BioVendor Group CLIA

Chromogranin A

Chromogranin A

Clinical area
Oncology

IVD CE 2265

Diagnostic kits are intended for professional use in the laboratory.

Designed for the platform Kleeya®

Introduction

Chromogranin A (CgA) is a protein released into the bloodstream by neuroendocrine cells, which together with endocrine glands can give rise to various benign and malignant tumors. Neuroendocrine tumors (NETs) represent a rare but clinically significant group of tumors that originate from neuroendocrine cells, and they respond to neural stimulation by producing hormones, which may lead to the development of various endocrine syndromes. Diagnosing NETs is challenging because these tumors grow slowly, and their symptoms often appear only after several years. In most of these tumors, elevated levels of CgA are observed, which makes CgA a key biomarker for the diagnosis and monitoring of NETs.

Examples of NETs include carcinoids, pheochromocytoma, small cell lung carcinoma, tumors of the pancreatic islet cells, and medullary thyroid carcinoma.

Origin and risk factors

Neuroendocrine tumors arise from the uncontrolled division of neuroendocrine cells, and their exact cause is not fully understood. However, several factors may contribute to their development:

Genetic predisposition
Some cases of NETs are associated with inherited syndromes, such as Multiple Endocrine Neoplasia type 1 (MEN1).

Mutations
These may be inherited or acquired during a person's lifetime.

Hormonal imbalance
Excessive stimulation of neuroendocrine cells by hormones.

Exposure to carcinogens
For example, chemical substances in the environment.

Chronic inflammation and stress
Long-term inflammatory processes may increase the risk of cellular transformation.

Incidence and prevalence

Neuroendocrine tumors (NETs) most commonly occur in the digestive tract, especially in the small and large intestines (65% of cases), in the lungs (approximately 25% of cases), in the pancreas, and in other organs.

The prevalence of NETs in Europe is about 3 cases per 100,000 people, and it has been increasing in recent years. NETs more frequently affect women and patients with stomach ulcers.

Diagnosis of neuroendocrine tumors

Non-functional tumors are difficult to diagnose due to the absence of clear symptoms. While NETs can produce various biologically active substances such as insulin, glucagon, gastrin, or serotonin, most neuroendocrine cells secrete non-specific biomarkers such as CgA and neuron-specific enolase (NSE), which have diagnostic and prognostic significance.

It is essential to interpret CgA results in the context of the overall clinical picture, as elevated CgA levels can occur not only in the presence of NETs but also due to other medical conditions such as chronic kidney failure, atrophic gastritis, or the use of proton pump inhibitors (PPIs), such as omeprazole.

Advantages of Chromogranin A

- CgA is present in all neuroendocrine cells and is a component of their secretory granules, which enhances its diagnostic value.
- CgA levels are elevated in the majority of NET cases.
- CgA is more suitable for monitoring disease progression and response to treatment.
- CgA is measured in plasma and represents a more reliable method than the determination of 5-hydroxyindoleacetic acid (5-HIAA) in urine.
- Urinary 5-HIAA analysis can be influenced by dietary factors, such as the consumption of foods rich in serotonin.
- NSE is mainly present in highly metabolically active neuroendocrine cells, which limits its specificity for NETs.
- NSE levels are primarily elevated in aggressive and poorly differentiated neuroendocrine tumors, such as small cell lung carcinoma.
- In comparison with 5-HIAA, which is a serotonin metabolite and typically elevated in carcinoid tumors of the gastrointestinal tract, CgA is a more universal biomarker suitable for a broader range of NETs.

Clinical application

- Detection and quantitation of Chromogranin A in human serum or EDTA plasma

Chromogranin A

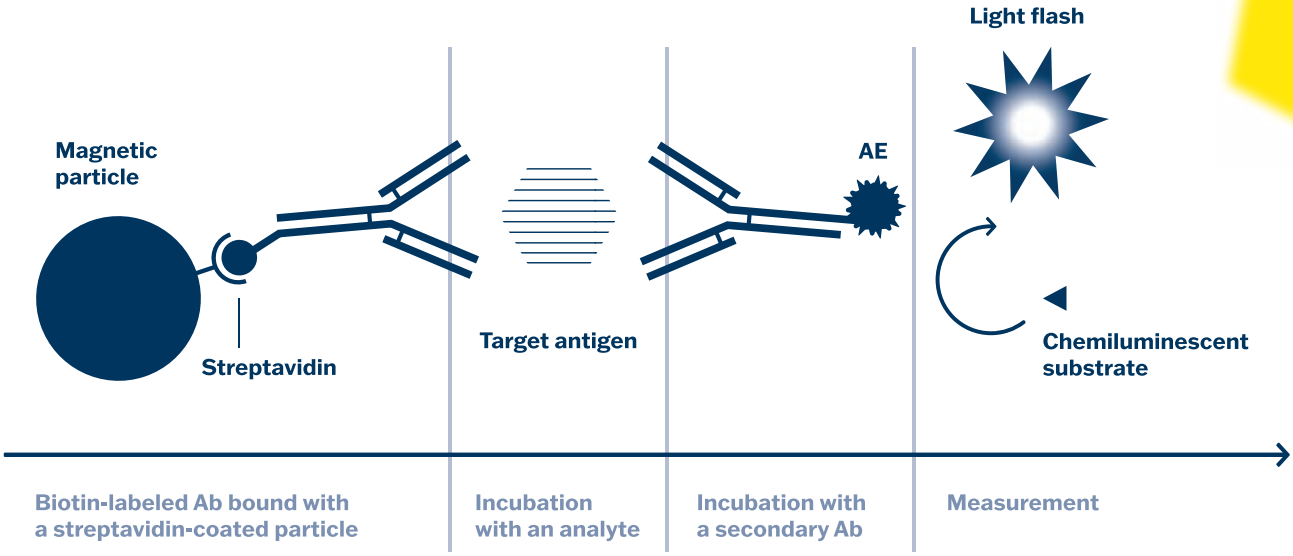
- CgA is a non-specific tumor marker produced in the secretory granules of neuroendocrine cells and within the diffuse neuroendocrine system.
- It serves as a precursor to various functional peptides and is an important marker for the diagnosis of NETs, especially in patients without typical symptoms.
- Plasma CgA levels correlate with tumor size and allow for the monitoring of treatment effectiveness.

Test characteristics

	Chromogranin A
Sample	serum, EDTA plasma
Measuring range	0–2000 ng/ml
Assay time	20 min

How does CLIA method work?

CLIA- Chemiluminescent Immunoassay is a highly advanced method known for its complete automation, rapidity, specificity, and sensitivity. It leverages magnetic particles to separate antigens in immunocomplexes and utilizes flash chemiluminescence for precise detection. The magnetic particle suspension enables automation, reduces reaction times significantly, and enhances specificity. Flash chemiluminescence using acridinium ester produces a strong light signal even at extremely low antigen concentrations, measured in relative light units (RLU). CLIA kits are specifically designed for seamless operation on the KleeYa® automated platform.



The scheme illustrates a sandwich-type reaction.

CLIA kits

Diagnostic CLIA kits are used for the detection and quantification of Chromogranin A in human serum or plasma in the general population on the KleeYa® analyzer. Results are reported in ng/ml.

Control set CLIA

Control sets CLIA are designed to ensure the accuracy and reliability of results obtained from analyses using CLIA kits.

Ease of use

- Fully automated method
- Kits include all necessary reagents, incl. calibrators
- Control materials are available as independent sets

Advantages

- High diagnostic sensitivity and specificity
- Low sample (10 µl) and reagent consumption
- Short test time
- Full traceability of reagent consumption and number of tests available using RFID tags
- LIS connectivity available
- Superior customer service

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Ordering information

CLIA kits

Diagnostic CLIA kits are used for the detection and quantification of Chromogranin A in human serum or plasma in the general population on the KleeYa® analyzer.

Kit	Catalogue number	Number of tests	
CLIA Chromogranin A	CL-CGA100	100	IVD CE 2265

Control sets

Control sets CLIA are designed to ensure the accuracy and reliability of results obtained from analyses using CLIA kits.

Kit	Catalogue number	Number of tests
Control set CLIA Chromogranin A	CL-CGACON	2 x 20

Contact us at

clia@biovendor.group

or visit our website

clia.biovendor.group

BIOVENDOR.GROUP

PRODUCER:

TestLine®

TestLine Clinical Diagnostics s.r.o.
Křižíkova 68
612 00 Brno
Czech Republic

ENCT0101