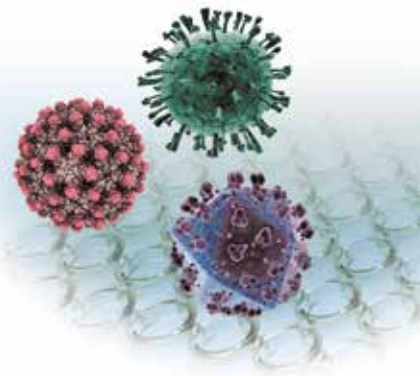


# Murex HCV Ag/Ab Combination\*

## ELISA Infectious disease



### ■ Technical Assay Details

Article Number:	4J2453 (96 tests, 1 plate, €€ marked) 4J2454 (480 tests, 5 plates, €€ marked)
Microplate Coating:	Anti-Core monoclonal antibody, recombinant antigen and peptides representing the immunodominant regions of NS3 and core.
Incubation Time:	60 min sample / 60 min conjugate / 30 min substrate (total 2.5 hours)
Incubation Temp.:	37°C ± 1 / 15-28°C / 37°C ± 1
Assay Volumes:	50 µl diluent / 50 µl sample / 120 µl conjugate 80 µl TMB substrate / 50 µl stop solution
Wash Steps:	Two wash steps with 5x washes each. Each wash using 500 µl / well of wash buffer

### ■ Quality Control and Cut Off Criteria

Controls (C):	The kit includes Negative, Antibody Positive and Antigen Positive controls. Each run requires: <ul style="list-style-type: none"><li>– 2 Negative control wells</li><li>– 1 Ab Positive control well</li><li>– 1 Ag Positive control well</li></ul>
QC Neg. Cont. (NC value):	Mean Value of NC < 0.25 OD (optical density)
QC Pos. Cont. (PC value):	Mean Value of PC > 0.8 OD than mean value of NC
Cut off Definition:	Mean value of NC + 0.2 OD
Results Interpretation:	OD value of the sample < cut off (non-reactive) OD value of the sample ≥ cut off (initially reactive)

### ■ Assay Performance

#### Specificity:

A total of 8292 samples from blood donors were analyzed in two blood donor centers. Initial and repeat reactive rates were 0.18% (15/8292). The specificity of Murex HCV Ag/Ab combination assay on this population was **99,82%**, with a lower 95% confidence limit of 99.70%.

#### Sensitivity:

A total of 509 specimens from patients with established hepatitis C infection were tested and all were found to be reactive with the Murex HCV Ag/Ab Combination assay. The diagnostic sensitivity of the Murex HCV Ag/Ab Combination assay on this population of specimens was observed to be **100%** (509/509), with a lower 95% confidence limit of 99.28%.

\* = only for special destinations

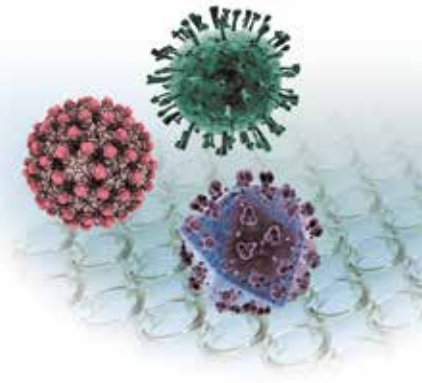


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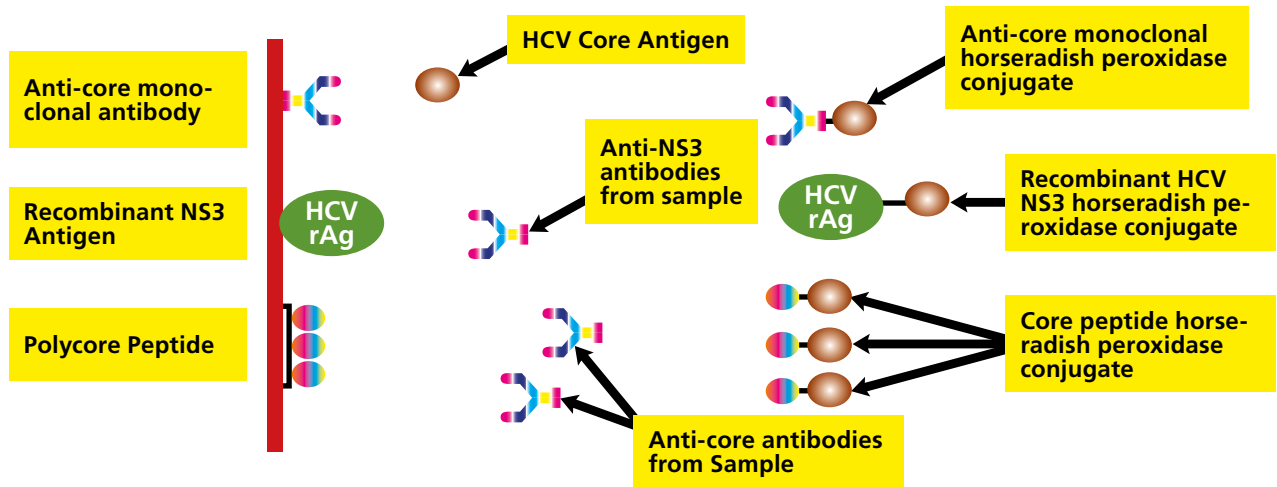
# Murex HCV Ag/Ab Combination\*

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### Assay Principle

Ag and Ab sandwich 4th generation ELISA



### Your Advantages

- **Improved throughput** by simultaneous detection of HCV antigen and antibody in a single assay run.
- **High security** for the operator with dispense monitoring for all steps.
- **Ease of use** by performing the Murex HCV Ag/Ab Combination assay in manual, semi-automated or fully automated way.
- **Significant reduction of the window period** by using HCV combination assays by at least 26 days compared to anti-HCV assays (S. Laperche, 2008 Transfusion 57, Vol. 48, p576-579)
- **More blood safety** by earlier detection of HCV infection (average 20.57 days earlier than in the antibody only assays, assessed on 30 commercial seroconversion panels).
- **Viable and economic alternative** in countries not currently using nucleic acid testing (NAT).
- **Detection** of all major HCV genotypes.

\* = only for special destinations

Product availability subject to required regulatory approval



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FOR OUTSIDE THE US AND CANADA ONLY

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