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Hepatitis C virus (HCV) Antigen Tests

The diagnosis of HCV infection relies heavily on the anti-HCV antibody and molecular detection of HCV-RNA (1). Several assays in research and commercial formats have been developed recently to detect HCV antigens using serum samples, plasma and whole blood (1, 2, 3, 4). HCV core protein, is a structural protein and its sequence is highly conserved among all HCV genotypes (1). The role and significance of HCV core antigen have been studied in different clinical settings. In the blood transfusion setting, four prospective and retrospective studies showed that HCV core assays could detect HCV infection about 40 to 50 days earlier than anti-HCV antibody with a an overall sensitivity versus NAT of 94 -97% and specificity of 99.5-99.9% in low risk populations (2,6,7,8). One study proved that HCV core antigen could not be considered to be equivalent to HCV nucleic acid testing (NAT) (9). Another study reported, HCV core antigen ELISA (enzyme –linked immunosorbent assay (Total HCV Core AG; Ortho- Clinical Diagnostics, Raritan, N.J.) accurate and specific, but lacked in sensitivity (lower limit of detection, 20,000 IU/ml) (10). Antigen testing could be useful in detecting early viral response (NPV and PPV = 100%) (1).

Ortho Clinical Diagnostic is most common provider worldwide, but there are other commercially available assays which detect antigen and antibody simultaneously, such Monolisa Ultra Ag/Ab assay, aiming to narrow the window period for positive diagnosis (11).

At present, the importance of the HCV antigen testing in HCV diagnosis is controversial. It has good specificity but currently inadequate sensitivity in the setting of HCV therapeutic monitoring or defining sustained viral response (SVR). However, it has started to gain some popularity in some countries (including resource poor countries) where it has been used for early diagnosis of HCV (2,11)

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