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RECOMMENDATIONS OF EUROPEAN UNION FOR DIAGNOSTIC
DETERMINATION OF HBV AND HCV

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Despite of the development of anti-HBV vaccine, infections with hepatotropic viruses B and C still pose a global health problem due to initiation of immune-related chronic diseases. The aim of the study was to delineate the diagnostic demands for hepatotropic viruses as requested by European Commission. The EU recommendations will be used to control 39 laboratories of Infectious Diseases Clinics, Institute of Hematology and Transfusiology and Sanitary Epidemiological Stations through the country which responded to our questionnaire. The diseases covered by the diagnostic procedures include: symptomless carriership of HBV, acute hepatitis B and C, chronic hepatitis B with/without delta virus; chronic hepatitis C and autoimmune hepatitis.

The following methods were evaluated: detection of HBsAg, anti-HBs, HBeAg, anti-HBe, anti-HBc, HBV-DNA; determination of anti-HCV, RIBA anti-HCV confirmatory test, and HCV-RNA. The technical requirements for these tests are delineated in the directive of European Commission: Commission Decision of 7 May 2002 on common technical specifications for in vitro - diagnostic medical devices. The most important is to report that the analytical sensitivity, ie. limit of detection for HBsAg should be 0.5 ng/ml = 0.04 PEI units = 0.09 IU/ml. The second antigen of HBV, HBeAg, should be detected at the level of <1.0 IU/ml. Requirements for the diagnostic specificity of the tests were the following: HBsAg and anti-HCV: 99%, anti-HBs, HBeAg, anti-HBe, anti-HDV: 98%; anti-HBc: 96%. There are recommendations for sensitivity of molecular tests formulated by Canadian-American group of researchers: HCV-RNA should be detected at the concentration of 32 IU/ml. The highest sensitivity achieved by the Institute of Hematology and Transfusiology: HBV-DNA as 10 IU/ml and HCV RNA as 3.0 IU/ml is recommended for all Regional Centers of Transfusion in Poland.

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ZALECENIA UNII EUROPEJSKIEJ DOTYCZĄCE DIAGNOSTYKI ZAKAŻEŃ WIRUSAMI
HBV I HCV

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