

DIARECT Newsletter

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Dear Madam or Sir,

The **AACC Annual Scientific Meeting and Clinical Lab Expo** is the world's premier trade fair for cutting edge science and technology shaping the future of laboratory medicine. Professionals from 112 countries with about 21,000 attendees and more than 800 exhibitors are expected to attend. You will have the opportunity to connect with global leaders in clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management and buyers of your *in vitro* diagnostic products.

The 71st AACC Annual Scientific Meeting and Clinical Lab Expo will take place in Anaheim, CA from August 6 – 8, 2019. To learn more about the event click [here](#).

DIARECT will be attending and would like to invite you to stop by our booth #1923. It is our pleasure to meet up with business partners, customers and potential new clients.

This issue of our Newsletter gives you a first impression and description of the newest additions to DIARECT's extensive product portfolio. To get an overview of all our products, including the antigens to be presented at this year's AACC, have a look at our new product list, available at this link: [product list](#)

If you wish to personally meet with a member of the DIARECT team at the Clinical Lab Expo or are interested in receiving more information, please feel free to contact us at:

Email info@diarect.com

Tel. +49 761 47979-0

We are looking forward to seeing you in Anaheim!

DIARECT AG

New additions to DIARECT's liver panel: SLA/LP antigen and human chimeric SLA/LP antibody

Autoimmune hepatitis (AIH) is a chronic, progressive inflammation of the liver and was first described in 1965 by Mackay *et al.* It was hypothesized that pathogenesis comprises environmental triggers, failure of immune tolerance mechanism and genetic predisposition (Vergani *et al.* 2002).

The disease does not exhibit pathognomonic symptoms; therefore diagnosis should combine clinical, serological, histological and genetic parameters. When diagnosed correctly, AIH is usually responsive to immuno-suppressive therapy. In the end stage the only therapeutic approach remaining is a liver transplantation (Costa *et al.* 2000).

Two types of AIH have been classified: AIH-2 and AIH-1. AIH-1 is most common and characterized by antinuclear antibodies (ANA) and smooth muscle antibodies (SMA). Detection of SLA/LP autoantibodies indicate a more severe progression of both types of the disease. AIH-2 is typified by seropositivity of patients with LKM1 and LC1 autoantibodies (Costa *et al.* 2000; Gelpi *et al.* 1992).

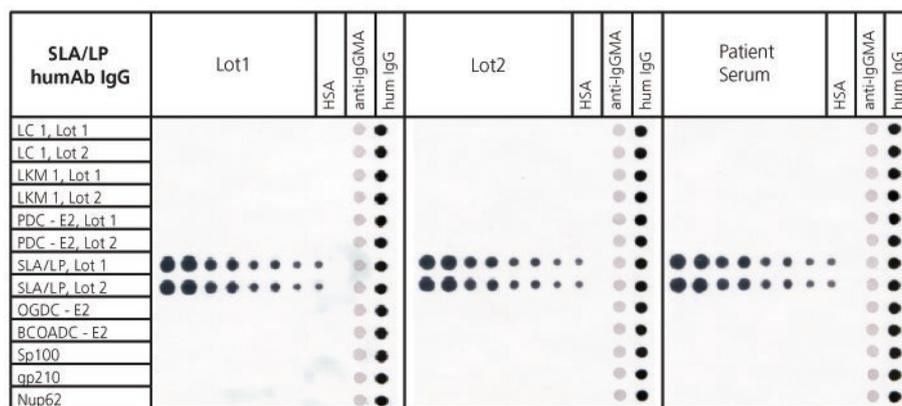


Figure: Immunodot analysis using an anti-SLA/LP human chimeric IgG antibody and one patient sample, showing reactivity with the recombinant liver antigen SLA/LP. Proteins and controls were printed on nitrocellulose membrane as indicated.

SLA/LP was first reported in supernatant of liver and kidney homogenates by Manns *et al.* 1987. It is a cytosolic soluble liver antigen / liver pancreas antigen specifically detected in about 20% of the patients with AIH. The target of anti-SLA/LP is a approx. 50-kDa UGA serine tRNA-associated protein complex (tRNP^{(Ser) Sec}) (Wies *et al.* 2000). Costa *et al.* 2000 showed a high specificity and frequency (47.5 %) of anti-tRNP^{(Ser) Sec} autoantibodies for severe forms of type-1 AIH.

The RNA is a UGA suppressor serine tRNA (tRNA^{(Ser) Sec}) and it functions in the pathway of selenoprotein synthesis in human cells. The tRNA is a requisite for co-translational incorporation of selenocystein into growing polypeptide chains. Therefore the RNA is shared with serine to seryl-tRNA and then converted to selenocysteyl-tRNA sec by the action of a selenocysteine synthase (Bock *et al.* 1991).

Diagnostic assays for autoantibody detection requires reference material to determine cut-off values and assay integrity. Mostly, pools of disease state serum or plasma are used. Main drawbacks of these standards are limited availability and variability. More consistent is the advanced use of chimeric monoclonal antibodies as positive controls in IVD kit development. This approach ensures consistent concentration, specificity and avidity, and furthermore eliminates safety and ethical concern.

At this year's AACC/CLE DIARECT is pleased to introduce the SLA/LP antigen and the corresponding human chimeric antibody.

Catalog No.	Product name
19800 / 19801	Cytochrome P450 2D6 (LKM 1 hp)
13700 / 13701	Formiminotransferase Cyclodeaminase (LC1)
30800 / 30801	SLA/LP NEW!
17700 / 17701	BCOADC-E2
17800 / 17801	OGDC-E2
17900 / 17901	PDC-E2
18000 / 18001	M2
18900 / 18901	Sp100
19000 / 19001	gp210
19400 / 19401	Nup62
36400 / 36401	LKM1 humAb IgG
37100	LC1 humAb IgG
36200 / 36201	SLA/LP humAb IgG NEW!
37200	PDC-E2 humAb IgG
37000	Sp100 humAb IgG

References:

Mackay et al. (1965) *Ann Ny Acad Sci.* 124(2): 767-780
Vergani et al. (2002) *Clin Liver Dis.* 6: 727-737
Costa et al. (2000) *Clin Exp Immunol.* 121: 364-374
Manns et al. (1987) *Lancet.* 1: 292-294
Wies et al. (2000) *Lancet.* 355: 1510-1515
Bock et al. (1991) *Trends Biochem Sci.* 16: 463-467
Gelpi et al. (1992) *Proc Natl Acad Si USA.* 89: 9739-9743

For questions or additional information please feel free to contact us at:

Tel: +49 761 47979-0

Email: [info\(at\)diarect.com](mailto:info@direct.com)

Successful ISO Recertification and Agreement Renewal with Surmodics

We are pleased to announce that DIARECT AG has been recertified in compliance with ISO 9001:2015 and ISO 13485:2016 by mdc medical device certification GmbH.

High quality has always been the key criterion for DIARECT products. As a high-grade key component manufacturer and provider, DIARECT realized our customer's needs very early and first implemented a quality management system certified according to ISO 9001 in 2002, followed by ISO 13485 standards in 2008.

DIARECT is dedicated to provide our customers the best services in all aspects of our business, particularly the design, development, manufacturing and distribution of raw materials and intermediates for IVD devices (autoimmune and infectious disease antigens, allergens, antibodies).

To download a copy of the new certificates, please follow the links below:

[ISO 9001:2015](#)

[ISO 13485:2016](#)

Agreement Renewal

To guarantee long-term availability of Surmodics stabilization products and substrates for European customers, our supply agreement with Surmodics, first signed in 2000, was extended for a further five years until 2025.

Moreover, Surmodics' distributorship agreement with DIARECT was also extended for a further five years to guarantee long-term availability of DIARECT's antigens and antibodies for customers in the United States and Canada.

Surmodics is also certified as raw material supplier according to [ISO 9001:2015](#) and [ISO 13485:2016](#) standards.

Distributors

To facilitate the world-wide sales of our antigens, DIARECT has distribution agreements with select companies.

If you are located in North America, DIARECT's products are exclusively distributed by:

SurModics IVD, Inc.
9924 West 74th Street
Eden Prairie, MN 55344
USA
Phone +1 952 500 7200
Toll-free +1 800 755 7793
Fax +1 952 500 7201
orders@surmodics.com
www.surmodics.com



If you are located in China, DIARECT's products are distributed by:

Shanghai BioSun Sci&Tech Co., Ltd.
Room K, 5F, Bldg. No.1
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