

Use of a rapid visual immunological test on whole capillary blood (NG-Test hCG WB) in A&E for early diagnosis of pregnancy through detection of Beta-hCG.

Accident & Emergency department of Parly2 Private Hospital- Le Chesnay- FRANCE

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Summary :

Human chorionic gonadotropin (hCG) is a glycoprotein secreted by viable placenta tissue during pregnancy. In normal pregnancy, hCG can be detected in whole blood as early as 7 to 10 days after conception. hCG levels continue to rise very rapidly, frequently exceeding 100mIU/mL making it an excellent marker for confirming pregnancy.

Test Methodology and Principle

The NG-Test hCG WB is a rapid chromatographic immunoassay for the qualitative detection of Human Chorionic gonadotropin (hCG) in whole blood.

The test uses hCG monoclonal antibodies to selectively detect elevated levels of hCG in whole blood. The assay is conducted by placing an adequate volume of the blood sample into the sample well of the cassette. A buffer solution is added to the well to facilitate migration of the reagent by capillary action across the strip held in the cassette.

The sample thus migrates across a membrane where the labeled hCG complex is captured in a test line region containing immobilized monoclonal anti-hCG. The control region, whatever the result, should show a colored band. It indicates that the test has been performed correctly.

The appearance of two red lines, one at T (Test) and the other at C (Control) indicates the presence of hCG in the sample. If a detectable level of hCG is not present, only the control band will appear in the result window.

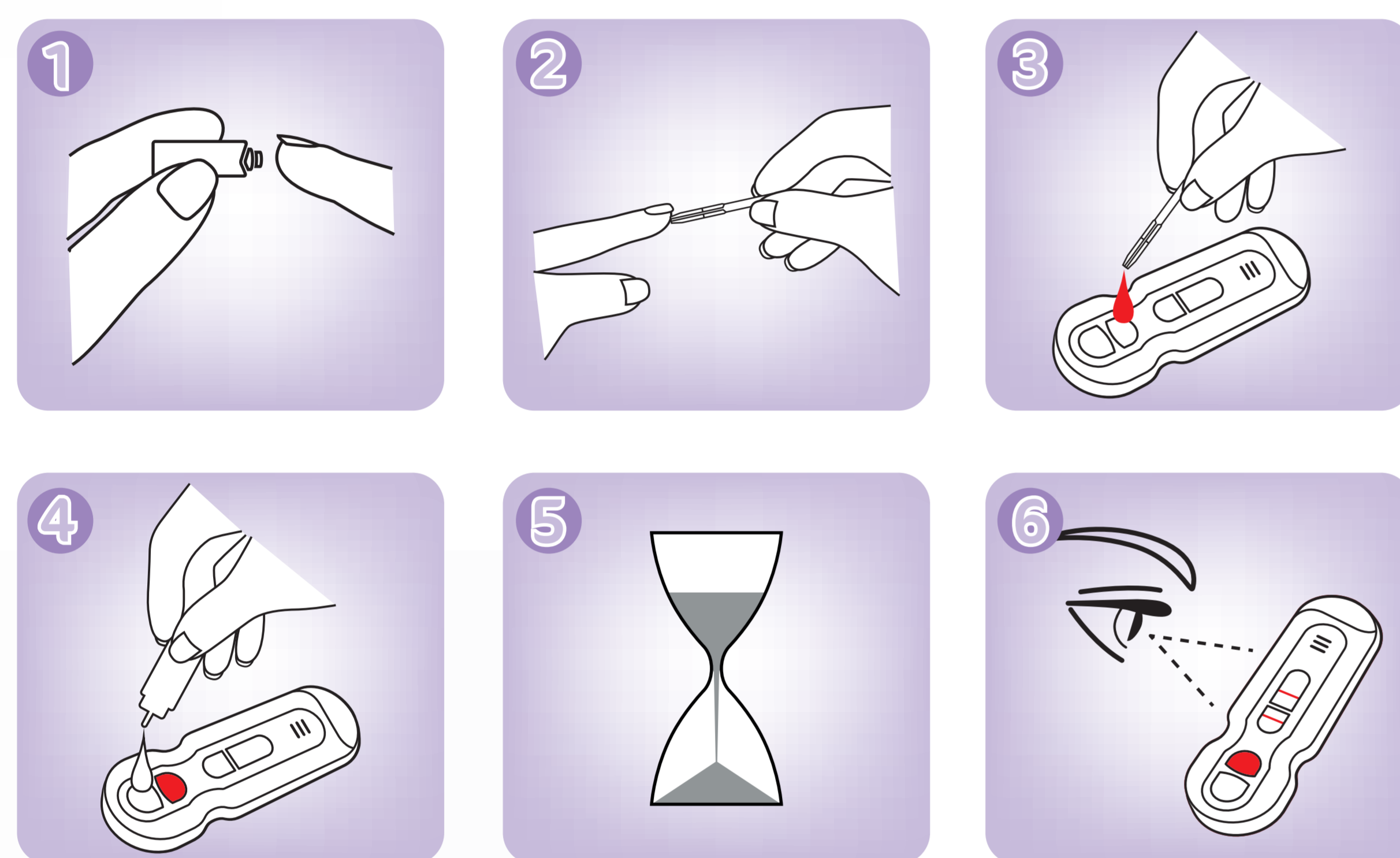


Evaluation and operating protocol

We wanted to evaluate this test in the Accident & Emergency department of Parly2 hospital, including all women needing a Beta hCG test (suspected pregnancy, abdominal pain, metrorrhagia) and any woman suspected of being pregnant, before X-ray, drug administration or Emergency surgical procedure...

The study concerned the practicality of the test, its speed of application, ease of sampling and interpretation of the test as well as patient satisfaction and comfort.

The qualitative results obtained were expressed in intensity to the naked eye (+, ++, +++, +++) and confirmed by values obtained in the laboratory on a sample of venous blood.



Summary Table of Results

The hCG assays in the lab (mIU/ml) were compared with the visible results of the Biotech NG test (cross-intensity)

Number of patients analysed : 182

Number of patients confirmed negative : 117

Number of patients confirmed positive : 65

Number of patients presenting a real medical emergency (Ectopic pregnancy-miscarriage) : 10

Incorporation in Accident & Emergency department

Since its arrival in A&E, after patient interview and agreement, a sample of capillary blood was taken in situ in accordance with the defined protocol.

The test was carried out immediately with results interpretation. The tests are stored away from light for a retrospective study if needed.

A venous blood sample was taken at the same time for a laboratory assay. A comparison between the two methods was systematically carried out.

Number of patients : 182	Type of emergency	Rapid test result	Lab test result*	Clinical comments
1	Metrorrhagia Miscarriage ?	Positive (+-) visible	16 mIU/mL	At D-2 value 46 mIU/mL Confirmed miscarriage
5	Metrorrhagia	Positive (+++)	>1800 mIU/mL	Confirmed pregnancy, without miscarriage
59	Abdominal pain without metrorrhagia. Pregnancy ?	Positive from (++) to (++++)	> 100 mIU/mL < 50.000 mIU/mL	Confirmed pregnancy (50) Miscarriage (9)
117	Abdominal pain with metrorrhagia. Pregnancy ?	Negative	0 mIU/mL	

* Cobas-Roche

CONCLUSIONS

- Good correlation with the Laboratory results
- Sensitive test /threshold 10mIU/ml (detection confirmed at 16 mIU/ml for one patient).
- Sensitivity equivalent to venous sample
- Immediate result (5min) compared with laboratory assay (sometimes several hours)
- Test well accepted by the patient (easy, painless, hygienic)

Impact on Accident & Emergency department

- Almost instant response
- Reduced waiting time in A&E (fast results and decisions).
- Faster decisional orientation (Radiology or not in a pregnant woman, medication if contraindications, specialist orientation)
- Patient satisfaction (less stress and reduced waiting time)
- Care-giver satisfaction (improved patient risk)
- Overall medical-economic aspect combining patient and emergency personnel comfort.
- Reduced treatment risk.

TheNGbiotech NG-Test hCG WB provides rapid and safe orientation of patients examined in A&E, presenting with abdominal pain, notably with suspected ectopic pregnancy or spontaneous miscarriage.

This rapid test allows emergency workers to ask for more pertinent Gynaecological advice, being in possession of a positive or negative result with fast capillary blood Beta hCG (less than 5 min. in A&E).

The laboratory confirmations were in conformity.

It would now be desirable to confirm these tests with a larger trial in A&E to reveal a medical-economic picture as well as more effective and correct orientation of patients consulting with abdominal pain and/or meno-metrorrhagia.

Test satisfaction was assessed as very good by care-givers and patients, notably because of the optimised waiting time and virtually immediate response times in A&E.

Finally, this rapid capillary blood test is carried out at the bedside of a patient who does not need particular treatment or have to move, and is virtually painless, involving a sample taken at the finger tip, and less stress while awaiting results.