hCG-CHECK-1

Quantitative determination of hCG in whole blood, plasma or serum samples

FOR EASY READER® AND EASY READER+® USE ONLY

Ref. 3191-3L - PATENTED TEST -

I- PRINCIPLE

The hCG-CHECK-1 test is a rapid quantitative assay for the detection of human chorionic gonadotropin in plasma, serum and whole blood. The method, which is patented, employs a unique combination of monoclonal-dye conjugate and polyclonal-solid phase antibodies to selectively identify hCG in the test samples with a high degree of sensitivity.

Depending on the hCG concentration, different lines will appear on the test allowing the quantitative measurements of hCG level in serum, plasma or whole blood samples when used in combination with VEDALAB's rapid test readers (EASY READER® or EASY READER+®).

II- HCG-CHECK-1 KIT COMPONENTS

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

1- hCG-CHECK-1 reaction devices:	10	20
2- Disposable plastic pipettes:	10	20
3- Diluent in a dropper bottle:	2.5mL	5mL
4- Instruction leaflet:	1	1

5- **Controls (Optional): Positive controls (ref. V050B freeze-dried) and Negative controls (ref. V051 liquid)**: the controls (1 x 0.5 mL) are prepared from non-infectious human chorionic gonadotropin, tested and found negative for anti-HIV, anti-HCV and HBs antigen and contain 0.05 % sodium azide. The concentration range is indicated on the vial label.

III- STORAGE AND STABILITY

1- All hCG-CHECK-1 test components should be stored at room temperature (+4°C to +30°C).

2- *Do not freeze the test kit.*

3- The hCG-CHECK-1 test 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- Read carefully the instructions before using this test.

3- 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.

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

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

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

7- Do not use beyond the expiry date which appears on the package label.

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

V- SPECIMEN COLLECTION AND PREPARATION

1- The hCG-CHECK-1 rapid test is performed on plasma, serum or whole blood sample.

2- The serum specimen should be collected under the standard laboratory conditions (aseptically in such a way as to avoid haemolysis).

3- If anticoagulant is needed, only citrate, EDTA or heparin should be used

4- Each specimen should be treated as if potentially infectious.

5- Whole blood samples should be tested immediately (< 4 hours). Finger prick samples should be assayed just after collection.

6- If the test is to be run within 48 hours after collection the specimen should be stored in the refrigerator (+2°C to +8°C). If testing is delayed more than 48 hours, the specimen should be frozen. The frozen specimen must be completely thawed, thoroughly mixed and brought to room temperature prior to testing. Avoid repeated freezing and thawing.

7- In case of cloudiness, high viscosity or presence of particulate matter into the serum specimen, it should be diluted with equal volume (V/V) of diluting buffer (not provided but available upon request) before testing.

VI- ASSAY PROCEDURE

a) Control testing

1/ Positive control

- Wait for 15 minutes after freeze-dried dissolving.
- Add the requested volume (25µL) with **lab pipette (disposable tips)** into the sample well of the cassette and add 4 drops of diluent.
- read the result at 15 minutes.

Notes : - The expected concentration levels (**in IU/L**) is indicated on the vial label and obtained result must match with the indicated value. The concentration level could slightly vary depending on lot number.

- The reconstituted vial should be kept between +2°C and +8°C and should be used within 7 days after reconstitution.

2/ Negative control:

- Ready to use.
- Add the requested volume (25µL) with **lab pipette (disposable tips)** into the sample well of the cassette and add 4 drops of diluent.
- read the result at 15 minutes.

Note : - After each use, promptly replace the stopper and keep the vial between +4°C to +30°C.

b) Samples testing

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

1. Allow specimen and hCG-CHECK-1 test device 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 plastic pipette with serum or plasma specimen and by holding it vertically, dispense 1 drop (25µL) into sample well. If whole blood is to be used, dispense 2 drops (50µL) into the well (▷) **and wait for the whole blood sample to be completely absorbed before adding diluent.**
5. Hold the dropper bottle vertically and slowly add exactly 4 drops of diluent in the sample well (▷) of the device with an interval of 2-3 seconds between each drops.
6. Read the result **(in IU/L**) at **exactly 10 minutes** when using the immediate reading mode (see MD-361018 part V. Assay procedure). In case the result reading is made at different time, wrong results will be obtained. If the countdown mode is preferred, the instrument will measure the test result automatically at the specified time.

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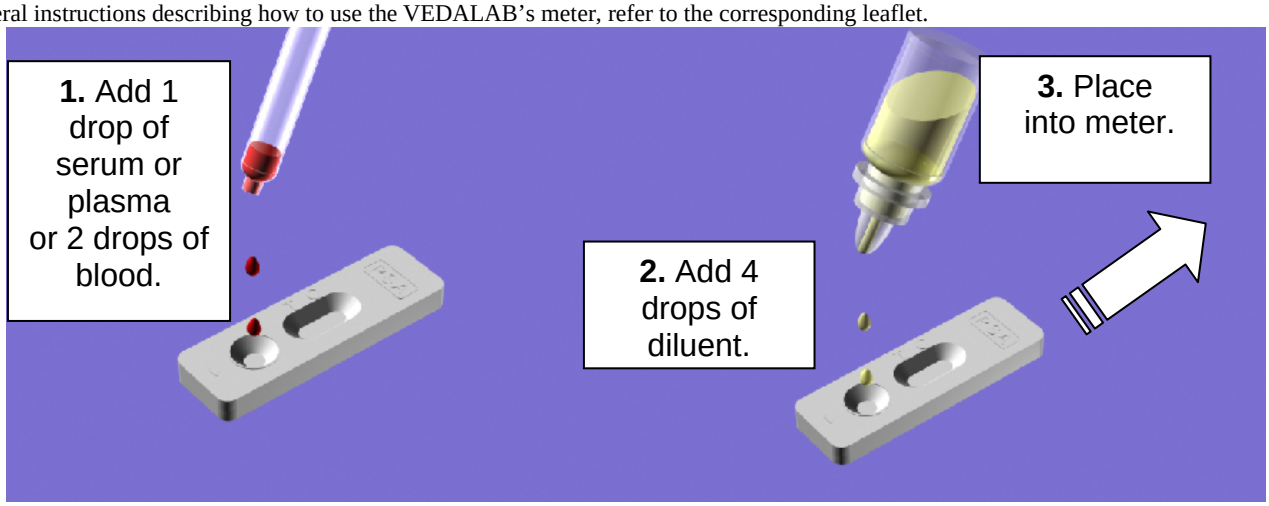
For general instructions describing how to use the VEDALAB's meter, refer to the corresponding leaflet.



Picture n°1

VII- PERFORMANCES CHARACTERISTICS

a) Linearity

The measuring range is 5 to 500,000 IU/L (500 kIU/L) and results will be given as per the table hereunder:

hCG concentration in sample		Reader Results (Expressed either in IU/L or kIU/L)		Sample dilution factor for quantitative value*
IU/L	kIU/L	IU/L	kIU/L	
0 – 4,9	0- 4,9	« < 5 IU/L »		None
5 – 999	5 – 999	Quantitative result		None
1,000 - 4,999	1- 4.999	« 1000 – 5000 IU/L »	1-5 kIU/L	1/50
5,000 - 49,999	5 – 49.999	« 5000 – 50000 IU/L »	5 –50 kIU/L	1/100
50,000 - 249,999	50 – 249.999	« 50000 – 250000 IU/L »	50-250 kIU/L	1/1000 (1/20 + 1/50)
250,000 - 499,999	250 – 499.999	« 250000 – 500000 IU/L »	250-500 kIU/L	1/1000 (1/20 + 1/50)
500,000 and over	500 and over	« > 500000 IU/L »	>500 kIU/L	1/2000 (1/50 + 1/40)

The linear measuring range being 5 to 1,000 UI/L (1 kIU/L), there will be a need to perform a second test with diluted sample (as per the table above) in case an exact hCG value is requested for samples having an hCG concentration over 1,000 IU/L (1 kIU/L).

Please multiply the obtained hCG value by using the sample dilution factor, in order to get the final hCG concentration in the sample.

Saline should always be used as diluent for the patient's sample (whatever the matrix, i.e. serum, plasma or whole blood).

b) Sensitivity

Concentrations close to 3 IU/L could be detected by hCG-CHECK-1 test. In these cases, results will be rendered as "<5 IU/L".

c) Hook effect

Specimen containing high levels of hCG (1,000,000 IU/L or 1,000 kIU/L) when tested consistently gave positive results (>500 kIU/L).

d) Cross reactivity

The following concentrations of homologous hormones are found to have no interferences with HCG-CHECK-1 test.

- hTSH 1,000 µIU/mL WHO 81/565
- hLH 800 mIU/mL WHO 2nd IS 80/552
- hFSH 1,000 mIU/mL WHO 1st IS 83/575

e) Correlation

A panel of 52 human sera pre-assayed on ACCESS BECKMAN-COULTER analyser is assayed using the hCG-CHECK-1 rapid test. Results are quantified using the VEDALAB's reader.

The obtained results show an overall correlation of 99.8% between VEDALAB hCG-CHECK-1 test (and VEDALAB's reader) and BECKMAN–COULTER ACCESS analyser.

f) Intra-assay reproducibility

Within run reproducibility was evaluated by measuring 20 replicates of three samples containing respectively 10, 25 and 500 IU/L of hCG. The obtained CV's (coefficient of variation) are respectively 14.3 %, 8.1 % and 8.0 %.

VIII- LIMITATIONS

1. As for any diagnostic procedure, the physician should confirm the data obtained using this test by other clinical methods.
2. Whole blood samples should be tested immediately (<4 hours). Finger prick samples should be assayed just after collection.
2. A normal pregnancy can not be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results.
3. A very early pregnancy containing an extremely low concentration of hCG can give a negative result. In this case, another specimen should be obtained at least 48 hours later and tested.
4. hCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion, or therapeutic abortion.
5. Some specimens with high concentration of rheumatoid factor (RF), heterophiles or Forssman antibodies may yield non specific positive results during testing. Such cases should be discriminated before testing.
6. The test is designed to eliminate the potential interference of human antibodies to murine IgG (HAMA). However, high level of HAMA could give falsely positive results.
7. As for any diagnostic procedure, the physician should evaluate data obtained by the use of this kit in light of other clinical information.
8. This format of the test is to be only used with VEDALAB rapid test readers (EASY READER® or EASY READER+®).
9. If the reading time (10 minutes) is not strictly respected, wrong results will be obtained.
10. This format of test should not be used for visual reading.
11. 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.

IX- BIBLIOGRAPHY

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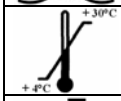
	Read the instructions before use		For *in vitro* diagnostic use
	Temperature limitations		Do not reuse
	Manufacturer		

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