NG-Test® hCG Blood Precision

An all in one rapid test for the qualitative detection of pregnancy using human chorionic gonadotropin (hCG) in whole blood
For professional use only.

Ref: ENO009HCG / Rev: 220704/ EN

Intended use

The **NG-Test® hCG Blood Precision** is a all-in-one rapid immunoassay for the qualitative detection of human chorionic gonadotropin[1] (hCG) in human whole blood as an aid for the early detection of pregnancy.

Summary

Human chorionic gonadotropin (hCG) is a glycoprotein secreted by trophoblast cells during pregnancy. This hormone interacts with ovary specific receptors and promotes the maintenance of the corpus luteum for the maternal recognition of pregnancy. This allows the corpus luteum to secrete progesterone which play key roles to prepare uterus for fetus growth. The possible detection of hCG in whole blood and serum as early as 7 to 10 days after conception makes it an excellent marker for confirming rapidly pregnancy[2-4].
The NG-Test® hCG Whole Blood uses highly specific monoclonal antibodies targeting hCG in human whole blood and serum. Its detection at a level above 10 mIU/mL is used to detect early pregnancy.

Test principle

NG-Test® hCG Blood Precision uses monoclonal antibodies to hCG to selectively detect elevated levels of hCG in whole blood. The assay is conducted by dispensing an adequate volume of blood specimen into the sample well of the device by using the blood collection unit. A buffer solution is added automatically pushing on the ''button'', to facilitate the capillary action across the strip held in the cassette. Then the sample migrates across a membrane toward the results window where the labeled hCG complex is captured at a test line region containing immobilized monoclonal anti-hCG. The appearance of two red lines, one at test region (T) and the other at the control region (C) indicates the presence of hCG in the sample. A colored line should always appear in the control line region (marked "C"), indicating that the proper volume of specimen has been added and that the test worked correctly. If hCG is absent or below the detection limit (< 10 mIU/mL), only the control line will appear in the result window.

Material provided

Each kit contains:

- 5 individual pouches
- 5 alcohol swabs
- 1 package insert

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Material required but not provided

- Timer
- Disposable gloves

Precautions

- For Professional in vitro diagnostic use only.
- Do not use after the expiration date.
- Do not use test if pouch is torn or damaged.
- The test device should remain in the sealed pouch until use.
- Perform the test quickly after opening the aluminum pouch.
- Wear protective clothing such as laboratory coat, disposable gloves and eye protection when specimens are assayed.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Make sure all collected blood is transferred on test strip. Too much or too little sample size may lead to deviation of results.
- Only use the buffer provided in the kit.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- The test must be placed on a flat surface while waiting for the results. The test should never be oriented upwards.
- The test device should not be reused.
- The test device should be discarded in a suitable biohazardous waste container after testing according to local regulations.

Elimination

The test device should be discarded in a suitable biohazardous waste container after testing.

Storage and stability

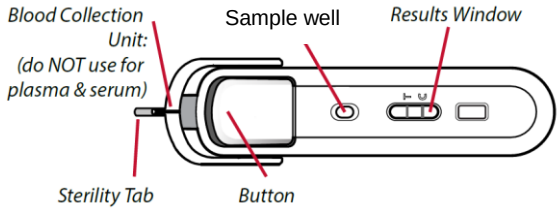
Store as packaged in the sealed pouch at 4-30°C.Test devices are stable until the expiration date printed on the kit or foil pouch**. DO NOT FREEZE**. If the kit has been stored at 4-8°C, bring it to room temperature for at least 10 minutes.

Specimen collection

Fresh blood from finger prick / puncture should be used as a test specimen.

Procedure

The test can be performed at any time of the day, as the concentration of hCG in the blood remains more stable than in the urine in case of a positive test.



Whole Blood – Capillary Collection:

Refer to procedure with diagrams on last page.

NOTE: Once the blood sample has been collected, start the test immediately to prevent clotting risk.

Interpretation of results

Positive
Both test line (T) and control line (C) appear in the result window.
NOTE : *The intensity of the color in the test line regions may vary depending on the concentration of the hCG in the sample. A faint line (C or T) should be considered as positive result.*
Neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

Negative
Only the control line (C) appears in the result window. The absence of a test line (T) indicates a negative result.

Invalid
If the control line (C) does not appear, the test result is invalid.
Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations

1. If a negative result is obtained although pregnancy is still suspected, the hCG level in the specimen may be below the detection limit of the test (10 mIU/mL) It is recommanded to repeat the test 24 to 48 hours later.
2. Very low levels of hCG are present in whole blood specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons[5], a test result weakly positive should be confirmed by retesting 48 hours later.

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3. A number of conditions other than pregnancy, including trophoblastic disease, testicular tumors, prostate cancer, breast cancer and lung cancer cause elevated levels of hCG [6-9]. Therefore, the presence of hCG in whole blood specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
4. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should be made by a physician after all clinical and laboratory findings have been evaluated.

Performance characteristics

1.Specificity

NG TEST® hCG Blood Precision was performed on 20 fresh blood samples assayed by a reference laboratory. Three replicates were carried out on each lot (3 lots) for the 20 samples (180 tests in total).
All tests initiated were negative, the specificity of the test is 100% (Confidence interval 95%: 98.8% -100%).

2. Sensitivity

NG TEST® hCG Blood Precision performed out on 15 positive samples with a concentration greater than 10 mIU/mL.
Three repetitions are carried out on each lot (3 lots) for the 15 samples (135 tests in total).
All tests were positive, the sensitivity of the test was 100% (Confidence interval 95%: 98.7% -100%).

3. Limit of detection

The detection threshold is 10 mIU/mL.

4.Interfering substances

The following potentially interfering substances were added to hCG negative and positive (10 mIU/mL) specimens.
None of the substances at concentration tested interfered in the assay.

Interfering substances	Concentration level
Rheumatoid Factor	300 IU/mL
Anti-nuclear antibodies	> 1280
Human Anti Mouse Antibodies	715 ng/mL
TSH	1 mIU/mL
LH	1000 mIU/mL
FSH	1000 mIU/mL
Acetaminophen	20 mg/dL
Caffeine	20 mg/dL
Methanol	1 %
Ethanol	1%
Bilirubin	1000 µg/dL
Ascorbic Acid	20 mg/dL
Acetylsalicylic Acid	30 mg/dL
Ampicillin	20 mg/dL
Triglyceride	500 mg/dL
Glucose	2000 mg/dL

5. Hook Effect

No Hook Effect observed up to 450,000 mIU/mL. The test line may appear with a less intensive color than expected for samples containing high levels of hCG > 450,000 mIU/mL.

6.Repeatability and reproductibility

The repeatability and reproducibility of the NG-Test® hCG Blood Precision was evaluated with positive and negative samples. No significant difference was observed between batches, operators and inter-run results.

7. Standardization

The test has been standardized to the WHO 5th International Standard (NIBSC - 07/364).

Bibliography:

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Symbols

Σ 5	Content sufficient for 5 tests		Expiry date
IVD	*In Vitro* Diagnostic medical device		Do not reuse
LOT	Batch number	REF	Productreference
	Read instructions before use	+4°C +30°C	Temperature limits
	Manufacturer		Do not use if package is damaged

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PREPARE FINGER

1

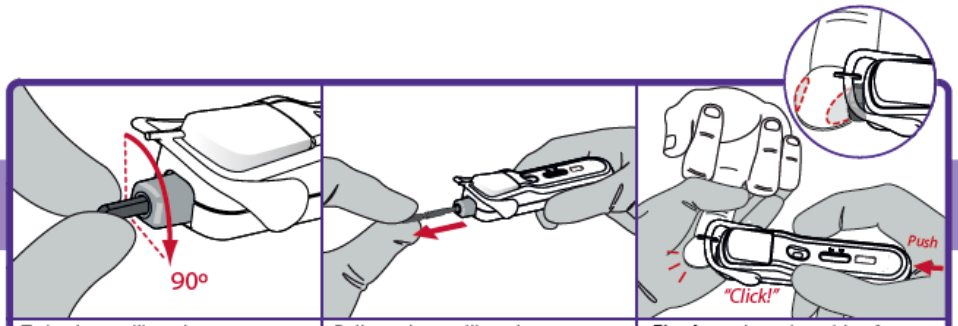
Select the 3rd or 4th finger and **firmly** massage for 5-10 seconds.

Clean fingertip with alcohol swab then **air dry**.

Tear open foil pouch and remove device.

PUNCTURE FINGER

2



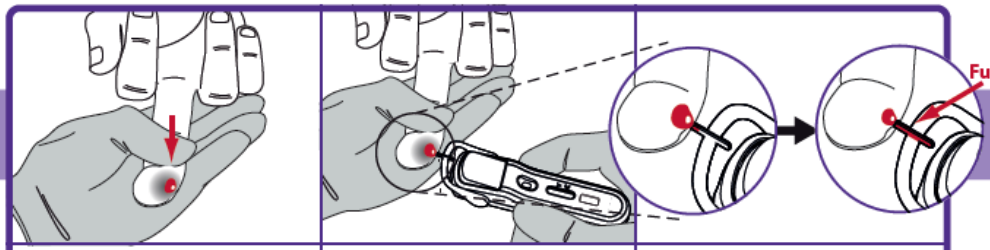
Twist the sterility tab.

Pull out the sterility tab.

Firmly push against side of finger.

COLLECT BLOOD

3



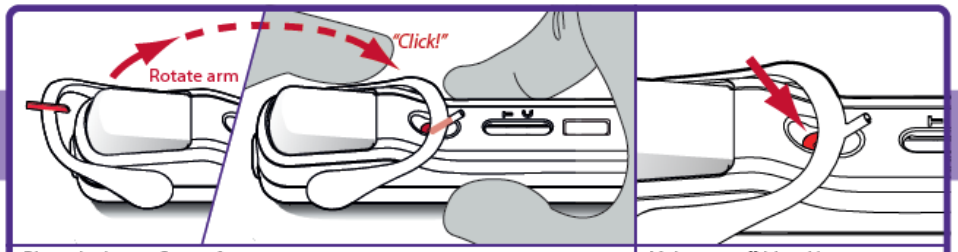
Squeeze behind sample site to form blood droplet.

Fill tube with blood.

Squeeze the finger if necessary to completely fill the blood tube.

DELIVER BLOOD

4



Place device on flat surface.
Rotate arm until it clicks to release blood.

Make sure **all** blood is on the test strip.

ADD DILUENT/ BUFFER

5

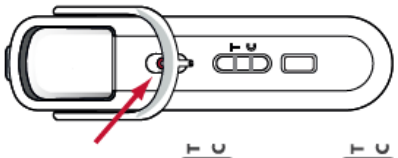
Use your thumb to push the button down firmly until it clicks to release buffer.

Wait for 5 minutes for results.

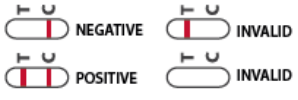
5 min

Do not read after 10 min.*

RESULT INTERPRETATION



NOTE: **blood must** be present on test strip.



**Do not read after 10 min in order not to declare false positive.*

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