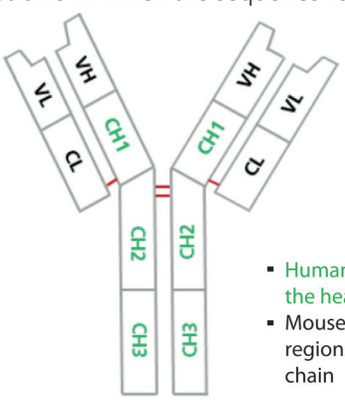
DIARECT

Human Chimeric Antibodies - Liver Diseases

Technological breakthroughs and innovative technologies continue to shape the in vitro diagnostic field. One of these advances in assay development are chimeric monoclonal antibodies for use as positive controls, or calibrators in IVD kits as an alternative to characterized disease state plasma.

The detection of antibodies in patient samples requires reference material to determine cut-off values and test assay integrity. Most often this reference material consists of pools of disease state serum or plasma, but main drawbacks of these standards are their limited availability and variability, and there are also safety and ethical issues. What is required is a virtually unlimited supply of antibodies with a consistent concentration, specificity and avidity.
Chimeric monoclonal antibodies are produced in transgenic mouse strains in which the sequence for the mouse IgG1 Fc



- Human constant region of the heavy chain
- Mouse constant and variable regions of heavy and light chain

region is substituted with the human sequence. After mouse immunization and hybridoma technology, antibodies are generated that retain a human constant region required for recognition by the anti-human conjugate. These monoclonal antibodies can then be produced using standard cell culture technologies.

Detection of cytochrome P450 2D6 autoantibodies against the so-called "liver-kidney microsomal antigen 1" (LKM 1) have been reported to be a characteristic for diagnosis of autoimmune hepatitis (AIH) type 2. Formiminotransferase cyclodeaminase or liver cytosol antigen type 1 (LC 1) autoantibodies were shown to represent the only serological marker for AIH type 2 in approximately 10% of the patients.

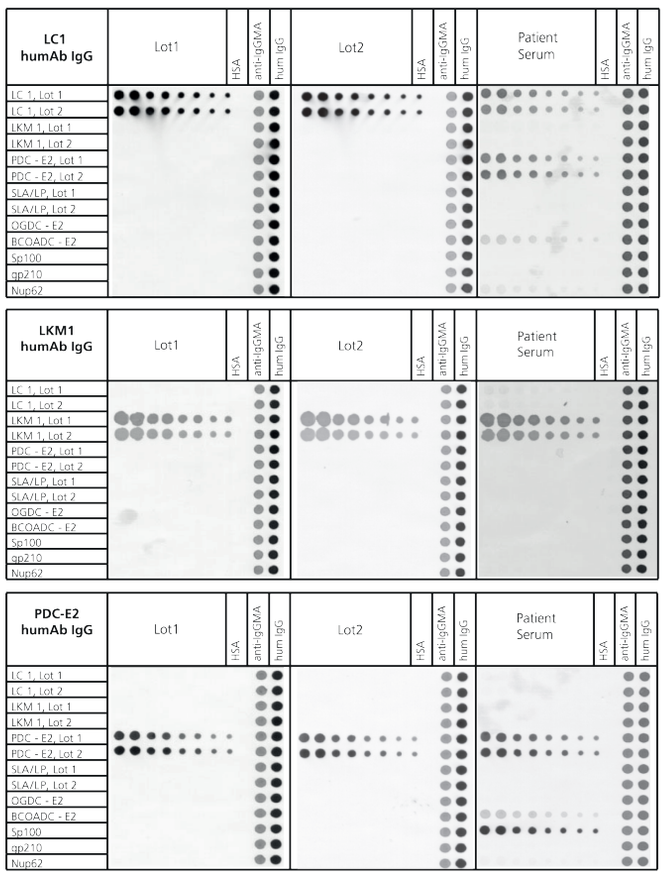


Figure: Immunodot analysis using anti-LC1, anti-LKM1 and anti-PDC-E2 human chimeric IgG antibodies and patient samples, showing reactivity with the recombinant liver antigens LC1, LKM1 and PDC-E2. Proteins and controls were printed on nitrocellulose membranes as indicated.

Serological diagnosis of Primary Biliary Cirrhosis (PBC) involves detection of M2 antibodies, found in approximately 95% of the patients. Apart from subunits of other mitochondrial complexes the M2 antigen contains mainly the E2-subunit of pyruvate dehydrogenase complex: PDC-E2. It has been shown that up to 98% of M2 positive patient samples react with PDC-E2. Additional PBC specific autoantibodies are directed against Sp100 and found in approximately 25% of the patients.

DIARECT provides tissue-specific chimeric antibodies for the detection and diagnosis of autoimmune liver diseases.

Ordering Information

37100	LC1 humAb IgG		0.1 mg
36400	LKM1 humAb IgG		0.1 mg
36401			1.0 mg
37200	PDC-E2 humAb IgG		0.1 mg
37000	Sp100 humAb IgG	NEW!	0.1 mg

References:
Cogné *et al.* (2013) European Patent N°13305964.2
Invernizzi *et al.* (2008) World J Gastroenterol. 21:3374-3387
Oertelt *et al.* (2007) Hepatology. 45 (3): 659-665

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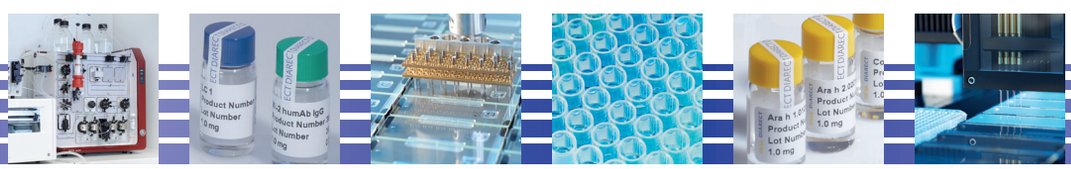

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