

- Title** Update of laboratory medicine procedures related to the diagnosis and management of hepatitis B, C and D
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Aim

The objective of this work is to assess the relevance of the update of the laboratory medicine procedures, reimbursement by the health insurance system in France, and to identify the indications of the procedures indicated in the diagnosis and follow-up of viral hepatitis B, C and D.

Conclusions and results

This work reports a homogeneity between most of the changes suggested by demand and the recommendations of the guidelines and the positions of the stakeholders.

In regards to HBV:

- HAS recalls that screening involves the search for the three markers: HBsAg, anti-HBc Ab and anti-HBs Ab;
- HAS supports eliminating the repeat testing for HBsAg in a second sample after a positive result for this test in a first sample, carried out in the context of a screening based on testing for the three markers. This repeat testing for HBsAg has no regulatory or technical basis and is of no clinical use;
- HAS supports maintaining the testing for IgM anti-HBc, which has its place in confirming the diagnosis of a recent infection, in particular with testing for HBV DNA in a second sample after a positive result for HBsAg in a first sample, in the context of a screening based on testing for the three markers;
- HAS supports eliminating the isolated testing procedures for HBeAg and anti-HBe Ab and maintaining the concomitant testing for these markers, which has its place in the management of chronic hepatitis B;
- HAS supports including HBV DNA detection-quantification, which has its place in the diagnosis (with serological testing), choice of management, treatment follow-up, post-treatment follow-up and follow-up of untreated patients;
- HAS supports maintaining immunity testing prior to vaccination in persons likely to be in direct contact with patients and/or to be exposed to blood and other biological products, directly or indirectly, which may be carried out with the procedure used for screening;

- HAS supports including immunity testing after vaccination, which is indicated in the following situations:
 - persons who, in the context of professional or volunteering activities, are likely to be in direct contact with patients and/or to be exposed to blood and other biological products,
 - persons likely to receive massive and/or repeat transfusions or blood-derived products (haemophiliacs, dialysis patients, patients with renal impairment, etc.),
 - candidates for an organ, tissue or cell transplant,
 - sexual partners of a person at risk for infection by the hepatitis B virus,
 - immunosuppressed persons.

In regards to HDV:

- HAS supports maintaining anti-HDV Ab testing, which has its place in the screening for this virus in HBsAg carriers;
- HAS supports maintaining HDV RNA detection-quantification, which has its place in diagnosis (with serological testing), treatment follow-up and post-treatment follow-up;
- HAS supports maintaining IgM anti-HDV testing, which has its place in the diagnosis and follow-up of patients infected with this virus, especially because this marker, if it remains positive, can be predictive of a relapse after stopping treatment;
- HAS supports eliminating HDVAg testing and HDV RNA qualitative testing.

In regards to HCV:

- HAS supports maintaining anti-HCV Ab testing, which has its place in the screening for this virus;
- HAS supports eliminating the repeat testing for anti-HCV Ab in a second sample after a positive result for this test in a first sample. This repeat testing for anti-HCV Ab has no regulatory or technical basis and is of no clinical use;
- HAS supports including HCV RNA detection-quantification, which has its place in diagnosis (with serological testing), choice of management, treatment follow-up and post-treatment follow-up;
- HAS supports eliminating HCV RNA qualitative testing and serotyping.

Methods

The method used is an assessment procedure that involves:

- making a critical analysis of the literature reviews identified by a systematic literature search;
- obtaining the reasoned views of the professional bodies concerned (infectious diseases, hepatogastroenterology, laboratory medicine) and of the National Reference Centre for Hepatitis B, C and D;
- investigating the consistency between the data collected in this way (good practice guidelines and the reasoned views of professional bodies and the National Reference Centre) and demand;

this material was summarised in a proposal submitted to the HAS Board for validation.

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