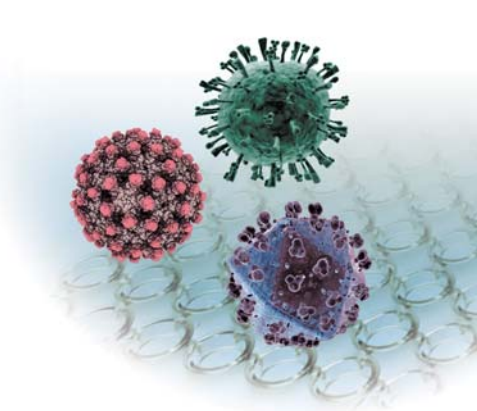


Murex anti-HCV (version 4.0)*

ELISA Infectious disease



■ Technical Assay Details

Article Number:	7F51-01 (96 tests, 1 plate, non €€ marked) 7F51-02 (480 tests, 5 plates, non €€ marked) 7F51-06 (96 tests, 1 plate, €€ marked) 7F51-07 (480 tests, 5 plates, €€ marked)
Microplate Coating:	Highly purified antigens representing core, NS3, NS4 and NS5
Incubation Time:	60 min sample / 30 min conjugate / 30 min substrate (total 2.0 hours)
Incubation Temp.:	37°C / 37°C / 37°C (± 1°C each)
Assay Volumes:	180 µl diluent / 20 µl sample / 100 µl conjugate 100 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 and Positive controls. Each run requires: <ul style="list-style-type: none">– 1 Negative control well– 1 Positive control well
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 + 0.6 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 8835 samples from blood donors were analyzed in Europe and Australia. Initial and repeat reactive rates were 0.18% (16/8835) and 0.12% (11/8835) respectively. The specificity of Murex anti-HCV (version 4.0) on this population of presumed negative samples is estimated to be **99.88%** (8824/8835), with a 95% confidence interval of 99.77 to 99.94%.

Sensitivity:

A total of 69 samples with antibody to HCV, confirmed with an alternative Immunoassay (Western blot), were reactive with Murex anti-HCV (version 4.0). The diagnostic sensitivity of the Murex anti-HCV assay on this population of specimens was observed to be **100%** (69/69), with a lower 95% confidence limit of 94.79%.

* = only for special destinations



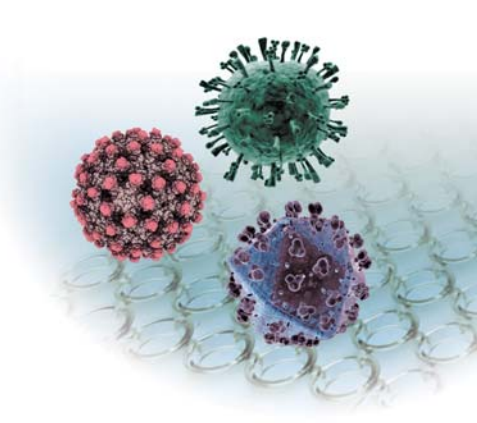
The Diagnostic Specialist



Murex® is a DiaSorin trademark

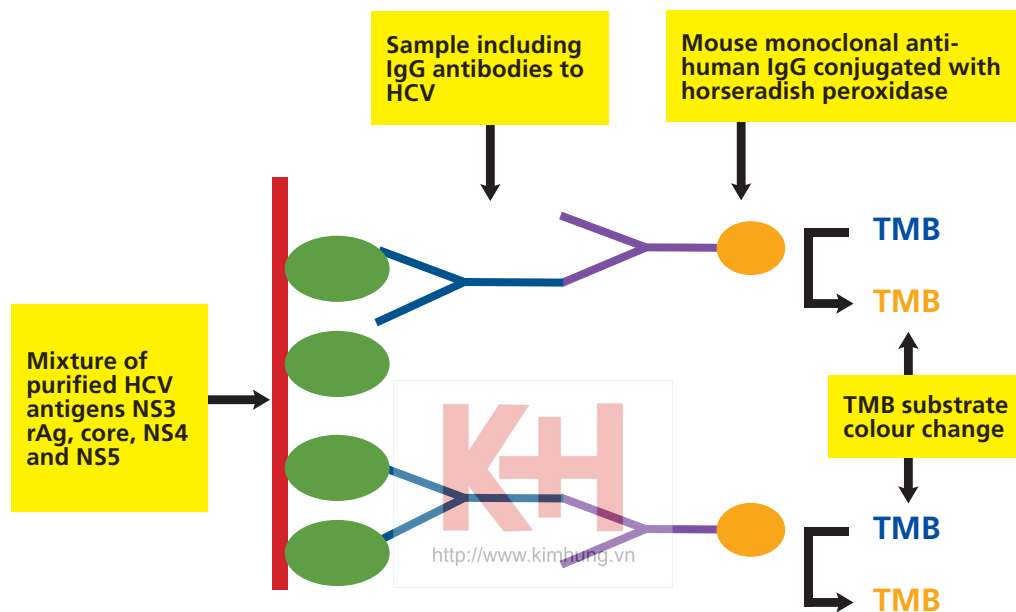
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Assay Principle

Antibody sandwich 3rd generation ELISA



Your Advantages

- **High security** for the operator with dispense monitoring for all steps.
- **Ease of use** by performing the Murex anti-HCV (version 4) assay in manual, semi-automated or fully automated way.
- **Less extra work**, because of a low rate of repeat reactive samples.
- **Optimal specificity** using highly purified and recombinant antigens and peptides.
- **Ideally used as an HCV confirmation assay** when it is done together with the Murex HCV Ag/Ab Combination* assay (Art. No. 4J24).
- **High sensitivity**: earlier detection compared to other tests on seroconversion panels.
- **Detection** of all major HCV genotypes.

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