INSTRUCTIONS FOR USE

Liver Kidney Microsomal Positive Control

Liver Kidney Microsomal Positive Control 1ml C049CE

INTENDED USE
The Bio-Diagnostics controls are intended for use in indirect immunofluorescent antibody (IFA) tests to detect autoantibodies in human serum.

SUMMARY AND EXPLANATION

Liver - Kidney Microsomal (LKM) Antibodies stain the cytoplasm of hepatocytes and proximal renal tubules. They are detected in a subgroup of autoimmune chronic active Hepatitis (CAH) that is ANA negative and by definition is considered HBsAg negative. Autoimmune chronic active hepatitis (CAH) can be separated into two groups by the IFA results, smooth muscle antibody (SMA) or liver-kidney microsome antibody (LKM1). LKM1 antibodies represent less than 10% of HBsAg-negative (CAH) but are the most common autoimmune liver disease in children and young adults, having a relatively poor prognosis.
Rat Liver / Kidney / Stomach tissue sections are utilized in this test. The liver substrate is used to detect hepatocytes staining and the kidney is used to identify staining in the proximal tubules. The stomach is added to detect smooth muscle activity and also to help differentiate mitochondrial staining from LKM1.

PRINCIPLES

LKM antibodies are organ specific. The primary test reaction involves circulating antibodies present in the patient's serum which attach to the antigen substrate. This occurs during the incubation period while the serum covers the antigen surface. A rinsing period is followed by a secondary reaction. The reagent used in the secondary reaction is a fluorescein labelled anti-human globulin conjugate. The antigen surface is then thoroughly rinsed free of unbound conjugate and viewed under an appropriate fluorescent microscope to visually identify various morphological patterns of nuclear fluorescence.

Bio-Diagnostics Ltd, Upton Industrial Estate, Rectory Road, Upton-upon-Severn, Worcestershire, WR8 0LX, United Kingdom. ☎+44 (0) 1684 592262 email: enquiries@bio-diagnostics.co.uk

PRECAUTIONS

1. All human components have been tested by radioimmunoassay for (HBsAg) and HTLVIII/LAV by an FDA approved method and found to be negative. (Not repeatedly reactive). However, this does not assure the absence of HBsAg or HTLVIII/LAV. All human components should be handled with appropriate care.

2. The thimerosal (0.095%) included in the controls and conjugate is toxic if ingested.

3. Do not use components beyond their expiration date.

4. Follow the procedural instructions exactly as they appear in the relevant insert to insure valid results.

5. For *in vitro* diagnostic use only.

MATERIALS PROVIDED / STORAGE & STABILITY

CONTROL	+	LKM Positive Control C049CE

The control must be stored at 2-8°C upon receipt. Check label for expiry date.

ADDITIONAL MATERIALS REQUIRED BUT NOT PROVIDED
Substrate section slides as appropriate
FITC Conjugate
Negative controls
Mounting Medium (Bio-Diagnostics R005).
Phosphate Buffered Saline (PBS) (Bio-Diagnostics R002).

Test tubes and rack or microtitre system	Disposable pipettes	Coverslips
Staining Dish and Slide Forceps	Moisture Chamber	Distilled Water
Volumetric Flask (500 ml)	Fluorescence Microscope	Paper Towels – lint free

All reagents required are available from Bio-Diagnostics Ltd - see catalogue for details.

KEY FOR OTHER SYMBOLS
Used in this instruction leaflet and on accompanying product packaging:

	Manufacture	RFU	Ready for use
	Temperature limitation	IVD	In vitro diagnostic medical device

TEST INSTRUCTIONS
These controls are supplied ready to use for testing on Bio-Diagnostics slides.
For use in other systems the user should perform a checkerboard titration to ensure an appropriate dilution.

Issue date: 30/10/2014

CE