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Aktenzeichen

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Bremen, den 15 March 1996

Hepatitis-B Effectiveness of CRYOFECT

EXPERT'S INVESTIGATION REPORT

The testing of disinfectants for their effectiveness to the Hepatitis-B virus (HBV) is a requirement, as disinfecting large surfaces, instruments, hands and clothing in hospitals and in the medical and dental practice is of vital importance in order to interrupt the chains of HBV infections. However, the evaluation of disinfectants can be carried out almost only by employing indirect methods as *in vitro* reproduction systems are not available for HBV and chimpanzee experiments (bio-assays in chimpanzees) can be carried out only in a few exceptional cases.

The indirect methods of investigation indicate an inactivating effect of a disinfectant with regard to HBV, however, when assessing the results, it has to be considered that a residual infectivity possibly still exists, which cannot be eliminated by using any of the methods described in the following. Up to present, three indirect methods have been published:

1. Destruction of the surface antigen (hepatitis-B surface antigen = HBsAg)
2. Morphologic alteration and disintegration test (MADT)
3. Inactivation of the HBV associated DNA polymerase

For the investigations with the CRYOFECT disinfectant, the destruction of the antigenicity of the HBsAg was used as an indirect marker for the Hepatitis-B effectiveness.