T3-CHECK-1

Quantitative determination of Triiodothyronine (Total T3) in plasma or serum samples for the detection of hyperthyroid

FOR EASY READER® OR EASY READER+® USE ONLY

Ref. 62091 (20 tests) / Ref. 62091-10T (10 tests)

I. PRINCIPLE

The Thyroid hormones, thyroxine (3, 5, 3'5' – tetraiodothyronine or T4) and liothyronine (3, 5, 3'-triiodothyronine or T3) have a great effect on metabolic activity.

The release of T4 and T3 from the thyroid gland is markedly influenced by the pituitary thyroid-stimulating hormone (TSH) which in turn is influenced by the hypothalamic thyrotropin-releasing hormone (TRH). Normally, increased blood levels of T4 and T3 act to decrease the amount of TSH secreted, thereby inhibiting the production and release of T4 and T3. Decreased blood levels of T4 and T3 produce the opposite effect, leading to increased production and secretion of T4 and T3. In this manner a normal circulating thyroid hormone balance is maintained. Most of the circulating T4 and T3 in the blood is bound to serum proteins, thyroxine-binding globulin (TBG), thyroxine –binding prealbumin (TBPA), and albumin.

The T3 is increased in almost all cases of hyperthyroidism and usually goes up before the T4 does. Therefore the total T3 is a more sensitive indicator of hyperthyroidism that the total T4. A small fraction of T3 (0.5%) is free. This free triiodothyronine is considered to be the metabolically active form in its effect on target tissue. The free fraction of T3 is influenced not only by the total circulating T3, but also by the concentration of binding proteins in the blood.

The T3-CHECK-1 is a rapid quantitative assay for the detection of Total T3 in serum or plasma to be used as a screening test for the detection of hyperthyroid The method employs a unique combination of monoclonal dye conjugate and T3 antigen coated on solid phase to identify T3 in the test samples with a high degree of specificity.

As the sample flows through the absorbent device, the labelled antibody-dye conjugate binds competitively to the T3 contained in sample and to the T3 coated in the reaction zone (T). The colour intensity of the band appearing in the test zone (T) is inversely proportional to the concentration of T3 in the sample. The mixture continues flowing through the absorbent device past the reactive zone (T) and control zone (C). Unbound conjugate binds to the reagents in the control zone (C), producing a pink colour band and demonstrating that the reagents are functioning correctly.

II- T3-CHECK-1 KIT COMPONENTS

Each kit contains everything needed to perform 10 or 20 tests.

- T3-CHECK-1 test devices:	10	20
- Disposable plastic pipettes:	10	20
- Diluent in a dropper bottle:	2.5 mL	5 mL
- Instructions leaflet	1	1

- Controls (Optional):

Positive control (ref. V6200) and Negative control (ref. V6201): a freeze-dried preparation of a non-infectious compound in diluted human serum tested and found negative for anti-HIV, anti-HCV and HBs antigen, containing 0.05 % sodium azide is optionally available as a positive and negative control (1x 0.25 mL). The concentration range is indicated on the vial label.

III- STORAGE AND STABILITY

1- All T3-CHECK-1 kit components, including the optional controls before reconstitution should be stored at room temperature (+4°C to +30°C).

2- ***Do not freeze the test kit.***

3- The T3-CHECK-1 kit is stable until the expiry date stated on the package label.

IV- PRECAUTIONS

1- This test is designed for *in vitro* diagnostic use and professional use only.

2- Handle all specimens as if they contained infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving them for at least one hour. Alternatively, they can be treated with 0.5% to 1% solution of sodium hypochlorite for one hour before disposal.

3- Wear protective clothing such as laboratory coats and disposable gloves while assaying samples.

4- Do not eat, drink or smoke in the area where specimens and kit reagents are handled.

5- Avoid any contact between hands and eyes or nose during specimen collection and testing.

6- Do not use beyond the expiration date which appears on the package label.

7- Do not use a test from a damaged protective wrapper.

8- **IMPORTANT**: For better results, the test should be performed at an ambient temperature of +20°C as the minimum up to +30°C as the maximum. When the ambient temperature is +25°C or below, the countdown mode (internal incubation) should be preferred while the immediate mode (external incubation) should be used in case of ambient temperature over +25°C.

V- SPECIMEN COLLECTION AND PREPARATION

1- T3-CHECK-1 test is performed on human serum or plasma.

2- Patients samples are best performed if tested immediately.

3- Specimens containing precipitate may give inconsistent test results. Such specimens should be clarified prior to assaying.

4- Specimens should be refrigerated immediately at +2°C to +8°C following collection up to 3 days. If the testing within 3 days is not possible, the specimens should be frozen (-20°C). If specimens have to be shipped, they should be packed in compliance with regulations covering the transportation of etiologic agents.

VI. ASSAY PROCEDURE

IMPORTANT: Switch the reader on and allow it to warm up for at least 30 minutes before performing any measurements.

a) Controls testing

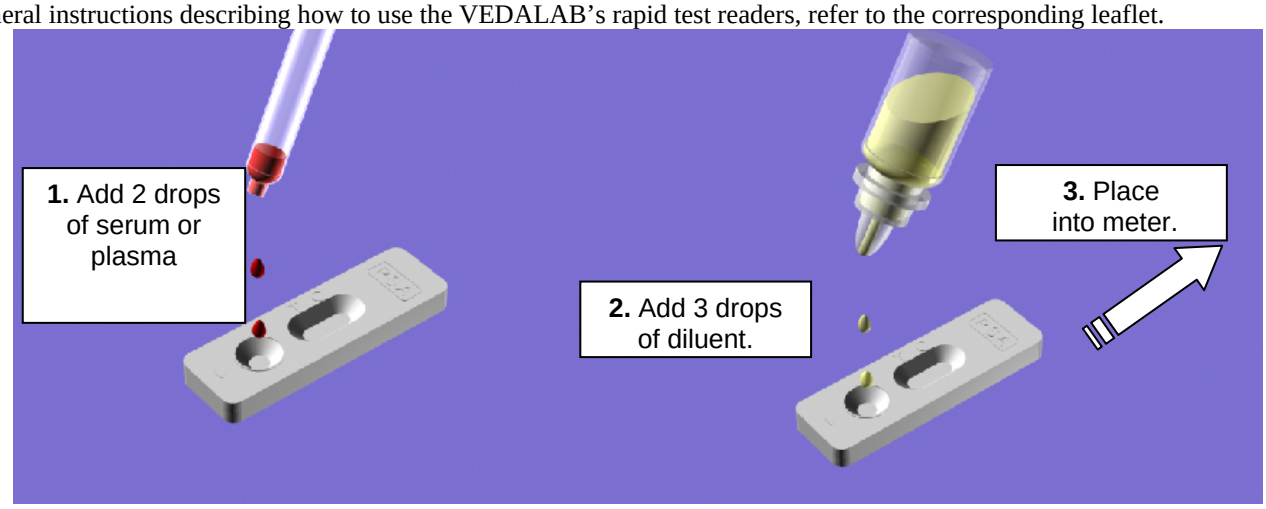
- Wait for 15 minutes after the freeze-dried control has dissolved.
- Add the requested volume (50µL) with **lab pipette (disposable tips)** into the sample well of the cassette and proceed in the same way as for a patient's sample.
- The expected concentration level (**in ng/mL**) is indicated on the vial label and obtained result must match the indicated value. The concentration level can change slightly depending on lot number.
- **The reconstituted vial should be kept at +2°C to +8°C and should be used within 7 days after reconstitution**.

b) Samples testing

Follow the below instructions or refer to the picture n°1.

1- Allow samples and T3-CHECK-1 test devices to come to room temperature prior to testing.
2- Remove the reaction device from its protective wrapper by tearing along the split.
3- Label device with the patient's name or control number.
4- Fill the serum dropper with specimens (serum or plasma) and by holding it vertically, dispense 2 drops (50 µL) into sample well.
5- Hold the diluent vial vertically and slowly add exactly 3 drops of diluent (100 µL) in the sample well (▷) **with an interval of 2-3 seconds between each drop.**
6- Read the result **(in ng/mL**) after 15 minutes either using the immediate or countdown reading mode (see corresponding leaflet).

For general instructions describing how to use the VEDALAB's rapid test readers, refer to the corresponding leaflet.



Picture n° 1

VII. PERFORMANCES CHARACTERISTICS

a) Linearity

The measuring range is 0.3 – 6 ng/mL.
For the T3 concentration lower than 0.3 ng/mL, the result will be shown as "<0.3 ng/mL".
For the T3 concentration higher than 6 ng/mL, the result will be shown as ">6 ng/mL".
For the sample having a T3 concentration exceeding 6 ng/mL, dilute with saline and repeat the assay as per instructions (Part VI).
The obtained result should then be corrected using the dilution factors.

b) Accuracy

A study has been performed using the T3 European reference standard ref. IRMM-469 and serum samples pre-assayed on the COBAS (ROCHE) or VIDAS (BIOMERIEUX) analysers. Optical densities expressed as a function of T3 concentration are described by following polynominal formulation.

$$Y= 496.00-164.48x + 34.13x^2-2.68x^3$$

The results show a good correlation (r>95.5) of Easy Reader and T3-CHECK-1 versus both analysers.

c) Sensitivity

The sensitivity of T3-CHECK-1 is 0.3 ng/mL.
Lower T3 concentrations will be shown as "<0.3 ng/mL".

d) Precision
A panel of pre-assayed serum samples, using either BIOMERIEUX Vidas or ROCHE Cobas analysers has been measured using T3-CHECK-1 quantitative test and VEDALAB's readers.
The result shows a satisfactory coefficient of correlation of 90.7%. (CI* 95% [79-96]).
**Confidence Interval*

e) Hook effect
The T3-CHECK-1 quantitative test is a competitive assay showing an OD decrease for increasing concentration of T3.
Therefore, there is no possibility of a hook effect in this assay.

f) Intra-assay reproducibility
The intra assay reproducibility was evaluated by running 30 replicates of three serum samples having a Total T3 concentration of 0.8; 1.8 and 3.3 ng/mL.
The obtained CV's (coefficient of correlation) are 14.9%; 15% and 13.5% respectively.

g) Inter assay reproducibility
Between lots reproducibility was determined by using three specimens containing 1.2, 2.3 and 3.4 ng/mL of T3, tested in 3 independent assays with three different lots of reaction device.
The obtained coefficients of variation (CV) are respectively 14.4%, 11.3% and 11.9%.

h) Cross reactivity
The following substances were tested for cross reactivity (Data supplied by the anti-T3 antibody manufacturer reported in table 1)

Substances	Cross reactivity
L-Triiodothyronine	100%
D-Triiodothyronine	100%
D-Thyroxine	0.10%
L-Thyroxine	0.04%

Table 1: Cross reactivity

i) References values
Total T3 normal ranges have been obtained from literature (2, 4) and are ranging from 0.7 to 2 ng/mL:

Total triiodothyronine (T3) values higher than 2 ng/mL are consistent with hyperthyroidism or increased concentration of thyroïd hormone binding proteins.

j) Conversion factors
The total T3 concentration could be expressed either in ng/mL, ng/dL or in nmol/L.

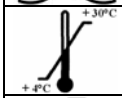
The conversion factors to obtain Total T3 values in ng/dL or nmol/L are respectively:

- **ng/dL = concentration in ng/mL x 100**
- **nmol/L= concentration in ng/mL x 100 / 65.1**

VIII. LIMITATIONS
1- As for any diagnostic procedure, the physician should evaluate the data obtained using this kit in the light of the other clinical information available.
2- This format of test is to be only used with VEDALAB rapid test readers (EASY READER® or EASY READER+®)
3- If the reading time (15 minutes) is not strictly respected, wrong results will be obtained.
4- This format of test should not be used for visual reading.
5- As for any diagnostic method or for any measurements through analysers, there is a variability of the obtained result. Therefore, a confidence range of +/- 25% should be considered for the final value and for the clinical significance of the result.
6- It is recommended that each laboratory establish its own references ranges based on representative patient population in order to test the validity of the supplied data. Therefore, the data given should only be intended as orientational guidelines.
7- For better results, it is recommended to strictly follow the proceeding temperature recommendations as well as to warm up the reader for 30 minutes before starting measurements.

IX. BIBILIOGRAPHY

1. **Hulbert, A, J:** Thyroid hormones and their effects: a new perspective. Biol. Rev. 75:519-631 (2000).
2. **Kratzsch, J.et al**. : New reference intervals for thyrotropin and thyroid hormones based on National Academy of Clinical Biochemistry criteria and regular ultrasonography of the thyroid. Clin. Chem. 51 (8): 1480-1486 (2005).
3. **Plateroti, Mo et al.** Thyroid hormones and their receptors From development to Disease J of Thyroid Research. 2011: doi 10.4061/2011/284737.
4. **Zurakowski, D et al.** Pediatric reference intervals for serum thyroxine, trïodothyronine, thyrotropine and free thyroxine. Clin.C hem. 47 (7): 1087-1091.1999.
5. **Narayanan, S.** Current concepts of thyroid function and laboratory evaluation. Indian Journal of Clinical Biochemistry. 12 (1):25-34 (1997).

	Read the instructions before use		For *in vitro* diagnostic use
	Temperature limitations		Do not reuse
	Manufacturer		

Manufactured by VEDALAB - France