Murex HCV Ag/Ab Combination*

ELISA Infectious disease

**Technical Assay Details**

- **Article Number:**
  - 4J24-01 (96 tests, 1 plate, non-C marked)  4J24-02 (480 tests, 5 plates, non-C marked)  4J24-03 (96 tests, 1 plate, C marked)  4J24-04 (480 tests, 5 plates, C 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:
    - 2 Negative control wells
    - 1 Ab Positive control well
    - 1 Ag 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 + 0.2 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
**Murex HCV Ag/Ab Combination**

**ELISA Infectious disease**

- **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.

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