

Hepa-Ab

XG001

Antibody for the immunohistochemical detection of Hepatocellular Carcinoma (HCC) from liver biopsies

Hepatocellular Carcinoma (HCC) is one of the most common fatal cancers worldwide, ranking four for incidence rate. Most patients with HCC die within one year after diagnosis, and mortality has not improved over the past 20 years, in part due the poor performance of currently available diagnostic methods, which are not very effective but useful only to detect HCC in an advanced stage of evolution.

Detection of HCC at an early stage is mandatory to improve the poor prognosis of this disease. Risk patients including chronic carriers of hepatitis B and individuals with cirrhotic hepatitis C should be involved in screening programs, but currently available HCC serum biomarkers such as alpha-fetoprotein and DCP lack adequate detection specificity and sensitivity.

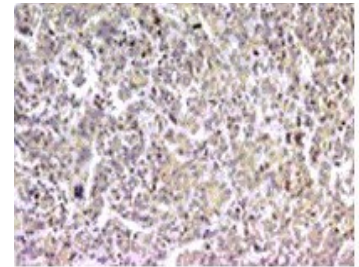
Hepa-Ab is an immunohistochemical kit for the detection of Squamous Cell Carcinoma Antigen (SCCA) variants (SCCA1, SCCA2, SCCA-PD) in liver specimens. SCCA variants are extraordinarily overexpressed in liver cells undergoing neoplastic transformation (Ref. 1-3), and 100% of HCC surgical tumors are positive by SCCA variants immunohistochemistry, while in normal liver SCCA variants are undetectable (Ref. 3-4). As shown in FIG.1, Hepa-Ab staining can be classified

according to three different scoring grades, based on the percentage of positive hepatocytes detected. A score 3-like staining is a highly specific condition of HCC degeneration of liver tissue, as 70% of HCC SCCA-positive specimens show a score 3 staining, versus 18% of cirrhotic and 12% of chronic hepatitis specimens (FIG.2).

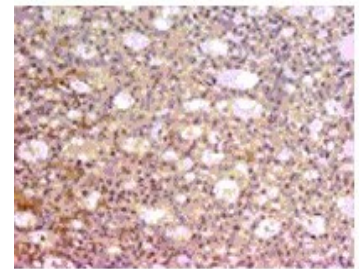
Hepa-Ab is useful for the *in vitro* diagnosis of HCC from liver specimens (Ref. 1-5) and can be used in immunohistochemical techniques by both manual and automatic procedures.

Hepa-Ab allows easy HCC determination independently from the etiology (FIG.3) and may be used to confirm HCC diagnosis, complementing other methods. Hepa-Ab provides much higher detection sensitivity and specificity compared to the detection of other non specific tumoral biomarkers such as Ki-67, p53, and PCNA which are used just to identify proliferating cells in liver tissue but lack sensitivity and specificity.

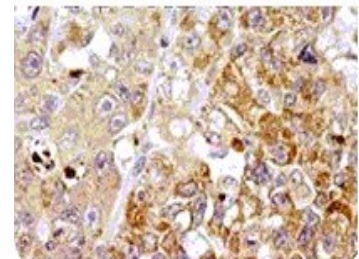
Hepa-Ab staining has been observed with dysplastic cells in damaged liver tissues (cirrhosis or chronic hepatitis). Liver cell dysplasia developing in cirrhosis or chronic hepatitis background has been associated with high risk of HCC onset.



SCORE 1



SCORE 2



SCORE 3

FIG.1: Hepa-Ab immunostaining of surgically obtained liver biopsies

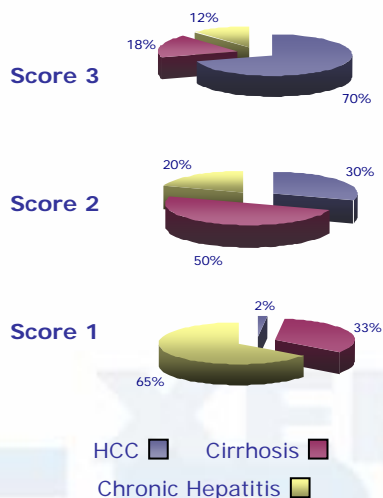


FIG.2: Scoring distribution in hepatocellular carcinoma, cirrhosis and chronic hepatitis. Hepa-Ab does not stain normal human liver.

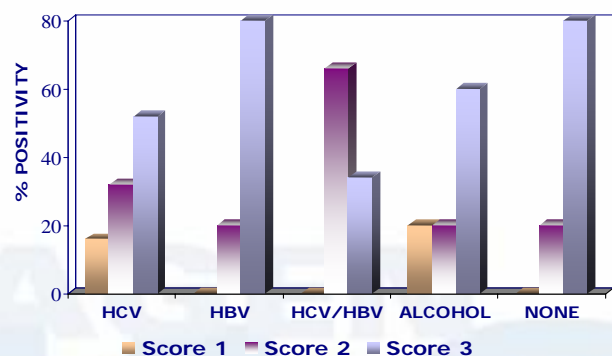


FIG.3: SCCA variants expression in HCC of different etiology
Score 1 = rare positive hepatocytes
Score 2 = <50% positive hepatocytes
Score 3 = >50% positive hepatocytes

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Hepa-Ab antibody recognizes large, multinucleate dysplastic hepatocytes in a more intense manner than MIB-1 antibodies by immunohistochemistry (FIG.4).

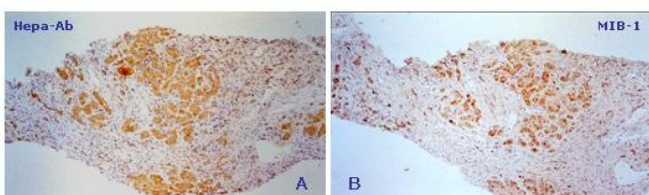


FIG.4: A. Strongly cytoplasmic Hepa-Ab positive staining of mostly dysplastic hepatocytes (50X magnification); B. Positive immunostaining with MIB-1 antibody of dysplastic area (50X magnification).

Hepa-Ab can be also easily used by conventional manual or automatic immunohistochemical procedures on liver biopsies, obtained through fine needle aspiration (FIG.5) with 80 % sensitivity confirming the lower sensitivity of the single fine-needle procedure compared to surgical biopsy (Ref. 6).

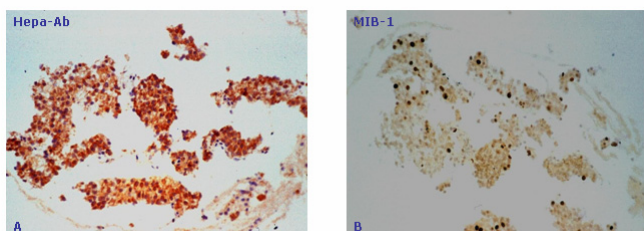


FIG.5: Immunohistochemical staining with Hepa-Ab (A) or MIB-1 (B) antibodies of HCC specimen obtained by fine needle aspiration (Score 3, 50X magnification)

References

1. Calabrese F et al. (2002), *Digestive & Liver Diseases*, 34:155
2. Ruvoletto MG et al. (2002), *J. Hepatology*, 36: 83
3. Pontisso P et al. (2004) in *Viral Hepatitis and Liver Diseases* (Jilbert A, Grgacic E, VickeryK, Burrell C, Cossart Y Eds.) pp. 445-456.
4. Pontisso P et al. (2004), *Br. J. Cancer*, 90(4):833-837
5. Guido M et al. (2008), *J Clinical Pathology*, 61:445
6. Borzio M et al. (1994) *J. Hepatology*, 20: 117

Specifications

Antibody: Oligoclonal

Host species: Rabbit

Purity: Affinity chromatography (SCCA variants-sepharose column) purified (> 95%)

Physical state: Lyophilized powder from a solution containing 20 mM phosphate pH 7.2. Reconstitution buffer (phosphate buffer, 1 mL) provided

Specificity: Purified recombinant Squamous Cell Carcinoma Antigen (SCCA)

Recommended concentration: Add to the vial 1 mL of reconstitution buffer (provided). Rotate the vial gently until powder dissolves. Typical working dilution of reconstituted sample is 1:10

Storage info: 4° C for unopened vial. Reconstituted antibody may be stored frozen (- 20° C) in working aliquots. Repeated freezing and thawing must be avoided. Prepare working dilutions on the day of use

Brief description of procedure

1. Effective on formalin-fixed paraffin embedded or frozen tissues
2. Endogenous biotin and enzyme activity blocking
3. High-temperature antigen unmasking technique
4. Non specific protein binding blocking
5. 1 hour Hepa-Ab antibody incubation at 25° C
6. Standard ABC technique

Code XG001 100 Determinations

For *in vitro* use only

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