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

www.ngbiotech.com
# 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.

<table>
<thead>
<tr>
<th>Lot</th>
<th>[HCG] &lt;2 mIU/mL</th>
<th>[HCG] = 8 mIU/mL</th>
<th>[HCG] = 10 mIU/mL</th>
<th>[HCG] = 11 mIU/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>neg</td>
<td>neg</td>
<td>pos</td>
<td>pos</td>
</tr>
<tr>
<td>2</td>
<td>neg</td>
<td>neg</td>
<td>pos</td>
<td>pos</td>
</tr>
<tr>
<td>3</td>
<td>neg</td>
<td>neg</td>
<td>pos</td>
<td>pos</td>
</tr>
</tbody>
</table>

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 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:

<table>
<thead>
<tr>
<th>Reference hCG Method</th>
<th>positive</th>
<th>negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>NG-Test hCG WB</td>
<td>72</td>
<td>0</td>
</tr>
<tr>
<td>negative</td>
<td>0</td>
<td>96</td>
</tr>
</tbody>
</table>

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**