

# Whole Blood Pregnancy Test

- 20 µl of whole blood
- Results in 5 minutes
- Sensitivity 10mIU/mL



*For Professional use only*

- Emergency rooms
- Clinics - Hospitals
- Pharmacies
- Gynecology offices



## PRODUCTS

Product	Specimen	Format	Packaging	Storage	Shelf-life	Cat. Ref.
NG-Test hCG WB	Whole blood	Device	20 tests	4-30°C	24 months	NGB-hCG-W23-001
NG-Test hCG WB	Whole blood	Device	10 tests	4-30°C	24 months	NGB-hCG-W23-017

## INTENDED USE

The NG Whole Blood hCG Test is a rapid visual immunoassay for the qualitative presumptive detection of human chorionic gonadotropin in human whole blood to aid in the early detection of pregnancy. NG-WB-hCG Test detects hCG concentrations of 10mIU/mL or greater in whole blood.

## PERFORMANCE CHARACTERISTICS

### Sensitivity

The tests were performed on true samples measured by a reference laboratory.

Patient 1: [HCG] <2 mIU/mL  
 Patient 2: [HCG] = 8 mIU/mL  
 Patient 3: [HCG] = 10 mIU/mL  
 Patient 4: [HCG] = 11 mIU/mL

	1[HCG] <2 mIU/ml	2[HCG] = 8 mIU/ml	3[HCG] = 10 mIU/ml	3[HCG] = 11 mIU/ml
Lot 1	neg	neg	pos	pos
Lot 2	neg	neg	pos	pos
Lot 3	neg	neg	pos	pos

Twenty repetitions were performed on each lot (3 lots) with a blood sample at a concentration of [HCG] <2 mIU/mL for a total of 60 tests.

Twelve repetitions were performed on each lot (3 lots) with sera at a concentrations of [HCG] = 8 mIU/mL; [HCG] = 10 mIU/mL and [HCG] = 11 mIU/mL.

The sensitivity of NG-hCG test whole blood is 10 mIU/mL with greater than 99.9% probability.

### Accuracy

A study included 168 blood samples, 72 positive hCG samples at a concentration of 10 mIU/mL or greater and 96 negative hCG samples provided the following results:

NG-Test hCG WB	Reference hCG Method	
	positive	negative
positive	72	0
negative	0	96

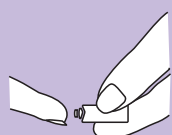
The results demonstrated a 100% overall agreement (for an accuracy of >99%) of the NG-Test hCG WB when compared to the reference method (ELISA).

### Hook Effect

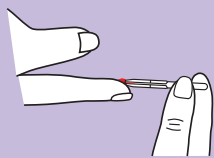
No Prozone effect observed up to 500,000 mIU/mL.

The test bands may appear with a less intensive color than expected for samples containing high levels of hCG > 500,000 mIU/mL.

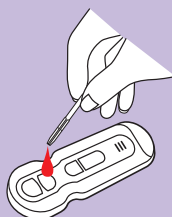
## GENERAL PROCEDURE



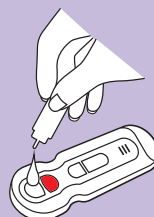
Press the trigger to prick the finger



Collect 20 µl of blood sample using Micro Pipette



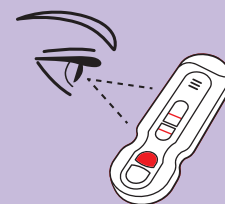
Add 20 µl of whole blood



Add 2 drops of Reaction buffer

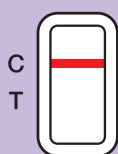


Results in 5 minutes

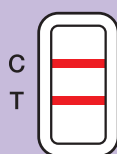


Read the results

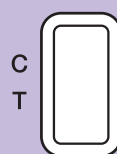
## INTERPRETATION



Negative



Positive



Invalid



Invalid