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Chromogranin A | ELISA Kit

Chromogranin A is the most reliable plasma marker for diagnosis and follow-up of neuroendocrine tumors

- Easy-to-use one-step Chromogranin A ELISA Kit
- Reliable results
- High accuracy

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Chromogranin A – Reliable Marker in the Diagnosis and Follow-Up of Neuroendocrine Tumors (NET)

Neuroendocrine tumors (NETs), also referred to as gastroenteropancreatic (GEP) tumors, are rare tumors with an incidence of 1–2/100,000/yr. According to the World Health Organization (WHO), NETs are classified as either well-differentiated or poorly differentiated (neuro)endocrine tumors of the gastroenteropancreatic tract [1]. A common characteristic of advanced stages of these malignancies is the overproduction and/or secretion of usually one specific peptide per tumor type [2], through which the tumors cause clinically relevant symptoms.

For the screening of patients who are free of symptoms, easy to assess tests or reliable tumor markers are required [3], especially if there is no high secretion of a peptide or a hormone. Among various tested markers, chromogranin A (CgA) is considered the best as well as the most reliable plasma marker that is currently available for both diagnosis and therapeutic evaluation of all neuroendocrine tumors [4, 5].

Chromogranins are ubiquitously present in neuroendocrine tissues. One or more chromogranin/secretogranin proteins are concomitantly secreted with the overproduced peptides. Through this co-secretion, chromogranin A can be utilized as a suitable tissue and plasma marker for neoplasms of neuroendocrine origin [3].

Chromogranin A is increased in up to 80-100% of patients with a diagnosed NET [6] whereby the observed specificity is broad and ranges from 70-95% [7], depending on the primary tumor site and the differentiation [8]. The highest accuracy has been observed in tumors with an intense secretory activity, but its specificity and sensitivity also remains very high in nonfunctioning tumors [8]. This is of particular interest as no or non-detectable peptides are secreted in non-functioning tumors and therefore no accurate diagnosis can be performed by classical testings [3].

Various studies confirmed a direct correlation between the measured CgA level values and the tumor load [9] and CgA can therefore be used to differentiate between patients under remission and patients suffering from a relapse [10]. In the referenced article, a sensitivity of 91.7% was accompanied by a specificity of 96.4% [10]. All these findings indicate that CgA is important in diagnosis as well as in the follow-up of patients with neuroendocrine malignancies [9]. In patients with renal impairment, CgA levels might be abnormally elevated without the presence of a neuroendocrine malignancy. In order not to misinterpret the measured values, it is recommended to determine concomitantly either serum creatinine or serum cystatin C [11]. The testing of CgA as a conclusive marker is indicated when classical tests give instable or fluctuating levels [3].

Chromogranin A is currently the best tumor marker to identify patients suffering from neuroendocrine tumors of the GEP system, lung carcinoids and neuroblastomas. It has not only strategic value in diagnosis, but also in the follow-up of patients with such tumor entities [4, 12].

Chromogranin A ELISA Kit

Intended Use
The assay is intended to quantitatively measure chromogranin A in human plasma.

Interpretation of results should be made within the context of the patient's clinical history and other diagnostic tests by certified professionals.

Principle of the Assay
The Chromogranin A ELISA Kit is a simplified one-step antibody sandwich assay where sample and peroxidase-conjugated polyclonal anti-chromogranin A are incubated simultaneously in microwells coated with polyclonal anti-chromogranin A.

The use of polyclonal rabbit antibodies to a 23 kDa C-terminal fragment of human chromogranin A permits detection of the intact protein as well as the majority of peptides originating hereof.

The inclusion of six standards allows a calibration curve to be constructed from which the chromogranin A concentration in patient samples can be determined.

In Figure 1 the principle of the ELISA assay is depicted.

Assay Time: 2.5 hours

Sample Type: Plasma (EDTA or heparin)

Test Plate: 6 x (2 x 8) microwell strips (1 plate per kit)

Sample Dilution Plate: 6 x (2 x 8) microwell strips (1 plate per kit)

Measuring Range: 5 – 450 U/L

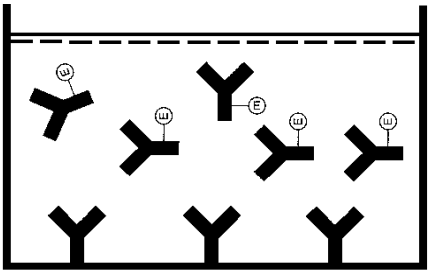
Detection Limit: 2 U/L

Reading Wavelength: 450 nm, with 650 nm as reference (optional)

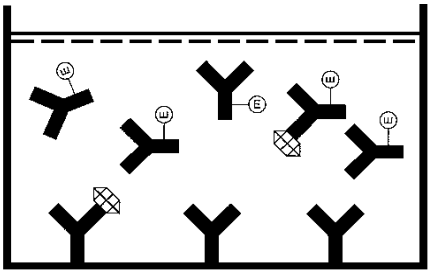
Expected Results: The range of normal values in 30 subjects (healthy persons) obtained using the Chromogranin A ELISA Kit is depicted in Table 1 below. However, it is recommended that each laboratory establishes its own range of reference values.

n	Mean U/L	Standard Deviation	Range U/L
30	10	4	2-18

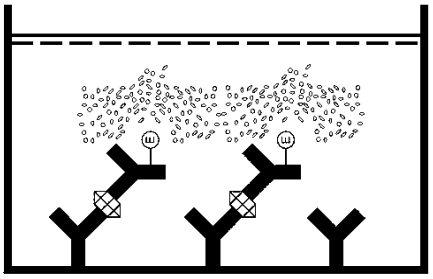
Table 1



1. Addition of enzyme-conjugated anti-chromogranin A to wells precoated with polyclonal anti-chromogranin A.



2. Addition of prediluted samples to the wells. A sandwich consisting of solid-phase anti-chromogranin A, chromogranin A and enzyme-conjungated anti-chromogranin A is formed.



3. After a washing step, the chromogenic substrate is added. Color development results from the oxidation of substrate through an enzyme-catalyzed reaction.

Symbols

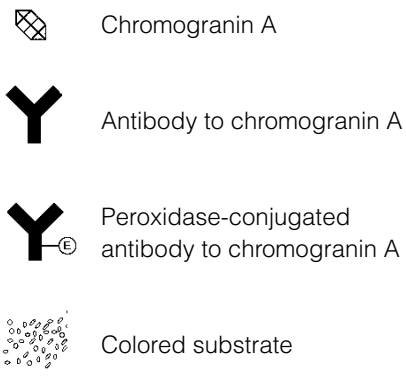


Figure 1

Ordering Information

Product	Size	Code	Regulatory status EU
Chromogranin A ELISA Kit	96 test wells	K0025	CE-IVD*

** Complies with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices*

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