

# Whole Blood Pregnancy Test

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



*For Professional use only*

- Emergency rooms
- Clinics
- Hospitals
- Gynecology office

## 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 | 5 tests   | 4-30°C  | 24 months  | NGB-hCG-W23-011 |
| 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]<br><2 mIU/ml | 2[HCG]<br>= 8 mIU/ml | 3[HCG]<br>= 10 mIU/ml | 3[HCG]<br>= 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       |

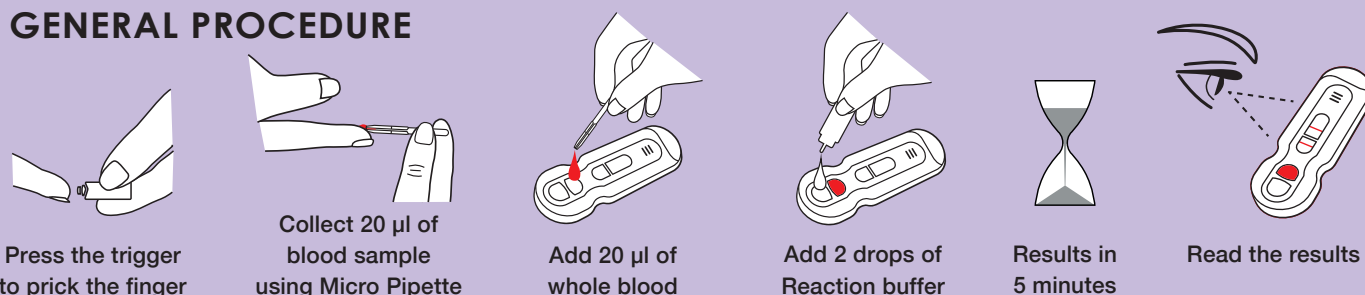
The results demonstrated a 100% overall agreement (for an accuracy of >99%) of the NG-Test hCG WB when compared to the reference method (ELISA).

### 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



## INTERPRETATION

