

**研究用**  
**IIFT: Autoimmune Encephalitis Mosaic 6**

ORDER NO.	ANTIBODIES AGAINST	SUBSTRATE	SPECIES	
FA 112d-6	glutamate receptor (type NMDA) glutamate receptor (type AMPA1/2) contactin-associated protein 2 (CASPR2) dipeptidyl aminopeptidase-like protein 6 (DPPX) leucine-rich glioma-inactivated protein 1 (LGI1) GABA <sub>B</sub> receptor (GABARB1/B2)	transfected cells	EU 90	10 x 05 (050) 10 x 10 (100)

**Indication:** This test kit provides qualitative or semiquantitative in vitro determination of human antibodies of immunoglobulin class IgG against neuronal antigens in patient samples to support the diagnosis of neurological diseases (encephalitis). The fluorescence is either evaluated using the fluorescence microscope (specifications see chapter "Incubation", section "Evaluation") or, following automated image recording by the EUROPattern microscope at the computer screen, optionally supported by the EUROPattern Classifier software. The product is designed for use as IVD. If cerebrospinal fluid is used as the sample material, the results for the parameters dipeptidyl aminopeptidase-like protein 6 (DPPX), leucine-rich glioma-inactivated protein 1 (LGI1) and glutamate receptor (type AMPA1/2) must be confirmed using a CE-labelled test.

**Method comparison – Specificity and sensitivity:**

**Anti-Glutamate receptor (type NMDA) IIFT (serum/plasma)**

Overview of the tested samples / reference test system:	n
Samples of patients with anti-NMDA receptor encephalitis (n = 29) and a control group (16 patients with other encephalopathies, 1 patient with cerebellar degeneration, 1 patient with retinopathy; origin: Prof. J. Dalmau, USA). The samples were serologically precharacterised as positive or negative by in-house cell-based assay*.	47
<b>Number of samples</b>	47

\* Literature reference: Prüss H, Dalmau J, Harms L, Holtje M, Ahnert-Hilger G, Borowski K, Stoecker W, Wandinger KP. **Retrospective analysis of NMDA receptor antibodies in encephalitis of unknown origin.** Neurology 75 (2010) 1735-1739.

n = 47		In-house Anti-NMDA-R CBA	
		positive	negative
EUROIMMUN	positive	29	0
Anti-Glutamate receptor (type NMDA) IIFT	negative	0	18
<b>Specificity</b>		<b>100%</b>	
<b>Sensitivity</b>		<b>100%</b>	

### **Anti-GABARB1/B2 IIFT (serum/plasma)**

Overview of the tested samples / reference test system:	n
Samples of patients with limbic encephalitis, positive serological precharacterisation by in-house methods (origin: Prof. Dalmau, Hospital of the University of Philadelphia, Dept. of Neurology, Philadelphia, USA).	17
<b>Number of samples</b>	<b>17</b>

n = 17	Reference	
	positive	negative
<b>EUROIMMUN</b>	14	0
<b>Anti-GABARB1/B2 IIFT</b>	3	0

<b>Specificity</b>	---
<b>Sensitivity</b>	<b>82.4%</b>

### **Anti-GABARB1/B2 IIFT (CSF)**

Overview of the tested samples / reference test system:	n
Samples of patients with limbic encephalitis, antibody positive precharacterisation by in-house methods (origin: Prof. Dalmau Hospital of the University of Philadelphia, Dept. of Neurology, Philadelphia, USA). 6/8 of the associated serum samples were anti-GABA <sub>B</sub> receptor positive, no serum material was available for two CSF samples.	10
<b>Number of samples</b>	<b>10</b>

n = 10	Reference	
	positive	negative
<b>EUROIMMUN</b>	6	0
<b>Anti-GABARB1/B2 IIFT</b>	4	0

<b>Specificity</b>	---
<b>Sensitivity</b>	<b>60%</b>

### **Anti-LGI1 IIFT (serum/plasma)**

Overview of the tested samples / reference test system:	n
Samples of patients with positive or negative serological precharacterisation. The precharacterisation was carried out by means of different in-house methods (in-house-CBA and tissue section) (origin: Prof. Angela Vincent, University of Oxford, United Kingdom).	21
<b>Number of samples</b>	<b>21</b>

n = 21	In-house IFT	
	positive	negative
<b>EUROIMMUN</b>	8	0
<b>Anti-LGI1 IIFT</b>	0	13

<b>Specificity</b>	<b>100%</b>
<b>Sensitivity</b>	<b>100%</b>

### **Anti-CASPR2 IIFT (serum/plasma)**

<b>Overview of the tested samples / reference test system:</b>	<b>n</b>
1. Preselected samples of patients with limbic encephalitis, which were serologically precharacterised by in-house IFT (origin: Prof. Angela Vincent, University of Oxford, United Kingdom).	9
2. Samples of patients with various neurological disorders (incl. limbic encephalitis, epilepsy) and healthy controls, which were serologically precharacterised by in-house IFT (origin: Prof. Angela Vincent, University of Oxford, United Kingdom).	22
<b>Number of samples</b>	<b>31</b>

n = 31	<b>In-house IFT</b>	
	positive	negative
<b>EUROIMMUN</b>	14	0
<b>Anti-CASPR2 IIFT</b>	0	17

<b>Specificity</b>	<b>100%</b>
<b>Sensitivity</b>	<b>100%</b>

### **Anti-Glutamate receptor (type AMPA1/2) IIFT (serum/plasma)**

<b>Overview of the tested samples / reference test system:</b>	<b>n</b>
Preselected samples of patients with positive or negative serological precharacterisation. The precharacterisation was carried out using an in-house IFT (origin: Prof. Josep Dalmau, Hospital Clinic, Dept. of Neurology, Center of Neuroimmunology and Paraneoplastic Disorders, Barcelona, Spain).	13
<b>Number of samples</b>	<b>13</b>

n = 13	<b>In-house IFT</b>	
	positive	negative
<b>EUROIMMUN</b>	5	0
<b>Anti-AMPAR1/R2 IIFT</b>	0	8

<b>Specificity</b>	<b>100%</b>
<b>Sensitivity</b>	<b>100%</b>

### **Anti-DPPX IIFT (serum/plasma)**

<b>Overview of the tested samples / reference test system:</b>	<b>n</b>
1. Samples of patients with positive or negative serological precharacterisation were investigated. The precharacterisation was done using an in-house method (origin: Prof. Josep Dalmau, Hospital Clinic, Dept. of Neurology, Center of Neuroimmunology and Paraneoplastic Disorders, Barcelona Spain).	8
2. Samples of patients with positive serological precharacterisation were investigated. The precharacterisation was done using an IFT (tissue sections; origin: Prof. Vanda Lennon, Department of Laboratory Medicine and Pathology, Neuroimmunology Laboratory, Mayo Clinic, USA).	3
<b>Number of samples</b>	<b>11</b>

n = 11	<b>Reference</b>	
	positive	negative
<b>EUROIMMUN</b>	8	0
<b>Anti-DPPX IIFT</b>	0	3

<b>Specificity</b>	<b>100%</b>
<b>Sensitivity</b>	<b>100%</b>

## Literature

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