Elecsys® Anti-HCV II: a sensitive and specific assay for diagnosing hepatitis C virus (HCV) infection

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36 panels were tested and data supplied by the vendor were used for 19 panels.

**Data from panel vendor.**

Background:
- Worldwide, approximately 170 million people are chronically infected with the hepatitis C virus (HCV) and HCV-related liver disease causes over 350,000 deaths annually.
- In initial testing the majority of responses are appropriate. In 15–20% of patients this acute HCV infection resolves spontaneously but 70–85% of patients are not able to clear the virus within 6 months and develop chronic hepatitis C.
- Treatment with the current standard of care (pegylated interferon in combination with ribavirin) can eradicate the virus in 60–65% of patients responding to the HCV genotype.1,2 Recently, the direct-acting antiviral agents telaprevir and boceprevir (both NS3-NS4a protease inhibitors) have been licensed for use in addition to the standard treatments and have increased cure rates to 70–75% among HCV genotype 1 infected patients.3
- With improvement in the therapeutic options now available, and given the asymptomatic nature of most chronic infections, routine screening of patients at risk of HCV infection (including intravenous drug users, patients receiving donated blood or organs prior to 1992, persons undergoing haemodialysis, and those infected with HIV) has become a priority to allow treatment of undiagnosed cases.

The Elecsys® Anti-HCV II assay is a quantitative third-generation immunoenzyme. It has been developed to offer enhanced coverage over the Elecsys® Anti-HCV II assay in addition to improved specificity in samples from bone donors and clinical samples, and improved seroconversion sensitivity.

Aim:
- We aimed to evaluate the performance of the Elecsys® Anti-HCV II assay compared with currently available tests, and assess its suitability for use in routine diagnostic testing.

Methods:
- Elecsys® Anti-HCV II is a dual-antigen sandwich (DASG) assay. The sample is incubated with a mixture of biotin- and radio-labeled HCV specific antigens to form a DASG in the presence of the corresponding antibodies. Stepwise-coupled immunoplates are then added and the immune complexes bind to the solid phase by biotin–streptavidin interaction. The microparticles are magnetically captured on the electrode, and a voltage applied to induce chemiluminescence, which is measured by a photomultiplier. The total assay time is 18 minutes.
- The Elecsys® Anti-HCV II assay can be performed on the Elecsys® (MODULAR®: E170, E160, and e111) and e411 and e460 systems.

Samples:
- Commercially available seroconversion panels were used to determine how early the assays could detect infection.
- Sensitivity was assessed using samples from patients known to be HCV positive and infected with HCV genotype 1b.
- 1s/co: All positive samples were analyzed in duplicate using either Elecsys® Anti-HCV II assay on the Elecsys® (MODULAR®: E170, E160, and e111) and e411 and e460 systems, and patients with potential cross-reacting factors or from high-risk groups were included.

Results:
- The Elecsys® Anti-HCV II assay detected more positive trends than comparator assays (Table 1) and detected seroconversions on average 3.4 days earlier than the Elecsys® Anti-HCV assay.

In conclusion, the Elecsys® Anti-HCV II assay was more sensitive in recognizing early HCV infection than the comparator assays. Hence, this assay determines the window of infection between infection and the detection of antibodies.

Conclusions:
- The Elecsys® Anti-HCV II assay currently identifies all known HCV positive samples (s/CO), regardless of genotype.
- The overall specificity of the Elecsys® Anti-HCV II assay using blinded donor samples was 99.8% (95% CI: 99.54–99.94) and a good discrimination between negative and positive samples was observed. Data from individual centers are shown in Table 2.
- The overall specificity of the assay in samples from hospitalized patients/normal samples was 99.9% (95% CI: 99.8–100) from data from individual centers are shown in Table 4.

References: