Anti-HTLV Mixed Titer Panel

REF Catalogue No: MTP-HTLV-001

The Biomex GmbH Anti-HTLV Mixed Titer Panel consists of 15 members with each member containing 1.0 mL of human plasma. One individual features Human T-lymphotropic Virus Type I, 8 individuals HTLV Type II, one individual either HTLV Type I or Type II, two individuals are inconclusive and three are negative to HTLV.

1. Intended Use

This Mixed Titer Panel (MTP) is intended for standard testing by diagnostic manufacturers and researchers during assay development, evaluation, troubleshooting and post-marked surveillance of IgG antibody test systems and methods. Moreover, it serves as validation tool for diagnostic specificity, determination of analytical sensitivity or for the identification of cut-off values.

2. Storage and Stability

Store the MTP at -20°C to -80°C. Thaw samples at room temperature and mix gently by inversion before usage. Avoid foaming, contamination and repeated freeze and thaw cycles. After usage, return immediately to storage conditions.

3. Warnings and Precautions

Potentially infectious materials. Handle the product as if capable of transmitting infectious diseases. Do not pipette by mouth.

Prevention:

P264: Wash hands thoroughly after handling.

P270: Do not eat, drink or smoke when using this product

P273: Avoid the release to the environment

Disposal:

P501: Dispose of waste in accordance to applicable local or national regulations. Waste must be disposed in a secured manner.

Declaration of used symbols

REF	LOT			2°C 8°C
Catalog Number	Lot Number	Consult Instructions for Use	Manufactured by	Temperature Limitation

4. Donor Information

All panel members have been tested and found negative/non-reactive for anti-HIV, anti-HCV, HBsAg and Syphilis with CE marked tests.

5. Detection Methods

Each panel member is assayed for HTLV I/II antibodies with Abbott ARCHITECT® and DiaSorin MUREX®. Confirmatory Immunoassays are also conducted using the MP-Blot and INNO-LIA systems. Testing is performed with CE marked test.

6. Limitations and Restrictions

This panel is for Research Use Only and not intended for human or animal diagnostics, or for therapeutic purposes. Each laboratory has the responsibility to ascertain the suitability of the MTP for its particular application and to establish their own guidelines for interpretation of results. Data is provided for informational purposes only. The Biomex GmbH does not claim that others can duplicate these test results exactly.

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Panel Member	Bleed Date	Specification	Abbott Architect	DiaSorin Murex	Murex Units	MP-Blot Banden	INNO-LIA Confirmation	INNO-LIA Distinction	INNO-LIA Identification
			s/co	s/co					
1	22.05.2011	HTLV-1	72.3	>13.3	408	GD21,19=24,46-I	19,24,46,21	19I 3+,46-I 3+,46-II 0	HTLV-1
2	17.01.2011	HTLV-2	69.5	nd		GD21, p24, 46-II *			nd
3	24.04.2011	HTLV-2	134.1	nd		GD21,p19, p24, p26, p36, 46-II			nd
4	06.02.2011	HTLV-2	118.2	nd		GD21,p19, p24, p36, 46-II			nd
5	11.10.2011	HTLV-2	81.6	nd		GD21, p24, 46-II *			nd
6	21.07.2009	HTLV-2	133.7	>13.3	5984	GD21,19<24,46-II	19,24,46,21	19I 2+,46-I 2+,46-II 4+	HTLV-2
7	12.07.2009	HTLV-2	98.8	>13.3	237	GD21,19<24,46-II	19,24,46,21	19-I+-,46-I +-,46-II 2+	HTLV-2
8	13.08.2011	HTLV-2	73.7	>13.3	1323	GD21,24,46-II	(19),24,46,21	19-I 0,46-I 0,46-II 2+	HTLV-2
9	16.07.2011	HTLV-2	74.1	>13.3	4639	GD21,19<24,46-II	19,24,46,21	19I 2+,46-I 2+,46-II 4+	HTLV-2
10	07.10.2010	HTLV 1 or 2	45.2	>13.3	98	GD21	46 +-,21 2+	46-I +-	HTLV-1?
11	08.03.2010	**	0.1	0.7	0	p19	19,46,24+/-	19-I 0,46-I 2+,46-II 0	positive**
12	20.09.2011	**	0.1	0.5	0	GD21**	19 +-,46 2+,21+-	19-I +-,46-I 1+,46-II +-	HTLV-1
13	28.01.2010	HTLV neg.							
14	20.03.2010	HTLV neg.							
15	17.04.2010	HTLV neg.							

* weak, **questionable, nd = not detected

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