

# GB HCV Ag-Ab COMB

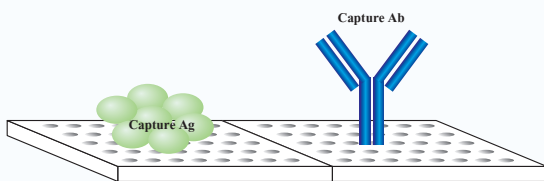
For in vitro qualitative detection and screening assay of Hepatitis C virus infection in human serum or plasma.

## Advantage

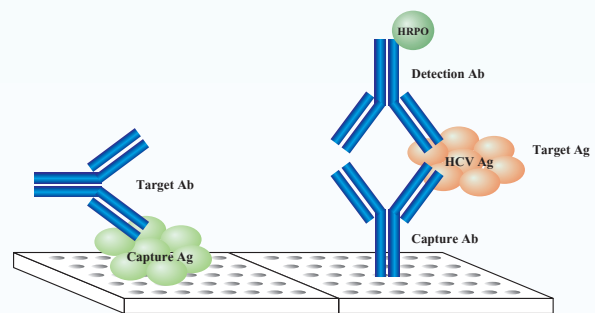
- Saving experiment time
- High sensitivity

## Assay Principle

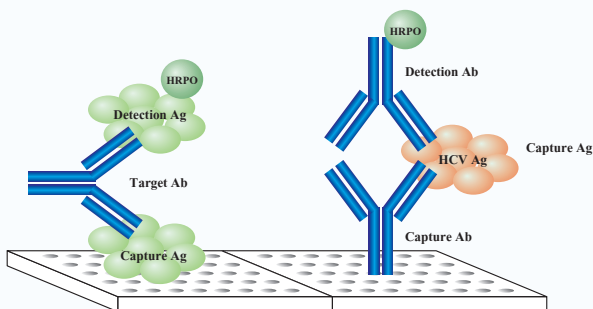
- Reaction procedure and principle of GB HCV Ag-Ab COMB



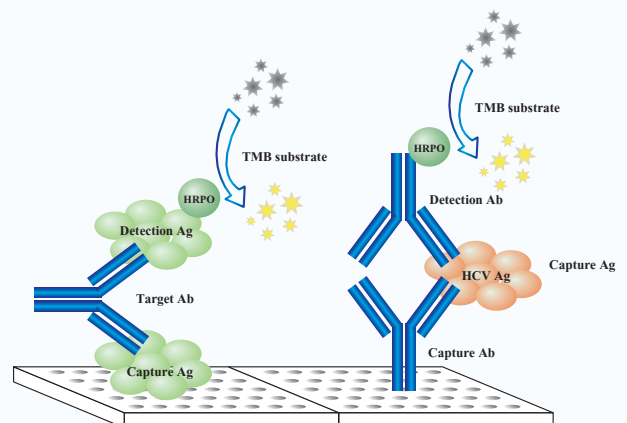
1. The Ag- and Ab- coated microplate.



2. The antigen-antibody reaction in wells.



3. The interaction of anti-HCV Ab in specimens and HCV Ag · HRPO conjugates.



4. Color development.

2017.Mar.



## Technical Assay Details

<b>Microplate Coating</b>	Anti-Core monoclonal antibody, recombinant antigen and peptides representing the immunodominant regions of NS3 and core
<b>Incubation Time</b>	90 min sample/ 30 min conjugate/ 15 min substrate (total 135 min)
<b>Incubation Temp</b>	37 ± 1°C/ 37 ± 1°C/ 37 ± 1°C
<b>Assay Volumes</b>	50 µL sample/ 100 µL Ab · HRPO conjugate/ 150 µL Ab · HRPO conjugate/ 150 µL TMB substrate/ 50 µL stop solution
<b>Wash Steps</b>	Six cycles with at least 400 µL wash buffer per well per wash and soaking at least 10 seconds. Wash with overflow aspirating function

## Quality Control and Cut Off Criteria

<b>Controls</b>	The kit involve the negative control, Ab Positive control, and Ag Positive control. Each run needs : 3 Negative control wells : 2 Ab Positive control wells : 2 Ag Positive control wells
<b>QC Neg. Cont.</b>	Mean value of NCx ≤ 0.2 OD (optical density)
<b>QC Pos. Cont.</b>	Mean value of Ab-PCx ≥ 1.0 OD : Mean value of Ag-PCx ≥ 0.8 OD Mean Value of PC ≥ 0.4 OD than mean value of NC
<b>Cut off definition</b>	Mean value of NCx + 0.1 OD
<b>Results Interpretation</b>	OD value of the sample < cut off (non-reactive) OD value of the sample ≥ cut off (reactive)

## Assay Performance

<b>Specificity</b>	A total of 88 samples from blood donors were analyzed. Initial and repeat reactive rates were 4.55% (4/88). The specificity of GB HCV Ag/Ab COMB assay on this population was 95.45%.
<b>Sensitivity</b>	A total of 50 specimens from patients with established hepatitis C infection were tested and all were found to be reactive with the GB HCV Ag/Ab COMB assay. The diagnostic sensitivity of the GB HCV Ag/Ab COMB assay on this population of specimens was observed to be 100% (50/50).
<b>Window period of HCV infection</b>	Six commercial HCV seroconversion panels were used to compare the window period of HCV infection. GB HCV Ag/Ab COMB showed 6 days (average) earlier in detecting HCV infection than other brand.