

Department of Transplant Immunology & Immunogenetics
A.I.I.M.S., New Delhi-110029.

Dated:...../2018

Ref No. 2/7II/2018-19

Subject:- Purchase the Kit and consumables from "One Lambda" on Proprietary Basis.

The department of Transplant Immunology & Immunogenetics want to purchase of Kit & Consumables from One Lambda on Propriety Basis. The proposal submitted by the local authorized dealer M/s. Biogenuix Medsystems.

The above documents are being uploaded for open information to submit objection comments, if any from any manufacture regarding proprietary nature of the reagents and consumables within 15 days from the date issue/uploading the notification reference No. _____.

The comments should be sent to Professor & Head, department of Transplant Immunology & Immunogenetics, Room No. 75, AIIMS, New Delhi on or before _____ upto 5.00 p.m. failing which it will be presumed that nay other vendor is having no comments to offer and case will be decided on merits.



(Prof. D.K.Mitra)
Prof.& Head
Deptt. Of Transplant, Immunology & Immunogenetics
AIIMS, New Delhi.

Encl:-

Qutation, Lowest Price Certificate

PAC Certificate

Letter of authorization

The Head
Dept. of Transplant Immunology & Immunogenetics
All India Institute of Medical Sciences
Ansari Nagar, 29 Aurobindo Marg,
Delhi 110029

Subject: Quotation

Dear Sir/Madam,

This is with reference to the above subject; we are pleased to quote our products for your perusal and orders.

Cat No.	Product Description
LS1PRA	LS PRA HLA Class I
LS2PRA	LABScreen PRA Class II
LS1A04	LS Single Antigen û Combi (A locus/B locus/C locus)
LS2A01	LS Single Antigen HLA Class II û Group 1
LT-SAPE	PE - Conjugated Streptavidin
LS-AB2	PE-Conjugated Goat Anti-Human, Lyophilized, 1 ml
LS-NC	LABScreen Negative Control Serum
RSS01A	LABType SSO Class I A Locus Typing Test
RSS01B	LABType SSO Class I B Locus Typing Test
RSS01C	LABType SSO Class I C Locus Typing Test
RSS02B1	LABType SSO DRB1 Typing Test
RSS02Q	LABType SSO Class II DQA1 and DQB1 Typing Test
CABC-1D	Class I Rabbit Complement Lyophilized per unit
SSPT1-G1	Micro SSP AmbiStrips HLA Class I B27 B73B*27 with B*73:02
SSP1A	Micro SSP Generic HLA Class I A Locus DNA Typing Tray
SSP1B	Micro SSP HLA Class I B Locus Specific DNA Typing Tray
SSP1C	Micro SSP HLA Class I C Locus Specific DNA Typing Tray
SSP2LB	Micro SSP Generic HLA Class II DNA Typing Tray - DRB only
SSP2LQB1	Micro SSP Generic HLA Class II DNA Typing Tray - DQB1 Only
SSPABDR	Micro SSP Generic HLA Class I and II ABDR DNA Typing Tray
5300025	SeCore A Locus Sequencing Kit
5311025D	SeCore B Locus Sequencing Kit
5320025	SeCore C Locus Sequencing Kit
A15571	SeCore DRB1 Locus Sequencing Kit
5341025D	SeCore DQB1 Locus Sequencing Kit

Thanking you.

Biogenuix Medsystems Pvt. Ltd

Biogenuix Medsystems Pvt. Ltd.

412-B, Jyoti Shikhar Building, District Centre, Janakpuri, New Delhi-110058, INDIA
Phone: +91-11-4875 4875 • Fax: +91-11-2561 2008 • Email: contact@biogenuix.com



www.biogenuix.com

Ref No.BMPL/AIIMS/Cover/XIV/APRIL-2018

APRIL, 24 2018

Head of the Department
Dept. of Transplant Immunology & Immunogenetics
All India Institute of Medical Sciences
Ansari nagar, 29 Aurobindo
Marg, Delhi 110029

Ref: - Our Quotation No. MSQ-18-19-00053 Dated 24.04.2018

Subject- Rates Reasonable Certificate

Dear Sir,

We hereby certify that these are the most reasonable prices which have been charged to AIIMS, New Delhi and all endeavors have been made to keep the rates to the lowest possible.

The above information is true to the best of my knowledge.

Thanking you
Yours Sincerely

For Biogenuix Medsystems Pvt. Ltd

Biogenuix Medsystems Pvt. Ltd.

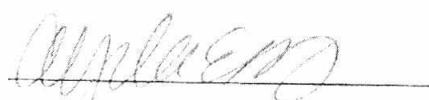
Correspondence Address: 412-B, 4th Floor, Jyoti Shikhar, District Center, Janak Puri, NewDelhi -110058
Phone: 91-11-48754875; Fax:-+91-11-25612008; Email- contact@biogenuix.com

Proprietary Certificate

This is to state that the below mentioned One Lambda products and One Lambda software, HLA Fusion, are proprietary to One Lambda. These products may be analyzed using the HLA Fusion software.

One Lambda makes no claims or assurances for use of One Lambda HLA Fusion software with any products other than those specified in the HLA Fusion Software User Manual.

Model or Catalog Number	Product
LS12 PRA	LABScreen® PRA Class I & II
LS1PRA	LABScreen® PRA Class I
LS2PRA	LABScreen® PRA Class II
LSM12	LABScreen® PRA Class I & II Mixed
LS1A04	LABScreen® Class I Single Antigen Combi
LS2A01	LABScreen® Single Antigen HLA Class II Antibody Detection Test
LSMICA001	LABScreen® MICA Single Antigen - Group 1
LS-NC	LabScreen® Negative Control Serum
LS-AB2	PE-Conjugated Goat Anti-Human IgG



Angela Estany
Regulatory Affairs Manager



17 Jun 2013

Date

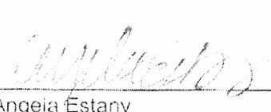


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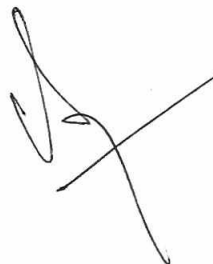
LABType® SSO DRB 3,4,5 Typing Test	RSSO2345 RSO2345T
LABType® SSO DRB1 Typing Test	RSSO2B1 RSO2B1T
LABType® SSO A-locus Typing Test	RSSO1A RSO1AT
LABType® SSO B-locus Typing Test	RSSO1B RSO1BT
LABType® SSO C-locus Typing Test	RSSO1C RSO1CT
LABType® SSO DQB1 Typing Test	RSSO2QB1
LABType® SSO DQA1 Typing Test	RSSO2QA1
LABType® SSO Class II DPA1/DPB1 Typing Test	RSSO2P RSO2PT
LABType® SSO B-locus Supplement Typing Test	RSSO1S4 RSO1S4T
LABType® MICA Genotyping Test	RSSOMICA
LABType® SSO DQA1 & DQB1 Typing Test	RSSO2Q RSO2QT
LABType® SSO B7 Supplement Typing Test	RSSO1S1 RSO1S1T
LABType® SSO HD Class II DRB1 Typing Test	RSSOH2B1 RSOH2B1T
LABType® SSO HD Class I A Locus Typing Test	RSSOH1A RSOH1AT
LABType® SSO HD Class I B Locus Typing Test	RSSOH1B RSOH1BT
LABType® SSO HD Class I C Locus Typing Test	RSSOH1C RSOH1CT
LABType® Exon 4-7 Supplemental DNA Typing Test	RSSO1E47 RSO1E47T
PE Conjugated Streptavidin	LTSAPE


Angela Estany
Regulatory Affairs Manager

08 OCT 2012
Date









ONE LAMBDA

One Lambda, Inc.
A Thermo Fisher Scientific Brand
21001 Kittridge Street
Canoga Park, CA 91308
Tel (800) 822-8824
Fax (818) 702-6904
www.onelambda.com

January 10, 2018

DISTRIBUTOR LETTER

One Lambda, Inc. (hereinafter "One Lambda"), part of Thermo Fisher Scientific Inc., is an established and reputable manufacturer specialized in, among other things, the design, manufacture, and sales and marketing of several lines of histocompatibility (HLA) typing tests utilizing both serological and molecular technologies. One Lambda also manufactures a comprehensive line of antibody detection products, laboratory instrumentation, and computer software that are used to simplify and automate testing procedures and final test evaluations. Products covered by this authorization letter are as set forth in the International Distributor Agreement by and between One Lambda and distributor (collectively referred to as the "Products").

One Lambda is located at 21001 Kittridge Street, Canoga Park, California 91303-2801 U.S.A.

With this letter, we hereby confirm that the company named below is a distributor of the Products to the centers in India as outlined in Schedule A, attached hereto, and is fully authorized to present quotations for tenders on its own behalf; provide sales, after-sales service, service assistance, spare parts during the specified warranty period, and to sign and receive contracts in its own name.


Biogenuix Medsystems Pvt. Ltd.
412-B, 4th floor Jyoti Shikhar Towers
District Center, Janak Puri
New Delhi 110058
India

This appointment is valid until December 31, 2019.

This letter is for information purposes only and One Lambda does not grant any rights to Biogenuix Medsystems Pvt. Ltd. by the issuance of this letter. Biogenuix Medsystems Pvt. Ltd.'s authorization is subject to the terms and conditions of the International Distributor Agreement by and between the parties.

All offers related to the Products are subject to One Lambda's latest Terms and Conditions of Sale.

Sincerely,


Parisa Khosropour
President, Transplant Diagnostics



HLA Typing kits for A,B,C, DRB1, DQA1/DQB1

- The test kits should be compatible with the Luminex 200 and FM3d platform
- The test kits should apply Luminex® technology to the reverse SSO DNA typing method
- The test kits should contain sequence-specific oligonucleotide probes immobilized on microspheres for identification of HLA alleles in amplified genomic DNA samples through a controlled DNA hybridization reaction, followed by flow analysis using the Luminex 200/FM3D platform
- The kit should be based upon PCR amplification of the target DNA using a group-specific primer. The PCR product should then be denatured and allowed to rehybridize to complementary DNA probes conjugated to fluorescently coded microspheres. The hybridization process should include manual washing steps in order to ensure minimal backgrounds
- The PCR product should be biotinylated, which would allow it to be detected using R-Phycoerythrin-conjugated Streptavidin (SAPE). The fluorescent intensity should then be identified with the help of a Flow analyser either a Luminex 200 and FM3d
- The microspheres in the kit should include negative and positive control microspheres for subtraction of non-specific background signals and normalization of raw data to adjust for possible variation in sample quantity and reaction efficiency
- It should be possible to analyse the acquired results through a dedicated software unique to that kit



PRA detection:

- The kit should be able to determine the percent PRA and assign specificities against the HLA Antigens in each panel utilising the Luminex xMAP technology
- The kit should have the capability of running either the HLA Class I & HLA Class II PRA tests separately or together as per user requirement
- The test kits should be compatible with the Luminex 200 and FM3d platform
- The principle of the test should be based upon incubation of the test serum with the test beads. Any HLA antibodies present in the test serum should bind to the antigens on the beads and then are labelled with R-Phycoerythrin (PE)-conjugated goat anti-human IgG. The Luminex 200/FM3d flow analyzer(s) should simultaneously be able to detect the fluorescent emission of PE and a dye signature from each bead, should allow almost real-time data acquisition.
- It should be possible to analyse the acquired results through a dedicated software unique to that kit
- The assay should be able to eliminate false positive reactions due to non-HLA antibodies or auto antibodies



Single Antigen products:

- The Single Antigen assay should allow confirmation of antibody specificity suggested by a previous PRA test, while individual Singles beads should be used to focus on reactions against one or a few antigens
- A negative control serum should be used to establish the background value for each bead in a test batch
- The test kits should be compatible with the Luminex 200 and FM3d platform
- The principle of the test should be based upon incubation of the test serum with the test beads. Any HLA antibodies present in the test serum should bind to the antigens on the beads and then are labelled with R-Phycoerythrin (PE)-conjugated goat anti-human IgG. The Luminex 200/FM3d flow analyzer(s) should be simultaneously able to detect the fluorescent emission of PE and a dye signature from each bead, should allow almost real-time data acquisition.
- It should be possible to analyse the acquired results through a dedicated software unique to that kit
- The assay should contain a purified single antigen or a defined pool of HLA antigens, including rare alleles
- The assay should be able to eliminate false positive reactions due to non-HLA antibodies or auto antibodies
- Single antigen assay should be able to identify negative or safe antigens, even for high PRA patients

