follow the order for addition of reagents:

Distribute 200 µL of incubation buffer in all the wells.
Add 20 µL of calibrators, controls or samples to be assayed.
Cover with the adhesive film, **agitate for 2h at 700 rpm** at room temperature **(18-25°C)**.

Wash the wells as follows:
Aspirate the content of the wells.
Distribute 300 µL washing solution in each well. **TWEEN 20**
Repeat this operation another two times for a total of three washing cycles.
Finish by aspirating. The residual washing solution volume must be as low as possible.

Distribute 200 µL HRP conjugate in all the wells.
Cover with the adhesive film and **incubate for 2 h +/- 5 min** at room temperature **(18-25°C) under agitation at 700 rpm**
Wash the wells as above then:
Distribute 100 µL of TMB in all the wells. Cover with the adhesive film.
Allow the colorimetric reaction to develop **for exactly 10 min** at room temperature (18-25°C), **under agitation (700 rpm**).
Stop the reaction by adding 50 µL stop solution to all the wells.
Cover with the adhesive film.
Agitate for 1 min at 700 rpm.

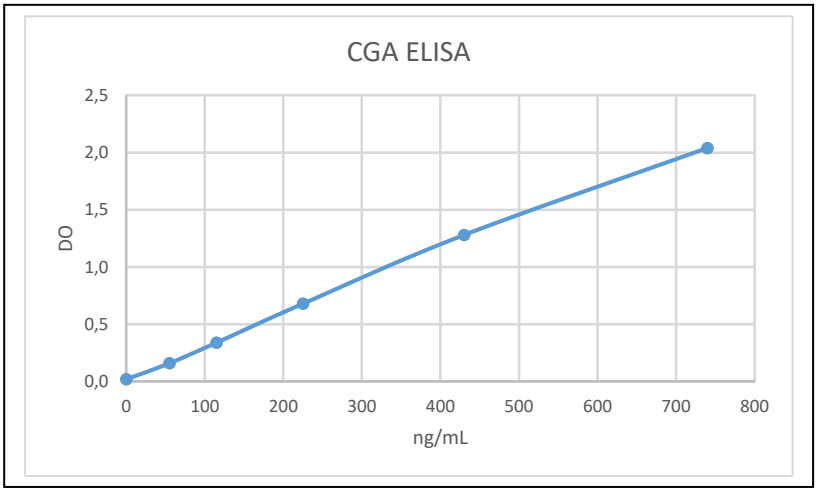
Remove the adhesive film.
Read off the absorbance at 450 nm. Perform a second reading (optional) of the absorbance at a wavelength of between 610 nm and 650 nm.

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 appropriate statistical methods is recommended.

9. RESULTS
For each duplicate, calculate the mean OD.
Optional OD correction: subtract readings at 620 nm (610 to 650 nm) from the readings at 450 nm
Construct the calibration curve expressing the ODs of the calibrators according to their concentration. The mathematical fitting model recommended is the 4 Parameter Logistic "4PL". Other smoothing models may give slightly different results.
Read the values of the samples off the curve and correct using the dilution factor if necessary.

Calibration curve (example only): this data must under no circumstances be substituted for results obtained in the laboratory.

Calibrators	Mean	Concentrations
	OD	ng/mL
CAL 0	0,02	0
CAL 1	0,16	55
CAL 2	0,34	115
CAL 3	0,68	225
CAL 4	1,28	430
CAL 5	2,04	740
Control 1	0,24	82
Control 2	1,70	567



10. LIMITATION OF THE PROCEDURE
Samples presenting cloudiness, hemolysis, hyperlipemia or containing fibrin may give inaccurate results. Do not extrapolate sample values beyond the last calibrator. Dilute the samples concerned and retest.

11. EXPECTED VALUES
It is recommended that each laboratory determines its own normal values depending on the type of sample commonly used. Chromogranin A is a calcium-binding protein and its circulating levels are affected by the Ca++ concentration. The normal human values found differ depending on whether sera sampled on dry tubes or EDTA plasmas are assayed. The values presented below are given as indication only and were obtained on serum or EDTA plasma, with a population of 114 or 60 presumed healthy subjects respectively.

Normal values on serum samples:
95% of the population is between 27 and 94 ng/mL, and the median is 44 ng/mL

Normal values on EDTA plasma samples:
95% of the population is between 32 and 104 ng/mL, and the median is 52 ng/mL.

For any use of this assay on heparin plasma, it is recommended that the normal values be determined on heparin plasma samples.

12. SPECIFIC CHARACTERISTICS OF THE ASSAY
12.1. Imprecision

Samples	n	Concentration Mean (ng/mL)	Within-series (CV%)
9	35	29.2	5
10	35	94	5
11	35	313	4
12	35	501	6

Samples	n	Concentration Mean (ng/mL)	Between-series (CV%)
13	11	38.0	12
14	9	103	6
15	11	198	6
16	9	460	4

12.2. Recovery test
Known quantities of CGA were added to human sera. The recovery percentages in the samples ranged between 90 and 110%.

12.3. Dilution test

Samples with high concentrations were diluted. The recovery percentages obtained were between 100% and 140%.

12.4. Specificity

The two monoclonal antibodies make it possible to assay whole and fragmented circulating CGA.

12.5 Measurement range

The samples must be measured in the range between the limit of detection and the highest concentration of the calibration range, i.e. between 7 and 820 ng/mL.

12.6 Limit of detection

The limit of detection is defined as being the lowest detectable concentration that differs from zero with a probability of 95%. It was measured at 7 ng/mL..
The functional sensitivity is defined as being the concentration measured by the imprecision profile at a CV equal to 20%. It is estimated to be 11 ng/mL.

12.7. Hook effect

There is no hook effect up to 1.000.000 ng/mL.

12.8. Interference

- When the assay protocol provided in the instructions for use is followed, no interference with biotin (for concentration ranging from 0 to 1200 ng/mL) is measured
- No interference with **bilirubin, hemoglobin, triglycerides** and **rheumatoid factors** measured up to respective concentrations of 500 µg/mL, 12 g/L, 12 g/L and 138 IU/mL was observed.
- The immunoassay is protected against any **human anti-mouse antibody-type (HAMA)** interference by the addition of a protector in the conjugate (non-specific mouse immunoglobulins).
  Nevertheless, “false positive” or “false negative” results due to the presence in patient samples of heterophilic antibody-type interferences, rheumatoid factor, etc. cannot be totally excluded.

ASSAY FLOW CHART

WELLS	DIL/CAL 0 µL	Calibrators Controls and Samples µL	Agitate for 1 min at 700 rpm --- Incubate for 2 hours (+/- 5 min) at 18-25°C under agitation at 700 rpm --- Wash 3 times and aspirate	Conjugate µL	Incubate for 2 hours (+/- 5 min) at 18-25°C Under agitation 700 rpm ---- Wash 3 times and aspirate	TMB µL	Incubate for 10 min at 18-25°C Under agitation 700 rpm	STOP Solution µL	Agitate for 1 min 700 rpm --- Measure OD at 450 nm
Calibrator 0	200	20		200		100		50	
Calibrators	200	20		200		100		50	
Controls	200	20		200		100		50	
Samples	200	20		200		100		50	

Bibliography

Jun E et al.
Diagnostic value of chromogranin A in pancreatic neuroendocrine tumors depends on tumor size: A prospective observational study from a single institute.
Surgery. 2017 Jul;162(1):120-30

Rogowski W et al.
Baseline chromogranin A and its dynamics are prognostic markers in gastroenteropancreatic neuroendocrine tumors.
Future Oncol. 2017;13(12):1069-79

Cheng Y et al.
Serum chromogranin A levels for the diagnosis and follow-up of well-differentiated non-functioning neuroendocrine tumors.
Tumour biology. 2016; 37(3):2863-9

d'Herbomez M et al.
Biomarkers of neuroendocrine tumors.
Ann Biol Clin. 2016; 74(6):669-79.

Erickson JA et al.
A chromogranin A ELISA absent of an apparent high-dose hook effect observed in other chromogranin A ELISAs.
Clin Chim Acta. 2016; 452:120-3

Ferrero E et al.
Plasma Chromogranin A as a marker of cardiovascular involvement in Erdheim-Chester disease.
Oncoimmunology. 2016; 5(7): e1181244

Gut P et al.
Chromogranin A - unspecific neuroendocrine marker. Clinical utility and potential diagnostic pitfalls.
Arch Medical Sci: AMS. 2016; 12(1):1-9

Kim M et al.
The Role of Plasma Chromogranin A as Assessment of Treatment Response in Non-functioning Gastroenteropancreatic Neuroendocrine Tumors.
Cancer Res treat. 2016; 48(1):153-61

Lyubimova NV et al.
Chromogranin As a Biochemical Marker of Neuroendocrine Tumors.
Bull Exp Biol Med. 2016; 160(5):702-4

Niedworok C et al.
Serum Chromogranin A as a Complementary Marker for the Prediction of Prostate Cancer-Specific Survival.
Pathol Oncol Res. 2017 Jul;23(3):643-650.

Shanahan MA et al.
Chromogranin A predicts survival for resected pancreatic neuroendocrine tumors.
J Surg Res. 2016; 201(1):38-43

Esfahani M et al.
Biomarkers for evaluation of prostate cancer prognosis
Asian Pac J Cancer Prev. 2015; 16(7):2601-11.

Glinicki P et al.
Comparison of chromogranin A (CgA) levels in serum and plasma (EDTA2K) and the respective reference ranges in healthy males.
Endokrynol Pol. 2015; 66(1):53-6.

Hallet J et al.
Exploring the rising incidence of neuroendocrine tumors: a population-based analysis of epidemiology, metastatic presentation, and outcomes.
Cancer. 2015; 121(4):589-97

Han X et al.
The value of serum chromogranin A as a predictor of tumor burden, therapeutic response, and nomogram-based survival in well-moderate nonfunctional pancreatic neuroendocrine tumors with liver metastases.
Eur J Gastroenterol Hepatol. 2015; 27(5):527-35.

Hsu CH Reyes et al.
Chromogranin A levels and mortality in patients with severe sepsis.
Biomarkers. 2015; 20(3):171-6

Kim M et al.
The Role of Plasma Chromogranin A as Assessment of Treatment Response in Non-functioning Gastroenteropancreatic Neuroendocrine Tumors.
Cancer Res Treat. 2016; 48(1):153-61

Attwood SE et al.
Long-term safety of proton pump inhibitor therapy assessed under controlled, randomised clinical trial conditions: data from the SOPRAN and LOTUS studies.
Aliment Pharmacol Ther. 2015; 41(11):1162-74.

Rehfeld JF.
Chromogranin A in gastrinomas: Promises and pitfalls.
Clin Chim Acta. 2015; 15;446:15-20.

Wu PB et al.
Increased plasma CgA levels associated with nonalcoholic fatty liver disease.
The Turkish journal of gastroenterology. 2015; 26(5):404-7

P Glinicki et al.
Chromogranin A (CgA): structure, biological function, pre-analytical, analytical, and clinical aspects of its measurement in blood
Postepy Nauk Medycznych. 2014; XXVII(12):847-51.

Piotr Glinicki et al.
Comparison of chromogranin A levels in serum and plasma (EDTA2K) and the respective reference ranges in healthy males
Endocrine Abstracts. 2014; (35):532

Hijioka M et al.
Serum chromogranin A is a useful marker for Japanese patients with pancreatic neuroendocrine tumors.
Cancer Sci. 2014; 105(11):1464-71.

Modlin IM et al.
Neuroendocrine tumor biomarkers: current status and perspectives.
Neuroendocrinology. 2014; 100(4):265-77.

Onal IK et al.
Chromogranin A as a marker of disease activity in inflammatory bowel disease.
Scand J Gastroenterol. 2014; 49(12):1501-2.

Pedersen L et al.
Preanalytical factors of importance for measurement of Chromogranin A.
Clin Chim Acta. 2014; 436:41-4.