



Calcitonin Semi-Quantitative Rapid Test Cassette (Serum / Plasma)

REF: FCI-402

English

INTENDED USE

The RightSign™ Calcitonin Semi-Quantitative Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the semi-quantitative detection of calcitonin (CAL) in human serum or plasma. This test is intended for professional use only as an aid in the diagnosis and monitoring of medullary thyroid carcinoma (MTC) and other conditions associated with elevated calcitonin levels. This test provides a visual interpretation of CAL concentration ranges and should not be used as the sole basis for clinical diagnosis.

SUMMARY

Calcitonin (CAL) is a 32-amino-acid peptide hormone produced by the parafollicular C-cells of the thyroid gland. It plays a role in calcium homeostasis by inhibiting osteoclast-mediated bone resorption. Elevated serum calcitonin levels are primarily associated with medullary thyroid carcinoma (MTC), a neuroendocrine tumor of the thyroid, and can also be seen in other conditions such as C-cell hyperplasia, renal failure, and certain endocrine disorders. Semi-quantitative detection of CAL can assist in early diagnosis, monitoring treatment response, and detecting recurrence of MTC.

PRINCIPLE

The RightSign™ Calcitonin Semi-Quantitative Rapid Test Cassette (Serum/Plasma) is a lateral flow immunoassay based on the sandwich principle. A membrane is pre-coated with anti-calcitonin antibodies in three separate test lines (T1, T2, T3) corresponding to different CAL concentration ranges, and a control line (C). During the test, the specimen reacts with gold-conjugated anti-calcitonin antibodies and migrates along the membrane by capillary action. Depending on the CAL concentration, one or more test lines (T1, T2, T3) will develop. The control line (C) must always appear to indicate a valid test.

MATERIALS PROVIDED

- Test cassettes (individually packaged with desiccant)
- Disposable droppers
- Assay buffer
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

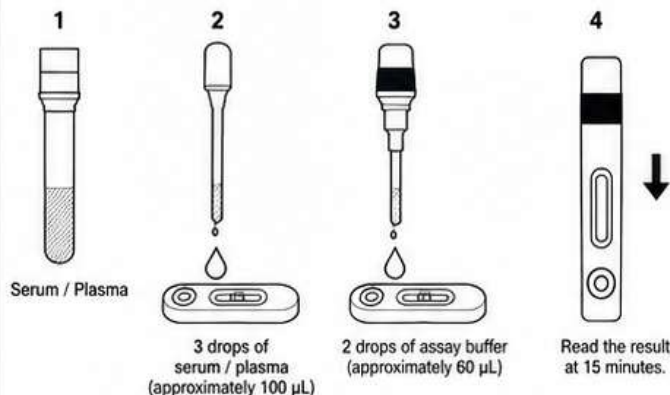
- Specimen collection containers
- Centrifuge (for plasma)
- Timer

SPECIMEN COLLECTION AND PREPARATION

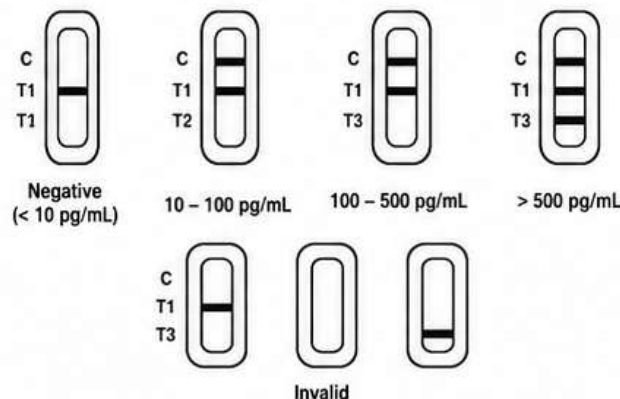
1. Collect venous blood using standard procedures.
2. Separate serum or plasma by centrifugation.
3. Use fresh specimens whenever possible. If not testing immediately, store at 2–8°C for up to 3 days. For longer storage, freeze at -20°C.
4. Bring specimens to room temperature (15–30°C) before testing.
5. Avoid repeated freeze-thaw cycles.

TEST PROCEDURE

1. Bring the test cassette, specimen and assay buffer to room temperature (15–30°C) before use.
2. Add 3 drops (approximately 100 µL) of serum or plasma into the sample well (S) using the provided dropper.
3. Add 2 drops (approximately 60 µL) of assay buffer into the same sample well (S).
4. Start the timer and read the result at 15 minutes. Do not read results after 20 minutes.



INTERPRETATION OF RESULTS



EXPECTED VALUES

Normal serum calcitonin levels are generally < 10 pg/mL. However, reference ranges may vary between laboratories. It is recommended that each laboratory establish its own reference range based on the local population.

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The RightSign™ Calcitonin Semi-Quantitative Rapid Test Cassette (Serum/Plasma) has been evaluated using clinical specimens. The results show high agreement with a reference immunoassay method.

Method		Reference Method		Total
		Positive	Negative	
RightSign™	Positive	142	3	145
	Negative	5	250	255
	Total	147	253	400

Relative Sensitivity: 96.6% (95% CI: 92.1% – 98.9%)

Relative Specificity: 98.8% (95% CI: 96.5% – 99.8%)

Overall Accuracy: 98.0% (95% CI: 96.0% – 99.1%)

LIMITATIONS

1. This test is for *in vitro* diagnostic use only.
2. The result should be interpreted in conjunction with clinical findings and other laboratory test results.
3. This test provides a semi-quantitative result and is not intended to provide a precise quantitative measurement of calcitonin.
4. Elevated calcitonin levels may be observed in conditions other than medullary thyroid carcinoma, including C-cell hyperplasia, renal failure, and certain endocrine disorders.
5. A negative result does not exclude the presence of disease, especially in early stages or in cases with low calcitonin levels.
6. Use fresh specimens and avoid repeated freeze-thaw cycles.

PRECAUTIONS

1. For professional use only.
2. Do not use the test cassette beyond the expiration date.
3. Do not use if the foil pouch is damaged or opened.
4. Handle all specimens as potentially infectious.
5. Wear appropriate personal protective equipment and follow good laboratory practices.
6. Dispose of used test cassettes, droppers and other materials in accordance with local regulations.

STORAGE AND STABILITY

Store at 2–30°C in the sealed pouch. Do not freeze.

The test cassette is stable until the expiration date printed on the pouch. Keep away from direct sunlight, moisture and heat.

ORDERING INFORMATION

Cat. No.	Product Name	Specimen	Pack Size
FCI-402	RightSign™ Calcitonin Semi-Quantitative Rapid Test Cassette	Serum / Plasma	25 Tests

SYMBOLS INDEX

IVD	For in vitro diagnostic use only		Storage temperature 2–30°C
	Contains sufficient for <n> tests		Do not reuse
	Consult instructions for use		Keep dry
LOT	Batch code		Keep away from sunlight
	Use by	REF	Catalogue number
	Manufacturer	CE	CE marking
		EC REP	Authorized representative in the European Community

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