

Digitally signed by Ceaicovschi Tudor
Date: 2021.09.20 14:09:00 EEST
Reason: MoldSign Signature
Location: Moldova



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**One Lambda, Inc.
22801 Roscoe Blvd
West Hills CA 91304
USA**

has established and applies a quality management system for medical devices
for the following scope:

(see attachment for scope and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-07-07
Certificate Registration No.: SX 60143059 0001
An audit was performed. Report No.: 31895531 001
This Certificate is valid until: 2022-07-11

Certification Body



Date 2020-07-07



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60143059 0001
Report No.: 31895531 001

Organization: One Lambda, Inc.
22801 Roscoe Blvd
West Hills CA 91304
USA

Scope: Design and Development, Manufacturing, Distribution,
Servicing and Installation of in vitro diagnostic assays,
reagents, instruments and software for determination of
tissue groups used in the field for compatibility
testing for transplantation diagnostics

Certification Body



Date: 2020-07-07



S. Liu
S. Liu

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60143059 0001
Report No.: 31895531 001

Organization: One Lambda, Inc.
22801 Roscoe Blvd
West Hills CA 91304
USA

Scope: Additional Site:

One Lambda GmbH
Neuendorfstr. 25
16761 Henningsdorf
Germany

Scope: Activities related to customer service and
complaint investigation

Certification Body



Date: 2020-07-07



S. Liu

EC Certificate
Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60143129 0001

Report No.: 31895531 005

Manufacturer: One Lambda, Inc.
22801 Roscoe Blvd
West Hills CA 91304
USA

Products: In vitro diagnostic assays and reagents for the
determination of HLA tissue groups

Products: see attachment

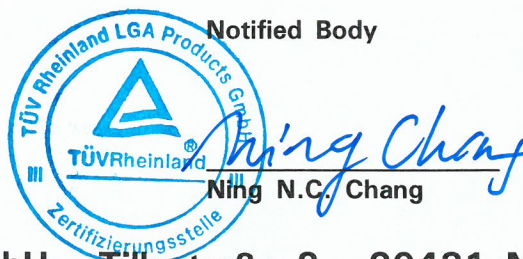
Replaces Approval, Registration No.: HL 60150524 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2020-07-08

Date: 2020-07-08



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC
concerning in vitro diagnostic medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HL 60143129 0001
Report No.: 31895531 006

Manufacturer: One Lambda, Inc.
22801 Roscoe Blvd
West Hills CA 91304
USA

Products:

HLA Class I and Class Antigen Typing Products

- AllSet Gold+ SSP
- SeCore Sequence Based Typing
- Micro SSP DNA Typing Tests
- LABType
- HLA Tissue Typing Tests
- AllType NGS 11-Loci Amplification Kit
- LinkSeq HLA Typing Kits

HLA Antibody Screening

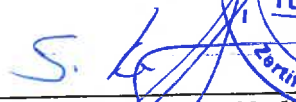
- ClqScreen
- FlowPRA Screening Tests
- LABScreenMulti
- LABScreen
- Lambda Cell Trays
- Lambda Antigen Trays

Monoclonal Antibodies for cell surface antigens

- Fluorescent Conjugated Monoclonal Antibodies

Date: 2021-01-15

Notified Body


Dipl.-Ing. Sven Hoffmann



Certificate



Certificate No.: MD 2233216 234120969-10 rev 01

Manufacturer: **One Lambda, Inc.**

22801 Roscoe Blvd.
West Hills, CA 91304
USA

REPs Facility ID: F003909

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure

Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC
ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

Scope: Design and Development, Manufacture, Distribution, Servicing and
Installation of in Vitro Diagnostics assays reagents, instruments and
software for determination of tissue groups used in the field of
compatibility testing for transplantation diagnostics.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the
quality management system of the Manufacturer has been audited against and found to conform the
Certification criteria for the Scope contained in this certificate. The quality management system is
subject to annual surveillance audit(s).

Project No.: 31895531.002

Issue Date: 2021-02-17

Effective Date: 2021-02-17

Expiry Date: 2023-02-26



A handwritten signature in blue ink, appearing to read 'Song Liu'.

Certification officer: Song Liu
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000010776?locale=en
or calling 1-888-743-4652.

Certificate



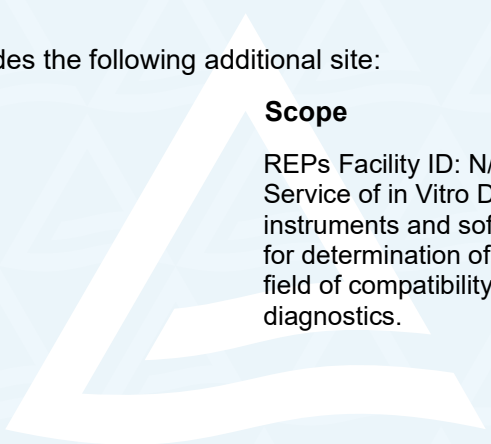
Certificate No.: MD 2233216 234120969-10 rev 01

Manufacturer: **One Lambda, Inc.**

22801 Roscoe Blvd.
West Hills, CA 91304
USA

The scope of certification includes the following additional site:

No.	Location	Scope
/02	One Lambda GmbH Neuendorfstr. 25 16761 Henningsdorf Germany	REPs Facility ID: N/A Service of in Vitro Diagnostics assays reagents, instruments and software for determination of tissue groups used in the field of compatibility testing for transplantation diagnostics.


TÜV Rheinland®

Project No.: 31895531.002

Issue Date: 2021-02-17

Effective Date: 2021-02-17

Expiry Date: 2023-02-26



Sangji

Certification officer: S. Liu
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000010776?locale=en
or calling 1-888-743-4652.

**LABType® SSO Class I A Locus Typing Test, Lot #010**

Name

☐ Patient
☐ Donor☐ Male
☐ Female

Race

ABO/Rh

Sample I.D.

Birthdate

Relationship to Patient

Disease

DNA Extraction Method

Bead Mix Exp. Date

DNA Concentration

Bead Mix Lot#

Taq Lot #

Primer Mix Lot#

D-mix Lot #/Batch #

SAPE Solution Lot#

Results

Comments:

LABScan™ 100 Serial#

Raw Data File ID

Test Performed by

Date

Read by

Date

Reviewed by

Date

Photo Documentation

The allele nomenclature includes the HLA alleles listed in the July 2009 update of the IMGT/HLA database release 2.26.0 (Robinson J, et al., "IMGT/HLA and IMGT/MHC: sequence databases for the study of the major histocompatibility complex" Nucleic Acids Research (2003), 31, 311-314). Complete update information is located at www.ebi.ac.uk/imgt/hla/.

Revision summary: July 2009 nomenclature update based on IMGT/HLA database version 2.26.0.

A*0111N is not amplified by the primers for this kit. A*1130 and A*3216 may have weak or no amplification. A*68020102 may have weak or no amplification with primers for exons 1 and 2.



A Locus

Sample ID

[illegible]



A Locus

Sample ID

[illegible]

Name

Sample ID

A Locus

[illegible]



A Locus

Sample ID

TDX-OLI-DMR-LOT-2271 REV 01: PAGE 5 OF 10

[illegible]

Name

Sample ID

A Locus

[illegible]

Name

Sample ID

A Locus

A Locus	
Reaction Results (mark positive locations)	
Cut Off Value	
Serology Equivalent	A Locus Allele Group
A-	A*3210
A-	A*3211Q
A-	A*3213
A-	A*3215
A-	A*3217
A33,A-	A*330101~0301/0303~06/12/14~ 15/20/23/25
A33	A*330302
A-	A*3307
A-	A*3308-09
A-	A*3310
A-	A*3311
A-	A*3313
A-	A*3316
A-	A*3317
A-	A*3318
A-	A*3319
A-	A*3321
A-	A*3322
A-	A*3324
A34,A-	A*340101/05
A34	A*340102
A34	A*3402/04
A-	A*3403
A-	A*3406
A-	A*3407
A-	A*3408
A36	A*3601
A-	A*3602
A36	A*3603
A-	A*3604
A43	A*4301
A66,A-	A*6601/04/08
A66	A*6602
A10	A*6603
A-	A*6605
A-	A*6606
A-	A*6607
A-	A*6609
A-	A*6610
A68,A-	A*680101/0103~0105/0107/22/25/ 35/43
A68,A-,A"Blank"	A*680102/0106/07/11N/17/21/32~ 33/38/47
A68,A"Blank",A-	A*68020101/020103~0202/18N/44
A68	A*68020102
A28	A*680301~0302
A68	A*6804
A68,A-	A*6805/20
A-	A*6806

Name

Sample ID

A Locus

[illegible]



A Locus

Sample ID

A Locus	
Reaction Results (mark positive locations)	
Cut Off Value	
Serology Equivalent	A Locus Allele Group
A-	A*9246
A-	A*9254
A-	A*9256
A-	A*9269
A-	A*9271

Revision summary: July 2020 nomenclature update based on MGT/HLA 3.41.0

Allele sequences are obtained from the IMGT database. Updates, including modifications to allele sequences may alter bead specificity

Beads (27, 39, 56, 60, 63, 71, 83, 89, 90): Typing results for a sample having positive reaction with these beads may also include C*06:02:01:15.

Beads (27, 39, 56, 60, 63, 71, 83, 89, 90): Typing results for a sample having positive reaction with these beads may also include C*12:03:01:04.

Beads (39, 56, 71, 80, 86, 90): Typing results for a sample having positive reaction with these beads may also include C*07:01:01:86.

Not all alleles were directly tested. Untested alleles were predicted and, therefore, may cause false reactions. Refer to 'Nomenclature List' for the list of tested alleles.

Serological equivalent for alleles are based on the HLA Dictionary (S.G.Marsh, et al.: "Nomenclature for factors of the HLA system, 2010." Tissue Antigens (2010) 75:291-455)

This product is intended for low resolution HLA typing results. Typing results outside this specification may produce ambiguities that require additional testing to resolve.

The following alleles are not included in this kit: None

HLA Locus

[illegible]

HLA Locus

[illegible]

HLA Locus

[illegible]

HLA Locus

[illegible]

Sample ID

[illegible]

Name _____

Sample ID

HLA Locus

[illegible]

Reaction Results (mark positive locations)	
Cut Off Value	
Serology Equivalent	Allele Group
B62, B"Blank", B-, B15	B*15:01:01:01-01:01:37/01:03-01:09/01:12/01:17/01:20/01:22-01:25/01:28-01:29/01:31-01:35/01:38/01:41-01:46/01:48/01:51-01:63/34:01/60/78:03/79N82/92/102/104/122/140/146-147/159-160/01:02/166-167/169/178/181N-182N/187/190N/192/201/203/205/211/227-228/231/247/257/260-261/276/295/316-317/320-321Q/326/333/343/346-347/349:01-349:02/353/355/359/370-373/375N/377Q/385/390-391/400N-401/409/413/419/422/432/440-441/443/456-457/459/464-467/471-474/476-478/482-483N/489/496N501/512/514-515/520Q/522/528N-529/533/535-536/538/542/547/549N558/565/568
B62, B-	B*15:01:01:38: B*46:77
B62, B-	B*15:01:02/278
B62, B-, B"Blank"	B*15:01:10/96/172/258N/296/365/562N
B62, B-	B*15:01:11/70/97/267
B62, B"Blank"	B*15:01:13/01:37/111N
B62, B-, B"Blank"	B*15:01:14/26N/27:02/110/286
B62, B-	B*15:01:15/01:36/01:39/71/125:02/171/175/234/469/493
B62, B-	B*15:01:16/83/113/183/217/244/315/406/561
B62, B-	B*15:01:18/75/105/145
B62, B-, B"Blank"	B*15:01:19/28/120/246N/392/428/492
B62	B*15:01:21
B62, B-, B"Blank"	B*15:01:26/01:47/01:50/163/202/280/340/480/525/540N
B62, B-	B*15:01:27/430/521
B62, B-, B"Blank"	B*15:01:30/94N/164/318
B62, B-, B"Blank"	B*15:01:40/128/232/269/272N/279/309/334/387/416/453
B62	B*15:01:49
B75, B-, B"Blank"	B*15:02:01:01-02:01:04/02:03-02:04/02:06-02:07/02:09/02:12/213-214/302N/325/357-358/425/437-438/454N/491/495/537/557
B75, B-	B*15:02:02/170/567
B75	B*15:02:05
B75	B*15:02:08
B75, B-	B*15:02:10-02:11/341/374
B72, B70, B-	B*15:03:01:01-03:03/03:04/03:06/03:08-03:09/103/132/158/173/220:01:01-220:02/242:01/266/274/281-282/369/444/475/502/560
B72	B*15:03:03/03:11
B72	B*15:03:05
B72	B*15:03:07
B72, B-	B*15:03:10/98
B62	B*15:04:01:01-04:04
B62, B-	B*15:05:01-05:02/107/332
B62	B*15:05:03
B62	B*15:06
B62, B-	B*15:07:01:01-07:03/126/207/431/450/524
B75, B-	B*15:08:01-08:02/479
B70	B*15:09:01-09:02
B71, B-	B*15:10:01:01-10:01:06/10:03/10:05/313/427/439/445/455/503/506
B71	B*15:10:02
B71, B-	B*15:10:04/530/563
B-	B*15:10:1
B-	B*15:10:6
B71	B*15:10:8
B-	B*15:10:9/398

HLA Locus

[illegible]

Reaction Results (mark positive locations)	
Cut Off Value	
Serology Equivalent	Allele Group
B-	B*15:219/288
B-	B*15:221
B-	B*15:222
B-	B*15:223
B-	B*15:224
B-	B*15:225
B-	B*15:229
B-	B*15:23
B-	B*15:230
B-	B*15:233
B-	B*15:235
B-	B*15:236
B-	B*15:237
B-	B*15:238
B-	B*15:239
B-, B62	B*15:24.01-24.02/157/442
B-	B*15:241
B-	B*15:242.02
B-	B*15:243
B-	B*15:245.01Q-245.02Q/484
B-	B*15:248/287
B-	B*15:249
B-, B62, B"Blank"	B*15:25.01.01-25.01.02/25.03-25.04/240/271/366/395/458/463N/468/543-544N/564
B62	B*15:25.02
B-	B*15:250
B-	B*15:251.01-251.03/545
B-	B*15:252
B-	B*15:253
B-	B*15:255
B-	B*15:256
B-	B*15:259
B-	B*15:265
B-	B*15:268
B62, B-	B*15:27.01/27.03/327
B62	B*15:27.04
B-	B*15:273
B-	B*15:275.01-275.02
B-	B*15:277
B-	B*15:283
B-	B*15:285/452
B-	B*15:289
B15	B*15:29.01.01-29.01.02
B-	B*15:291/301
B-	B*15:293
B"Blank", B-	B*15:294N/526
B-	B*15:297
B62, B-	B*15:30.01.01-30.01.03/541
B-	B*15:309/322
B-	B*15:303
B"Blank"	B*15:304N
B-	B*15:306
B-	B*15:308
B75	B*15:31.01.01-31.01.03
B-	B*15:310
B-	B*15:311
B-	B*15:312
B-	B*15:319/345
B-, B62	B*15:32.01/299
B62	B*15:32.02
B-	B*15:323
B-	B*15:324
B-	B*15:328
B-	B*15:329
B15	B*15:378.01.01-78.02/78.04
B-	B*15:330
B-	B*15:331
B-	B*15:335
B-	B*15:336
B-	B*15:337
B-	B*15:338
B-	B*15:339
B62	B*15:34.02
B-	B*15:342
B-	B*15:344

Reaction Results (mark positive locations)	
Cut Off Value	
Serology Equivalent	Allele Group
B-	B*15:348
B-, B"Blank", B62	B*15:35/118/129/184/262N/264/ 417/470/534
B-	B*15:350
B-	B*15:352
B-	B*15:356
B-	B*15:36
B-	B*15:360
B-	B*15:361
B-	B*15:362
B-	B*15:364
B-	B*15:368
B70	B*15:37
B-	B*15:376
B-	B*15:378
B-	B*15:379
B-	B*15:38.01-38.02
B-	B*15:381
B-	B*15:383
B-	B*15:384
B-	B*15:389
B62	B*15:39.01.01-39.02
B-	B*15:394
B-	B*15:396
B-	B*15:397
B-	B*15:399
B-	B*15:40.01-40.02
B-	B*15:402
B-	B*15:403
B-	B*15:405
B-	B*15:408
B-	B*15:412
B-	B*15:415
B-	B*15:42
B-	B*15:421
B-	B*15:426
B-	B*15:429
B-	B*15:43
B-	B*15:434
B-	B*15:435
B-	B*15:44
B-	B*15:446
B-	B*15:447
B-	B*15:448/527
B-	B*15:449
B62	B*15:45
B72	B*15:46
B-	B*15:460
B-	B*15:462
B-	B*15:47.01-47.02/49
B62	B*15:48
B-	B*15:481
B-	B*15:485
B-	B*15:486
B-	B*15:488
B-	B*15:490
B-	B*15:494
B-	B*15:497
B-	B*15:498
B-	B*15:499
B-	B*15:50
B-	B*15:504
B-	B*15:507
B-	B*15:508
B-	B*15:509
B70	B*15:51
B-	B*15:510
B-	B*15:511
B-	B*15:513
B-	B*15:516
B-	B*15:517
B-	B*15:518
B-	B*15:519
B70, B15	B*15:52/114
B-	B*15:53
B-	B*15:531

Sample ID

[illegible]

HLA LOCUS

Reaction Results (mark positive locations)	
Cut Off Value	
Serology Equivalent	Allele Group
B-	B*18:12:01-12:02
B-	B*18:121
B-	B*18:122/148
B-	B*18:125
B-	B*18:13
B-	B*18:136
B-	B*18:137
B-	B*18:14
B-	B*18:147/190
B-	B*18:15
B-	B*18:150
B-	B*18:152
B-	B*18:164
B-	B*18:165
B-	B*18:166
B-	B*18:168
B-	B*18:169
B-	B*18:171
B-	B*18:178
B-	B*18:179
B-	B*18:18:01:01-18:01:02
B-	B*18:189
B-	B*18:19
B-	B*18:191
B-	B*18:194
B-	B*18:195
B-	B*18:20(4)/97
B-	B*18:21
B-	B*18:22/105
B-	B*18:25
B-	B*18:26/61
B-	B*18:28/31/46/118
B-	B*18:29
B-	B*18:30
B-	B*18:33
B-	B*18:35
B-	B*18:36
B-	B*18:37_01
B-	B*18:37:02/45/66/133/143
B-	B*18:39/69/149
B-	B*18:43
B-	B*18:44:02
B-	B*18:48
B-	B*18:49/132/142
B-	B*18:50
B-	B*18:52
B-	B*18:54
B-	B*18:56
B-	B*18:57_01-57:02
B-	B*18:58
B-	B*18:67
B-	B*18:68
B-	B*18:77
B-	B*18:79
B-	B*18:98:01
B27	B*27:01
B27, B-	B*27:02:01:01-02:03/57/95/134/ 163/171-172/181/197/232
B27	B*27:02:04
B27	B*27:02:05
B27, B-, B"Blank"	B*27:03/05:02:01-05:06/05:10/ 05:12-05:18:02/05:22-05:24/ 05:27-05:31/05:34-05:35/05:38- 05:46/05:48/13:01-13:02/17/95- 55/58/60/64N/72/74/80/82/84/ 87-88/90:01-90:04/93-94N/ 96:01-99/104/110-111/117/123- 124/135/140-141/143-146/150/ 155/159/162/166-167/174/178/ 182/184/190-191/193-196/199/ 201/205-207/212N/215N-217/220/ 228/230-231
B27, B-	B*27:04:01-04:02/04:04-04:06/ 68-69/79/100/103/112-114/149/ 183/210-211/226/229
B27	B*27:04:03

HLA Locus

[illegible]

Sample ID

[illegible]

Sample ID

[illegible]

Sample ID

HLA Locus

[illegible]

Sample ID

HLA Locus

[illegible]

HLA Locus

[illegible]

HLA Locus

Name _____

Sample ID

[illegible]

HLA Locus

[illegible]

HLA Locus

[illegible]

Sample ID

HLA Locus

Reaction Results (mark positive locations)		001	002	003	004	005	006	007	008	009	010	011	012	013	014	015	016	017	018	019	020	021	022	023	024	025	026	027	028	029	030	031	032	033	034	035	036	037	038	039	040	041	042	043	044	045	046	047	048	049	050	051	052	053	054	055	056	057	058	059	060	061	062	063	064	065	066	067	068	069	070	071	072	073	074	075	076	077	078	079	080	081	082	083	084	085	086	087	088	089	090	091	092	093	094	095	096	097	098	099																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																	
Cut Off Value		18%	30%	35%	15%	20%	15%	30%	20%	25%	45%	19%	10%	98%	100%	15%	30%	20%	18%	30%	018	25%	30%	10%	30%	20%	20%	30%	35%	25%	20%	20%	15%	20%	20%	20%	30%	35%	15%	037	038	100%	30%	15%	15%	15%	15%	15%	15%	15%	25%	25%	30%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%</

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Reaction Results (mark positive locations)	
Cut Off Value	
Serology Equivalent	Allele Group
B*	B*40:130
B-	B*40:134
B-	B*40:44
B-	B*40:449
B-	B*40:45
B-	B*40:457
B-	B*40:458
B-	B*40:46
B-	B*40:462
B40	B*40:47
B-, B60	B*40:48/377
B-, B61	B*40:50:01-01-50:01-02/200
B-	B*40:51
B60	B*40:52
B61	B*40:53
B-	B*40:58/219
B-	B*40:59
B-	B*40:60
B-	B*40:61
B-	B*40:63
B40, B-	B*40:64:02/99
B-	B*40:67/153/239/249/262
B-	B*40:68
B-	B*40:69/357
B-	B*40:71
B-	B*40:75
B-	B*40:79/135/400
B-	B*40:77
B-	B*40:80
B-	B*40:86
B-	B*40:90
B40	B*40:92
B-	B*40:93
B-	B*40:95
B-	B*40:96
B-	B*40:99
B41, B-	B*41:01:01-01-01:05/01-07/07/ 14/20/25/28/34-35/37/57/59/61/ 64
B41, B-	B*41:01:06/16/48
B41, B-, B"Blank"	B*41:02:01-01-02-04/02-06-- 02-08/11/13/38-39/43/45N/49/65
B41, B-	B*41:02-05/27
B41	B*41:02-09
B41	B*41:03:01-03-02
B-	B*41:04
B-	B*41:05/26
B-	B*41:06/29/32
B-	B*41:08
B-	B*41:09
B-	B*41:10/24/52
B-	B*41:12
B-	B*41:15
B-	B*41:17
B-	B*41:18
B-	B*41:19
B-	B*41:21
B-	B*41:22
B-	B*41:23
B-	B*41:30/44
B-	B*41:31
B-	B*41:33
B-	B*41:36
B-	B*41:40
B-	B*41:41-42/58
B-	B*41:46
B-	B*41:47
B-	B*41:50
B-	B*41:51
B-	B*41:53
B-	B*41:54
B-	B*41:55
B-	B*41:59Q
B-	B*41:60
B-	B*41:62
B-	B*41:63

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Sample ID

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Sample ID

Reaction Results (mark positive locations)	
Cut Off Value	
Serology Equivalent	Allele Group
B-	B*44:163.02
B-	B*44:166
B-	B*44:169
B44	B*44:17
B-	B*44:170/455
B-	B*44:174
B-	B*44:176
B-	B*44:18
B-	B*44:181
B-	B*44:182
B-	B*44:184
B-	B*44:188
B-	B*44:190
B-	B*44:20
B-	B*44:203.01
B-	B*44:203.02
B-	B*44:205.01
B-	B*44:205.02
B-	B*44:209
B-	B*44:21
B-	B*44:210.01
B-	B*44:210.02
B-	B*44:213
B-	B*44:22
B-	B*44:221
B-	B*44:224
B-	B*44:225
B-	B*44:227
B-	B*44:230
B-	B*44:232
B-	B*44:236
B-	B*44:24
B-	B*44:245
B-	B*44:247/295
B-	B*44:25
B-	B*44:251
B-	B*44:254
B-	B*44:256
B-	B*44:257
B-	B*44:258
B-	B*44:263
B-	B*44:268
B-	B*44:269
B-	B*44:275
B-	B*44:276
B-	B*44:277
B-	B*44:28.01
B-	B*44:28.02
B-	B*44:282
B-, B44	B*44:29/285
B-	B*44:290
B-	B*44:299
B-	B*44:30/160Q/215
B44	B*44:31
B-	B*44:339
B-	B*44:34.01
B-	B*44:34.02
B-	B*44:340
B-	B*44:342
B"Blank", B-	B*44:345N/458
B-	B*44:37.02/294
B44	B*44:40
B-	B*44:41.01
B-	B*44:41.02
B21	B*44:42
B44	B*44:43.01
B44	B*44:43.02
B"Blank"	B*44:43BN
B-	B*44:44
B-	B*44:442
B-	B*44:445
B-	B*44:446
B-	B*44:447
B-	B*44:452
B-	B*44:459
B-	B*44:46.01/129

Sample ID

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Sample ID

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Sample ID

Reaction Results (mark positive locations)	
Cut Off Value	
Serology Equivalent	Allele Group
B ⁻ Blank*, B-	B*51:118N/231
B-	B*51:12/202/291
B-	B*51:13.01
B-	B*51:13.02
B-	B*51:135
B-	B*51:139
B-	B*51:140
B-	B*51:143
B-	B*51:144/180
B-	B*51:148
B-	B*51:15
B-	B*51:151
B-	B*51:153
B-	B*51:157
B5	B*51:16
B-	B*51:170
B-	B*51:176
B-	B*51:179
B-	B*51:185
B-	B*51:186
B-	B*51:19/276
B-	B*51:194
B-	B*51:197
B-	B*51:20
B-	B*51:21
B-	B*51:211
B-	B*51:214/251
B-	B*51:217
B-	B*51:218
B-	B*51:22
B-	B*51:220
B-	B*51:227/281
B-	B*51:23
B-	B*51:261
B-	B*51:267
B-	B*51:274
B-	B*51:280
B-, B51	B*51:29/279
B-	B*51:295
B-	B*51:300
B51	B*51:31
B-	B*51:310
B-	B*51:34
B-	B*51:36
B-	B*51:37
B-	B*51:39
B-	B*51:40
B-, B ⁻ Blank*	B*51:41N/52/201/208/258/302/ 318N
B-	B*51:42
B ⁻ Blank*	B*51:44N
B-	B*51:45
B-, B ⁻ Blank*	B*51:53/72/87/91/115/120/181/ 228/287N
B-	B*51:54
B-	B*51:56.02
B-	B*51:57
B-	B*51:59
B-	B*51:61.01-61.02
B-	B*51:62
B-	B*51:63.02
B-	B*51:64
B-	B*51:68
B-	B*51:74
B-	B*51:78.01
B-	B*51:78.02
B-	B*51:81
B-	B*51:82
B-	B*51:85
B-	B*51:90
B-	B*51:92.01
B-	B*51:92.02/172
B-	B*51:93
B-	B*51:97

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Sample ID

Reaction Results (mark positive locations)	
Cut Off Value	
Serology Equivalent	Allele Group
B-	B*53:05:01
B-	B*53:05:02
B-	B*53:06
B53	B*53:07
B-	B*53:08:01-08:02
B-	B*53:09
B53	B*53:11
B-	B*53:12
B-	B*53:13
B-	B*53:14
B-	B*53:15
B-	B*53:16
B53	B*53:17:01
B53	B*53:17:02
B-	B*53:19
B-	B*53:21
B-	B*53:22
B-	B*53:23
B-	B*53:24
B-	B*53:27/57
B-	B*53:28
B-	B*53:30
B-	B*53:31
B-	B*53:33
B-	B*53:35
B-	B*53:36
B-	B*53:38
B-	B*53:40
B-	B*53:41
B-	B*53:42
B-	B*53:43:01-43:02
B-	B*53:44
B-	B*53:47
B"Blank", B-	B*53:48N50
B-	B*53:55
B-	B*53:56
B-	B*53:62
B54, B-	B*54:01:01:01-01:06/01:08-01:09/07/17-18/23-25/27/29/31-32/34/36/41
B54	B*54:01:07
B54, B-	B*54:02/19/39
B-	B*54:03
B-	B*54:04
B"Blank"	B*54:05N
B-	B*54:06
B"Blank"	B*54:08N
B-	B*54:09
B-	B*54:10
B54	B*54:11
B-	B*54:12
B-	B*54:13
B-	B*54:14
B-	B*54:15
B-	B*54:16
B-	B*54:20
B-	B*54:21
B-	B*54:22
B-	B*54:26
B-	B*54:28
B-	B*54:30
B-	B*54:33
B-	B*54:35
B-	B*54:37-38
B-	B*54:40
B55, B-, B"Blank"	B*55:01:01:01-01:01:16/ 01:01:18-01:03/01:06/01:08/ 01:10/01:12/01:15-01:16/01:18- 01:20/01:22-01:24/01:26/03/15/ 25/29/33/38/44-45/53/55N/59- 60/74-76/84-85/87/91-92/94-95/ 97N-99/101-102/105/108-109
B55	B*55:01:01:17
B55	B*55:01:04
B55	B*55:01:05
B55, B-	B*55:01:07/11

Sample ID

Reaction Results (mark positive locations)	
Cut Off Value	
Serology Equivalent	Allele Group
B55, B-	B*55:01:09/01:14/66
B55, B-	B*55:01:11/13/36
B55, B-	B*55:01:13/73
B55	B*55:01:17
B55	B*55:01:21
B55, B-	B*55:01:25/79/93/104
B55, B-, B22, B"Blank"	B*55:02:01:01-02:02/02:04-02:10/02:12-02:13/02:15/12/19/39/42-43/48/50/61-62/65/67/69/71-72/80/83N/107
	B*55:02:03/63
	B*55:02:11
	B*55:02:14
	B*55:04/49/86
B22	B*55:05
B54	B*55:07
B56	B*55:08
B22	B*55:09
B55	B*55:10
B-	B*55:100
B-	B*55:103
B-	B*55:106
B-	B*55:13
B-	B*55:14
B22	B*55:16
B-	B*55:17/28_01
B-	B*55:18
B-	B*55:20
B-	B*55:21
B55	B*55:22
B-	B*55:23
B-	B*55:24
B-	B*55:26/77
B-	B*55:27
B-	B*55:28:02
B-	B*55:30
B-	B*55:31
B-	B*55:32/41/46
B-	B*55:34
B-	B*55:35
B-	B*55:37
B-	B*55:40
B-	B*55:47
B-	B*55:51
B-	B*55:52
B-	B*55:54/96
B-	B*55:56
B-	B*55:57
B-	B*55:58
B-	B*55:64
B-	B*55:68
B-	B*55:70
B-	B*55:78
B-	B*55:81
B-	B*55:82
B-	B*55:88
B"Blank"	B*55:89N
B-	B*55:90
B-	B*55:99
B56, B"Blank", B-	B*56:01:01:01-01:01:12/01:03-01:04/01:09-01:10/01:14/20:01-20:02/24/26-27/29/40-41/46-49/52/55:01:02/58/61-62/68-70/72
	B*56:01:02/01_11
B56	B*56:01:05
B56, B-	B*56:01:06/01:12/73
B56	B*56:01:07
B56	B*56:01:08
B56	B*56:01:13
B56	B*56:01:15
B56, B-	B*56:02:01:01-02:03/04:01:01-04:04/56
B22	B*56:03
B56	B*56:05:01
B56	B*56:05:02
B78	B*56:06

Sample ID

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Sample ID

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Sample ID

Reaction Results (mark positive locations)	
Cut Off Value	
Serology Equivalent	Allele Group
B-	B*58:102/124
B-	B*58:111
B-	B*58:114
B-	B*58:12
B-	B*58:121
B-	B*58:122
B-	B*58:14
B-	B*58:15/42/70
B-	B*58:16.01
B-	B*58:16.02
B*	B*58:17N/75
B-	B*58:18
B-	B*58:19/91
B58	B*58:20
B-	B*58:22
B-	B*58:27
B-	B*58:28.01
B-	B*58:28.02
B-	B*58:34
B-	B*58:35
B-	B*58:36
B-	B*58:37
B-	B*58:38
B-	B*58:40/45.01-45.02
B-	B*58:41
B-	B*58:44
B-	B*58:47/79-80/107
B-	B*58:59.02
B-	B*58:64
B-	B*58:65
B-	B*58:73
B-	B*58:76
B-	B*58:78
B-	B*58:84
B-	B*58:96
B59, B-, B*Blank	B*59.01:01.01-01.01:02/07/10N
B59	B*59.02
B-	B*59.03
B-	B*59.04
B-	B*59.05
B-	B*59.06
B-	B*59.08
B-	B*59.09
B67, B-	B*67.01:01/03
B67, B-	B*67.01:02-01:03/05
B-	B*67.02:01.01-02.01:02
B-	B*67.04
B-	B*67.06
B-	B*67.07
B73	B*73.01:01.01-01.01:02
B78	B*78.01:01:02-01:01:03
B78	B*78.01:02
B78	B*78.02:01
B78	B*78.02:02
B-	B*78.03
B-	B*78.04
B-	B*78.05
B-	B*78.06
B-	B*78.07
B-	B*78.08
B-	B*78.09
B-	B*78.10
B81, B-	B*81.01:01.01-01:02/01:04-03/ 05/07/10
B81	B*81.01:03
B*Blank	B*81.04N
B-	B*81.06
B-	B*81.08
B-	B*81.09
B82	B*82.01:01:01-01:03
B-	B*82.02:01.01-02.01:02
B-	B*82.02:02
B-	B*82.03
B-	B*82.04
B-	B*83.01

Sample ID

HLA Locus

[illegible]

The following alleles are not included in this kit: None

Name

Sample ID

C Locus

[illegible]

Sample ID

[illegible]

Name

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]

Name _____

Sample ID

C Locus

[illegible]



C Locus

TDX-OLI-TEMPLATE-0243 REV 02: PAGE 12 OF 34

Name _____

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]



C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]

Name _____

Sample ID

C Locus

[illegible]

Name _____

Sample ID

C Locus

[illegible]

Name _____

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]

Sample ID

[illegible]

Name _____

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]



C Locus

C Locus																																																				
Reaction Results (mark positive locations)																																																				
Cut Off Value																																																				
Serology Equivalent	C Locus Allele Group																																																			
C-	C*12:176		3	4		16	17			25			29				36		40										55		57						73			80				94		99						
C-	C*12:178		3	4					25	25								36		40											57		57			61			73			80				94		99				
C-	C*12:18:01~18:02		3	4					25	25									40	41											57		57			61			73			80				94		99				
C-	C*12:181		3	4			16		17	25	25								40											55		57				61			73							94		99				
C-	C*12:185		3	4				17		25	25								40			43									57		57			61			73		76		80				89		99			
C-	C*12:188		3						18	25	25								40	41											57		57			61			73			80				88		91		99		
C-	C*12:19		3	4				17		25	25								40												57		57			61			73							94		99				
C-	C*12:194		3	4					17	25	25								40												57		57			61			73			80				94		99				
C-	C*12:195:03		3	4				17											40												57				61			73			80					94		99				
C-	C*12:198		3	4						25	25							38	40	41											57				61			73			80						94		99			
C-	C*12:20/175		3	4				17		25	25								40												57		57			61			73			80					94		99			
C-	C*12:203		3	4				17		25	26								40												57		57			61			73			80					94		99			
C-	C*12:208		3	4						25	25								40											54		57			61			73			80						94		99			
C-	C*12:21			4						25	26								40				31								57		57			61			73		78	80			86			91		94		99
C-	C*12:222/328		3	4						25	25								40												57				61			73			80						94		99			
C-	C*12:227		3	4				17		25	25								40												57		57			61			73			80					94		99			
C-	C*12:233		3	4					17	25	25								40			42								51	52	56	57		60	61			73			80					94		99			
C-	C*12:24		3	4				17		25	25								40												56	57			60	61			73			80					94		99			
C-	C*12:252		3	4						25	25								40	41														61			73			80	83						94		99			
C-	C*12:279		3	4						25	25								40	41											52		57			61			73			80					94		99			
C-	C*12:28/325		3	4				17		25	25								40																61			73			80						94		99			
C-	C*12:287		3					18		25	25								40	41														61			73			80							94		99			
C-	C*12:309		3	4						25	25								40											50		57			61			73			80						94		99			
C-	C*12:31:01~31:02		3	4				17		25	25								40			42												61			73			80						94		99				
C-	C*12:314/326		3	4					17	25	25								40															61			73			80					93			94		99		
C-	C*12:33			4				17		25	26								40				31								57			61			73			78	80			86			91			94		99
C-	C*12:333		3	4			16	17		25			29						40													57			61			73			80						94		99			
C-	C*12:41			4						25				31					40			41									57			61			73			80			86					94		99		
C-	C*12:44		3	4						25									40										50		57			61			73			80							94		99			
C-	C*12:49		3	4						25									40	41											57			61			73			80							94		99			
C-	C*12:54		3	4				17		25									40												57			61			73			80						91			94		99	
C-	C*12:55/269		3	4		6		17											40												57			61			73			80							94		99			
C-	C*12:58		3	4				17		25									40															61			73			80	83						94		99			
C-	C*12:60			4						25									40				31								57			61			73			80			86				94		99			
C-	C*12:69/161		3	4						25									40													57			61			73			80						94		99			
C-	C*12:72			4						25				31					40				31										61			73			80							94		99				
C-	C*12:81		3					17	18	25	25								40												57			61			73			80						94		99				
C-	C*12:83		3	4						25	25								40	41											57			61			70	73									94		99			
C-	C*12:85		3	4						25	25								40	41											56	57		60	61			73			80						94		99			
C-	C*12:98		3	4				17		25	25								40													57			61			73			80					91			94		99	

Name _____

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]



C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]

Name

Sample ID

C Locus

[illegible]

[illegible]

WORKSHEET
LABType™ SSO Class II DRB1 Typing Test, Lot #020

Name _____		☐ Patient ☐ Donor	☐ Male ☐ Female	Race _____	ABO/Rh _____
Sample I.D. _____		Birthdate _____		Relationship to Patient _____	
Disease _____		DNA Extraction Method _____		Bead Mix Exp. Date _____	
Results 		DNA Concentration _____		Bead Mix Lot# _____	
		Taq Lot # _____		Primer Mix Lot# _____	
		D-mix Lot #/Batch # _____		SAPE Solution Lot# _____	
Comments: 		LABScan™ 100 Serial# _____		Raw Data File ID _____	
		Test Performed by _____		Date _____	
		Read by _____		Date _____	
		Reviewed by _____		Date _____	

Photo Documentation

The allele nomenclature includes the HLA alleles listed in the July 2020 update of the IMGT/HLA database release 3.41.0 (Robinson J, et al., "IMGT/HLA and IMGT/MHC: sequence databases for the study of the major histocompatibility complex" Nucleic Acids Research (2003), 31, 311-314). Complete update information is located at www.ebi.ac.uk/imgt/hla/.

Revision summary: July 2020 nomenclature update based on IMGT/HLA 3.41.0.

(Bead 89) DRB1*04:49 is added to the bead specificity.

Allele sequences are obtained from the IMGT database. Updates, including modifications to allele sequences may alter bead specificity.

DRB1*01:39N, DRB1*01:40N, DRB1*01:63, DRB1*01:65:02, DRB1*01:108, DRB1*03:01:14, DRB1*03:42, DRB1*03:87, DRB1*03:123, DRB1*03:135, DRB1*04:298, DRB1*07:71, DRB1*08:64, DRB1*08:65, DRB1*09:07, DRB1*09:09, DRB1*09:20, DRB1*10:35, DRB1*11:04:11, DRB1*11:30, DRB1*11:95, DRB1*11:201, DRB1*12:57, DRB1*13:67, DRB1*13:109, DRB1*13:121, DRB1*13:195, DRB1*13:199, DRB1*14:46, DRB1*14:141, DRB1*15:19, DRB1*15:74, DRB1*15:105:01, DRB1*15:105:02, DRB1*15:110, DRB1*15:139, DRB1*15:150, DRB1*15:161, DRB1*16:22, DRB1*16:39 are not amplified by the primers for this kit. DRB3*01:14, DRB4*01:97, DRB4*01:125 are amplified. The following alleles have mismatches with primers in this kit, and their amplifiability has not been determined: DRB1*04:195, DRB1*08:39, DRB1*11:247, DRB1*14:142

Not all alleles were directly tested. Untested alleles were predicted and, therefore, may cause false reactions. Refer to "Nomenclature List" for the list of tested alleles.

Serological equivalent for alleles are based on the HLA Dictionary (S.G.Marsh, et al.: "Nomenclature for factors of the HLA system, 2010," Tissue Antigens (2010) 75:291-455)

The allele specificity for some beads include alleles with unsequenced regions at the target site. (Sequence information is available at www.ebi.ac.uk/imgt/hla/.) For these alleles, the published sequence from the most closely related allele is used as reference for the unsequenced regions. The reference allele provides the most likely prediction of the unsequenced regions. There may be a disparity between the predicted and newly sequenced information, which may alter the allele specificity of a bead. Allele specificity information will be updated as new sequence information is available.

This product is intended for low resolution HLA typing results. Typing results outside this specification may produce ambiguities that require additional testing to resolve.

The following alleles are not included in this kit: DRB1*01:39N, DRB1*01:40N, DRB1*01:63, DRB1*01:65:02, DRB1*01:108, DRB1*03:01:14, DRB1*03:42, DRB1*03:87, DRB1*03:123, DRB1*03:135, DRB1*04:298, DRB1*07:71, DRB1*08:64, DRB1*08:65, DRB1*09:07, DRB1*09:09, DRB1*09:20, DRB1*10:35, DRB1*11:04:11, DRB1*11:30, DRB1*11:95, DRB1*11:201, DRB1*12:57, DRB1*13:67, DRB1*13:109, DRB1*13:121, DRB1*13:195, DRB1*13:199, DRB1*14:46, DRB1*14:141, DRB1*15:19, DRB1*15:74, DRB1*15:105:01, DRB1*15:105:02, DRB1*15:110, DRB1*15:139, DRB1*15:150, DRB1*15:161, DRB1*16:22, DRB1*16:39

Name _____

Sample ID

DRB1 Locus

[illegible]

Name _____

Sample ID

DRB1 Locus

[illegible]

Name _____

Sample ID

DRB1 Locus

[illegible]

Name _____

Sample ID

DRB1 Locus

[illegible]

Name

Sample ID

DRB1 Locus

[illegible]

[illegible]

Name _____

Sample ID

DRB1 Locus

[illegible]

Name _____

Sample ID

DRB1 Locus

[illegible]

Name

Sample ID

DRB1 Locus

[illegible]

Name

Sample ID

DRB1 Locus

[illegible]

[illegible]

Name

Sample ID

DRB1 Locus

[illegible]

Name _____

Sample ID

DRB1 Locus

[illegible]

Name _____

Sample ID

DRB1 Locus

[illegible]

Name

Sample ID

DRB1 Locus

[illegible]

Name _____

Sample ID

DRB1 Locus

[illegible]

Name

Sample ID

DRB1 Locus

[illegible]

Name

Sample ID

DRB1 Locus

[illegible]

Name

Sample ID

DRB1 Locus

[illegible]

Name

Sample ID

DRB1 Locus

[illegible]

Name ☐ Male ☐ Female
 Patient HLA Typing
 Donor HLA Typing Date Collected

PRA

$\frac{\# \text{ Pos. Reactions}}{\# \text{ Valid Reactions}} \times 100 = \text{PRA}$

Changes from Previous Lot: The PC bead values on average are ~30% lower than the previous lot. This does not affect the performance of any other beads in the assay. No changes in antigen panel. Replace beads ID #15 through #39 with beads ID #14 through #38, bead ID #60 with bead ID #63, and bead ID #63 with bead ID #60.

Changes from Previous Revision: N/A

	Bead ID	Antigen ID	Molecular Typing	Serological Typing	W6/32	Results
1	1	NC	NA	N/A	203	
2	2	PC	NA	N/A	333	
3	3	RA0101	A*01:01	A1	24434	
4	4	RA0201	A*02:01	A2	24665	
5	5	RA0203	A*02:03	A2	24932	
6	6	RA0206	A*02:06	A2	23876	
7	7	RA0301	A*03:01	A3	24459	
8	8	RA1101	A*11:01	A11	23988	
9	9	RA1102	A*11:02	A11	24770	
10	10	RA2301	A*23:01	A23	24685	
11	11	RA2402	A*24:02	A24	24811	
12	12	RA2403	A*24:03	A24	24442	
13	13	RA2501	A*25:01	A25	24173	
14	14	RA2601	A*26:01	A26	23748	
15	15	RA2901	A*29:01	A29	23985	
16	16	RB2705	B*27:05	B27 BW4	23923	
17	17	RA2902	A*29:02	A29	24555	
18	18	RA3001	A*30:01	A30	24406	
19	19	RA3002	A*30:02	A30	24175	
20	20	RA3101	A*31:01	A31	24419	
21	21	RA3201	A*32:01	A32	24049	
22	22	RA3301	A*33:01	A33	23746	
23	23	RA3401	A*34:01	A34	23767	
24	24	RA3402	A*34:02	A34	24435	
25	25	RA3601	A*36:01	A36	23651	
26	26	RA4301	A*43:01	A43	24331	
27	27	RA6601	A*66:01	A66	24291	
28	28	RA6602	A*66:02	A66	24049	
29	29	RA6801	A*68:01	A68	23950	
30	30	RA6802	A*68:02	A68	24110	
31	31	RA6901	A*69:01	A69	23390	
32	32	RA7401	A*74:01	A74	24378	
33	33	RA8001	A*80:01	A80	23512	
34	34	RB0702	B*07:02	B7 BW6	24297	
35	35	RB0801	B*08:01	B8 BW6	24608	
36	36	RB1302	B*13:02	B13 BW4	24156	
37	37	RB1401	B*14:01	B64 BW6	23958	
38	38	RB1402	B*14:02	B65 BW6	23530	
39	40	RB1501	B*15:01	B62 BW6	24063	
40	41	RB1502	B*15:02	B75 BW6	24083	
41	42	RB1503	B*15:03	B72 BW6	24237	
42	43	RB1510	B*15:10	B71 BW6	24243	
43	44	RB1512	B*15:12	B76 BW6	24689	
44	45	RB1513	B*15:13	B77 BW4	22883	
45	46	RB1516	B*15:16	B63 BW4	23950	
46	47	RB1801	B*18:01	B18 BW6	25093	
47	48	RB2708	B*27:08	B27 BW6	24368	
48	49	RB3501	B*35:01	B35 BW6	23777	
49	50	RB3701	B*37:01	B37 BW4	24454	
50	51	RB3801	B*38:01	B38 BW4	24313	

Antigen Distribution			
Aq	#	Aq	#
A1	1	B53	1
A2	3	B54	1
A3	1	B55	1
A11	2	B56	1
A23	1	B57	2
A24	2	B58	1
A25	1	B59	1
A26	1	B60	1
A29	2	B61	2
A30	2	B62	1
A31	1	B63	1
A32	1	B64	1
A33	2	B65	1
A34	2	B67	1
A36	1	B71	1
A43	1	B72	1
A66	2	B73	1
A68	2	B75	2
A69	1	B76	1
A74	1	B77	1
A80	1	B78	1
B7	1	B81	1
B8	1	B82	1
B13	2	BW4	19
B18	1	BW6	31
B27	2	Cw1	1
B35	1	Cw2	1
B37	1	Cw4	1
B38	1	Cw5	1
B39	1	Cw6	1
B41	1	Cw7	1
B42	1	Cw8	1
B44	2	Cw12	1
B45	1	Cw14	1
B46	1	Cw15	1
B47	1	Cw16	1
B48	1	Cw17	1
B49	1	Cw18	1
B50	1	Cw9	1
B51	2	Cw10	2
B52	1		

Name ☐ Male ☐ Female
 Patient HLA Typing
 Donor HLA Typing Date Collected

PRA

$\frac{\text{\# Pos. Reactions}}{\text{\# Valid Reactions}} \times 100 = \text{PRA}$

Changes from Previous Lot: The PC bead values on average are ~30% lower than the previous lot. This does not affect the performance of any other beads in the assay. No changes in antigen panel. Replace beads ID #15 through # 39 with beads ID #14 through #38, bead ID #60 with bead ID #63, and bead ID #63 with bead ID #60.

Changes from Previous Revision: N/A

	Bead ID	Antigen ID	Molecular Typing	Serological Typing	W6/32	Results
51	52	RB3901	B*39:01	B39 BW6	24508	
52	53	RB4001	B*40:01	B60 BW6	24098	
53	54	RB4002	B*40:02	B61 BW6	24466	
54	55	RB4101	B*41:01	B41 BW6	23820	
55	56	RB4201	B*42:01	B42 BW6	24578	
56	57	RB4402	B*44:02	B44 BW4	22666	
57	58	RB4403	B*44:03	B44 BW4	23786	
58	59	RB4501	B*45:01	B45 BW6	23793	
59	60	RB4901	B*49:01	B49 BW4	23752	
60	61	RB4701	B*47:01	B47 BW4	22515	
61	62	RB4801	B*48:01	B48 BW6	24036	
62	63	RB4601	B*46:01	B46 BW6	24770	
63	64	RB5001	B*50:01	B50 BW6	24039	
64	65	RB5101	B*51:01	B51 BW4	23703	
65	66	RB5102	B*51:02	B51 BW4	24287	
66	67	RB5201	B*52:01	B52 BW4	23224	
67	68	RB5301	B*53:01	B53 BW4	23819	
68	69	RB5401	B*54:01	B54 BW6	24510	
69	70	RB5501	B*55:01	B55 BW6	23853	
70	71	RB5601	B*56:01	B56 BW6	24647	
71	72	RB5701	B*57:01	B57 BW4	23788	
72	73	RB5703	B*57:03	B57 BW4	24796	
73	74	RB5801	B*58:01	B58 BW4	24438	
74	75	RB5901	B*59:01	B59 BW4	22017	
75	76	RB6701	B*67:01	B67 BW6	24618	
76	77	RB7301	B*73:01	B73 BW6	24318	
77	78	RB7801	B*78:01	B78 BW6	23932	
78	79	RB8101	B*81:01	B81 BW6	24727	
79	80	RB8201	B*82:01	B82 BW6	24420	
80	81	RC0102	C*01:02	Cw1	24751	
81	82	RC0202	C*02:02	Cw2	22957	
82	83	RC0302	C*03:02	Cw10	24497	
83	84	RC0303	C*03:03	Cw9	24942	
84	85	RC0304	C*03:04	Cw10	24515	
85	86	RC0401	C*04:01	Cw4	19742	
86	87	RC0501	C*05:01	Cw5	24396	
87	88	RC0602	C*06:02	Cw6	23399	
88	89	RC0702	C*07:02	Cw7	21906	
89	90	RC0801	C*08:01	Cw8	24344	
90	91	RC1203	C*12:03	Cw12	23845	
91	92	RC1402	C*14:02	Cw14	22776	
92	93	RC1502	C*15:02	Cw15	24849	
93	94	RC1601	C*16:01	Cw16	23426	
94	95	RC1701	C*17:01	Cw17	19901	
95	96	RC1802	C*18:02	Cw18	22723	
96	97	RB1301	B*13:01	B13 BW4	23673	
97	98	RB1511	B*15:11	B75 BW6	23359	
98	99	RB4006	B*40:06	B61 BW6	23282	
99	100	RA3303	A*33:03	A33	23430	

*Trimmed mean value

LABScreen™

REF	Catalog ID	Product Name
	LS1PRA*	LABScreen™ PRA Class I
	LS2PRA*	LABScreen™ PRA Class II
	LS12PRA*	LABScreen™ PRA Class I & II
	LSM12*	LABScreen™ Mixed Class I & II
	LS1A04*	LABScreen™ Single Antigen HLA Class I - Combi
	LS1ASP01*	LABScreen™ Single Antigen HLA Class I Supplement - Group 1
	LS2A01*	LABScreen™ Single Antigen HLA Class II - Group 1
	LS2ASP01*	LABScreen™ Single Antigen HLA Class II Supplement - Group 1
	LS1AEX01*	LABScreen™ Single Antigen HLA Class I ExPlex
	LS2AEX01*	LABScreen™ Single Antigen HLA Class II ExPlex
	LSMICA001	LABScreen™ MICA Single Antigen - Group 1
	LSPWABUF	LABScreen™ Wash Buffer

IVD In Vitro Diagnostic Medical Device.

INTENDED USE



LABScreen products are intended for use in detection of HLA antibody using flow cytometric technology

SUMMARY AND EXPLANATION

LABScreen products use microbeads coated with purified Class I or Class II HLA antigens and pre-optimized reagents for the detection of Class I or Class II HLA antibodies in human sera. LABScreen products utilize the LABScan™ 100 (Luminex® 100/200) or LABScan3D™ (Luminex® FLEXMAP 3D®) for analysis of up to 100 or 500 bead regions, respectively, in a single test.

The Mixed assay detects the presence of antibody to Class I and/or Class II HLA antigens. The PRA tests can detect antibodies and their specificities against the HLA antigens in each LABScreen panel. The Single Antigen assay allows confirmation of antibody specificity suggested by a previous PRA test, while individual Singles beads are used to focus on reactions against one or a few antigens, e.g. to compare reactivity of different serum samples from the same individual. A negative control serum is used to establish the background value for each bead in a test batch.

PRINCIPLE(S)

Test serum is incubated with LABScreen beads. Any HLA antibodies present in the test serum bind to the antigens on the beads and then are labeled with R-Phycoerythrin (PE)-conjugated goat anti-human IgG. The LABScan™ 100 or LABScan3D™ flow analyzer(s) simultaneously detects the fluorescent emission of PE and a dye signature from each bead, allowing almost real-time data acquisition. To assign PRA and HLA specificity, the reaction pattern of the test serum is compared to the lot-specific worksheet defining the antigen array.

REAGENTS

A. Identification

See LABScreen Reference Table for product description.



**B. Warning or Caution**

1. **Warning:** LABScreen PRA test reagents contain 0.1% sodium azide (NaN₃) as a preservative. Under acidic conditions, sodium azide yields hydrazoic acid, an extremely toxic compound. Dilute reagents containing sodium azide in running water before discarding, to avoid deposits in plumbing where explosive conditions may develop. (Refer to Material Safety Data Sheet for detail.)
2. **Warning:** All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.
3. **Caution:** For manual flicking of trays, use a quick downward arm motion without wrist movement to prevent repetitive motion effects.
4. Refer to the Material Safety Data Sheet for detailed information.

**C. Preparing Reagents for Use**

1. See Directions for Use, below.
2. If buffer salts have precipitated out of solution during shipment or storage, re-dissolve by gently warming before preparing working dilution.

**D. Storage Instructions**

1. LABScreen products are shipped to the end user on dry ice. The entire package may be stored in a freezer at -65° C or below until first use, up to the labeled expiration date.
2. Once beads are thawed, DO NOT REFREEZE. Store at 2 - 8° C for up to three months or until the expiration date (if earlier).
3. After first use, store wash buffer at 2 - 8°C for up to three months or until the expiration date, if earlier.

E. Purification or Treatment Required for Use

See Directions for Use, below.

F. Instability Indications

None

INSTRUMENT REQUIREMENTS**A. Required Equipment**

- LABScan 100 flow analyzer (Luminex® 100/200) with Luminex® XY platform (for automated 96-sample data acquisition) and sheath fluid delivery system (OLI Cat. # LABSCNXS3) OR LABScan3D flow analyzer (Luminex® FLEXMAP 3D®) with XY platform and sheath fluid delivery system (OLI Cat. # LABSCNXS4)
- Centrifuge
- Rotor for 1.5 ml microcentrifuge tube (9,300 g), or a swinging bucket rotor for 96-well microplate (1,300 g)
- Vortex mixer
- Plate shaker or rotating platform

For Filter Plate Option:

- Vacuum manifold, 96-well (Millipore Cat. # MAVM0960R or equivalent)
- Vacuum pump with a pressure less than 100 mm Hg
- Plate shaker or rotating platform

B. Equipment Calibration

Follow manufacturer's instructions for calibration of the LABScan 100 or LABScan3D flow analyzer.

C. Recommended Software

HLA Fusion™ (OLI Cat. # FUSPGR)

SPECIMEN COLLECTION AND PREPARATION

- Unopened blood specimens may be kept at room temperature up to 4 days. Separated serum (from clotted samples) or plasma (in ACD or K-EDTA) may be refrigerated up to 7 days, or aliquots may be frozen at -20°C or below and thawed just before the assay. Aggregates should be removed from the test serum/plasma by centrifugation (8,000 – 10,000 g for 10 minutes) or filtration (0.2 µm) prior to testing. Any aggregates or contamination of the sample may generate invalid results.
- Samples may be treated or diluted to reduce non-specific background or to remove inhibitory factor – see limitation section.

Note:

- Test serum or plasma should not be heat inactivated, because it may give a high background in the test.
 - Undiluted serum or plasma is generally used for the test. However, if a high background serum sample is diluted for this assay, the negative control serum should be tested at the same dilution.
- Diluting serum and plasma may reduce the reactivity (MFI) for the ExPlex Products.

PROCEDURE**A. Materials Provided**

1. See the LABScreen Reference Table in Product Documentation on the One Lambda, Inc. web site for a list of materials provided for each product.
2. The volumes provided exceed the amount required for testing by a small amount to allow for pipetting losses.

B. Materials Required, But Not Provided

1. PE-Conjugated Goat Anti-Human IgG (OLI Cat. # LS-AB2)
2. PBS, filtered [USA Scientific Cat. # 9242 (500 ml 10X) or equivalent]
3. 1.5 ml microcentrifuge tube (USA Scientific Cat. # 1415-2500 or equivalent)
4. Pipette tips
5. Negative Control Serum, containing no HLA antibody when tested by LABScreen method (OLI Cat. # LS-NC or equivalent)

If the test is performed in a 96-well microplate:

1. 96-well microplate, 250 µl, non-treated surface (Whatman Cat. # 7701-3250 or equivalent)
2. Tray seal (OLI Cat. # SSPSEA300 or equivalent)

For the Filter Plate option:

1. Filter plate (Multiscreen-BV, Millipore Cat. No. MABVN1250 or equivalent)

C. Directions for Use

Notes:

- Take special care in the aliquoting process. Failure to follow the steps described below may result in reagent loss.
- Sections A through C indicate the volumes of reagents needed for testing a single bead group. If you are running a combined test, see Section D before proceeding.
- Turn on the LABScan 100 or LABScan3D flow analyzer at least 30 minutes before starting the assay.
- Create a filename and sample code sheet for each test tray.

I. For each test batch, test a negative control serum (e.g. OLI Cat. # LS-NC or equivalent) to establish background values. To complete the test in a 1.5 ml microcentrifuge tube

1. Mix the LABScreen beads well by gently vortexing or pipetting up and down several times prior to use.
2. Incubate 5 µl of LABScreen beads with 20 µl of test serum in a 1.5 ml micro-centrifuge tube for 30 minutes, in the dark at 20 - 25° C with gentle shaking.
3. Dilute 10X wash buffer (OLI Cat. # LSPWABUF) in distilled water to make a 1X solution.
4. Add 1 ml of 1X wash buffer to each bead/serum solution tube and vortex. Centrifuge at 9,300 g for 2 minutes. Aspirate and discard the supernatant.
5. Repeat Step 4 twice.
6. Dilute 1 µl per test of 100X PE-conjugated anti-human IgG (OLI Cat. # LS-AB2) with 99 µl of 1X wash buffer to make a 1X solution.
7. Add 100 µl of 1X PE-conjugated anti-human IgG to each tube. Vortex and then incubate in the dark for 30 minutes at 20 - 25° C with gentle shaking.
8. Repeat Step 4 twice.
9. Add 80 µl 1X PBS to each tube. Proceed to data acquisition and analysis, or store tray at 2 - 8° C in the dark for up to 24 hours before analysis.

II. To complete the test in a 96-well plate

Caution: Seal the 96-well tray carefully and completely to prevent well-to-well sample contamination by pressing the seal against each rim of the 96 wells. Do not re-use tray seals. Use a fresh seal for each step that requires application of a tray seal.

1. Mix the LABScreen beads well by gently vortexing or pipetting up and down several times prior to use.
2. Add 5 µl of LABScreen beads with 20 µl of test serum in each well of a 96-well plate, seal plate, and incubate for 30 minutes in the dark at 20 - 25° C with gentle shaking.
3. Dilute 10X wash buffer (Cat. # LSPWABUF) in distilled water to make a 1X wash solution.
4. After incubation, remove seal and add 150 µl of 1X wash buffer to each well of the plate. Cover with tray seal (OLI Cat. # SSPSEA300 or equivalent) and vortex. Centrifuge at 1,300 g for 5 minutes.
5. Remove wash buffer from wells of plate by flicking or with vacuum aspiration.
6. Add 200 µl of 1X wash buffer to each well of the plate. Cover with a new tray seal and vortex. Centrifuge at 1,300 g for 5 minutes.
7. Remove supernatant from wells of plate by flicking or with vacuum aspiration.
8. Repeat Steps 6 and 7.
9. Dilute 1 µl per test of 100X PE-conjugated anti-human IgG (OLI Cat. # LS-AB2) with 99 µl of 1X wash buffer to make a 1X solution.
10. Add 100 µl of 1X PE-conjugated anti-human IgG to each well. Cover with tray seal and vortex. Incubate in the dark for 30 minutes at 20 - 25° C with gentle shaking.
11. Centrifuge at 1,300 g for 5 minutes.
12. Remove supernatant from wells of plate by flicking or with vacuum aspiration.
13. Repeat Steps 6 and 7 twice.
14. Add 80 µl 1X PBS to each well. Cover with a new tray seal and vortex. Proceed to data acquisition and analysis, or store tray at 2 - 8° C in the dark for up to 24 hours before analysis.

III. To complete the test in a 96-well filter plate

1. Mix the LABScreen beads well by gently vortexing or pipetting up and down several times prior to use.
2. Dilute 10X wash buffer (OLI Cat. # LSPWABUF) in distilled water to make a 1X solution (approximately 3.2 ml/tray/wash).
3. Cover any wells of the plate that will remain unused during the test with a tray seal to assure that the unused wells remain dry. Pre-wet filters in the filter plate by dispensing 300 µl wash buffer into only those wells that will be used for the assay.
4. Incubate the plate for 10 minutes on a platform plate shaker at low speed.
5. Aspirate all wash buffers from the wells using a Millipore vacuum manifold. Do not exceed 100 mm Hg vacuum pressure!
6. Add 5 µl of LABScreen beads and 20 µl of test serum per test well.
Note: During bead and sample dispensing steps, press pipette tip gently against filter plate well to avoid filter rupture.
7. Incubate the plate in the dark for 30 minutes at 20 - 25° C with gentle shaking.
8. Add 175 µl wash buffer per well.
9. Turn on vacuum pump. Press the plate firmly on the vacuum manifold. Make sure liquid drains out slowly. Make sure all liquid has drained from the wells before proceeding.



Caution: Do not exceed 100 mm Hg vacuum pressure. A rapid vacuum will cause loss of beads due to be entrapment in the pores of the filter paper.

10. Repeat Steps 8 and 9, above, four times.
11. Add 100 µl of 1X PE-conjugated anti-human IgG to each well.
12. Incubate in the dark for 30 minutes at 20 - 25° C with gentle shaking.
13. Repeat Steps 8 and 9 five times.
14. Add 80 µl of 1X PBS to each well.
15. Read sample on the LABScan 100 or LABScan3D flow analyzer, adjusting probe height if necessary.

Note: LABScreen Single Antigen HLA Class I and Class II ExPlex products can be used on the LABScan3D flow analyzer only.

IV. Combined tests

Any of the above protocols can be used for a combined test of certain LABScreen products.

- For acceptable lot combinations of LS12PRA see www.onelambda.com (Antibody Detection>LABScreen>LABScreen PRA/ Product Documentation: LABScreen Bead Combo – Multiple IDs DataSheet).
 - Do not combine LABScreen Single Antigen Class I Combi and Class II panels (bead IDs would overlap).
1. Mix equal volumes of beads. Then dispense the appropriate aggregate amount (10 or 15 µl) of bead mixture per test.
 2. Bead combinations and amounts to dispense are listed in the table below.

Catalog ID	Bead volume per Test	Control (NC/PC) Beads	Test Serum per Test	Instrument
LS12PRA (CI and CII beads)	5 µl + 5 µl	Included	40 µl	LABScan 100 or LABScan3D
LS1A04 + LS1AEX01	5 µl + 5 µl	Included	40 µl	LABScan3D
LS2A01 + LS2AEX01	5 µl + 5 µl	Included	40 µl	LABScan3D
LS1A04	5 µl	Included	20 µl	LABScan 100 or LABScan3D

RESULTS

A. Data Acquisition

1. Set up the LABScan 100 or LABScan3D flow analyzer for sample acquisition and calibration according to the Luminex User's Manual.¹
2. Choose a template according to product kit catalog ID and lot number.
 - a. Acquisition templates are available from OLI by CD or via our download website.
 - b. To create your own acquisition template, follow instructions in the Acquisition chapter of the Luminex User's Manual.
 - c. Luminex software versions - LABScan 100 (xPONENT 3.1 or higher); LABScan 3D (xPONENT 4.2 or higher) must be used.
3. Create a file name for the samples to be run.
4. Make sure all the template settings are correct. Template specifications are:
 - a. Set sample volume to 50 µl.
 - b. Set sample time-out to 80 seconds.
 - c. Set doublet discriminator gate to 8,000 (low limit) and 16,000 (high limit).
 - d. Set number and ID of beads selected according to the product-specific worksheet provided with the product.
 - e. Set minimum events collected to 100 per bead.
5. Enter the sample IDs (if the same sample is tested more than once, assign a different ID).
6. Load the plate onto the XY platform and fill the reservoir with sheath fluid.
7. Click the START button to initiate the session. After the samples have finished running, save the data output in a .csv file.
8. Wash the machine twice with sheath fluid at the end of the session.

B. Data Analysis

1. The reactivity of a test sample is calculated from the "raw" fluorescence values recorded by the LABScan device (.csv file) for each HLA coated bead.
2. Calculate anti-HLA serum reactivity by correcting for non-specific binding to the negative control bead and background values (obtained by testing with a negative control serum (OLI Cat. # LS-NC) to determine the normalized background ratio (NBG ratio). See Calculations, below.
3. For LABScreen PRA or LABScreen Single Antigen, the normalized fluorescent value for each HLA coated bead equals the value of that bead divided by the value of the NC bead. (For LABScreen Mixed, the normalized fluorescent signal equals the value of the Class I or Class II coated bead minus the value of the NC bead.)

Note: The fluorescent signal (value) can be either the trimmed mean or median value.

C. Calculations

1. The abbreviations used in this section are defined below:

NBG ratio	Normalized Background ratio used to assign strength of each anti-HLA reaction
S#N	Sample-specific fluorescent value for bead #N
SNC bead	Sample-specific fluorescent value for Negative Control bead
BG#N	Background NC Serum fluorescent value for bead #N
BGNC bead	Background NC Serum fluorescent value for Negative Control bead
NC Serum	Negative Control Serum (OLI Cat. # LS-NC) validated for a given lot of LABScreen beads

2. For LABScreen PRA or LABScreen Single Antigen:

$$\text{NBG ratio} = \frac{\text{S\#N / SNC bead}}{\text{BG\#N / BGNC bead}}$$

For LABScreen Mixed:

$$\text{NBG ratio} = \frac{\text{S\#N - SNC bead}}{\text{BG\#N - BGNC bead}}$$

Note: If (BG#N-BGNC bead) <50 then use 50 as a default threshold value.

D. Determination of Positive/Negative Cut-Off

1. For LABScreen PRA and LABScreen Mixed:
 - a. Select the NBG ratio that gives a significant shift over background fluorescent value when the background value is obtained using the negative control serum in 3 - 5 replicate tests. If you prefer, test 5 - 10 serum samples from non-transfused, non-transplanted male donors to obtain an average background value.
 - b. Validate the cut-off using 5 - 10 reference alloserum samples with defined HLA antibody specificity. The NGB ratio values for expected positive antigen reactions should be above the cut-off.
 - c. Additional positive/negative reactions may be noted. If necessary, adjust the LABScreen assay cut-off to match the sensitivity of a previously accepted antibody detection assay.
 - d. For high PRA serum, the patient's own antigen(s) may show weak positive reactions. For such cases, the fluorescence value for the patient's own antigen may be used as the cut-off.
2. For LABScreen Single Antigen:
 - a. Test negative control serum or several negative serum samples (see 1a, above).
 - b. Define working range:
Working Range = NBG ratio maximum - NBG ratio minimum
 - c. Define cut-off points within the working range:
Relative NBG ratio cut-off = X% (working range) + NBG ratio minimum, where X% = user-defined percent cut-off point within the working range for negative (1), gray area(2), weak positive (4) and strong positive (8).
 - d. Set criteria to define positive vs. negative reactions, for example:
 - (1) If [NBG ratio max/NBG ratio min] >8, apply the calculation in 2c.
 - (2) If [NBG ratio max/NBG ratio min] <8 AND
 - (a) NBG ratio max >5, then NBG ratio min should be adjusted to one half of the NBG ratio max and the relative NBG ratio cut-off should be re-computed (as in 2c) based on the adjusted NBG ratio min. The reaction is then scored as above.
 - (b) NBG ratio max <5, then the reaction of the test serum with that bead is negative. Assign a score of "1".
 - e. Test several reference allosera as in 1b above, using the relative NBG ratio to validate the cut-off.
 - (1) Establish a strong and weak reactivity cut-off based on the performance of the reference allosera, relative to an established assay.
 - (2) It may be helpful to plot the NBG ratio values in a histogram for visualization of the HLA reactivity pattern of each serum.
3. Higher or lower sensitivities can be obtained by adjusting the cut-off.
4. Optional analysis – HLA Fusion™ software.

LIMITATIONS OF THE PROCEDURE

- Sera or plasma samples that contain contaminants or aggregates may clog the LABScan flow analyzer and generate inaccurate data. Aggregates in the test specimen should be removed by centrifugation or filtering the serum prior to testing.
- The presence of IgG-IgM immune complex may cause inhibition in some patient samples. Samples should be treated to reduce this presence according to the protocols determined by the laboratory, however, samples should not be heat treated as they may cause non-specific background – please reference bibliography section for more information.^{7,8,9,10, 11}
- Ambient temperature may affect LABScan 100 and LABScan3D performance. If the ambient temperature changes, the machine may need to be re-calibrated. Consult the manufacturer's manual for more information.
- The LABScan 100 and LABScan3D flow analyzer must be properly calibrated and maintained. If insufficiently flushed, aggregates of the sample may cause the machine to clog and generate invalid data.
- Assignment of antibody specificity is limited to the HLA antigens presented in each bead panel (see lot-specific worksheet).
- The bead region used for each antigen and the antigen composition of the panel may change from lot-to-lot of product (see the lot specific worksheet).
- Because of the complexity of the HLA allelic definitions, a certified HLA technician or specialist should review and interpret the data, and assign the HLA typing.
- This test must not be used as the sole basis for making a clinical decision.

EXPECTED VALUES**A. LABScreen PRA Class I or Class II**

- The reactivity strength of a test serum to each bead can be compared to distinguish the strong positive, weak positive and negative reactions. Reactivity ratios can be ranked within different ranges, if a scoring system is desired.
- Our data show NBG ratios > 1.5 in the LABScreen PRA test (using the LABScan 100) correlate well with positive reactions in the FlowPRA test.
- For calculation of percent PRA (Panel Reactive Antibody), divide the number of positive reactions by the number of valid reactions for that test serum.
- To determine the specificity of HLA antibody, enter the reaction score into the lot specific Worksheet to analyze the reaction pattern.

B. LABScreen Mixed

- Score HLA Class I and Class II reactions separately, according to reactivity strength of the serum for each bead set.
- If anyone bead in the mixed assay is positive, then the result should be assigned as positive.
- Our data show that NBG ratios >2.2 in the LABScreen Mixed test (using the LABScan 100) correlate well with positive reactions in LAT™ Mixed.

C. LABScreen Single Antigen

- Allosera may produce signal/background ratios that are much higher than those obtained in the PRA assay. Establishing the assay cut-off(s) using the relative NBG ratio is one way of normalizing the data (see Results, Section D-2c).
- Our data show that a positive/negative cut-off or relative NBG ratio >15% of the working range NBG ratio calculated for each test serum (using the LABScan 100) will give results comparable to the LABScreen PRA assay.

D. General Guidelines

- Each bead count should be over 50. A lower bead count may be due to sample loss during the wash steps. It could also be due to improper calibration or clogging of the LABScan 100 or LABScan3D flow analyzer, or by photo-bleached beads that dropped out from the mapped region.
- Signal values are the fluorescence intensity of each bead set vs. the test serum. A negative control serum should be tested with the same batch of samples to establish the background value(s) for that test run.
- Negative Control Serum (OLI Cat. # LS-NC or equivalent) is recommended. Using any other negative control serum may require adjustment of cut-off values.
- Negative Control Beads (Ag ID = NC) are not coated with HLA antigen. The fluorescence value may vary among different sera due to non-specific binding of the sera or to insufficient washing. The NC value is usually less than 500 except for serum samples with a high background. It should always be lower than 1500 and less than or equal to half of the PC value.
- Positive Control Beads are coated with purified human IgG, which should bind to the secondary antibody to produce a positive signal. The PC value should be over 500 and at least twice the NC value.

E. Validation of the Assay

- The cut-off value of signal to background should be validated if a new negative control serum is used.
- For a given serum, the value for PC/NC should be greater than 2. A lower value may be due to an extremely high NC bead background value for the test serum, a high HLA bead signal for the NS control, or a low signal from the secondary antibody or the LABScan 100 and LABScan3D flow analyzer. In this case, the data may have to be confirmed.
- Each user should evaluate the performance of the assay in their laboratory to validate the cut-off value(s) selected.
- Plasma samples may give lower FI or higher background values than serum. The user may wish to normalize the data if comparing results between sera and plasma samples (see Reference 5) for the same or different test subjects.

SPECIFIC PERFORMANCE CHARACTERISTICS

- Using the assay cut-offs referenced under Expected Values, above, LABScreen assays have given results comparable to the results of the One Lambda FlowPRA® and LAT™ assays. However, HLA antibody patterns may be quite complex. A given test sample may contain several HLA Class I and Class II antibody specificities, each with a different avidity; however, not all specificities will be recognized in assays with lesser sensitivity. Therefore, each laboratory should establish and validate the assay cut-offs for their own use based on their expertise in recognizing HLA CREG patterns and an evaluation of the assay performance using HLA allosera with defined specificities.
- Comparison of serum vs. plasma for 1,000 blood donors in the NIH/NIH REIDS-II study (6) showed good correlation within the working range of the assay. For anti-HLA CI and CII antibodies the R2 values were 0.88 and 0.91, respectively. However, the NBG ratio was generally 1.3-fold higher for serum samples.
- If high background is seen, this may indicate improper washing during the test protocol. High negative control background may cause inaccurate normalized MFI values.
- Clinical performance testing was conducted for LABScreen products at three different clinical sites, using 240 random samples – See Table A. Clinical Performance.
- Clinical reproducibility testing was conducted for LABScreen products at three different clinical sites using 16 (LS1PRA, LS2PRA, LS1A04) and 32 (LSM12) samples, consisting of 10 runs each, in triplicate – see Table B. Clinical Reproducibility.
- Clinical testing used a default cut off value, with scores of >4 were considered positive.

Table A - Clinical Performance

LSM12		LABScan 3D		
		+	-	
LABScan 100	+	573	11	
	-	4	119	
		Undefined		40
		Total Defined		707
	Positive Agreement	Negative Agreement	Overall Agreement (excluding undefined)	Overall Agreement (including undefined)
Point estimate	98%	97%	98%	93%
One-sided 95% lower confidence limit	97%	93%	97%	91%

LS2PRA		LABScan 3D		
		+	-	
LABScan 100	+	939	57	
	-	187	7781	
		Total		8964
	Positive Agreement	Negative Agreement	Overall Agreement	
Point estimate	94%	98%	97%	
One-sided 95% lower confidence limit	93%	97%	97%	

LS1PRA		LABScan 3D		
		+	-	
LABScan 100	+	2060	260	
	-	446	16905	
		Total		19671
	Positive Agreement	Negative Agreement	Overall Agreement	
Point estimate	89%	97%	96%	
One-sided 95% lower confidence limit	88%	96%	96%	

LS1A04		LABScan 3D		
		+	-	
LABScan 100	+	3245	214	
	-	682	12062	
		Total		16203
	Positive Agreement	Negative Agreement	Overall Agreement	
Point estimate	94%	95%	94%	
One-sided 95% lower confidence limit	93%	94%	94%	

LS1AEX01		LS1AEX01 + LS1A04		
		+	-	
LS1AEX01	+	1364	36	
	-	51	12481	
		Total		13932
	Positive Agreement	Negative Agreement	Overall Agreement	
Point Estimate	96.4	99.7	99.4	
On-sided 95% Lower Confidence Limit	95.5	99.6	99.3	

LS2AEX01		LS2AEX01 + LS2A01		
		+	-	
LS2AEX01	+	431	4	
	-	35	5722	
		Total		6192
	Positive Agreement	Negative Agreement	Overall Agreement	
Point Estimate	92.5	99.9	99.4	
On-sided 95% Lower Confidence Limit	90.2	99.8	99.2	

LS1AEX01		LS1ASP01	
		+	-
LS1AEX01	+	1337	63
	-	143	12389
Total		13932	
	Positive Agreement	Negative Agreement	Overall Agreement
Point Estimate	90.3	99.5	98.5
On-sided 95% Lower Confidence Limit	89.6	99.4	98.3

LS2AEX01		LS2ASP01	
		+	-
LS2AEX01	+	375	60
	-	25	5732
Total		6192	
	Positive Agreement	Negative Agreement	Overall Agreement
Point Estimate	93.8	99.0	98.6
On-sided 95% Lower Confidence Limit	91.4	98.7	98.4

Table B - Clinical Reproducibility

LSM12	Overall Agreement (excluding undefined)	Overall Agreement (including undefined)
Point estimate	98%	93%
One-sided 95% lower confidence limit	97%	93%

LS1PRA	Overall Agreement	LS2PRA	Overall Agreement	LS1A04	Overall Agreement
Point estimate	99%	Point estimate	99%	Point estimate	98%
One-sided 95% lower confidence limit	99%	One-sided 95% lower confidence limit	99%	One-sided 95% lower confidence limit	98%

LS1AEX01 + LS1A04	Overall Agreement	LS2AEX01 + LS2A01	Overall Agreement
Point Estimate	96%	Point Estimate	98%
One-Sided 95% Lower Confidence Limit	96%	One-Sided 95% Lower Confidence Limit	98%

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TRADEMARKS AND DISCLAIMERS

™ LABScan, LABScan3D, HLA Fusion, Lambda Antigen Tray and LAT are trademarks of One Lambda, Inc.

™ FlowPRA and LABScreen are registered trademarks of One Lambda, Inc.

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All One Lambda products are designed to assist personnel experienced in HLA analysis by suggesting typing results or antibody assignments. All test results must be carefully reviewed by such qualified personnel to assure correctness.

EUROPEAN AUTHORIZED REPRESENTATIVE

EC REP MDSS GmbH, Schiffgraben 41, 30175, Hannover, Germany

EXPLANATION OF SYMBOLS (reference EN ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied)

Symbol	Description
 ISO 7000 Reg No. 2493	Catalog number
 ISO 7000 Reg No. 1641	In vitro diagnostic medical device
 ISO 7000 Reg No. 0434A	Consult instructions for use
 ISO 7000 Reg No. 0633	Caution
 ISO 7000 Reg No. 3082	Biological risks
 ISO 7000 Reg No. 2497	Upper limit of Temperature
 ISO 7000 Reg No. 2607	Manufacturer
 ISO 7000 Reg No. 2607	Authorized representative in the European Community
 ISO 7000 Reg No. 2607	Date of Manufacture
 ISO 7000 Reg No. 2607	Use By Date
 ISO 7000 Reg No. 2607	Batch Code

Batch field on the label is for traceability of manufacturing event

REVISION HISTORY

Revision	Date	Revision Description
05	01 Feb 2021	Update Explanation of Symbols table.
06	30 Mar 2021	Update IVD verbiage on page 1 to align with symbols table, Update Performance characteristics (B) to reference correct bibliography designation.
07	Current	Added additional information to sections for ExPlex catalog IDs: (1) Serum dilution statement to Specimen Collection Prep Section; and (2) added tables to Table A - Clinical Performance & Table B - Clinical Reproducibility. Removed reference to Rainin brand pipette tips from the <i>Materials Required, But Not Provided</i> section. Pipette tips do not need to be brand specific. Alignment to standard for caution symbol in Symbols table.



*0197 Applies to Annex II List B products only.

CERTIFICATE OF ANALYSIS

LABSCREEN™

Product Name: LABScreen™ Single Antigen HLA Class II - Group 1
Catalog Number: LS2A01
Lot Number: 014
Expiration Date: See printed expiration date on package.

Quality Control Requirement: Every LABScreen™ product must meet the established criteria or cut-off values set for each new raw material. The QC testing procedure utilizes a panel of known positive and negative human sera and mouse monoclonal antibodies (MAbs). The pass/fail criteria for each antigen-coated bead versus each test serum or plasma (obtained by Luminex analysis) are different for each test reagent and raw material bead lot.

Method of Analysis: LABScreen™ products use microbeads coated with purified HLA Class I, II, and/or MICA antigens for the detection anti-HLA antibodies in human sera.

Results: Passed

This product is prepared in accordance to GMP standards.

This certificate is applicable to all batches under the specified lot that meet the QC requirements as stated herein.



Christabel Aguele/Product Release Specialist

22 MAY 2020

Date Issued

LABScreen™

REF	Catalog ID	Product Name
	LS1PRA*	LABScreen™ PRA Class I
	LS2PRA*	LABScreen™ PRA Class II
	LS12PRA*	LABScreen™ PRA Class I & II
	LSM12*	LABScreen™ Mixed Class I & II
	LS1A04*	LABScreen™ Single Antigen HLA Class I - Combi
	LS1ASP01*	LABScreen™ Single Antigen HLA Class I Supplement - Group 1
	LS2A01*	LABScreen™ Single Antigen HLA Class II - Group 1
	LS2ASP01*	LABScreen™ Single Antigen HLA Class II Supplement - Group 1
	LS1AEX01*	LABScreen™ Single Antigen HLA Class I ExPlex
	LS2AEX01*	LABScreen™ Single Antigen HLA Class II ExPlex
	LSMICA001	LABScreen™ MICA Single Antigen - Group 1
	LSPWABUF	LABScreen™ Wash Buffer

IVD In Vitro Diagnostic Medical Device.

INTENDED USE



LABScreen products are intended for use in detection of HLA antibody using flow cytometric technology

SUMMARY AND EXPLANATION

LABScreen products use microbeads coated with purified Class I or Class II HLA antigens and pre-optimized reagents for the detection of Class I or Class II HLA antibodies in human sera. LABScreen products utilize the LABScan™ 100 (Luminex® 100/200) or LABScan3D™ (Luminex® FLEXMAP 3D®) for analysis of up to 100 or 500 bead regions, respectively, in a single test.

The Mixed assay detects the presence of antibody to Class I and/or Class II HLA antigens. The PRA tests can detect antibodies and their specificities against the HLA antigens in each LABScreen panel. The Single Antigen assay allows confirmation of antibody specificity suggested by a previous PRA test, while individual Singles beads are used to focus on reactions against one or a few antigens, e.g. to compare reactivity of different serum samples from the same individual. A negative control serum is used to establish the background value for each bead in a test batch.

PRINCIPLE(S)

Test serum is incubated with LABScreen beads. Any HLA antibodies present in the test serum bind to the antigens on the beads and then are labeled with R-Phycoerythrin (PE)-conjugated goat anti-human IgG. The LABScan™ 100 or LABScan3D™ flow analyzer(s) simultaneously detects the fluorescent emission of PE and a dye signature from each bead, allowing almost real-time data acquisition. To assign PRA and HLA specificity, the reaction pattern of the test serum is compared to the lot-specific worksheet defining the antigen array.

REAGENTS

A. Identification

See LABScreen Reference Table for product description.



**B. Warning or Caution**

1. **Warning:** LABScreen PRA test reagents contain 0.1% sodium azide (NaN₃) as a preservative. Under acidic conditions, sodium azide yields hydrazoic acid, an extremely toxic compound. Dilute reagents containing sodium azide in running water before discarding, to avoid deposits in plumbing where explosive conditions may develop. (Refer to Material Safety Data Sheet for detail.)
2. **Warning:** All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.
3. **Caution:** For manual flicking of trays, use a quick downward arm motion without wrist movement to prevent repetitive motion effects.
4. Refer to the Material Safety Data Sheet for detailed information.

**C. Preparing Reagents for Use**

1. See Directions for Use, below.
2. If buffer salts have precipitated out of solution during shipment or storage, re-dissolve by gently warming before preparing working dilution.

**D. Storage Instructions**

1. LABScreen products are shipped to the end user on dry ice. The entire package may be stored in a freezer at -65° C or below until first use, up to the labeled expiration date.
2. Once beads are thawed, DO NOT REFREEZE. Store at 2 - 8° C for up to three months or until the expiration date (if earlier).
3. After first use, store wash buffer at 2 - 8°C for up to three months or until the expiration date, if earlier.

E. Purification or Treatment Required for Use

See Directions for Use, below.

F. Instability Indications

None

INSTRUMENT REQUIREMENTS**A. Required Equipment**

- LABScan 100 flow analyzer (Luminex® 100/200) with Luminex® XY platform (for automated 96-sample data acquisition) and sheath fluid delivery system (OLI Cat. # LABSCNXS3) OR LABScan3D flow analyzer (Luminex® FLEXMAP 3D®) with XY platform and sheath fluid delivery system (OLI Cat. # LABSCNXS4)
- Centrifuge
- Rotor for 1.5 ml microcentrifuge tube (9,300 g), or a swinging bucket rotor for 96-well microplate (1,300 g)
- Vortex mixer
- Plate shaker or rotating platform

For Filter Plate Option:

- Vacuum manifold, 96-well (Millipore Cat. # MAVM0960R or equivalent)
- Vacuum pump with a pressure less than 100 mm Hg
- Plate shaker or rotating platform

B. Equipment Calibration

Follow manufacturer's instructions for calibration of the LABScan 100 or LABScan3D flow analyzer.

C. Recommended Software

HLA Fusion™ (OLI Cat. # FUSPGR)

SPECIMEN COLLECTION AND PREPARATION

- Unopened blood specimens may be kept at room temperature up to 4 days. Separated serum (from clotted samples) or plasma (in ACD or K-EDTA) may be refrigerated up to 7 days, or aliquots may be frozen at -20°C or below and thawed just before the assay. Aggregates should be removed from the test serum/plasma by centrifugation (8,000 – 10,000 g for 10 minutes) or filtration (0.2 µm) prior to testing. Any aggregates or contamination of the sample may generate invalid results.
- Samples may be treated or diluted to reduce non-specific background or to remove inhibitory factor – see limitation section.

Note:

- Test serum or plasma should not be heat inactivated, because it may give a high background in the test.
 - Undiluted serum or plasma is generally used for the test. However, if a high background serum sample is diluted for this assay, the negative control serum should be tested at the same dilution.
- Diluting serum and plasma may reduce the reactivity (MFI) for the ExPlex Products.

PROCEDURE**A. Materials Provided**

1. See the LABScreen Reference Table in Product Documentation on the One Lambda, Inc. web site for a list of materials provided for each product.
2. The volumes provided exceed the amount required for testing by a small amount to allow for pipetting losses.

B. Materials Required, But Not Provided

1. PE-Conjugated Goat Anti-Human IgG (OLI Cat. # LS-AB2)
2. PBS, filtered [USA Scientific Cat. # 9242 (500 ml 10X) or equivalent]
3. 1.5 ml microcentrifuge tube (USA Scientific Cat. # 1415-2500 or equivalent)
4. Pipette tips
5. Negative Control Serum, containing no HLA antibody when tested by LABScreen method (OLI Cat. # LS-NC or equivalent)

If the test is performed in a 96-well microplate:

1. 96-well microplate, 250 µl, non-treated surface (Whatman Cat. # 7701-3250 or equivalent)
2. Tray seal (OLI Cat. # SSPSEA300 or equivalent)

For the Filter Plate option:

1. Filter plate (Multiscreen-BV, Millipore Cat. No. MABVN1250 or equivalent)

C. Directions for Use

Notes:

- Take special care in the aliquoting process. Failure to follow the steps described below may result in reagent loss.
- Sections A through C indicate the volumes of reagents needed for testing a single bead group. If you are running a combined test, see Section D before proceeding.
- Turn on the LABScan 100 or LABScan3D flow analyzer at least 30 minutes before starting the assay.
- Create a filename and sample code sheet for each test tray.

I. For each test batch, test a negative control serum (e.g. OLI Cat. # LS-NC or equivalent) to establish background values. To complete the test in a 1.5 ml microcentrifuge tube

1. Mix the LABScreen beads well by gently vortexing or pipetting up and down several times prior to use.
2. Incubate 5 µl of LABScreen beads with 20 µl of test serum in a 1.5 ml micro-centrifuge tube for 30 minutes, in the dark at 20 - 25° C with gentle shaking.
3. Dilute 10X wash buffer (OLI Cat. # LSPWABUF) in distilled water to make a 1X solution.
4. Add 1 ml of 1X wash buffer to each bead/serum solution tube and vortex. Centrifuge at 9,300 g for 2 minutes. Aspirate and discard the supernatant.
5. Repeat Step 4 twice.
6. Dilute 1 µl per test of 100X PE-conjugated anti-human IgG (OLI Cat. # LS-AB2) with 99 µl of 1X wash buffer to make a 1X solution.
7. Add 100 µl of 1X PE-conjugated anti-human IgG to each tube. Vortex and then incubate in the dark for 30 minutes at 20 - 25° C with gentle shaking.
8. Repeat Step 4 twice.
9. Add 80 µl 1X PBS to each tube. Proceed to data acquisition and analysis, or store tray at 2 - 8° C in the dark for up to 24 hours before analysis.

II. To complete the test in a 96-well plate

Caution: Seal the 96-well tray carefully and completely to prevent well-to-well sample contamination by pressing the seal against each rim of the 96 wells. Do not re-use tray seals. Use a fresh seal for each step that requires application of a tray seal.

1. Mix the LABScreen beads well by gently vortexing or pipetting up and down several times prior to use.
2. Add 5 µl of LABScreen beads with 20 µl of test serum in each well of a 96-well plate, seal plate, and incubate for 30 minutes in the dark at 20 - 25° C with gentle shaking.
3. Dilute 10X wash buffer (Cat. # LSPWABUF) in distilled water to make a 1X wash solution.
4. After incubation, remove seal and add 150 µl of 1X wash buffer to each well of the plate. Cover with tray seal (OLI Cat. # SSPSEA300 or equivalent) and vortex. Centrifuge at 1,300 g for 5 minutes.
5. Remove wash buffer from wells of plate by flicking or with vacuum aspiration.
6. Add 200 µl of 1X wash buffer to each well of the plate. Cover with a new tray seal and vortex. Centrifuge at 1,300 g for 5 minutes.
7. Remove supernatant from wells of plate by flicking or with vacuum aspiration.
8. Repeat Steps 6 and 7.
9. Dilute 1 µl per test of 100X PE-conjugated anti-human IgG (OLI Cat. # LS-AB2) with 99 µl of 1X wash buffer to make a 1X solution.
10. Add 100 µl of 1X PE-conjugated anti-human IgG to each well. Cover with tray seal and vortex. Incubate in the dark for 30 minutes at 20 - 25° C with gentle shaking.
11. Centrifuge at 1,300 g for 5 minutes.
12. Remove supernatant from wells of plate by flicking or with vacuum aspiration.
13. Repeat Steps 6 and 7 twice.
14. Add 80 µl 1X PBS to each well. Cover with a new tray seal and vortex. Proceed to data acquisition and analysis, or store tray at 2 - 8° C in the dark for up to 24 hours before analysis.

III. To complete the test in a 96-well filter plate

1. Mix the LABScreen beads well by gently vortexing or pipetting up and down several times prior to use.
2. Dilute 10X wash buffer (OLI Cat. # LSPWABUF) in distilled water to make a 1X solution (approximately 3.2 ml/tray/wash).
3. Cover any wells of the plate that will remain unused during the test with a tray seal to assure that the unused wells remain dry. Pre-wet filters in the filter plate by dispensing 300 µl wash buffer into only those wells that will be used for the assay.
4. Incubate the plate for 10 minutes on a platform plate shaker at low speed.
5. Aspirate all wash buffers from the wells using a Millipore vacuum manifold. Do not exceed 100 mm Hg vacuum pressure!
6. Add 5 µl of LABScreen beads and 20 µl of test serum per test well.
Note: During bead and sample dispensing steps, press pipette tip gently against filter plate well to avoid filter rupture.
7. Incubate the plate in the dark for 30 minutes at 20 - 25° C with gentle shaking.
8. Add 175 µl wash buffer per well.
9. Turn on vacuum pump. Press the plate firmly on the vacuum manifold. Make sure liquid drains out slowly. Make sure all liquid has drained from the wells before proceeding.



Caution: Do not exceed 100 mm Hg vacuum pressure. A rapid vacuum will cause loss of beads due to be entrapment in the pores of the filter paper.

10. Repeat Steps 8 and 9, above, four times.
11. Add 100 µl of 1X PE-conjugated anti-human IgG to each well.
12. Incubate in the dark for 30 minutes at 20 - 25° C with gentle shaking.
13. Repeat Steps 8 and 9 five times.
14. Add 80 µl of 1X PBS to each well.
15. Read sample on the LABScan 100 or LABScan3D flow analyzer, adjusting probe height if necessary.

Note: LABScreen Single Antigen HLA Class I and Class II ExPlex products can be used on the LABScan3D flow analyzer only.

IV. Combined tests

Any of the above protocols can be used for a combined test of certain LABScreen products.

- For acceptable lot combinations of LS12PRA see www.onelambda.com (Antibody Detection>LABScreen>LABScreen PRA/ Product Documentation: LABScreen Bead Combo – Multiple IDs DataSheet).
 - Do not combine LABScreen Single Antigen Class I Combi and Class II panels (bead IDs would overlap).
1. Mix equal volumes of beads. Then dispense the appropriate aggregate amount (10 or 15 µl) of bead mixture per test.
 2. Bead combinations and amounts to dispense are listed in the table below.

Catalog ID	Bead volume per Test	Control (NC/PC) Beads	Test Serum per Test	Instrument
LS12PRA (CI and CII beads)	5 µl + 5 µl	Included	40 µl	LABScan 100 or LABScan3D
LS1A04 + LS1AEX01	5 µl + 5 µl	Included	40 µl	LABScan3D
LS2A01 + LS2AEX01	5 µl + 5 µl	Included	40 µl	LABScan3D
LS1A04	5 µl	Included	20 µl	LABScan 100 or LABScan3D

RESULTS

A. Data Acquisition

1. Set up the LABScan 100 or LABScan3D flow analyzer for sample acquisition and calibration according to the Luminex User's Manual.¹
2. Choose a template according to product kit catalog ID and lot number.
 - a. Acquisition templates are available from OLI by CD or via our download website.
 - b. To create your own acquisition template, follow instructions in the Acquisition chapter of the Luminex User's Manual.
 - c. Luminex software versions - LABScan 100 (xPONENT 3.1 or higher); LABScan 3D (xPONENT 4.2 or higher) must be used.
3. Create a file name for the samples to be run.
4. Make sure all the template settings are correct. Template specifications are:
 - a. Set sample volume to 50 µl.
 - b. Set sample time-out to 80 seconds.
 - c. Set doublet discriminator gate to 8,000 (low limit) and 16,000 (high limit).
 - d. Set number and ID of beads selected according to the product-specific worksheet provided with the product.
 - e. Set minimum events collected to 100 per bead.
5. Enter the sample IDs (if the same sample is tested more than once, assign a different ID).
6. Load the plate onto the XY platform and fill the reservoir with sheath fluid.
7. Click the START button to initiate the session. After the samples have finished running, save the data output in a .csv file.
8. Wash the machine twice with sheath fluid at the end of the session.

B. Data Analysis

1. The reactivity of a test sample is calculated from the "raw" fluorescence values recorded by the LABScan device (.csv file) for each HLA coated bead.
2. Calculate anti-HLA serum reactivity by correcting for non-specific binding to the negative control bead and background values (obtained by testing with a negative control serum (OLI Cat. # LS-NC) to determine the normalized background ratio (NBG ratio). See Calculations, below.
3. For LABScreen PRA or LABScreen Single Antigen, the normalized fluorescent value for each HLA coated bead equals the value of that bead divided by the value of the NC bead. (For LABScreen Mixed, the normalized fluorescent signal equals the value of the Class I or Class II coated bead minus the value of the NC bead.)

Note: The fluorescent signal (value) can be either the trimmed mean or median value.

C. Calculations

1. The abbreviations used in this section are defined below:

NBG ratio	Normalized Background ratio used to assign strength of each anti-HLA reaction
S#N	Sample-specific fluorescent value for bead #N
SNC bead	Sample-specific fluorescent value for Negative Control bead
BG#N	Background NC Serum fluorescent value for bead #N
BGNC bead	Background NC Serum fluorescent value for Negative Control bead
NC Serum	Negative Control Serum (OLI Cat. # LS-NC) validated for a given lot of LABScreen beads

2. For LABScreen PRA or LABScreen Single Antigen:

$$\text{NBG ratio} = \frac{\text{S\#N / SNC bead}}{\text{BG\#N / BGNC bead}}$$

For LABScreen Mixed:

$$\text{NBG ratio} = \frac{\text{S\#N - SNC bead}}{\text{BG\#N - BGNC bead}}$$

Note: If (BG#N-BGNC bead) <50 then use 50 as a default threshold value.

D. Determination of Positive/Negative Cut-Off

1. For LABScreen PRA and LABScreen Mixed:
 - a. Select the NBG ratio that gives a significant shift over background fluorescent value when the background value is obtained using the negative control serum in 3 - 5 replicate tests. If you prefer, test 5 - 10 serum samples from non-transfused, non-transplanted male donors to obtain an average background value.
 - b. Validate the cut-off using 5 - 10 reference alloserum samples with defined HLA antibody specificity. The NGB ratio values for expected positive antigen reactions should be above the cut-off.
 - c. Additional positive/negative reactions may be noted. If necessary, adjust the LABScreen assay cut-off to match the sensitivity of a previously accepted antibody detection assay.
 - d. For high PRA serum, the patient's own antigen(s) may show weak positive reactions. For such cases, the fluorescence value for the patient's own antigen may be used as the cut-off.
2. For LABScreen Single Antigen:
 - a. Test negative control serum or several negative serum samples (see 1a, above).
 - b. Define working range:
Working Range = NBG ratio maximum - NBG ratio minimum
 - c. Define cut-off points within the working range:
Relative NBG ratio cut-off = X% (working range) + NBG ratio minimum, where X% = user-defined percent cut-off point within the working range for negative (1), gray area(2), weak positive (4) and strong positive (8).
 - d. Set criteria to define positive vs. negative reactions, for example:
 - (1) If [NBG ratio max/NBG ratio min] >8, apply the calculation in 2c.
 - (2) If [NBG ratio max/NBG ratio min] <8 AND
 - (a) NBG ratio max >5, then NBG ratio min should be adjusted to one half of the NBG ratio max and the relative NBG ratio cut-off should be re-computed (as in 2c) based on the adjusted NBG ratio min. The reaction is then scored as above.
 - (b) NBG ratio max <5, then the reaction of the test serum with that bead is negative. Assign a score of "1".
 - e. Test several reference allosera as in 1b above, using the relative NBG ratio to validate the cut-off.
 - (1) Establish a strong and weak reactivity cut-off based on the performance of the reference allosera, relative to an established assay.
 - (2) It may be helpful to plot the NBG ratio values in a histogram for visualization of the HLA reactivity pattern of each serum.
3. Higher or lower sensitivities can be obtained by adjusting the cut-off.
4. Optional analysis – HLA Fusion™ software.

LIMITATIONS OF THE PROCEDURE

- Sera or plasma samples that contain contaminants or aggregates may clog the LABScan flow analyzer and generate inaccurate data. Aggregates in the test specimen should be removed by centrifugation or filtering the serum prior to testing.
- The presence of IgG-IgM immune complex may cause inhibition in some patient samples. Samples should be treated to reduce this presence according to the protocols determined by the laboratory, however, samples should not be heat treated as they may cause non-specific background – please reference bibliography section for more information.^{7,8,9,10, 11}
- Ambient temperature may affect LABScan 100 and LABScan3D performance. If the ambient temperature changes, the machine may need to be re-calibrated. Consult the manufacturer's manual for more information.
- The LABScan 100 and LABScan3D flow analyzer must be properly calibrated and maintained. If insufficiently flushed, aggregates of the sample may cause the machine to clog and generate invalid data.
- Assignment of antibody specificity is limited to the HLA antigens presented in each bead panel (see lot-specific worksheet).
- The bead region used for each antigen and the antigen composition of the panel may change from lot-to-lot of product (see the lot specific worksheet).
- Because of the complexity of the HLA allelic definitions, a certified HLA technician or specialist should review and interpret the data, and assign the HLA typing.
- This test must not be used as the sole basis for making a clinical decision.

EXPECTED VALUES

A. LABScreen PRA Class I or Class II

- The reactivity strength of a test serum to each bead can be compared to distinguish the strong positive, weak positive and negative reactions. Reactivity ratios can be ranked within different ranges, if a scoring system is desired.
- Our data show NBG ratios > 1.5 in the LABScreen PRA test (using the LABScan 100) correlate well with positive reactions in the FlowPRA test.
- For calculation of percent PRA (Panel Reactive Antibody), divide the number of positive reactions by the number of valid reactions for that test serum.
- To determine the specificity of HLA antibody, enter the reaction score into the lot specific Worksheet to analyze the reaction pattern.

B. LABScreen Mixed

- Score HLA Class I and Class II reactions separately, according to reactivity strength of the serum for each bead set.
- If anyone bead in the mixed assay is positive, then the result should be assigned as positive.
- Our data show that NBG ratios >2.2 in the LABScreen Mixed test (using the LABScan 100) correlate well with positive reactions in LAT™ Mixed.

C. LABScreen Single Antigen

- Allosera may produce signal/background ratios that are much higher than those obtained in the PRA assay. Establishing the assay cut-off(s) using the relative NBG ratio is one way of normalizing the data (see Results, Section D-2c).
- Our data show that a positive/negative cut-off or relative NBG ratio >15% of the working range NBG ratio calculated for each test serum (using the LABScan 100) will give results comparable to the LABScreen PRA assay.

D. General Guidelines

- Each bead count should be over 50. A lower bead count may be due to sample loss during the wash steps. It could also be due to improper calibration or clogging of the LABScan 100 or LABScan3D flow analyzer, or by photo-bleached beads that dropped out from the mapped region.
- Signal values are the fluorescence intensity of each bead set vs. the test serum. A negative control serum should be tested with the same batch of samples to establish the background value(s) for that test run.
- Negative Control Serum (OLI Cat. # LS-NC or equivalent) is recommended. Using any other negative control serum may require adjustment of cut-off values.
- Negative Control Beads (Ag ID = NC) are not coated with HLA antigen. The fluorescence value may vary among different sera due to non-specific binding of the sera or to insufficient washing. The NC value is usually less than 500 except for serum samples with a high background. It should always be lower than 1500 and less than or equal to half of the PC value.
- Positive Control Beads are coated with purified human IgG, which should bind to the secondary antibody to produce a positive signal. The PC value should be over 500 and at least twice the NC value.

E. Validation of the Assay

- The cut-off value of signal to background should be validated if a new negative control serum is used.
- For a given serum, the value for PC/NC should be greater than 2. A lower value may be due to an extremely high NC bead background value for the test serum, a high HLA bead signal for the NS control, or a low signal from the secondary antibody or the LABScan 100 and LABScan3D flow analyzer. In this case, the data may have to be confirmed.
- Each user should evaluate the performance of the assay in their laboratory to validate the cut-off value(s) selected.
- Plasma samples may give lower FI or higher background values than serum. The user may wish to normalize the data if comparing results between sera and plasma samples (see Reference 5) for the same or different test subjects.

SPECIFIC PERFORMANCE CHARACTERISTICS

- Using the assay cut-offs referenced under Expected Values, above, LABScreen assays have given results comparable to the results of the One Lambda FlowPRA® and LAT™ assays. However, HLA antibody patterns may be quite complex. A given test sample may contain several HLA Class I and Class II antibody specificities, each with a different avidity; however, not all specificities will be recognized in assays with lesser sensitivity. Therefore, each laboratory should establish and validate the assay cut-offs for their own use based on their expertise in recognizing HLA CREG patterns and an evaluation of the assay performance using HLA allosera with defined specificities.
- Comparison of serum vs. plasma for 1,000 blood donors in the NIH/NIH REFS-II study (6) showed good correlation within the working range of the assay. For anti-HLA CI and CII antibodies the R2 values were 0.88 and 0.91, respectively. However, the NBG ratio was generally 1.3-fold higher for serum samples.
- If high background is seen, this may indicate improper washing during the test protocol. High negative control background may cause inaccurate normalized MFI values.
- Clinical performance testing was conducted for LABScreen products at three different clinical sites, using 240 random samples – See Table A. Clinical Performance.
- Clinical reproducibility testing was conducted for LABScreen products at three different clinical sites using 16 (LS1PRA, LS2PRA, LS1A04) and 32 (LSM12) samples, consisting of 10 runs each, in triplicate – see Table B. Clinical Reproducibility.
- Clinical testing used a default cut off value, with scores of >4 were considered positive.

Table A - Clinical Performance

LSM12		LABScan 3D		
		+	-	
LABScan 100	+	573	11	
	-	4	119	
		Undefined		40
		Total Defined		707
	Positive Agreement	Negative Agreement	Overall Agreement (excluding undefined)	Overall Agreement (including undefined)
Point estimate	98%	97%	98%	93%
One-sided 95% lower confidence limit	97%	93%	97%	91%

LS2PRA		LABScan 3D		
		+	-	
LABScan 100	+	939	57	
	-	187	7781	
		Total		8964
	Positive Agreement	Negative Agreement	Overall Agreement	
Point estimate	94%	98%	97%	
One-sided 95% lower confidence limit	93%	97%	97%	

LS1PRA		LABScan 3D		
		+	-	
LABScan 100	+	2060	260	
	-	446	16905	
		Total		19671
	Positive Agreement	Negative Agreement	Overall Agreement	
Point estimate	89%	97%	96%	
One-sided 95% lower confidence limit	88%	96%	96%	

LS1A04		LABScan 3D		
		+	-	
LABScan 100	+	3245	214	
	-	682	12062	
		Total		16203
	Positive Agreement	Negative Agreement	Overall Agreement	
Point estimate	94%	95%	94%	
One-sided 95% lower confidence limit	93%	94%	94%	

LS1AEX01		LS1AEX01 + LS1A04		
		+	-	
LS1AEX01	+	1364	36	
	-	51	12481	
		Total		13932
	Positive Agreement	Negative Agreement	Overall Agreement	
Point Estimate	96.4	99.7	99.4	
On-sided 95% Lower Confidence Limit	95.5	99.6	99.3	

LS2AEX01		LS2AEX01 + LS2A01		
		+	-	
LS2AEX01	+	431	4	
	-	35	5722	
		Total		6192
	Positive Agreement	Negative Agreement	Overall Agreement	
Point Estimate	92.5	99.9	99.4	
On-sided 95% Lower Confidence Limit	90.2	99.8	99.2	

LS1AEX01		LS1ASP01	
		+	-
LS1AEX01	+	1337	63
	-	143	12389
Total		13932	
	Positive Agreement	Negative Agreement	Overall Agreement
Point Estimate	90.3	99.5	98.5
On-sided 95% Lower Confidence Limit	89.6	99.4	98.3

LS2AEX01		LS2ASP01	
		+	-
LS2AEX01	+	375	60
	-	25	5732
Total		6192	
	Positive Agreement	Negative Agreement	Overall Agreement
Point Estimate	93.8	99.0	98.6
On-sided 95% Lower Confidence Limit	91.4	98.7	98.4

Table B - Clinical Reproducibility

LSM12	Overall Agreement (excluding undefined)	Overall Agreement (including undefined)
Point estimate	98%	93%
One-sided 95% lower confidence limit	97%	93%

LS1PRA	Overall Agreement	LS2PRA	Overall Agreement	LS1A04	Overall Agreement
Point estimate	99%	Point estimate	99%	Point estimate	98%
One-sided 95% lower confidence limit	99%	One-sided 95% lower confidence limit	99%	One-sided 95% lower confidence limit	98%

LS1AEX01 + LS1A04	Overall Agreement	LS2AEX01 + LS2A01	Overall Agreement
Point Estimate	96%	Point Estimate	98%
One-Sided 95% Lower Confidence Limit	96%	One-Sided 95% Lower Confidence Limit	98%

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TRADEMARKS AND DISCLAIMERS

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™ FlowPRA and LABScreen are registered trademarks of One Lambda, Inc.

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All One Lambda products are designed to assist personnel experienced in HLA analysis by suggesting typing results or antibody assignments. All test results must be carefully reviewed by such qualified personnel to assure correctness.

EUROPEAN AUTHORIZED REPRESENTATIVE

EC REP MDSS GmbH, Schiffgraben 41, 30175, Hannover, Germany

EXPLANATION OF SYMBOLS (reference EN ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied)

Symbol	Description
 ISO 7000 Reg No. 2493	Catalog number
 ISO 7000 Reg No. 1641	In vitro diagnostic medical device
 ISO 7000 Reg No. 0434A	Consult instructions for use
 ISO 7000 Reg No. 0659	Caution
 ISO 7000 Reg No. 0633	Biological risks
 ISO 7000 Reg No. 3082	Upper limit of Temperature
 ISO 7000 Reg No. 2497	Manufacturer
 ISO 7000 Reg No. 2607	Authorized representative in the European Community
 ISO 7000 Reg No. 2607	Date of Manufacture
 ISO 7000 Reg No. 2607	Use By Date
 ISO 7000 Reg No. 2607	Batch Code

Batch field on the label is for traceability of manufacturing event

REVISION HISTORY

Revision	Date	Revision Description
05	01 Feb 2021	Update Explanation of Symbols table.
06	30 Mar 2021	Update IVD verbiage on page 1 to align with symbols table, Update Performance characteristics (B) to reference correct bibliography designation.
07	Current	Added additional information to sections for ExPlex catalog IDs: (1) Serum dilution statement to Specimen Collection Prep Section; and (2) added tables to Table A - Clinical Performance & Table B - Clinical Reproducibility. Removed reference to Rainin brand pipette tips from the <i>Materials Required, But Not Provided</i> section. Pipette tips do not need to be brand specific. Alignment to standard for caution symbol in Symbols table.



*0197 Applies to Annex II List B products only.



A New Era of Innovation
in Transplant Diagnostics

2019 • 2020
ONE LAMBDA
PRODUCT CATALOG

 **ONE LAMBDA**
A Thermo Fisher Scientific Brand



A Thermo Fisher Scientific Brand

One Lambda - Leading Transplant Diagnostics for over 35 years

Pioneering scientist Dr. Paul Terasaki created the technology used to identify the first HLA antigens at UCLA in 1964, immediately revolutionizing the field of HLA and transplantation. His drive to improve the lives of transplant patients and their families led to One Lambda's founding in 1984. For over 30 years, the company has been at the forefront of transplant diagnostics, bringing new and innovative solutions to HLA laboratories worldwide.

“FACILITATING A NEW STANDARD OF
CARE IN TRANSPLANT MONITORING”

Given our long history in the field of transplantation, we understand the challenges HLA laboratories face. We are committed to providing you with the most consistent and reliable reagents, state-of-the-art instruments and software, and unmatched customer support. Our goal to facilitate a new standard of care in in transplant monitoring remains the driving force behind our product development and education.

The Evolution of HLA Typing

The human leukocyte antigen (HLA) complex represents the most highly polymorphic region of the human genome. Genetic mutations within these HLA class I and class II genes translate to variation in cell surface antigens which are not only associated with autoimmune disorders and infectious diseases but also play an important role in allogeneic histocompatibility and transplant immunology.

With mounting evidence of the importance of HLA matching to long term graft survival, there was an undeniable need to quickly and accurately assign HLA alleles for patients and donors. At first, HLA typing was done using serological techniques which proved to be relatively quick and simple but yielded low typing resolution. Routine high resolution HLA typing didn't become a possibility until the 1980's with the introduction of molecular, PCR-based, DNA typing techniques.

Today, advances in Next Generation Sequencing (NGS) offer the promise of complete gene HLA typing at the highest levels of resolution. This revolutionary technology is rapidly changing the field of hematopoietic stem cell transplantation and will allow for the continued improvement of patient outcomes. With this in mind, One Lambda is introducing AllType NGS™ HLA Typing assay to its line of molecular typing products which includes Sequence Specific Oligonucleotides (SSO), Sequence Specific Primers (SSP) and Sequence Based Typing (SBT) technologies. We are confident that our continued drive to remain at the forefront of the industry will lead to significant breakthroughs in the field of research and transplantation diagnostics.

The Effect of Transplant Monitoring on Outcome

The presence of HLA antibodies in a patient post-transplant can lead to serious complications, including rejection, which may not be immediately apparent post-transplant. Severe damage may have already occurred by the time antibodies present clinically. Monitoring patients for HLA antibodies post-transplant can reveal potential challenges and facilitate intervention before damage or rejection occurs. In the absence of such screening, and in the presence of anti-HLA antibodies, the risk of organ failure increases over time.

DSA Monitoring – New Standard of Care

Data indicates that the presence of Donor Specific Antibodies (DSAs) results in Transplant Glomerulopathy (TG) and chronic rejection. Patients diagnosed with TG experience graft survival rates of less than 50% within five years of time of diagnosis.

Our full line of antibody detection products and data analysis software can identify DSA and support clinical intervention and immunosuppressive treatment.

Non-HLA Antibody Detection

One Lambda proudly offers an answer for all of your antibody detection needs including non-HLA antibodies. Our selection of assays varies in format and coverage from single plex ELISA AT1R and ETAR assays to multiplex solid-phase assays covering a broad range of targets including vimentin, Collagen, C1q, Cytokine, HNA, KIR, and many others. All products are designed for ease of use, lab efficiency and optimized for automation.

Solutions for all Monitoring Needs

The products listed in this catalog reflect One Lambda's continuing commitment to offering a new standard of care in transplant monitoring. We help clinicians to build better patient profiles in all phases of the transplant process. From finding the best donor/recipient match, to monitoring antibodies post-transplant, One Lambda has solutions that can help laboratories and clinicians continually improve the transplant outcomes.

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TRANSPLANTATION

ANTIBODY DETECTION FOR TRANSPLANT DIAGNOSTICS

A collection of integrated solutions to help you identify HLA antibodies that may cause graft rejection.

Transplant Monitoring Solutions

As the world leader in HLA tissue typing, One Lambda's HLA antibody detection technology is designed for highly specific pre -and post-transplant monitoring. Products are designed for ease of use, lab efficiency, and optimized automation.

Page

01 Single Antigen

Available on three testing platforms, the Single Antigen technology provides clinicians with flexible solutions to identify antibodies hidden by dominant epitopes in high PRA patients.

Page

03 LABScreen™

Using Luminex® xMAP® technology, our selection of LABScreen® reagents provide several assays for determining percent PRA, in addition to identifying antibodies against both Class I and Class II antigens, MICA and HNA.

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09

C1qScreen™

Designed for detection of complement binding antibodies.

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FlowDSA-XM™

Combines traditional flow cytometry and microbead technology to selectively distinguish leukocyte antibodies from autoantibodies.

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FlowPRA™

Designed for use in flow cytometric detection, your choice of FlowPRA test can screen human sera for antibodies, assigning percent PRA and antibody specificity for HLA Class I and Class II.

Page

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Lambda Antigen Tray™ (LAT)

Features Terasaki-format trays pre-coated with HLA Class I and Class II antigens that perform antibody detection based on ELISA techniques. LAT reagents are an economical and convenient method for screening patients, determining percent PRA and identifying antibodies.

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Lambda Cell Tray™ (LCT)

Panels of frozen lymphocytes dispensed in Terasaki trays, designed to determine PRA and HLA antibody screening by complement-dependent cytotoxicity

Non-HLA Antibody Detection

Page

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LABScreen™ Autoantibody

Discover a broad range of autoantibody targets in human sera and expand your antibody detection repertoire.

Page

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AT1R/ETAR

Designed for detection of antibodies against Angiotensin II type I receptors

Single Antigen Technology

Single antigen testing is a premiere technology that identifies hidden antibodies in high PRA patients that cannot be distinguished using phenotypic antigen panels. The comprehensive determination of Class I and Class II HLA antibodies allows clinicians to select acceptably mismatched donor-recipient pairs. In the post-transplant process, single antigen tests can help physicians to detect early signs of graft failure. LABScreen™, FlowPRA™ and LAT™ are available with human single antigen products to significantly improve antigen identification in both pre- and post-transplant monitoring.

“In post-transplant monitoring, the single antigen assay can help physicians to detect early signs of graft failure.”



Features and Benefits

Our single antigen assay product can be an important tool in the pre- and post-transplant monitoring of solid organ transplant patients, alerting physicians to possible complications, even before a decline in organ function is detected.

- Obtain clear analysis of HLA antibodies reactive to one or more dominant epitopes, leading to more accurate matches between high PRA patients and possible donors
- Detects HLA antibodies quickly and accurately
- Detects Class I and Class II HLA antibodies to facilitate the selection of acceptable donor/recipient pairs

Available on three testing platforms:

LABScreen (based on Luminex® xMAP® technology)

FlowPRA (flow cytometry)

Lambda Antigen Trays™ (ELISA)

Intended Use • Applications

Our single antigen products are used to determine HLA Class I and Class II antibodies for both pre- and post-transplant monitoring.

Methodologies

Each of our three testing platforms takes advantage of a different methodology, described below.

LABScreen Single Antigen

Powered by Luminex® xMAP® technology; a multiplex assay composed of single antigens bound to color-coded microbeads (Single Antigen Beads), detected by fluorescent emissions from R-Phycoerythrin (PE) conjugated goat antihuman IgG.

FlowPRA Single Antigen

An alternative single antigen bead technology using flow cytometry. Assigns percent PRA or antibody specificity for both HLA Class I and Class II by measuring fluorescent channel shifts produced by specific antibody binding detected by FITC-labeled antihuman IgG, compared to a control background signal produced by a negative serum.

LAT Single Antigen

An ELISA approach for patient HLA antibodies. Using alkaline phosphatase conjugated secondary antibodies, LAT Single Antigen identifies antibody specificities by reaction patterns with a panel of selected recombinant human HLA antigens.

Product Specifications	LABScreen Single Antigen	FlowPRA Single Antigen	LAT Single Antigen
Storage Temperature:	-65° C or below	-80° to -65° C	2° to 8° C
Shipping Considerations:	Dry Ice	Dry Ice	Cold Pack
Packaging:	25-test package	10-test package	20-test package

For In Vitro Diagnostic Use.

LABScreen reagents are powered by Luminex xMAP technology, a microbead platform used to test high PRA patients with multiplex antibody assays. This single antigen-bead based assay allows for a precise determination of antibody profiles against HLA, MICA or HNA. Within the transplant community, LABScreen™ is widely recognized as a consistent, reliable, and highly sensitive tool for PRA screening.

Features and Benefits

- Qualitatively measures the presence of specific HLA Class I and Class II, MICA, and HNA antibodies in human sera or plasma samples
- Contains a defined pool of HLA antigens, including rare alleles
- Eliminates false positive reactions due to non-HLA antibodies or auto-antibodies
- Multiplex analysis enhances lab automation and lowers labor costs, reagents and assay time
- 96 samples can be tested sequentially using the X-Y platform.
- Single antigen assays identify negative or safe antigens, even for high PRA patients
- Detects IgG antibodies

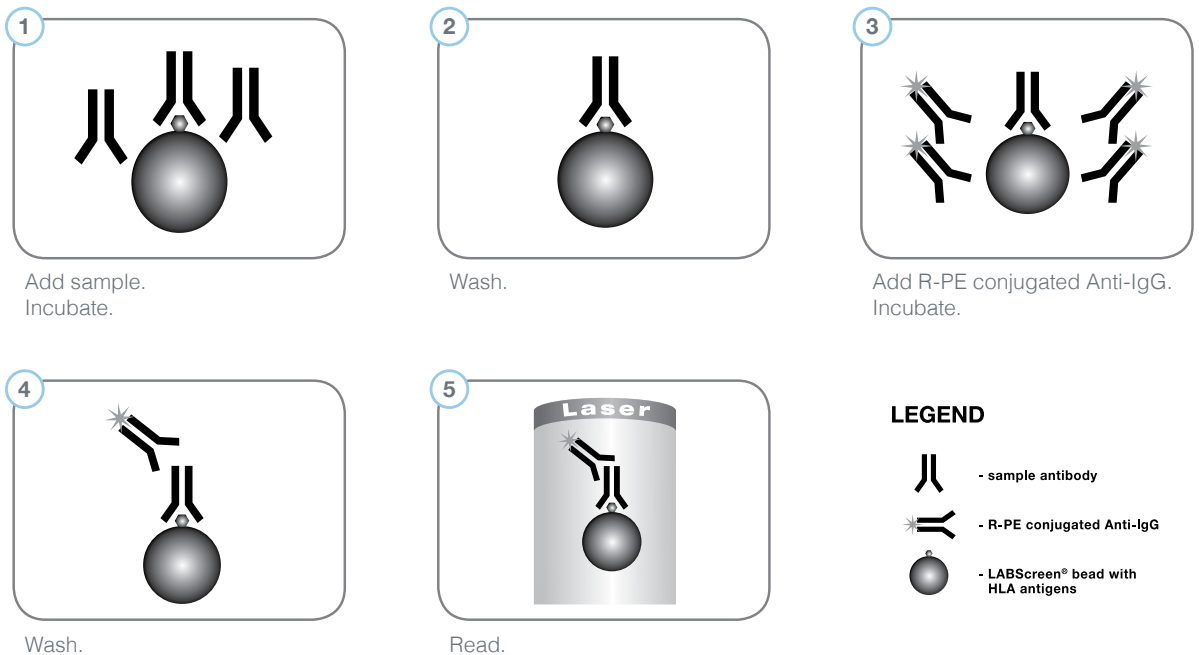
Principle

LABScreen products use a panel of color-coded microbeads, coated with purified HLA antigens. Up to 100 different beads can be combined in one suspension in a single test. Serum is incubated with LABScreen beads. Any HLA antibodies in the serum bind to the antigens and are labeled with PE-conjugated goat anti-human IgG. The LABScan™ 100 or LABScan3D™ detect fluorescent emission of PE from each bead, allowing nearly real-time data acquisition.



Methodology

Detection by R-Phycoerythrin Conjugated Antibody.



Intended Use • Applications

LABScreen products are intended for use in the detection of HLA antibodies using Luminex xMAP technology. Interpretation software is available for LABScreen products.

Product Specifications	LABscreen
Storage Temperature:	-65° C or below
Shipping Considerations:	Dry Ice
Packaging:	25-test package

For In Vitro Diagnostic Use. (Unless otherwise stated)

LABScreen Single Antigen HLA Class I/II

In high PRA patients, the sera may contain antibodies reactive to one or more dominant epitopes. Using LABScreen Single Antigen to assign specificity can be more effective than conventional methods in these cases. Our LABScreen Single Antigen kits have long been used to detect HLA antibodies pre and post transplantation. With the introduction of the new, enhanced LABScreen Single Antigen Supplement kits, you can now create more complete antibody profiles for your patients.

Product Description	Cat Id	Sale Unit	Tests
LABScreen Single Antigen HLA Class I - Combi	LS1A04	pkg	25 tests
LABScreen Single Antigen HLA Class II - Group 1	LS2A01	pkg	25 tests
LABScreen Single Antigen HLA Class I - Supplement (Group1)	LS1ASP01	pkg	25 tests
LABScreen Single Antigen HLA Class II - Supplement (Group1)	LS2ASP01	pkg	25 tests

LABScreen MICA Single Antigen

Created for HLA antibody screening and identifying MHC class I related chain A (MICA) antibodies, LABScreen MICA Single Antigen can also be a valuable tool in assigning specificity. Each MICA antigen is coated on a separate bead population. Based on Luminex xMAP technology, LABScreen MICA Single Antigen is comprised of a panel of 10 MICA antigens found frequently in the population.

Product Description	Cat Id	Sale Unit	Tests
LABScreen MICA Single Antigen - Group 1	LSMICA001	pkg	25 tests



LABScreen PRA Class I/ II

LABScreen PRA determines percent PRA and identifies antibody specificities using a panel of color-coded microbeads coated with HLA antigens purified from different cells. The Class I microspheres have HLA A,B,C antigens. The Class II microspheres have DR, DQ, DP antigens. The LABScan 100 and LABScan3D flow analyzers allow you to test for Class I and Class II separately or together.

Product Description	Cat Id	Sale Unit	Tests
LABScreen PRA Class I	LS1PRA	pkg	25 tests
LABScreen PRA Class II	LS2PRA	pkg	25 tests
LABScreen PRA Class I & II Set	LS12PRA	2 pkgs	25 tests each

LABScreen Mixed

LABScreen Mixed is a screening test dedicated to detecting antibodies against HLA Class I and Class II, in addition to MHC Class I related chain A (MICA) — another factor shown to cause transplant rejection. With its ease of use, processing up to 96 samples simultaneously, LABScreen Mixed is well-suited for monthly patient antibody screening in both low and high throughput laboratories.

Product Description	Cat Id	Sale Unit	Tests
LABScreen Mixed Class I & II	LSM12	pkg	100 tests

LABScreen Ancillary Reagents

One Lambda offers a selection of Ancillary Reagents for optimizing LABScreen testing.

Storage	Adsorb Out	Negative Control	PE-Conj Goat IgG	Quantiplex™ Beads	Luminex® Calibration Control Microspheres	Sheath Fluid
Storage Temperature:	-65° C or below	-20° C or below	2° to 8° C	2° to 8° C	2° to 8° C	Room Temperature
Shipping Considerations:	Dry Ice	Dry Ice	Cold Pack	Cold Pack	Cold Pack	Room Temperature
Packaging:	1 vial in foil bag	1 vial in foil bag	1 vial in foil bag	1 vial in foil bag	5ml per bottle	20L per bottle

Adsorb Out™

Adsorb Out beads remove reactivity to latex beads from test sera with high levels of non-specific binding. Preliminary adsorption of non-specific binding material from the serum can reduce or remove the high background in a flow cytometry test. Adsorb Out consists of a special preparation of microparticles without specific antigen coating.

Product Description	Cat Id	Sale Unit	Tests
Adsorb Out (75µl)	ADSORB	vial	25 tests

For General Laboratory Use.

LABScreen Controls

LABScreen Controls establishes the background value for each test batch in the detection of Class I or Class II HLA antibodies. It contains a pool of negative sera and works with the coated microbeads of LABScreen products.

Product Description	Cat Id	Sale Unit	Tests
LABScreen Negative Control Serum	LS-NC	vial	20 tests

For In Vitro Diagnostic Use.

PE-Conjugated Goat Anti-Human IgG

PE-Conjugated Goat Anti-Human IgG is required with LABScreen tests and must be purchased separately.

Product Description	Cat Id	Sale Unit	Tests
PE - Conjugated Goat Anti-Human, Lyophilized, 1ml	LS-AB2	vial	1,000

For In Vitro Diagnostic Use.

Quantiplex™ Beads

Quantiplex Beads consist of a set of Luminex microbeads with graduated levels of fluorochrome similar to PE. They are reference beads for the standardization of the fluorescent signal generated by assays using Luminex xMap technology. This technology uses the LABScan 100 flow analyzer for data acquisition and analysis.

Product Description	Cat Id	Sale Unit	Tests
Quantiplex Beads	LXQNTPLX	pkg	25 tests

For research use only. Not for use in diagnostic procedures.

LABScreen™ Ancillary Reagents for Transplant Research



IgM Positive Control Beads bind to PE-Conjugated Anti Human IgM (Secondary Antibody) to generate a positive signal.

IgM Positive Control Beads

Used with antigen-coated microbeads to provide a positive signal.

Product Description	Cat Id	Sale Unit	Tests
IgM Positive Control Beads	IGM-PCB	vial	25 tests

For research use only. Not for use in diagnostic procedures.

PE-Conjugated Anti-Human IgM

PE-conjugated anti-human IgM reacts with Fc5μ portion of the human IgM heavy chain.

Product Description	Cat Id	Sale Unit	Tests
PE- Conjugated Anti-Human IgM	IGM-PEC1	vial	1,000

For research use only. Not for use in diagnostic procedures.



Storage	IGM-PEC1	IGM-PCB
Storage Temperature:	-65° C or below	-65° C or below
Shipping Considerations:	Dry Ice	Dry Ice
Packaging:	1 vial in foil bag	1 vial in foil bag

For research use only. Not for use in diagnostic procedures.

C1qScreen

By allowing you to differentiate between complement binding and non-complement binding, C1qScreen allows you to investigate a fixing antibody's possible role in Antibody Mediated Rejection (AMR).

Principle

C1qScreen consists of four reagents, C1q and PE Conjugated C1q antibody. The complement component (C1q), bound by the antigen-antibody complex, is detected with an R-phycoerythrin (PE) labeled C1q antibody. The fluorescence intensity measured on a Luminex analyzer or flow cytometer indicates the relative amount of antibody bound to the test sample (either antigen-coated beads or cells).

Features and Benefits

- Identifies presence of complement binding antibodies
- Internal positive control bead included
- Robust software analysis

Intended Use • Applications

This product may be used in the identification and screening of complement binding antibodies in human serum.

Product Specifications	C1qScreen
Storage Temperature:	-65° C or below
Shipping Considerations:	Dry Ice

C1qScreen (IVD)

Product Description	Cat Id	Sale Unit	Tests
C1qScreen	C1Q	1-Box	25 tests
C1qScreen Class I Positive Control	C1QS-PC1	1-Box	20 tests
C1qScreen Negative Control Serum	C1QS-NC	1-Box	20 tests
C1qScreen Class II Positive Control	C1QS-PC2	1-Box	20 tests

CE\IVD: For In Vitro Diagnostic Use. (European Union Only)

C1qScreen for Transplantation Research (RUO)

Product Description	Cat Id	Sale Unit	Tests
C1qScreen	PEC1Q	4-Boxes	25 tests
C1qScreen Class I Positive Control	C1Q-PC1	1-Box	20 tests
C1qScreen Negative Control Serum	C1Q-NC	1-Box	20 tests
C1qScreen Class II Positive Control	C1Q-PC2	1-Box	20 tests

For Research Use Only. Not for use in diagnostic procedures.

Advanced Crossmatch Testing

The FlowDSA-XM is a flow cytometry based crossmatch assay optimized for the detection of leukocyte antibodies. Combining traditional flow cytometry cellular crossmatch testing with the specificity of microbeads technology, the FlowDSA-XM selectively distinguishes leukocyte antibodies from autoantibodies.

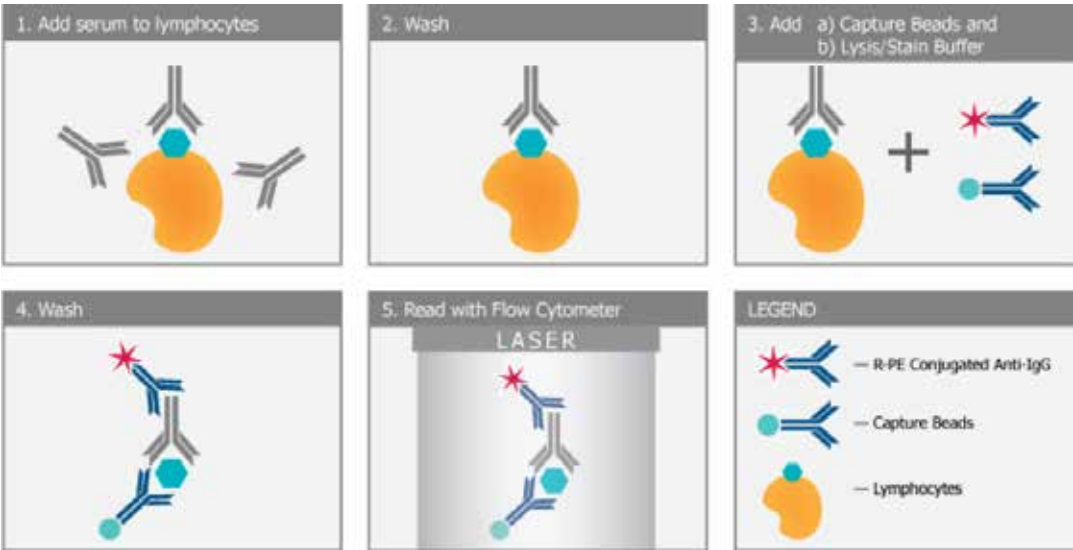
Features and Benefits

- Crossmatch testing that distinguishes leukocyte antibodies from autoantibodies
- Selectively detects any bound IgG on the cell surface
- Combines traditional flow cytometry cellular crossmatch with microbead technology
- Compatible with most basic flow cytometers
- Works with Lymphocytes from fresh or frozen sources (peripheral blood, lymph nodes, or spleen)

Principle

After incubating lymphocytes with human serum, any bound IgG on the cell surface is tagged with PE labeled anti-human IgG. FlowDSA-XM Capture Beads bind selectively with the resulting antibody/antigen/PE-anti-IgG complex and the fluorescent intensity is measured to indicate the relative amount of leukocyte antibody present in the serum.

Workflow



Product Description	Cat Id	Sale Unit	Tests
FlowDSA-XM	FLDSA	pkg	25 tests

For Research Use Only. Not for use in diagnostic procedures.

FlowPRA Single Antigen

One Lambda's FlowPRA Single Antigen products use flow cytometry to monitor acceptable antigens in high PRA patients before and after solid organ transplant procedures. Each bead is designed to react specifically to HLA Class I and HLA Class II antibodies. The two classes have different fluorescent properties, eliminating the possibility of cross reactivity.

Our sets of Class I and Class II FlowPRA reagents each consist of a pool of 32 beads, separated into four groups, and each coated with different antigens. These sets include rare HLA antigens, providing optimal profiling for high PRA patients. Control beads are also included to demonstrate test reliability. Six supplemental groups of Class I single antigen beads and a supplemental group of Class II antigen beads offer further specificities for antibody screening.

Features and Benefits

- Quickly identifies Class I and Class II HLA antibodies in high PRA patients
- Identifies negative or safe antigens, even for high PRA patients
- Confirms specificity by replacing dilution and absorption as strategies
- Clarifies ambiguous results
- Clarifies analysis of antibodies reactive to one or several dominant epitopes



Principle

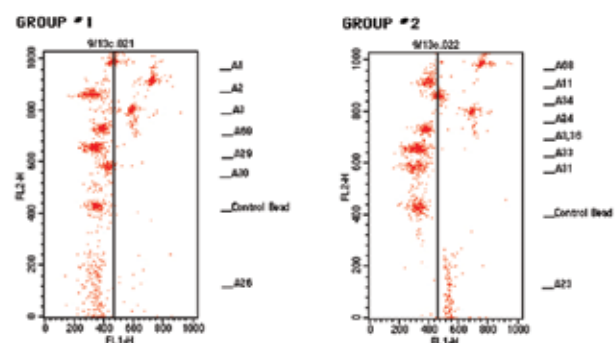
FlowPRA™ tests provide pre-optimized reagents for rapid flow cytometric detection of HLA antibodies and their specificities in human serum. The FlowPRA Single Antigen beads consist of a mixture of different colored beads with different fluorescent properties. These beads can be excited at 488 nm, generating a maximum emission of approximately 580 nm, similar to phycoerythrin (PE), which can be detected by the FL2 channel. Since different beads generate different FL2 channel shifts, different colored beads in a group can be separated by a flow cytometer on the FL2 channel.

Each group of beads is incubated separately with the test serum and then stained with a FITC conjugated anti-human IgG antibody. Beads reacting positively show an FL1 channel shift on the FL1 vs. FL2 dot plots when compared to the negative control serum and the control beads.

Intended Use • Applications

FlowPRA Single Antigen tests are used to screen highly sensitized patients, both pre- and post-transplant. They are used in identifying acceptable antigens prior to a solid organ transplant or re-transplant. The FlowPRA Single Antigen tests are designed for detailed discrimination of specificities in high PRA sera.

Results



Product Specifications	Reagents	Control Reagents
Storage Temperature:	-80° to -65° C	-80° to -20° C
Shipping Considerations:	Dry Ice	Dry Ice
Packaging:	10-tests	10-tests

For In Vitro Diagnostic Use.

Flow PRA Single Antigen HLA Class I/II Tests

Product Description	Loci	Cat Id	Sale Unit	Tests
Class I				
FlowPRA Single Antigen HLA Class I	A Locus / B Locus	FL1HD	pkg	10 tests
FlowPRA Single Antigen HLA Class I - Group 1	A Locus / B Locus	FL1HD01	pkg	10 tests
FlowPRA Single Antigen HLA Class I - Group 2	A Locus	FL1HD02	pkg	10 tests
FlowPRA Single Antigen HLA Class I - Group 3	B Locus	FL1HD03	pkg	10 tests
FlowPRA Single Antigen HLA Class I - Group 4	B Locus	FL1HD04	pkg	10 tests
FlowPRA Single Antigen HLA Class I - Supplement - Group 5	B Locus	FL1HD05	pkg	10 tests
FlowPRA Single Antigen HLA Class I Supplement - Group 6	B Locus	FL1HD06	pkg	10 tests
FlowPRA Single Antigen HLA Class I Supplement - Group 7	B Locus	FL1HD07	pkg	10 tests
FlowPRA Single Antigen HLA Class I Supplement - Group 8	A Locus / B Locus	FL1HD08	pkg	10 tests
FlowPRA Single Antigen HLA Class I Supplement - Group 9	C Locus	FL1HD09	pkg	10 tests
FlowPRA Single Antigen HLA Class I Supplement - Group 10	C Locus	FL1HD10	pkg	10 tests
Class II				
FlowPRA Single Antigen HLA Class II	DRB1/DRB3,4,5/DQB1	FL2HD	pkg	10 tests
FlowPRA Single Antigen HLA Class II - Group 1	DRB1	FL2HD01	pkg	10 tests
FlowPRA Single Antigen HLA Class II - Group 2	DRB1	FL2HD02	pkg	10 tests
FlowPRA Single Antigen HLA Class II - Group 3	DRB1 / DRB3,4,5	FL2HD03	pkg	10 tests
FlowPRA Single Antigen HLA Class II - Group 4	DQB1	FL2HD04	pkg	10 tests
FlowPRA Single Antigen HLA Class II Supplement - Group 5	DPB1	FL2HD05	pkg	10 tests

FlowPRA Screening

The FlowPRA Screening Tests can be used as a first test to detect HLA antibodies and percent PRA in human sera using flow cytometry. Each of the FlowPRA Class I and Class II assays consist of a pool of 30 different bead preparations, representing all common antigens as well as many rare HLA alleles. Intended to detect HLA-specific antibodies for pre- and post-transplantation monitoring, FlowPRA Screening provides a comprehensive and accurate assay.

Features and Benefits

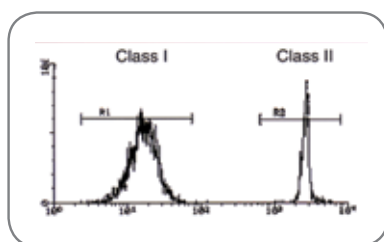
- The single tube method enables quick, easy use
- Class I and Class II antibodies can be screened separately or simultaneously
- Reduces false positive reactions due to non-HLA antibodies
- Convenient and simple, no frozen cell panels need to be maintained and no cell viability issues exist
- Works with most commercial flow cytometers
- Panel coverage is equivalent to 30 different lymphocytes
- Determines percent PRA for Class I and Class II
- Results are consistent, reproducibility is seamless
- Offers greater sensitivity than CDC-AHG
- Minimal shipping and storage costs incurred



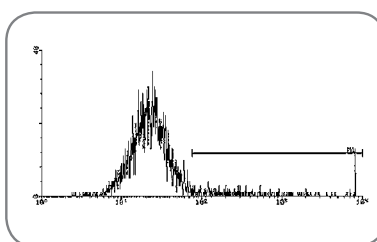
Principle

The FlowPRA Screening Test provides precalibrated reagents for rapid flow cytometric detection of PRA in human sera. Reactivity of FlowPRA beads has been confirmed by flow cytometry with human allosera and specific HLA monoclonal antibodies. HLA antibodies in the serum react specifically to the FlowPRA beads. After incubation of serum with FlowPRA beads, followed by a staining with fluorescent-labeled antihuman IgG antibody, the anti-IgG positive serum shows a fluorescent channel shift, compared to the negative serum. Percent PRA is represented by the percentage of beads that react positively with the serum.

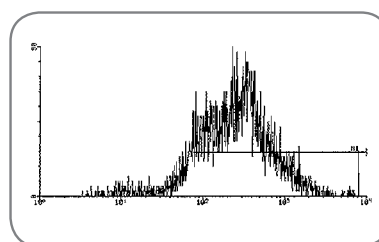
Results



FL2 histogram differentiating Class I and Class II beads



FL1 histogram of FlowPRA beads reacting with negative control serum



FL1 histogram of FlowPRA beads reacting with positive control serum

Intended Use • Applications

This test is intended for use in flow cytometric detection of HLA-specific antibodies in the sera of pre- and post-transplant organ recipients.

Product Specifications

Storage Temperature:

Reagents

-80° to -65° C

Shipping Considerations:

Dry Ice

Packaging:

10-tests

For In Vitro Diagnostic Use.

FlowPRA HLA Class I/II Screening Tests

Product Description	Cat Id	Sale Unit	Tests
FlowPRA Class I Screening Test	FL1-30	pkg	50 tests
FlowPRA Class II Screening Test	FL2-30	pkg	50 tests
FlowPRA Class I & II Screening Test	FL12-60	pkg	50 tests

FlowPRA Specific

These assays calculate percent PRA and use flow cytometry to accurately identify specific HLA antibodies. Each test consists of a panel of 32 FlowPRA Specific Class I and Class II beads, each coated with different purified Class I or Class II antigens from human cell lines. The beads are divided into four HLA groups, eight beads to a group. A serum sample must be tested separately with each group of beads to complete the bead panel analysis of the HLA Class I or Class II antibodies in that serum.



Features and Benefits

- High sensitivity and reproducibility
- Separate Class I and Class II tests available
- Specific HLA antibody detection is achieved with purified HLA antigens
- Reduced false positive reactions due to non-HLA antibodies and auto-antibodies
- No frozen lymphocyte panels to maintain and no cell viability problems to address
- Comprehensive analysis is achieved with HLA antibody specificities

Principle

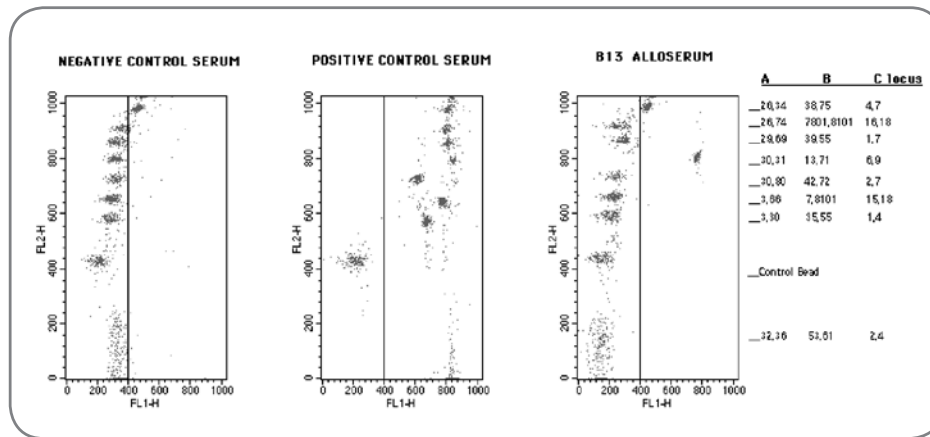
FlowPRA tests provide pre-optimized reagents for rapid flow cytometric detection of HLA antibodies and their specificities in human serum. The FlowPRA Specific Antibody Detection Test consists of a mixture of different colored beads with different fluorescent properties. These beads can be excited at 488 nm, generating a maximum emission of approximately 580 nm, similar to phycoerythrin (PE), which can be detected by the FL2 channel. Since different beads generate different FL2 channel shifts, different colored beads in a group can be separated by a flow cytometer on the FL2 channel.

Each group of beads is incubated separately with the test serum, then stained with a FITC conjugated anti-human IgG antibody. Beads reacting positively show an FL1 channel shift on the FL1 vs. FL2 dot plots when compared to the negative control serum and the control beads.

Intended Use • Applications

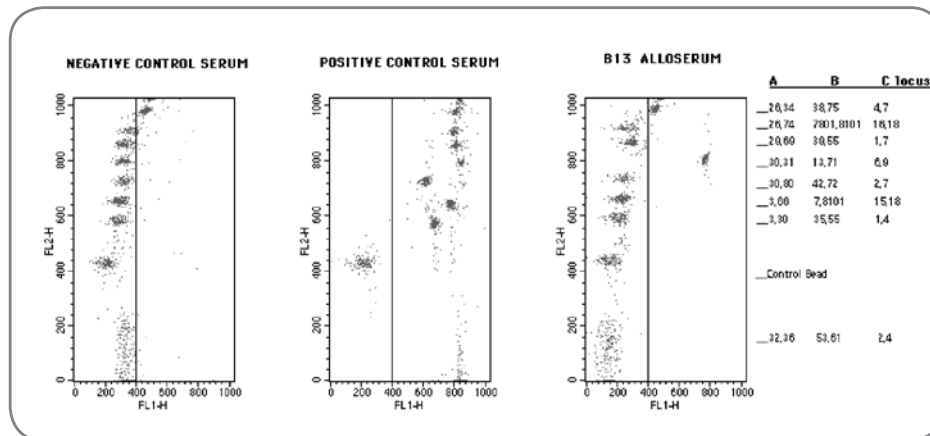
These tests are intended for use in flow cytometric detection of HLA antibodies and their specificities. FlowPRA Specific Antibody Detection Tests provide an extension to the FlowPRA Screening Tests. Both the specific and screening tests use microbeads coated with purified HLA antigens for flow cytometric detection of HLA antibodies in human sera. Screening tests can be used as a first test to detect HLA antibodies and percent PRA in human sera. Specific tests can subsequently be used to determine the antibody specificities in the serum.

Results



FlowPRA Specific Class I – Group 4*

Figure 1.
Sample dot plot for B13
positive alloserum



FlowPRA Specific Class II – Group 1*

Figure 2.
Sample dot plot for DR10
positive alloserum

*Figures depict only one out of four groups. Actual assay results consist of four groups plus positive and negative controls. Please consult product insert for more information.

Product Specifications

Reagents

Storage Temperature: -80° to -65° C

Shipping Considerations: Dry Ice

Packaging: 10-tests

For In Vitro Diagnostic Use.

FlowPRA Specific HLA Class I/II Tests

Product Description	Cat Id	Sale Unit	Tests
FlowPRA Specific HLA Class I Antibody Detection Test	FL1SP	pkg	10 tests
FlowPRA Specific HLA Class II Antibody Detection Test	FL2SP	pkg	10 tests

FlowPRA Ancillary Reagents

Product Specifications	Control Reagents	Other Reagents
Storage Temperature:	-80° to -20° C	-80° to -65° C
Shipping Considerations:	Dry Ice	Dry Ice
Packaging:	Various	Various

Ancillary Reagents

Product Description	Cat Id	Sale Unit	Tests
Control Reagents			
FlowPRA Control Beads (50 µl)	FLCNTBD	vial	50 tests
FlowPRA Class I & II Negative Control Serum (240µl)	FL-NC	vial	10 tests
FlowPRA Class I Positive Control Serum (240µl)	FL1-PC	vial	10 tests
FlowPRA Class II Positive Control Serum (240µl)	FL2-PC	vial	10 tests
Other Reagents			
FlowPRA Reagent Pack (Anti-Human IgG, 60 µl vial plus Wash Buffer, 26 ml bottle)	FL-RP	pkg	10 tests
FlowPRA Wash Buffer (10X) - 100 ml	FL-BF100	bottle	
For In Vitro Diagnostic Use.			
Adsorb Out (75µl)	ADSORB	vial	25 tests

For General Laboratory Use.

Lambda Antigen Tray™ (LAT)

One Lambda's LAT product line offers economical and convenient ELISA-based assays for the detection of the HLA IgG antibody. Three tray categories, each with distinct capabilities, are available in this product line. These trays feature pools of HLA antigens, which allow the determination of percent PRA and the identification of specific HLA Class I and Class II antibodies on a single tray.

Features and Benefits

- Antibody specificity is clear – LAT Class I or Class II panels allow detailed assignment of specificity
- LAT Mixed uses a pool of purified HLA Class I and Class II antigen for added specificity
- LAT ELISA results are comparable to CDC-AHG results
- Both cytotoxic and non-complement binding antibodies are recognized
- Eliminates interference from non-HLA antibodies and auto antibodies
- Distinguishes between HLA Class I and Class II specificities
- Quickly detects IgG
- Superb signal to background ratio for consistent results
- Convenient Terasaki tray format with smaller volume of reagents required
- Produced with defined pool of antigens, including rare HLA alleles

Principle

The LAT provides pre-calibrated ELISA reagents for the detection of IgG antibody to HLA Class I or Class II antigens in human serum. Defined amounts of affinity-purified HLA antigens are presented in different wells of a Terasaki tray. The specific binding of antibody from the test sample with any of these antigens is detected by a subsequent incubation with alkaline phosphatase-conjugated antibody that recognizes only human IgG. A quantitative measure of the extent of reaction is obtained by spectrophotometric determination following the addition of the appropriate enzyme substrate for the development of color. Qualitative assessment of antibody specificity is performed by analysis of the LAT reactivity pattern using the appropriate LAT worksheet.



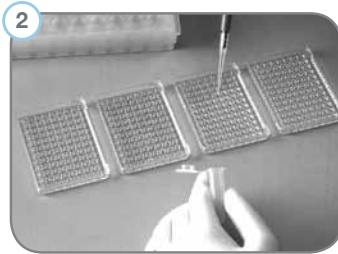
Intended Use • Applications

Intended for the identification of HLA-specific antibody in the serum of pre- and post-transplant organ recipients.

Methodology/Steps



Dilute test samples.



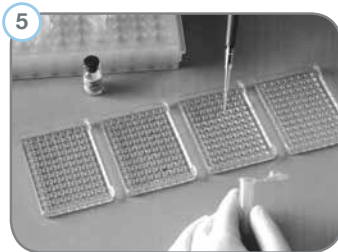
Add test samples to tray.



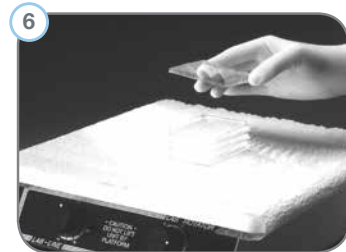
Incubate one hour. Wash and flick.



Dilute secondary antibody.



Add secondary antibody to tray.



Incubate 45 minutes. Wash and flick.



Add substrate. Incubate 15 minutes. Add stop reagent.



Read results.

Product Specifications

LAT

LAT Mixed

Storage Temperature:

2° - 8° C

2° - 8° C

Shipping Considerations:

Cold pack

Cold pack

Packaging:

20 trays per kit

5 trays per kit

For In Vitro Diagnostic Use.

LAT Single Antigen Class I

This ELISA-based assay detects and defines HLA antibodies in high PRA patients. Formatted on Terasaki trays, each Class I single antigen is coated in one well, allowing it to identify less common specificities that may be obscured by antibodies produced against the higher frequency antigens.

Product Description	Cat Id	Sale Unit	Tests
LAT Single Antigen Class I	LAT1HD	20 trays	20 tests

LAT Class I/II

Lambda Antigen Trays are designed for the detection of the HLA IgG antibody and feature purified HLA Class I and Class II antigens attached to each well of a Terasaki-format tray. With the addition of patient serum, the antibodies bind with the purified HLA antigens. The panel of HLA antigens can detect IgG complement-binding and non-complement-binding antibodies.

Product Description	Cat Id	Sale Unit	Tests
Lambda Antigen Tray Class I - 2 test	LAT140X2	20 trays	40 tests
Lambda Antigen Tray Class I - 1 test	LAT140	20 trays	20 tests
Lambda Antigen Tray Class II - 2 test	LAT240	20 trays	40 tests
Lambda Antigen Tray Class I & II - 2 test	LAT1240	20 trays	40 tests
Lambda Antigen Tray Class I & II	LAT1288	20 trays	20 tests

LAT Mixed Class I/II

A cost-effective, HLA antibody pre-screening test that rapidly processes multiple samples on a single tray. The mixed tray contains a defined pool of HLA antigens from several different cells, including rare HLA coverage, coated to each well of a Terasaki format tray.

Product Description	Cat Id	Sale Unit	Tests
Lambda Antigen Tray - Mixed Class I	LATM120	5 trays	100 tests
Lambda Antigen Tray - Mixed Class I & II	LATM10X5	5 trays	50 tests
Lambda Antigen Tray - Mixed Class I & II	LATM20X5	5 trays	100 tests



Lambda Cell Tray™ (LCT)

LCT trays are frozen cell panels designed for PRA and HLA antibody screening by complement-dependent cytotoxicity. They consist of panels of selected lymphocytes frozen onto Terasaki Tissue Trays, providing a diverse cell panel for cytotoxic screening of human sera.

Features and Benefits

- Superb viability, accurate results
- Extensive antigen coverage
- For larger cell panels, trays can be combined for greater efficiency
- Rapid test time – 90 minutes
- Well suited for dye exclusion and fluorescence methods

Principle

Lymphocytes with known antigens are incubated with an unknown serum and rabbit complement. If the serum contains antibodies that are able to bind specifically to those antigens present on the lymphocyte surface, complement mediated cytotoxicity can occur. If the unknown serum contains HLA antibodies, they can be characterized.

Intended Use • Applications

These trays are intended for the screening of sera for Class I and Class II antibodies with a complement-dependent microlymphocytotoxic technique.



Methodology/Steps



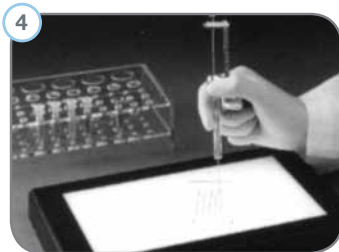
Thaw tray. Dispense McCoy's into each well.



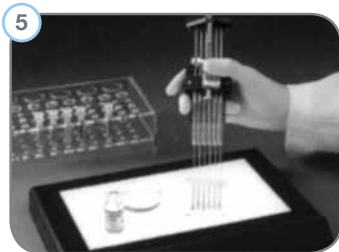
Flick tray to remove DMSO.



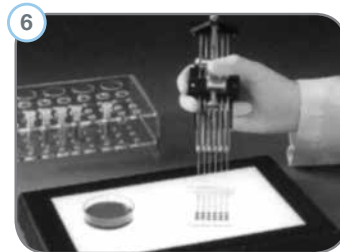
Dispense oil into each well.



Dispense sera into each well, except control wells.



Incubate tray for 30 minutes. Dispense complement into each well.



Incubate tray for 1 hour. Dispense stain/fixative into each well.

Product Specifications

Storage Temperature: -65°C or below

Shipping Considerations: Dry Ice

Packaging: 10 trays per box

For In Vitro Diagnostic Use.

LCT Cell Panels

Product Description	Cat Id	Sale Unit	Tests
Lambda Cell Tray 60 T Cell Panel	LCT1W60	10 trays	10 tests

Non-HLA Antibody Detection

LABScreen™ Autoantibody

Mounting evidence suggests the importance of testing autoantibodies. Employing single antigen bead technology, the LABScreen Autoantibody assays now allow you to characterize and monitor a broad range of autoantibody targets in human sera.

Following a familiar workflow and analysis algorithm, these assays can be easily integrated into your laboratory workflow without the need for new instrumentation or extensive retraining.

Expand your antibody detection capabilities and get the answers you need

Features and Benefits

- Characterize and monitor autoantibody targets
- Multiplexing capability – simultaneously detect up to 33 targets
- Negative and positive control sera available
- Minimal training required
- Use existing instrumentation (LABScan 100/200 and LABScan3D)
- Test up to 96 samples in under 4 hours
- Analyze results with HLA Fusion Research Software

Principle

LABScreen Autoantibody

The LABScreen Autoantibody assays provide a convenient way to characterize and study the autoantibody repertoire in human sera. Target antibodies can now be identified by single antigen bead technology.

Group 1 – 32 targets

Group 2‡ – 1 target

Group 3 – 6 targets

LABScreen Autoantibody Negative Control Serum

A negative control serum used as an indicator of the non-specific background signal of LABScreen Autoantibody Groups 1, 2, and 3 beads when reacting with a serum sample that does not contain the specified target antibodies.

LABScreen Autoantibody Positive Control Serum (for Group 1 and 2)

A positive control serum used as an indicator of the target-specific signal of LABScreen Autoantibody Group 1 and 2 beads when reacting with a serum sample that contains the specified target antibodies.

‡Note: Groups 1 and 2 can be combined in a single run.

Product Description	Cat Id	Sale Unit	Tests
LABScreen Autoantibody Group 1	LSAUT1	pkg	25 tests
LABScreen Autoantibody Group 2	LSAUT2	pkg	25 tests
LABScreen Autoantibody Group 3	LSAUT3	pkg	25 tests
LABScreen Autoantibody Negative Control Serum (For Group 1, 2, 3)	LSAUT-NC	pkg	10 tests
LABScreen Autoantibody Positive Control Serum (For Group 1 and 2)	LSAUT-PC	pkg	10 tests

For Research Use Only. Not for use in diagnostic procedures



AT1R - ETAR

Research has shown that antibodies against Angiotensin II Type I Receptors (AT1R) and Endothelin-1 Type A Receptors (ETAR) may have an associated risk for Antibody Mediated Rejection (AMR). One Lambda's exclusive, ELISA based, AT1R and ETAR assays can be used to research this possible link in pre- and post-transplant monitoring.

AT1R (IVD)

Product Description	Cat Id	Sale Unit	Tests
EIA for Quantitative Determination of anti-AT1R	EIA-AT1R	Kit	40 tests

For In Vitro Diagnostic Use. (Europe Only)

For Research Use Only. Not for use in diagnostic procedures. (USA and Canada)

ETAR (IVD)

Product Description	Cat Id	Sale Unit	Tests
EIA for Quantitative Determination of anti-ETAR Antibodies	EIA-ETAR	Kit	40 tests

For In Vitro Diagnostic Use. (Europe Only)

For Research Use Only. Not for use in diagnostic procedures. (USA and Canada)

AT1R – ETAR for Transplant Research

AT1R (RUO)

Product Description	Cat Id	Sale Unit	Tests
EIA for Quantitative Determination of anti-AT1R	EIA-AT1RX	Kit	40 tests

For Research Use Only. Not for use in diagnostic procedures.

ETAR (RUO)

Product Description	Cat Id	Sale Unit	Tests
EIA for Quantitative Determination of anti-ETAR Antibodies	EIA-ETARX	Kit	40 tests

For Research Use Only. Not for use in diagnostic procedures.

Product Specifications

Storage Temperature: 2° C to 8° C

Shipping Considerations: Ambient Temperature

Packing: 40 test package



MOLECULAR TYPING FOR TRANSPLANT DIAGNOSTICS

A comprehensive line of molecular products for HLA tissue typing that support laboratories and physicians worldwide.

DNA Technology Defined

One Lambda is renowned for its HLA typing technology that identifies HLA alleles. We offer a comprehensive line of molecular products for HLA tissue typing that supports laboratories and physicians worldwide. LABType™ (rSSO), LinkSēq™ Real-Time PCR, Micro SSP™, SeCore™, and AllType™ NGS products are available for HLA Class I and Class II typing. HLA laboratories can choose the DNA typing method that best meets their requirements.

Page 29	AllType™ NGS NGS-Based genotyping with fast turnaround – now available on both the Ion S5™ and Illumina MiSeq™ Systems.
Page 33	SeCore™ Sanger Sequence based typing of HLA alleles using Big Dye Terminator v1.1 Technology
Page 37	LABType™ Using Luminex xMAP technology and reverse sequence specific oligonucleotide technology, high throughput DNA typing is achieved.
Page 46	LinkSēq™ Real-Time PCR LinkSēq's innovative chemistry – developed for use on Real-Time PCR platforms. Detect PCR products without gels or probes.
Page 51	Micro SSP™ Sequence specific priming of genomic DNA to determine HLA class I and Class II alleles.
Page 64	GRES™ Combining proven technologies to deliver G Group-level genotyping.
Page 65	Cytokine Genotyping A proven tool in identifying cytokine genotypes, while using the same simple testing procedure employed by our Micro SSP line.
Page 66	KIR SSO Genotyping Featuring Luminex xMAP technology and designed to advance research on the impact of KIR on patient survival.
Page 67	LinkSēq™ KIR Real-Time PCR Genotyping A genotyping system designed to identify all 15 KIR genes and 2 pseudogenes.

AllType™ NGS

The AllType NGS Assay introduces the latest in long-range multiplex PCR technology. By amplifying all major Class I and Class II loci in a single PCR reaction, AllType significantly reduces labor, probability of error, and total time required for sample preparation.

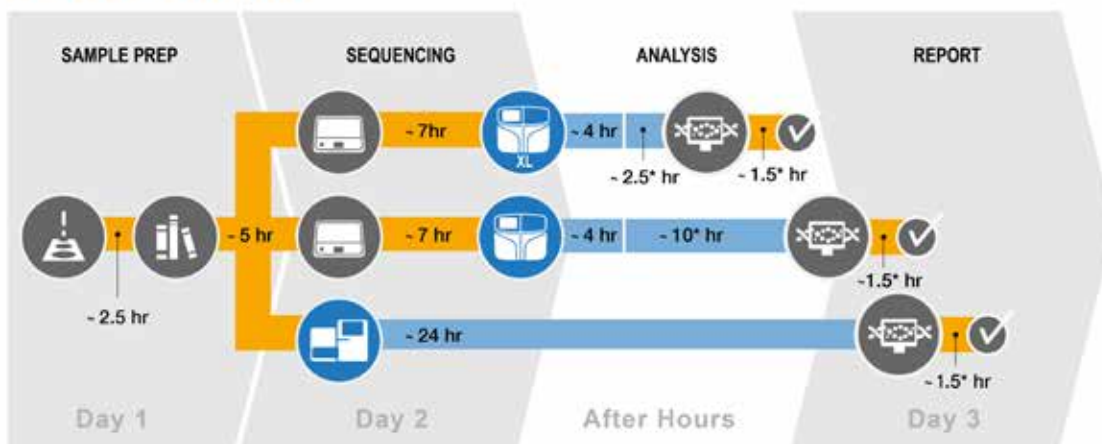
Make amplicon pooling a thing of the past – Take your samples directly to library preparation and begin sequencing in a single workday

Features and Benefits

- One multiplex PCR reaction per sample
- Multiplexed amplification of Class I and Class II loci in 2.5 hours
- No amplicon pooling
- Suitable for low and high volume laboratories
- Compatible with multiple platforms
- Easy protocol for manual processing (No automation needed)

Principle

AllType Workflow



*Actual times may vary depending on PC performance and run characteristics

Product Specifications

Storage Temperature: -80° to -20° C

Shipping Considerations: Dry Ice

Packaging: 4 Vials

Primer Coverage

Product Name	Catalog No.	Target	Coverage
AllType™ NGS 11-Loci Amplification Kit	ALL-11L	A	Full gene
		B	Full gene
		C	Full gene
		DRB1	Exon 2 thru 3' UTR
		DRB345	Exon 2 thru 3' UTR
		DQB1	Exon 2 thru 3' UTR
		DQA1	Full gene
		DPB1	Exon 2 thru 3' UTR
		DPA1	Full gene

For In Vitro Diagnostic Use in the European Union only.

AllType™ NGS 11-Loci Amplification Kit	ALL-11LX	A	Full gene
		B	Full gene
		C	Full gene
		DRB1	Exon 2 thru 3' UTR
		DRB345	Exon 2 thru 3' UTR
		DQB1	Exon 2 thru 3' UTR
		DQA1	Full gene
		DPB1	Exon 2 thru 3' UTR
		DPA1	Full gene

Research Use Only. Not for use in diagnostic procedures.

Continued on next page

Product Name	Catalog No.	Target	Coverage
AllType™ NGS 9-Loci Amplification Kit	ALL-9LX	A	Full gene
		B	Full gene
		C	Full gene
		DRB1	Exon 2 thru 3' UTR
		DRB345	Exon 2 thru 3' UTR
		DQB1	Exon 2 thru 3' UTR
		DPB1	Exon 2 thru 3' UTR

For Research Use Only. Not for Use in Diagnostic Procedures.

Product Name	Catalog No.	Target	Coverage
AllType™ NGS 8-Loci Amplification Kit	ALL-8LX	A	Full gene
		B	Full gene
		C	Full gene
		DRB1	Exon 2 thru 3' UTR
		DRB345	Exon 2 thru 3' UTR
		DQB1	Exon 2 thru 3' UTR

Research Use Only. Not for use in diagnostic procedures.

AllType Amplification Reagents

AllType – Ion Torrent Workflow	Catalog No.	Tests
AllType™ NGS 11-Loci Amplification Kit	ALL-11L	96 tests
AllType™ NGS 11-Loci Amplification Kit	ALL-11LX	96 tests
AllType™ NGS 9-Loci Amplification Kit	ALL-9LX	96 tests
AllType™ NGS 9-Loci Amplification Kit	ALL-8LX	96 tests

Research Use Only. Not for use in diagnostic procedures.

Sample Preparation

AllType – Ion Torrent Workflow	Catalog No.	Tests
Ion Xpress Plus Fragment Library Kit	ION-XLIB	20
Ion Xpress Barcode Adapters 1-16 Kit	ION-XBA1	10 each
Ion Xpress Barcode Adapters 17-32 Kit	ION-XBA2	10 each
Ion Xpress Barcode Adapters 33-48 Kit	ION-XBA3	10 each
Ion Xpress Barcode Adapters 49-64 Kit	ION-XBA4	10 each
Ion Xpress Barcode Adapters 65-80 Kit	ION-XBA5	10 each
Ion Xpress Barcode Adapters 81-96 Kit	ION-XBA6	10 each
Ion Xpress Barcode Adapters 1-96 Kit	ION-XBA7	10 each

For Research Use Only. Not For Use in Diagnostic Procedures.

AllType – Illumina Workflow	Catalog No.	Tests
AllType NGS 11-Loci Sample Prep Flex Kit ¹	ALL-PREP11LFX	96 tests
Ion Xpress Plus Fragment Library Kit ²	ION-XLIB	20
AllType NGS Index Flex Kit ³	ALL-FLEXX	96 tests

For Research Use Only. Not For Use in Diagnostic Procedures.

¹Includes ALL-11LX, ION-XLIB, and ALL-FLEXX

²Compatible with both Ion Torrent and Illumina workflows

³Compatible with Illumina workflow only

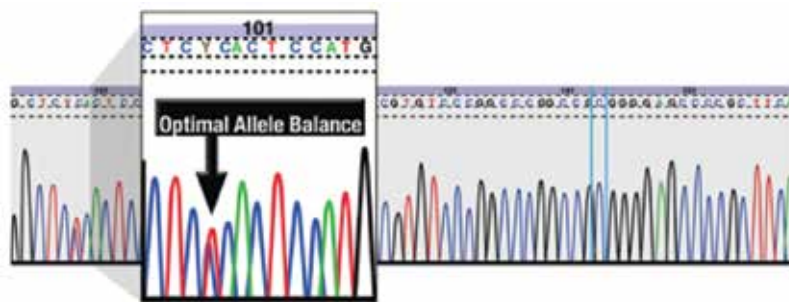
Template Preparation & Sequencing Reagents - Ion Torrent

Product Name	Sale Unit	Tests	Catalog No.
Ion 520 & Ion 530 ExT Kit - Chef	multi pkg	4 runs	IONCHEF-EXT
<i>*Contains the following kits:</i>			
<i>Ion S5TM ExT Sequencing Reagents</i>	1	4 runs	
<i>Ion S5TM ExT Sequencing Solutions</i>	1	4 runs	
<i>Ion S5TM Chef Solutions</i>	1	4 runs	
<i>Ion S5TM ExT Chef Supplies</i>	4	4 runs	
<i>Ion S5TM ExT Chef Reagents</i>	1	4 runs	IONS5-530C4
<i>Ion 530 Chip Kit</i>	1	4 runs	

The SeCore HLA SBT typing workflow solution uses the Sanger sequencing method. Sanger sequencing allows you to accurately detect and identify a high level of allelic diversity with a simple protocol. Only sequencing for HLA typing produces the sequenced DNA data in its contiguous form, allowing you to store and retrieve nucleotide data for reanalysis with future nomenclature alignment updates. This means your results have been established from the actual sequencing reads, and your analysis is mapped to most recent IMGT/HLA alignment database information.

Features and Benefits

- Accurate high resolution results; SeCore employs the gold standard for HLA typing
- Demonstrated accuracy, repeatability, and conformance proven in independent testing
- Time-to-result is within one workday
- An easy and efficient protocol with complete kits; Every kit includes the necessary enzymes and BigDye™ Terminator v1.1 chemistry reagents
- Sequencing primer mixes yield optimal allele balance with peak uniformity and low background
- Complete results - SeCore kits and uTYPE™ HLA Sequence Analysis Software are continually maintained through quarterly nomenclature allele library updates so your typing results are determined using the most recent IMGT/HLA information
- Powerful uTYPE™ HLA Sequence Analysis Software simplifies analysis; uTYPE™ HLA Sequence Analysis Software offers the ability to analyze and interpret the standard SeCore sequence data and SeCore GSSP sequence data separately or simultaneously



Workflow

1

Prepare samples,
Isolate DNA

2

Amplify samples
with SeCore kits

3

ExoSAP-IT®
Purification

4

Cycle
sequencing
with thermal
cyclers



 **ONE LAMBDA**
* Thermo Fisher Scientific Brand

SeCore Workflow Timing

Step	Hands-On Time	Hands-Off Time	Total Assay Time
Amplify DNA	15 minutes	90 minutes	105 minutes
ExoSAP-IT PCR Purification	5 minutes	40 minutes	45 minutes
Sequencing Reaction	20 minutes	60 minutes	80 minutes
Sequencing Purification	10 minutes	40 minutes	50 minutes
Capillary Electrophoresis •	10 minutes	•	10 minutes + •
Total Time	60 minutes	230 minutes + •	290 minutes + • (~4 hours 50 minutes)

Estimated typical workflow based on time required to process 96 reactions

- An additional 50 to 450 minutes should be added for Capillary Electrophoresis “Hands-off Time” depending on model of AB Genetic Analyzer used.

Capillary Electrophoresis “Hands-Off Time” by Instrument •

	3130xl (16 capillary)	3500xL Dx (24 capillary)	3730xl (96 capillary)
Time Per Injection	~50 minutes	~60 minutes	~50 minutes
Number of Injections Per 96 Reactions	6 injections	4 injections	1 injections
Total Time •	300 minutes (5 hours)	240 minutes (4 hours)	50 minutes

Capillary Electrophoresis is based on POP-6™ polymer

SeCore SBT Kits (IVD)

Product Name	Exon Target	Sale Unit	Cat Id/Tests 25 Tests	Cat Id/Tests 500 Tests
Class I				
SeCore A Locus Sequencing Kit	Bidirectional sequencing of exons 1, 2, 3, 4, and 5	pkg	5300025	22000D
SeCore B Locus Sequencing Kit, Single Amplification System	Bidirectional sequencing of exons 1*, 2, 3, 4, and 5	pkg	5311025D	22110D
SeCore C Locus Sequencing Kit	Bidirectional sequencing of exons 1, 2, 3, 4, and 5	pkg	5320025	22200D
Class II				
SeCore DRB1 Locus Exon 2 & 3 Sequencing Kit	Bidirectional sequencing of exon 2 and 3; and codon 86	pkg	A15571	A15573
SeCore DRB1, DRB3, DRB4, DRB5 Locus Sequencing Kit Group Specific Set	Bidirectional sequencing of exon 2; and codon 86	pkg	5331025	-
SeCore DQB1 Locus 2AMP	Bidirectional sequencing of exons 2 and 3	pkg	5341025D	22410D
SeCore DPB1 Locus Sequencing Kit	Bidirectional sequencing of exons 2, 3, and 4; and codons 8 and 85	pkg	5351025	22510D

* SeCore B Locus Sequencing Kit contains unidirectional sequencing primer for exon 1 forward (1F) only.
For In Vitro Diagnostic Use.

Product Specifications

Storage Temperature: -30 to -10C

Shipping Considerations: Dry Ice

Based on Luminex® xMap® Technology, LABType is a reverse SSO DNA typing system that consists of sequence specific oligonucleotide probes bound to color-coded microspheres. This multiplex analysis dramatically reduces labor, reagents, reaction-to-reaction inconsistencies, and time associated with a multi-well format assay. Our cost effective kits do not require handling of line strips or membranes, colorimetric reactions, or visual analysis of colored bands or dots. With LABType you get superior resolution and a cost-effective solution for HLA A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1, and DPB1 loci typing.



Features and Benefits

- Offers complete HLA A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1, and DPB1 loci typing, as well as MICA
- B7 and Bw4 are supplements of the B locus kit

Principle

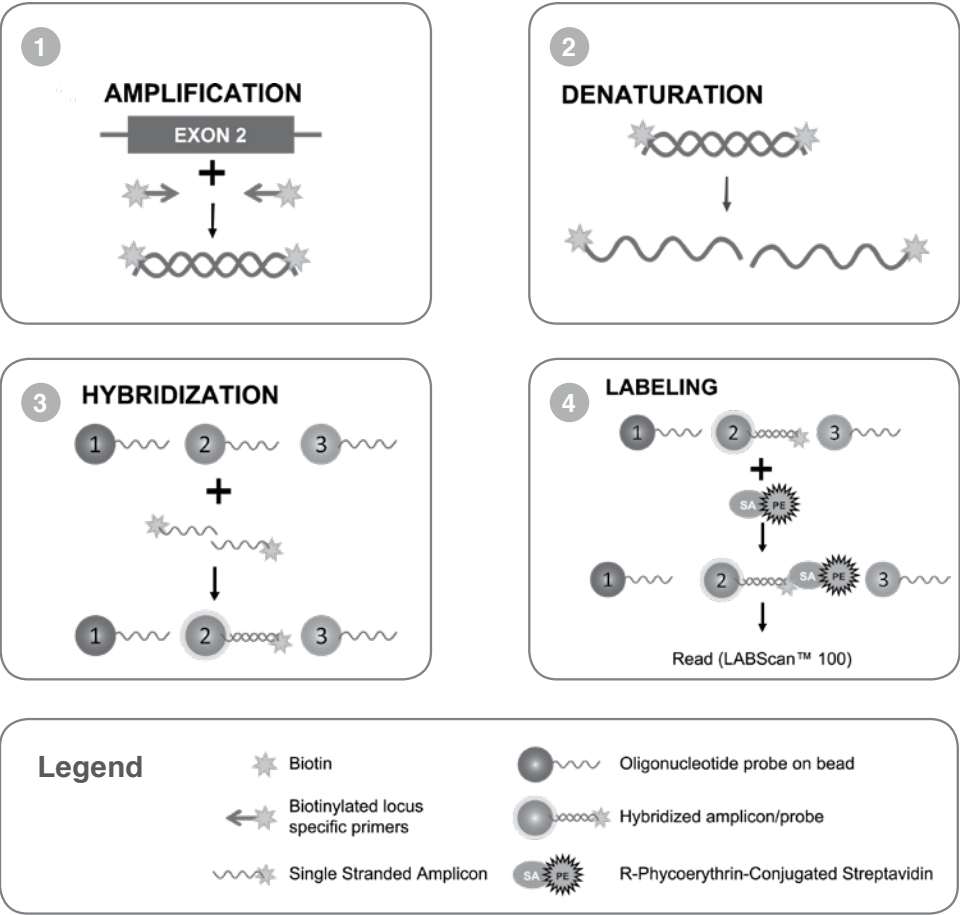
LABType uses Luminex instrumentation and is based on the reverse SSO method. Fluorescently coded microspheres are used as a solid support to immobilize oligonucleotide probes. First, target DNA is amplified using biotinylated locus-specific primers. The biotinylated amplified PCR product is denatured and allowed to hybridize to complementary DNA oligonucleotide probes which are conjugated to the fluorescently coded microspheres. Hybrids formed between amplification products and bead-bound probes are detected using R-Phycoerythrin-conjugated Streptavidin (SAPE).

The LABScan™ 100 or LABScan3D™ each identify the fluorescent intensity of PE (phycoerythrin) bound to each hybrid. The assignment of the HLA typing is based on a comparison of the obtained sample reaction pattern compared with the reaction pattern of HLA alleles determined from published HLA gene sequences.

Australian Patent 2002327046 and Canadian Patent 2,460,759

Intended Use / Applications: DNA Typing of HLA Class I or Class II alleles.

Principle



LABType XR and CWD DNA Typing Test

LABType XR and CWD assays each take advantage of the 500 bead regions exclusively available for use with the LABScan3D. Extended exon coverage for both assays, and the ability to multiplex up to 500 bead regions allows for higher resolution. The CWD assays are designed to resolve alleles as defined by the CWD catalog. The XR assays are designed for laboratories interested in increased resolution beyond the CWD assay. With up to 500 bead regions and extended exon coverage, increased typing resolution is more easily achieved.

Based on Luminex xMAP Technology, LABType is a reverse SSO DNA typing system that consists of sequence specific oligonucleotide probes bound to color-coded microspheres. This multiplex analysis technology allows you to process 96 samples at one time, dramatically reducing labor, reagents, reaction-to-reaction inconsistencies, and time associated with a multi-well format assay.

Features and Benefits

- 500 bead multiplexing
- Same workflow as LABType SSO and LABType HD
- Locus and Exon Coverage: A locus: Exons 2-5, B locus: Exons 2-5, DRB1 locus: Exon 2

LABType XR and CWD DNA Typing Test

Product Name	Sale Unit	Tests	Cat Id.
Class I			
LABType CWD Class I A Locus Typing Test - 20 tests	pkg	20 tests	RSOW1AT
LABType CWD Class I A Locus Typing Test	pkg	100 tests	RSSOW1A
LABType CWD Class I B Locus Typing Test - 20 tests	pkg	20 tests	RSOW1BT
LABType CWD Class I B Locus Typing Test	pkg	100 tests	RSSOW1B
LABType XR Class I A Locus Typing Test - 20 tests	pkg	20 tests	RSOX1AT
LABType XR Class I A Locus Typing Test	pkg	100 tests	RSSOX1A
LABType XR Class I B Locus Typing Test - 20 tests	pkg	20 tests	RSOX1BT
LABType XR Class I B Locus Typing Test	pkg	100 tests	RSSOX1B
Class II			
LABType CWD Class II DRB1 Typing Test - 20 tests	pkg	20 tests	RSOW2B1T
LABType CWD Class II DRB1 Typing Test	pkg	100 tests	RSSOW2B1
LABType XR Class II DRB1 Typing Test - 20 tests	pkg	20 tests	RSOX2B1T
LABType XR Class II DRB1 Typing Test	pkg	100 tests	RSSOX2B1

Product Specifications

Storage Temperature: -80 to -20C

Shipping Considerations: Cold pack

LABType® SSO HLA Class I/II Typing Test

Typing spans A, B, C; DRB1; DRB3, 4, 5; DPA1/DPB1; DQA1/DQB1; and MICA. DQA1/DQB1, and DPA1/DPB1 cover exons 2 and 3. Exon 4-7 is a Class I supplement for A, B, and C locus; B7 and Bw4 are supplements for B locus kits.

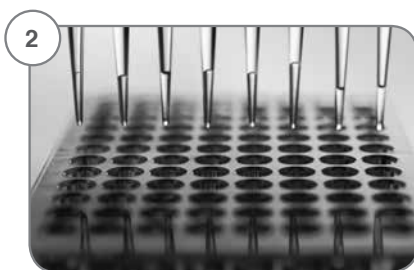
Features and Benefits

- Multiplex analysis, “all-in-one” reaction dramatically reduces labor, reagents, reaction-to-reaction inconsistency, and time involved in a multi-well format assay
- Specialty probe technology allows resolution of ambiguities that would require an additional assay with conventional SSO or SBT methods
- Automated data acquisition using LABScan 100 or LABScan3D
- Software-aided data analysis and HLA allele assignment via HLA Fusion
- Robust assay - no handling of line strips or membranes, no colorimetric reaction, and no visual analysis of colored bands or dots
- Post hybridization stability - allows batch processing
- Ideal solution - for both low volume and high throughput laboratories
- Cost-effective - saves money, labor, and processing time
- Superior resolution

Workflow



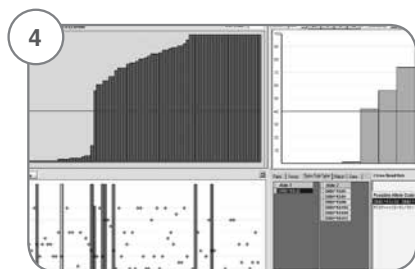
PCR Amplification



Hybridization of PCR products to beads



Detection using LABScan 100 or LABScan3D



Software analysis HLA assignment using HLA Fusion

LABType SSO HLA Class I/II Typing Tests

Product Name	Sale Unit	Tests	Cat Id.
Class I			
LABType SSO Class I A Locus Typing Test - 20 tests	pkg	20 tests	RSO1AT
LABType SSO Class I A Locus Typing Test	pkg	100 tests	RSSO1A
LABType SSO Class I B Locus Typing Test - 20 tests	pkg	20 tests	RSO1BT
LABType SSO Class I B Locus Typing Test	pkg	100 tests	RSSO1B
LABType SSO Class I B7 Supplement Typing Test - 20 tests	pkg	20 tests	RSO1S1T
LABType SSO Class I B7 Supplement Typing Test	pkg	100 tests	RSSO1S1
LABType SSO Class I Bw4 Supplement Typing Test - 20 tests	pkg	20 tests	RSO1S4T
LABType SSO Class I Bw4 Supplement Typing Test	pkg	100 tests	RSSO1S4
LABType SSO Class I C Locus Typing Test - 20 tests	pkg	20 tests	RSO1CT
LABType SSO Class I C Locus Typing Test	pkg	100 tests	RSSO1C
Class II			
LABType SSO Class II DPA1/DPB1 Typing Test - 20 tests	pkg	20 tests	RSO2PT
LABType SSO Class II DPA1/DPB1 Typing Test	pkg	100 tests	RSSO2P
LABType SSO Class II DQA1/DQB1 Typing Test - 20 tests	pkg	20 tests	RSO2QT
LABType SSO Class II DQA1/DQB1 Typing Test	pkg	100 tests	RSSO2Q
LABType SSO Class II DRB1 Typing Test - 20 tests	pkg	20 tests	RSO2B1T
LABType SSO Class II DRB1 Typing Test	pkg	100 tests	RSSO2B1
LABType SSO Class II DRB3,4,5 Typing Test - 20 tests	pkg	20 tests	RSO2345T
LABType SSO Class II DRB3,4,5 Typing Test	pkg	100 tests	RSSO2345

For In Vitro Diagnsotic Use.

Product Specifications

Storage Temperature:	-80 to -20C
Shipping Considerations:	Cold Pack

LABType SSO MICA

LABType SSO MICA types MICA alleles using Luminex xMAP technology. Typing for MICA can be instrumental in determining HLA-compatible donor-recipient matches. But it is also helpful in assuring that a patient is matched with a MICA-compatible donor. The test is also used to determine a patient's MICA typing to assure that MICA antibodies are not auto-reactive antibodies.

Product Description	Cat Id	Sale Unit	Tests
LABType SSO MICA	RSSOMICA	pkg	40 tests

For In Vitro Diagnostics Use.



Tray Aspirator LT

Our Tray Aspirator allows you to remove excess liquid from eight wells of a high profile PCR tray simultaneously. The probe depth of the manifold makes this device suited for high profile PCR trays.

Product Description	Cat Id
Tray Aspirator	TASPCR

For General Laboratory Use.



Ancillary Reagents

One Lambda offers a selection of Ancillary Reagents for optimizing LABType testing.

SAPE

Product Description	Cat Id	Sale Unit	Tests
PE - Conjugated Streptavidin, Lyophilized, 1ml	LT-SAPE	vial	2000 tests

For In Vitro Diagnostic Use.

Product Specifications

Storage Temperature: 2° to 8° C

Shipping Considerations: Cold Pack

Packaging: 1 Vial

TAQ Polymerase

Product Description	Cat Id	Sale Unit
Taq Polymerase - 30µl	TAQ30	bottle
Taq Polymerase - 50µl	TAQ50	bottle
Taq Polymerase - 75µl	TAQ75	bottle

For General Laboratory Use

Product Specifications

Storage Temperature: -20° or below

Shipping Considerations: Cold Pack

Packaging: bottle



LinkSēq™ Real-Time PCR

Fast and Easy Real-time PCR Genotyping

LinkSēq is a rapid genotyping method with a simple workflow that prevents post-amplification contamination. With a fast turnaround time of only 90 minutes, and minimal hands-on time, your lab's productivity will greatly increase.

With LinkSēq, you can achieve high throughput. By using inexpensive thermal cyclers for the first 60 minutes of the amplification step and only 10 minutes on a real time PCR instrument, you can type multiple samples per hour with unmatched simplicity. Products include HLA, KIR and ABO.

For LinkSeq KIR Genotyping products, see page 67

For LinkSeq ABO typing products, see page 93



Features and Benefits

- More productivity with less effort
- Fewer repeats with less steps and reproducible results
- SureTyper software for robust and automated analysis

LinkSēq HLA Typing Kits

The LinkSēq family of HLA typing kits provides a multitude of options for high throughput typing products. Available in both 96 well and 384 well configurations, the LinkSēq HLA typing kits cover Class I and Class II alleles across all 11 loci including specific typing kits and null allele typing kits.

LinkSēq HLA Typing Kits

Product Name Class I & II Typing	Tray Type	Layout	No. of Tests	Cat Id
LinkSēq HLA - ABCDRDQB1	96 well	1 Sample per 2 Trays	10	1054C
LinkSēq HLA - ABCDRDQA1DQB1 384	384 well	2 Samples per Tray	20	1550C
LinkSēq HLA - ABCDRDQB1 384	384 well	1 Samples per Tray	10	1551C
LinkSēq HLA - ABCDRDQB1 384	384 well	2 Samples per Tray	20	1554C
LinkSēq HLA - ABCDRDQDP+ 384	384 well	1 Sample per Tray	10	1575C
LinkSēq HLA - ABCDRDQDP SABR 384	384 well	1 Sample per Tray	10	1580C
LinkSēq HLA – Single-Locus AC-DRDQDP	384 well	1 sample per tray	10	2301C
LinkSēq HLA - ABDR	96 well	1 sample per 2 Trays	10	3030C
LinkSēq HLA - ABDR 384	384 well	1 Sample per Tray	10	3331C
LinkSēq HLA - ABDR 384	384 well	2 samples per Tray	20	3332C
LinkSēq HLA – ABDR/ ADR	96 well	1 Sample per Tray	10	3060C
Class I Typing				
LinkSēq HLA - ABC 384	384 well	1 sample per tray	10	1821C
LinkSēq HLA - ABC 384	384 well	2 samples per tray	20	1822C
LinkSēq HLA - A	96 well	1 sample per Tray	10	2011C
LinkSēq HLA – B	96 well	1 sample per Tray	10	2020C
LinkSēq HLA - B 384	384 well	2 sample per tray	20	2322C
Class II Typing				
LinkSēq HLA - DRDQDP 384	384 well	1 sample per tray	10	1861C
LinkSēq HLA - DRDQDP 384	384 well	2 sample per tray	20	1862C
HLA – Specific Genetic Markers				
LinkSēq HLA – B27	Strips	3 Samples per Strip	36	8011C
LinkSēq HLA – B*57:01	Strips	3 Samples per Strip	36	8020C

For In Vitro Diagnostic Use. (European Union only.)

For research use only. Not for use in diagnostic procedures. (USA and Canada)

LinkSēq HLA Typing Kits

Class I & II Typing	Tray Type	Layout	No. of Tests	Cat Id
LinkSēq HLA - ABCDRDQB1	96 well	1 Sample per 2 Trays	10	1054R
LinkSēq HLA - ABCDRDQA1DQB1 384	384 well	2 Samples per Tray	20	1550R
LinkSēq HLA - ABCDRDQB1 384	384 well	1 Samples per Tray	10	1551R
LinkSēq HLA - ABCDRDQB1 384	384 well	2 Samples per Tray	20	1554R
LinkSēq HLA - ABCDRDQDP+ 384	384 well	1 Sample per Tray	10	1575R
LinkSēq HLA - ABCDRDQDP SABR 384	384 well	1 Sample per Tray	10	1580R
LinkSēq HLA – Single-Locus ACDRDQDP	384 well	1 sample per tray	10	2301R
LinkSēq HLA - ABDR	96 well	1 sample per 2 Trays	10	3030R
LinkSēq HLA - ABDR 384	384 well	1 Sample per Tray	10	3331R
LinkSēq HLA - ABDR 384	384 well	2 samples per Tray	20	3332R
LinkSēq HLA – ABDR/ ADR	96 well	1 Sample per Tray	10	3060R
Class I Typing				
LinkSēq HLA - ABC 384	384 well	1 sample per tray	10	1821R
LinkSēq HLA - ABC 384	384 well	2 samples per tray	20	1822R
LinkSēq HLA - A	96 well	1 sample per Tray	10	2011R
LinkSēq HLA – B	96 well	1 sample per Tray	10	2020R
LinkSēq HLA - B 384	384 well	2 sample per tray	20	2322R
Class II Typing				
LinkSēq HLA - DRDQDP 384	384 well	1 sample per tray	10	1861R
LinkSēq HLA - DRDQDP 384	384 well	2 sample per tray	20	1862R

For research use only. Not for use in diagnostic procedures.

LinkSēq Real-Time PCR

HLA – Specific Genetic Markers	Tray Type	Layout	No. of Tests	Cat Id
LinkSēq HLA – B27	Strips	3 Samples per Strip	36	8011R
LinkSēq HLA – B*57:01	Strips	3 Samples per Strip	36	8020R
LinkSēq HLA – DQ2, DQ8, DQA1*05	Strips	1 Sample per Strip	12	8050R
LinkSēq HLA – DQ2, DQ8, DQA1*05	96 Well	12 Samples per tray	120	8051R
LinkSēq HLA – DQB1*06:02, DQA1*01:02	Strips	2 Samples per strip	24	8060R
Null Allele Typing				
LinkSēq HLA – Null Allele *01:04N, A*03:21N, A*24:09N, A*24:11N, A*68:11N, B*15:01:01:02N, B*51:11N, C*04:09N	Strips	1 Sample per strip	12	7100R

For research use only. Not for use in diagnostic procedures.

LinkSēq Real-Time PCR

LinkSēq HLA Typing Kits

Wipe Test	Tray Type	Layout	No. of Tests	Cat Id
LinkSēq Wipe Test 384	384 well	6 samples per Tray	24	9800R
LinkSēq Wipe Test	Strip	6 samples per 3 strips	24	9850R

For research use only. Not for use in diagnostic procedures.

Ancillary Reagents and Consumables

We provide ancillary reagents and consumables to help you get the most out of our LinkSēq products.

Miscellaneous	Layout	Cat Id
LinkSēq Laboratory Starter Kit	1 Kit	AC-001
Real-Time PCR Compression Pad	1 compression Pad	AC-010
Real-Time PCR Seal	1 pck (10 PCR seals)	AC-020
Optical Strip Covers	1 pck (10 Optical Strip Covers)	AC-025
Adhesive Seal Applicator	1 Applicator	AC-030
Roche LightCycler 480 Optical Strip Tube Adaptor	1 Adaptor	AC-040
384-Well Multi-Sample Starter Kit	1 Kit	AC-100
LinkSēq Enzyme & Buffer for 1575/1580 Trays	1 Enzyme & 5 Buffers	AC-200
LinkSēq Enzyme & Buffer for 1550/1554 Trays	1 Enzyme & 5 Buffers	AC-230

Product Specifications

Storage Temperature: -35 to -15C

Shipping Considerations: Cold Pack

One Lambda's portfolio of Micro SSP typing trays provide complete HLA Class I and Class II DNA typing.

Using Generic Trays, technologists can either assign HLA Class I or Class II alleles individually or simultaneously. If more detailed typing is needed, the High Resolution Allele Specific Trays will help eliminate ambiguities.

Features and Benefits

- Products for both serological and allele level typing
- Generic trays: Class I, Class II, combined Class I and II
- High resolution trays: DPA1/DPB1, DQA1 and DRB1,3, 4, 5
- Allele specific trays: Refines results for specific alleles
- Class I and Class II null trays – to resolve common null alleles
- Results you can trust - each test has a color-coded negative control to minimize technician variation and the chance for human error.
- Efficient workflow - kits include dried, predisposed primer mixes and pre-aliquoted buffer, making handling easier and faster

Principle

The PCR-SSP methodology is based on the principle that completely matched oligonucleotide primers are more efficiently used in amplifying a target sequence than a mismatched oligonucleotide primer by recombinant Taq polymerase. Primer pairs are designed to have perfect matches only with a single allele or group of alleles. Under strictly controlled PCR conditions, perfectly matched primer pairs result in the amplification of target sequences (positive result), while mismatched primer pairs do not result in amplification (negative result). After the PCR process, the amplified DNA fragments are separated by agarose gel electrophoresis and visualized by staining with ethidium bromide and exposure to ultraviolet light. Interpretation of PCR-SSP results is based on the presence or absence of a specific amplified DNA fragment.



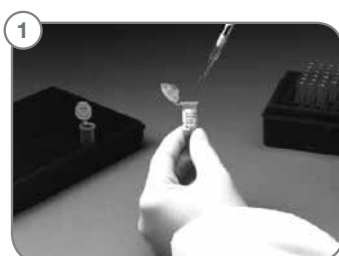
Product Specifications	Generic Trays	High-Resolution Trays	Allele Specific Trays	Seramates	AmbiStrips
Storage Temperature:	-80° to -20° C	-80° to -20° C	-80° to -20° C	-80° to -20° C	-80° to -20° C
Shipping Considerations:	Cold Pack	Cold Pack	Cold Pack	Cold Pack	Cold Pack
Packaging:	4 trays or 10 trays in box	4 trays or 10 trays in box	4 trays in box	4 trays in box	1 strip in box

For In Vitro Diagnostic Use.

Intended Use • Applications

DNA typing of Class I and Class II HLA alleles.

Workflow



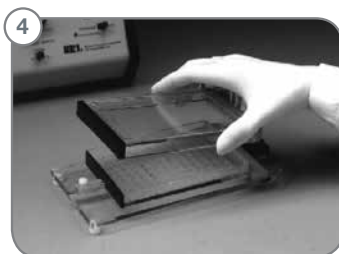
1 Add Taq polymerase D-mix tube.



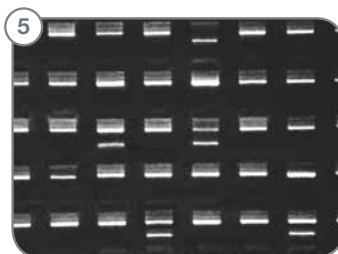
2 Add D-mix/Taq solution to the negative control well. Add DNA to the D-mix/Taq solution and add to the remaining wells.



3 Perform PCR.



4 Perform electrophoresis.



5 Photograph gel and analyze results.

Generic SSP Typing

Estimated typical workflow times	Hands-on time	Hands-off time
PCR set up	10 min	
PCR program		76 mins
Agarose gel preparation (can be completed prior to gel electrophoresis)	10 mins	
Gel loading	5 mins	
Gel electrophoresis	5 min	
	Total: 30 min	Total: 76 mins

Micro SSP Generic HLA Class I/II - DNA Typing Trays

These basic trays are used to assign either HLA Class I, or Class II alleles, or both Class I and Class II alleles simultaneously.

Product Name	Allele Coverage	Cat Id	Sale Unit	Tests
Class I				
Micro SSP Generic HLA Class I DNA Typing Tray	A,B,C Locus	SSP1L	10 trays	10 tests
Micro SSP HLA Class I A Locus Specific DNA Typing Tray	A Locus Specific	SSP1A	4 trays	12 tests
Micro SSP HLA Class I DNA Typing Tray	A, B Locus	SSP1AB	10 trays	10 tests
Micro SSP HLA Class I B Locus Specific DNA Typing Tray	B Locus Specific	SSP1B	4 trays	8 tests
Micro SSP HLA Class I C Locus Specific DNA Typing Tray	C Locus Specific	SSP1C	4 trays	16 tests
Class II				
Micro SSP Generic HLA Class II DNA Typing Tray	DRB Only	SSP2LB	10 trays	40 tests
Micro SSP Generic HLA Class II DNA Typing Tray	DQB Only	SSP2LQB1	4 trays	24 tests
Micro SSP Generic HLA Class II DNA Typing Tray	DRB/DQB	SSP2L	10 trays	30 tests
Micro SSP Generic HLA Class II DNA Typing Tray - DRB/DQB1/DPB1	DRB/DQB1/DPB1	SSPDRQP1	10 trays	10 tests
Class I & II				
Micro SSP Generic HLA Class I and II DNA Typing Tray	A,B,DR,DQ	SSPML02	4 trays	4 tests
Micro SSP Generic HLA Class I and II ABDR DNA Typing Tray	A,B,DR	SSPABDR	10 trays	10 tests

For In Vitro Diagnostic Use.

Micro SSP High Resolution HLA Class II Trays

High Resolution trays offer more detailed subtyping information for Class II alleles (DRB1, 3, 4, 5, DPA1/DPB1, and DQA1). They allow for focused testing, eliminating ambiguities, and confirmation of questionable results.

Product Name	Allele Coverage	Cat Id	Sale Unit	Tests
Class II				
Micro SSP High Resolution HLA Class II DNA Typing Tray	DRB1,3,4,5	SSP2H	10 trays	10 tests
Micro SSP High Resolution HLA Class II DNA Typing Tray	DPA1/DPB1	SSP2HDP	4 trays	4 tests
Micro SSP High Resolution HLA Class II DNA Typing Tray	DQA1	SSP2HQA1	4 trays	8 tests

For In Vitro Diagnostic Use.

Micro SSP Allele Specific HLA Class I/II Trays

Allele Specific trays are designed for HLA Class I and Class II sub-typing. They may be used alone or in combination with our generic and high resolution HLA typing trays.

Product Name	Cat Id	Sale Unit	Tests
Class I			
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*01/36	SSPR1-01	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*02	SSPR1-A2	4 trays	4 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*03	SSPR1-03	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*11	SSPR1-11	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*23	SSPR1-23	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*24	SSPR1-24	4 trays	4 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*25/34/66	SSPR1-25	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*26	SSPR1-26	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*29	SSPR1-29	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*30	SSPR1-30	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*31	SSPR1-31	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*32	SSPR1-32	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*33	SSPR1-33	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*68	SSPR1-68	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - A*74	SSPR1-74	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*07	SSPR1-07	4 trays	4 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*08	SSPR1-08	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*13	SSPR1-13	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*14	SSPR1-14	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*15	SSPR1-15	4 trays	4 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*18	SSPR1-18	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*27	SSPR1-27	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*35	SSPR1-35	4 trays	4 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*37	SSPR1-37	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*38/39	SSPR1-16	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*40	SSPR1-40	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*41	SSPR1-41	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*42	SSPR1-42	4 trays	8 tests

Micro SSP Allele Specific HLA Class I Trays (continued)

Product Name	Cat Id	Sale Unit	Tests
Class I			
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*44	SSPR1-44	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*45	SSPR1-45	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*46/67/81/82	SSPR1-46	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*47	SSPR1-47	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*48	SSPR1-48	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*49/50	SSPR1-21	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*51/52/78	SSPR1-05	4 trays	4 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*53	SSPR1-53	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*54-56	SSPR1-22	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*57	SSPR1-57	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B*58	SSPR1-58	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - C*01	SSPR1-C01	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - C*02	SSPR1-C02	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - C*03	SSPR1-C03	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - C*04	SSPR1-C04	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - C*05	SSPR1-C05	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - C*06	SSPR1-C06	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - C*07	SSPR1-C07	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - C*08	SSPR1-C08	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - C*12	SSPR1-C12	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - C*14	SSPR1-C14	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - C*15	SSPR1-C15	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - C*16/17/18	SSPR1-C16	4 trays	8 tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - Null Allele	SSP1-NL	4 trays	4 tests

For In Vitro Diagnostic Use.

Micro SSP Allele Specific HLA Class II Trays

Product Name	Cat Id	Sale Unit	Tests
Class II			
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DQB1	SSPR2-Q1	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DRB1*01	SSPR2-101	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DRB1*03	SSPR2-103	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DRB1*04	SSPR2-104	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DRB1*07/09/10	SSPR2-107	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DRB1*08	SSPR2-108	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DRB1*11	SSPR2-111	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DRB1*12	SSPR2-112	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DRB1*13	SSPR2-113	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DRB1*14	SSPR2-114	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DRB1*15	SSPR2-115	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DRB1*16	SSPR2-116	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DRB3	SSPR2-3	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DRB4	SSPR2-4	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - DRB5	SSPR2-5	4 trays	8 tests
Micro SSP Allele Specific HLA Class II DNA Typing Tray - Null Allele	SSP2-NL	4 trays	24 tests

For In Vitro Diagnostic Use.

Micro SSP AmbiStrips™

The Micro SSP™ AmbiStrips offers a simple PCR method for resolving Ambiguities and Null Alleles commonly found in allelic typing strings, or to distinguish between heterozygous variants of B27 typings. The eight well strip design lets users target single allele specificities as needed.

Features and Benefits

- Resolves common Class I Ambiguities including B27 variants
- Resolves common Class I and Class II Null Alleles
- Pre-Aliquoted, lyophilized, and dispensed primers in an 8 well strip format
- Each strip provides 8 tests for one allelic specificity
- Positive control primers in each well to indicate amplification
- Use all at once or at selected increments
- Pre-labeled wells allows for easy identification of allele specificity
- Optimized PCR buffer ready to use

Product Name	Resolved Ambiguities	Cat Id	Sale Unit	Tests
Class I				
Micro SSP AmbiStrips HLA Class I - A0101N	A*01:01:01:02N	SSPT1-E1	1 Strip	8 tests
Micro SSP AmbiStrips HLA Class I - A0104N+ A0321N+ A2411N	A*01:04N, A*03:21N, A*24:11N	SSPT1-A1	1 Strip	8 tests
Micro SSP AmbiStrips HLA Class I - A0301N	A*03:01:01:02N	SSPT1-D1	1 Strip	8 tests
Product Name	Resolved Null Allele	Cat Id	Sale Unit	Tests
Class I				
Micro SSP AmbiStrips HLA Class I - A2409N	A*24:09N	SSPT1-C1	1 Strip	8 tests
Micro SSP AmbiStrips HLA Class I - B1501N	B*15:01:01:02N	SSPT1-G4	1 Strip	8 tests
Micro SSP AmbiStrips HLA Class I - A6811N	A*68:11N	SSPT1-H4	1 Strip	8 tests
Micro SSP AmbiStrips HLA Class I - B5111N	B*51:11N	SSPT1-B1	1 Strip	8 tests
Micro SSP AmbiStrips HLA Class I - C0320N	C*03:20N	SSPT1-A1	1 Strip	8 tests
Micro SSP AmbiStrips HLA Class I - C0409N	C*04:09N	SSPT1-H2	1 Strip	8 tests
Product Name	Resolved B27 Variants	Cat Id	Sale Unit	Tests
Class I				
Micro SSP AmbiStrips HLA Class I - B27+ B73	B*27 with B*73:02	SSPT1-G1	1 Strip	8 tests
Micro SSP AmbiStrips HLA Class I - B27+ B81	B*27 with B*81:01	SSPT1-F1	1 Strip	8 tests

(continued)

Product Name	Resolved Null Allele	Cat Id	Sale Unit	Tests
Class II				
Micro SSP AmbiStrips HLA Class II - DRB40103N	DRB4*01:03:01:02N	SSPT1-G2	1 Strip	8 tests
Micro SSP AmbiStrips HLA Class II - DRB50108N	DRB5*01:08N	SSPT1-F2	1 Strip	8 tests
Micro SSP AmbiStrips HLA Class II - DRB50110N	DRB5*01:10N	SSPT1-E2	1 Strip	8 tests
Product Name	Negative Control	Cat Id	Sale Unit	Tests
Micro SSP AmbiStrips Negative Control		SSPT1-H1	1 Strip	8 tests

Negative Control sold separately

Each strip provides 8 tests.

Non-NMDP coded allele specificities found at www.onelambda.com

For In Vitro Diagnostic Use.

DNA Size Markers

These are used as a reference in agarose gel electrophoresis for sizing PCR amplicons and restriction fragments less than 2564 bp in size. They consist of five DNA fragments with sizes of 50, 150, 400, 750 and 2564 base pairs.

Product Description	Cat Id	Sale Unit	Tests
DNA Size Marker	SSP-SM	vial	50 tests

Product Specifications DNA Size Markers

Storage Temperature:	-80° to -20° C
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Shipping Considerations:	Dry ice
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Packaging:	500 µl vial
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For General Laboratory Use.

SSP D-Mix

SSP D-Mix, for use with our Micro SSP DNA Typing Tests, may also be ordered separately if additional volumes are required for use with Micro SSP products. Available in several volumes:

Product Description	Cat Id	Sale Unit
DNA SSP D-mix - 1000 µl vial	DM1000-5	5-pk
DNA SSP D-mix - 180 µl vial	DM180-5	5-pk
DNA SSP D-mix - 270 µl vial	DM270-5	5-pk
DNA SSP D-mix - 360 µl vial	DM360-5	5-pk
DNA SSP D-mix - 540 µl vial	DM540-5	5-pk

Product Specifications	SSP D-Mix
Storage Temperature:	-80° to -20° C
Shipping Considerations:	Cold pack
Packaging:	5 vials in a foil bag
For In Vitro Diagnostic Use.	

PCR Tray/Seal Bundle

Blank PCR trays and tray seals are packaged together for your convenience.

Product Description	Cat Id	Sale Unit
PCR Tray Seals	SSPSEA300	300 tray seals
PCR Tray/Seal Bundle	PCRTRAC	pkg

Product Specifications	PCR Tray/ Seal Bundle
Storage Temperature:	20° to 25° C
Shipping Considerations:	Ambient temperature
Packaging:	25 blank trays and 80 tray seals
For General Laboratory Use.	

Micro SSP Gel System

This patented design has a small footprint and mirrors a 96-well PCR plate. The small box size reduces reagent requirements and has a shorter run time than conventional gel boxes. The system has a 108-well format and supports a 96-well microplate.

Product Description	Cat Id	Sale Unit
Micro SSP™ Gel System - 108 Wells	MGS108	each

For In Vitro Diagnostic Use



96-Well Transfer Device

Designed for use with 96-well plates or the Micro SSP Gel System, this device is easy to load, aspirate and wash. Made from durable, non-corrosive materials, it simplifies the reagent transfer process, reducing multiple transfer actions into one simple step. The device uses 96 pipettes to transfer reagents quickly and simultaneously across the tray, ensuring consistency throughout the array. Although suited for numerous applications when transferring from a 96-well plate, it is standardized for the One Lambda Micro SSP 96-well DNA typing trays.

Product Description	Cat Id	Sale Unit
96-Well Transfer Device	TRNDV96	each
96-Well Transfer Device Alignment Plate	TRNDVAP	each
96-Well Transfer Device Combo	TRNDCOMBO	combo

For General Laboratory Use.



PCR Pressure Pads

Our Micro SSP™ DNA typing system features a tray-sealing mechanism that uses a PCR pressure pad. The pads are available for the PE 9600, the PE 9700, and for MJ Research thermo cyclers.

Product Description	Cat Id	Sale Unit
Micro SSP PCR Pressure Pad (for 9600 PE Thermocycler, 96 wells)	SSPPAD	pad
Micro SSP PCR Pressure Pad (for 9600 PE Thermocycler, 96 wells)	SSPPAD5	5 pads
Micro SSP PCR Pressure Pad (for MJR Thermocycler, 96/384 wells)	SSPPADGRY	pad
Micro SSP PCR Pressure Pad (for MJR Thermocycler, 96/384 wells)	SSPPADGY5	5 pads
Micro SSP PCR Pressure Pad (for 9700 PE Thermocycler, 96/384 wells)	SSPPADTN	pad
Micro SSP PCR Pressure Pad (for 9700 PE Thermocycler, 96/384 wells)	SSPPADTN5	5 pads

For General Laboratory Use.



Micro SSP Seramates HLA Class

Seramates offer a focused approach to resolving questionable typings found in serology by providing a DNA backup to individually confirm selected specificities not always resolved by the HLA serological testing.

Note: All Seramates products, except SSPSB5, have been discontinued.

Product Name	Cat Id	Sale Unit	Tests
Micro SSP Allele Specific HLA Class I DNA Typing Tray - B5	SSPSB5	4 Trays	24

For Research Use Only. Not for use in diagnostic procedures.

SSP B27 Bulk Primer Set

The B27 Liquid Bulk Primer Sets use SSP technology to type for SSP alleles. The primers allow customers to configure their own typing tests and use only the primers they need.

Product Description	Cat Id	Sale Unit
SSP B27 Primer Set Combo (BSSPB2773, BSSPB2781)	BSSPB27C	combo

For Research Use Only. Not for use in diagnostic procedures.

Product Specifications

Storage Temperature:	-65° to -20° C
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Shipping Considerations:	Dry Ice
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Ancillary Products

One Lambda has a variety of ancillary products and reagents.

Taq Polymerase

Product Description	Cat Id	Sale Unit
Taq Polymerase - 30µl	TAQ30	bottle
Taq Polymerase - 50µl	TAQ50	bottle
Taq Polymerase - 75µl	TAQ75	bottle

For General Laboratory Use.

Product Specifications

Storage Temperature:	-20° or below
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Shipping Considerations:	Cold Pack
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Packaging:	bottle
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Buffer with Ethidium Bromide

Use this product with the Micro SSP Gel System for optimal results.

Product Description	Cat Id	Sale Unit
5XTB Buffer with Ethidium Bromide	5XTBE100	bottle

Product Specifications	Buffer with EB
Storage Temperature:	20° to 25° C
Shipping Considerations:	Ambient temperature
Packaging:	100 ml bottle

For General Laboratory Use.

SSP Wipe Test

SSP Class I and Class II wipe tests are used to test for PCR amplicon contamination. The wipe test primer set amplifies the internal control amplicon generated in the Micro SSP typing trays to determine if there is contamination by human DNA.

Product Description	Cat Id	Sale Unit	Tests
SSP Class I & II Wipe Test	SSPWT12	vial	100 tests

Product Specifications	SSP Wipe Test
Storage Temperature:	-65° to -20°C
Shipping Considerations:	Dry Ice
Packaging:	Primer (200µl vial) D-Mix (1,000 µl tube)

For General Laboratory Use.

G-RES™

A growing number of laboratories are evaluating next-generation sequencing (NGS) because it provides allele-level typing with minimal ambiguity. However, concerns remain over turnaround time, complexity of the workflow and data analysis, and cost of NGS consumables.

G-Res combines sequenced based typing (SBT) and reverse sequence specific oligonucleotide typing (rSSO); two technologies currently available in many laboratories; to produce single genotypes at G level resolution.

Features and Benefits

- Flexible – Can be applied to both low and high volume labs.
- Low Cost – Uses equipment and workflows already available in many labs
- Simple – Combination of SBT and rSSO data provides DNA sequence information

Product Description	Cat Id	Sale Unit	Tests
G-RES Typing Test	GRES	Assay	100 tests

For Research Use Only. Not for use in diagnostic procedures.

Cytokine Genotyping Tray and Primer Pack

Ongoing research continues to reveal the role of cytokine expression levels in organ transplants, cancer, AIDS, and autoimmune diseases. Cytokines are crucial in cellular communication and are key elements in controlling the immune response. One Lambda's Cytokine Genotyping Tray is a proven tool in identifying cytokine genotypes, while using the same simple testing procedure employed by our Micro SSP product line.

Product Description	Cat Id	Sale Unit	Tests
Cytokine Genotyping	CYTGEN	4 trays	24 tests
Cytokine Genotyping Primer Pack	PCYTGEN	each	100 tests

Storage	Cytokine Genotyping Trays	Cytokine Genotyping Primer Pack
Storage Temperature:	-65° C to -20° C	-65° C to -20° C
Shipping Considerations:	Cold pack	Dry Ice
Packing:	24 test package	100 test package

For Research Use Only. Not for use in diagnostic procedures.



KIR SSO Genotyping Test

Research suggests that natural killer cell immunoglobulin-like receptor (KIR) incompatibility may have an influence on bone marrow transplant patient outcome. Our KIR SSO Genotyping Test was designed to advance research on the impact of KIR on patient survival. Featuring Luminex xMAP technology, this test uses the same reverse SSO protocol used by our LABType products.

The KIR SSO Genotyping Test covers the following KIR genes and variants:

2DL1	2DS1	3DL1
2DL2	2DS2	3DL2
2DL3	2DS3	3DL3
2DL4	2DS4*	3DS1
2DL5*	2DS5	2DP1**
		3DP1**

*Plus null alleles **Pseudogenes

KIR SSO Genotyping Test

Product Description	Cat Id	Sale Unit	Tests
KIR SSO Genotyping Test	RSSOKIR	Pkg	40 tests

Product Specifications KIR SSO Genotyping Test

Storage Temperature:	-80° to -20° C
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Shipping Considerations:	Cold Pack
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Packing:	40 Test Package
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For Research Use Only. Not for use in diagnostic procedures.

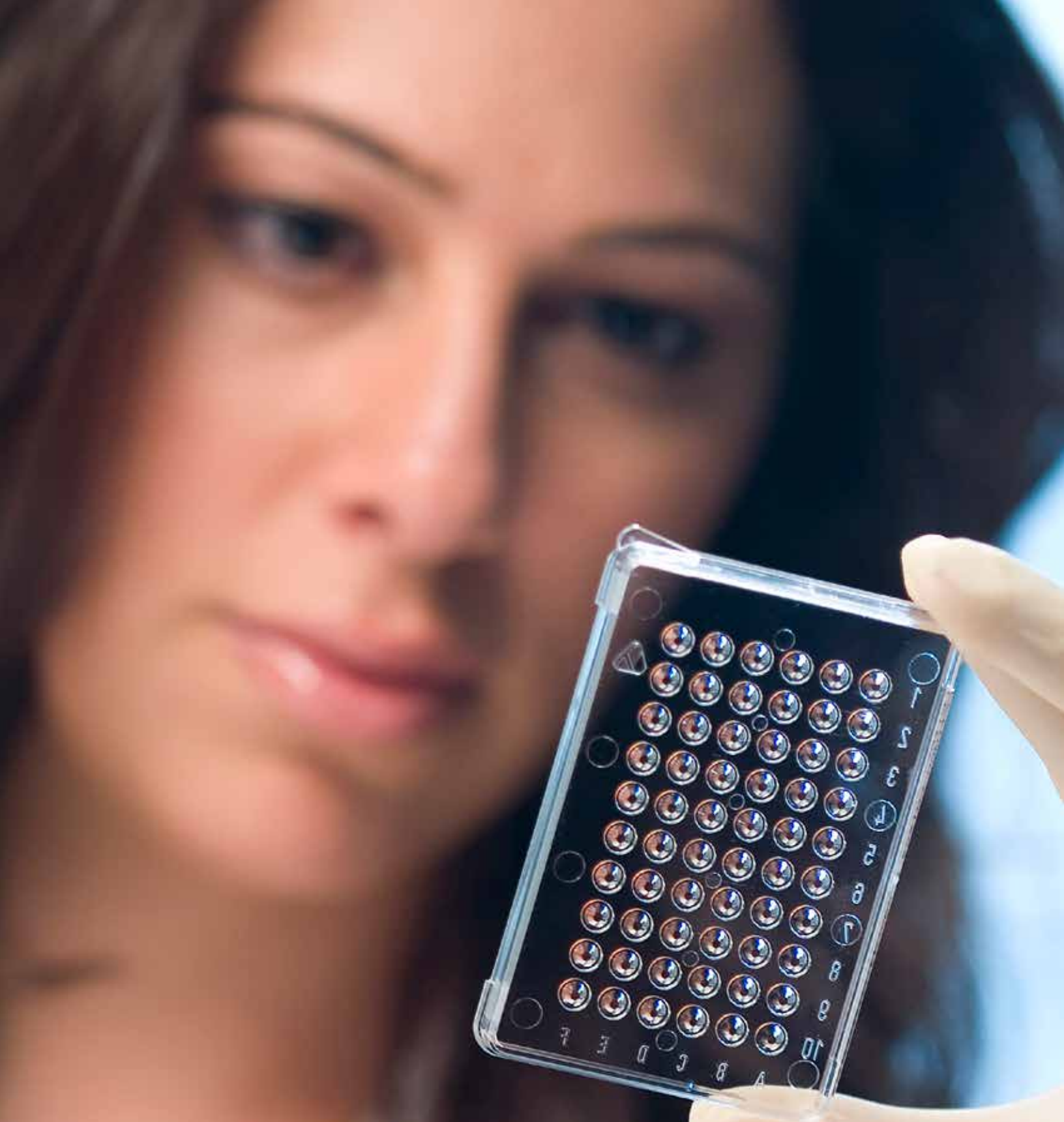
LinkSeq KIR Typing Kits

The LinkSeq family of KIR typing products are designed to advance research on the impact of KIR on patient survival rate. Killer cell immunoglobulin-like receptors (KIR) are a family of cell surface receptors found on human Natural Killer (NK) cells. Certain KIR types interact with Human Leukocyte Antigen (HLA) Class I molecules to inhibit the activity of NK cells while other KIR types can stimulate NK activity. Both HLA and KIR molecules are highly polymorphic. The LinkSeq™ KIR typing test is a genotyping system for identifying all 15 KIR genes and 2 pseudogenes including both full length and deleted forms of 3DP1 and 2DS4 and allele-specific variants in 3DL1, 2DL1, and others.

LinkSeq KIR Typing Kits

Product Description	Tray Type	Tests Per Kit	Cat ID
LinkSeq KIR Kit (1 Sample per Tray)	96 Well	10	5051R
LinkSeq KIR Kit (2 Sample per Tray)	96 Well	20	5052R
LinkSeq KIR 384 Kit (1 Sample per Tray)	384 Well	10	5351R
LinkSeq KIR 384 Kit (8 Sample per Tray)	384 Well	80	5358R

For Research Use Only. Not for use in diagnostic procedures.



SEROLOGY PRODUCTS

An industry vanguard in HLA tissue typing, One Lambda developed the first assays that accurately determine HLA antigens.

HLA Serological Typing

Serological HLA typing is a time honored methodology used in many laboratories around the world. One Lambda is recognized globally for its Terasaki Tissue Typing Trays, created by company founder Dr. Paul I. Terasaki. These typing trays were the first commercial assays capable of consistent and accurate determination of HLA antigens. As a proven technology, these assays are among the many products associated with One Lambda's pre-eminence in the field of HLA.

Our serological product line offers a broad spectrum of typing trays. In addition to the Terasaki T1, T2 and T3 NIH method typing trays, we offer a variety of specialty products that include locus specific, ethnic, supplemental and dry trays. One Lambda is the only commercial company that offers Lambda Monoclonal Typing Trays™ (LMT), a selection of typing trays that are completely composed of monoclonal antibodies pre-mixed with complement.

Our tissue typing family also includes lymphocyte isolation reagent products, LymphoKwik™ and FluoroBeads™, as well as other ancillary reagents optimized for use with HLA typing trays.

Page 88	Tissue Typing Trays Determination of HLA Class I & Class II antigens using the NIH complement dependent microlymphocytotoxic technique. Dry Tissue Typing Trays contain 1µl of dried HLA monoclonal antibody and comes with rabbit complement.
Page 92	Monoclonal Trays Lambda Monoclonal Trays are a dependable tool in determining HLA Class I & Class II using CDC in 1 hour.
Page 94	Reagents Designed for use with One Lambda HLA serological HLA typing trays.
Page 110	Ancillary One Lambda provides cover slides and blank 72-well Terasaki trays. Terasaki cover slides form a barrier over the reaction area of a Terasaki tray to prevent skin contact with reagents, and they provide a clear and distortion-free view of live and dead cells.

Tissue Typing Trays

One Lambda's Tissue Typing Trays produce accurate HLA typing of Class I and/or Class II antigens. Using a 72 well format, each tray includes both positive and negative controls using the NIH complement dependent cytotoxicity (CDC) method in 1.5 hours. Designed for use with either staining technique, eosin dye exclusion or fluorescence, each tray well contains 1 μ l of specific antiserum and 5 μ l of heavy mineral oil. Dry Tissue Typing Trays contain 1 μ l of dried HLA monoclonal antibody in each well. The Dry Class II trays also include anti-B and anti-T lymphocyte controls. Pre-screened rabbit complement is provided with all trays.

Features and Benefits

- Produces accurate typing assignments
- Supports consistent results due to long-lasting lots
- Offers a diverse tray selection
- Includes well characterized antisera
- May be used with both eosin dye exclusion and fluorescent techniques
- Kit includes prescreened rabbit complement
- 72-well Terasaki tray format

Principle

Viable lymphocytes are incubated with a complement-binding antibody. If the lymphocytes express an antigen recognized by a specific antibody, the Fab portion of the antibody binds to the antigen, forming the antigen-antibody complex. After these complexes have formed, rabbit complement is added. The C1q and Ca⁺⁺ from the complement binds to the FC portion of the antibody. One IgM antibody is required to bind one molecule of C1q or two IgG antibodies are required to bind one molecule of C1q. Binding of C1q with antigen-antibody complexes initiates the complement cascade that leads to cell lysis. In a negative reaction, the majority of lymphocytes appear intact. In a positive reaction, the majority of lymphocytes will be lysed. A score is assigned, depending on the percent of cells that have been lysed.

Intended Use • Applications

For use in the determination of HLA cell surface antigens with a complement dependent microlymphocytotoxic technique.

Workflow/Estimated Time

*Does not apply to Dry Trays.



2/10⁶ cell/ml lymphocytes



Dispense 1 µl of lymphocytes into each well



Incubate for 30 minutes at room temperature (20-25 °C)



Dispense 5 µl of rabbit complement into each well



Incubate for 1 hour at room temperature (20-25 °C)



Add 10 µl of Stain-Fix™ or 5 µl of FluoroQuench™ into each well



Read trays

Product Specifications

Tissue Typing Trays

Dry Tissue Typing Trays

Storage Temperature:

-65° C or below

2° to 5° C or below

Shipping Considerations:

Dry ice

Cold pack

Packaging:

10 trays per box

10 trays per box

For In Vitro Diagnostic Use.

Tissue Typing Trays

Product Name	Cat Id	Tests
Terasaki HLA-ABC First Tissue Typing Tray	T1-72	10 tests
Terasaki HLA-ABC Second Tissue Typing Tray	T2-72	10 tests
Terasaki HLA-ABC Third Tissue Typing Tray	T3-72	10 tests
Terasaki HLA-C Locus Tissue Typing Tray	C72	10 tests
Terasaki HLA-ABC Oriental Tissue Typing Tray	OT-72	10 tests
Terasaki HLA-A Locus Supplement Tissue Typing Tray	AS72	10 tests
Terasaki HLA-B Locus Supplement Tissue Typing Tray	BS72	10 tests
Terasaki HLA Class I Tissue Typing Tray Set	TM144	20 tests
Terasaki HLA Class II Tissue Typing Tray	DR72	10 tests

Dry Tissue Typing Trays

Product Name	Cat Id	Tests
Terasaki HLA Class I Dry Tissue Typing Tray	AB72D	10 tests
Terasaki HLA-B27 Dry Tissue Typing Tray	27-06D	10 tests
Terasaki HLA Class II Dry Tissue Typing Tray	DR72D	10 tests
Terasaki HLA Class I Asian Dry Tissue Typing Tray	ASN72D	10 tests

For In Vitro Diagnostic Use.



Monoclonal Trays™

Lambda Monoclonal Trays™, a One Lambda exclusive, are an extremely dependable tool in determining HLA Class I or Class II antigens. Each tray is comprised of monoclonal antibodies, rather than human anti-serum; each tray has both positive and negative controls using the CDC method in one hour. Designed for use with either staining technique, eosin dye exclusion or fluorescence, each tray well contains one μ l of monoclonal antibodies premixed with rabbit complement and five μ l of heavy mineral oil.

Features and Benefits

- Offers batch-to-batch consistency
- Eliminates complement QC testing
- Produces test results in one hour or less
- Can be used with both dye exclusion and fluorescent techniques
- Provides a consistent source of reagents
- Monoclonal antibodies and complement are pre-mixed in each well

Intended Use • Applications

For use in the determination of HLA Class I and Class II antigens with a complement dependent microlymphocytotoxic technique.

Workflow/Estimated Time



1 Add 1 μ l of lymphocytes. Thaw the LMT™ (s) at room temperature. Dispense 1 μ l of lymphocytes into each well. Incubate for 1 hour.



2 Stop Trays. Add the appropriate staining/fixing reagent to the LMT™ (s). The reagent for this purpose is FluoroQuench™ which has been standardized for use with the LMT™.

LMT HLA Class I/II

Product Name	Cat Id	Package	Tests
Class I			
Lambda Monoclonal Trays HLA Class I - 96 well	LM96	10 trays	10 tests
Lambda Monoclonal Trays First HLA Class I	LM172	10 trays	10 tests
Lambda Monoclonal Trays Second HLA Class I	LM272	10 trays	10 tests
Lambda Monoclonal Trays Set HLA Class I	2LM72	10 sets	20 tests
Lambda Monoclonal Trays Third HLA Class I	LM372	10 trays	10 tests
Lambda Monoclonal Trays HLA Class I (Oriental)	LM72OR	10 trays	10 tests
Lambda Monoclonal Trays Set HLA Class I (A,B) - 2-tray set	LM144	10 sets	20 tests
Class II			
Lambda Monoclonal Trays First HLA Class II	MDR172	10 trays	10 tests
Lambda Monoclonal Trays Second HLA Class II	MDR272	10 trays	10 tests

Product Specifications Lambda Monoclonal Trays™

Storage Temperature: -65° C or below

Shipping Considerations: Dry ice

Packaging: 10 trays per box

For In Vitro Diagnostic Use.

Reagents

LymphoKwik™

These reagents provide a unique method for isolating specific lymphocyte populations. Unlike standard density gradients, LymphoKwik uses a combination of monoclonal antibodies, complement and a stable density gradient to isolate the desired lymphocyte population. The procedure provides high purity and viability, saving valuable time in the process.

Lympho-Kwik Cell Isolations

Product Name	Cat Id	Package	Tests
Lympho-Kwik Mononuclear Cell, 50 isolations	LK-50-MN	Bottle	50 tests
Lympho-Kwik T Lymphocyte, 25 isolations	LKT25	Bottle	25 tests
Lympho-Kwik T Lymphocyte, 50 isolations	LK-50-T	Bottle	50 tests
Lympho-Kwik T/B Lymphocyte, 25 isolations	LKTB25	Bottle	25 tests
Lympho-Kwik T/B Lymphocyte, 50 isolations	LK-50-TB	Bottle	50 tests

Product Specifications LymphoKwik

Storage Temperature:	-65° C or below
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Shipping Considerations:	Dry ice
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Packaging:	20 ml bottle (25 isolations) or 40 ml bottle (50 isolations)
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For In Vitro Diagnostic Use.

FluoroBeads

FluoroBeads T and FluoroBeads B Isolation Reagents are supraparamagnetic particles coupled to monoclonal antibodies specific to T or B lymphocytes, respectively. The end result is a pure T or B lymphocyte population in less than 10 minutes.

FluoroBeads feature a particle size less than one micron in diameter, minimizing cell membrane damage, facilitating the use of automation, and increasing fluorescent intensities.

FluoroBeads Isolation Reagents

Product Name	Cat Id	Package	Tests
FluoroBeads T Lymphocyte - 25 isolations	FB1-25	bottle	25 tests
FluoroBeads T Lymphocyte - 100 isolations	FB1-100	bottle	100 tests
FluoroBeads T Developer (10X)	FB1-DEV	bottle	
FluoroBeads B Lymphocyte - 25 isolations	FB2-25	bottle	25 tests
FluoroBeads B Lymphocyte - 100 isolations	FB2-100	bottle	100 tests
Phosphate Buffered Saline/Citrate Reagent	PC1-500	bottle	
FluoroBeads Magnet	FBAMAG6+6	box	

Product Specifications	FluoroBeads	Magnets	PBS/Citrate Developer
Storage Temperature:	2° to 5° C	Not applicable	2° to 5° C
Shipping Considerations:	Cold pack	Strong magnetic field generated	Ambient temperature
Packaging:	Box	Individually boxed	Box

For In Vitro Diagnostic Use.



One Lambda has developed a host of ancillary reagents optimized for use as accessories with our HLA typing trays. These products include rabbit complement, staining, quenching and fixing reagents, mineral oil, AHG and controls.

Bulk Rabbit Complement

Our Class I and Class II rabbit complements are screened for activity and cytotoxicity using highly selective lymphocyte panels and characterized antisera to minimize lot-to-lot variation.

Rabbit serum is the most effective source of complement for HLA typing, antibody screening and crossmatching. Complement effectiveness is related to the titer, and to complement factors and heterophile antibodies.

Product Name	Cat Id	Package
Class I Complement - 5 ml	CABC-5	bottle
Class I Complement - 50 ml	CABC-50	bottle
Class II Complement - 5 ml	CDR-5	bottle
Class II Complement - 50 ml	CDR-50	bottle
Lyophilized Class I Complement - 1 ml	CABC-1D	bottle
Lyophilized Class II Complement - 1 ml	CDR-1D	bottle

Product Specifications	Frozen Complement	Lyophilized Complement
Storage Temperature:	-65° C or below	2° to 5° C
Shipping Considerations:	Dry ice	Ambient temperature
Packaging:	Complement: 5 ml or 50 ml bottle	1 ml bottle

For In Vitro Diagnostic Use.

FluoroQuench Staining/Quench Reagent

FluoroQuench is a unique mixture of fluorescent dyes and quench; used to stain lymphocytes, quench background fluorescence and stop the reaction in one simple step. FluoroQuench AO/EB distinguishes both live and dead cells by dye color and preserves the reaction in a microtoxicity assay. No additional dyes are required. FluoroQuench contains a fixative.

FluoroQuench Acridine Orange/Ethidium Bromide FQAEZ100

Product Name	Cat Id	Package
FluoroQuench Acridine Orange/Ethidium Bromide - 100 ml	FQAE100	bottle
FluoroQuench Acridine Orange/Ethidium Bromide - 500 ml	FQAE500	bottle
FluoroQuench Acridine Orange/Ethidium Bromide - 2000 ml	FQAE2000	4-500 ml bottles
FluoroQuench Plus Acridine Orange/Ethidium Bromide - 100 ml	FQZAE100	bottle

Product Specifications Fluoroquench

Storage Temperature:	2° to 5° C
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Shipping Considerations:	Cold Pack
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Packaging:	100 ml bottles 500 ml bottles
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For In Vitro Diagnostic Use.

Mineral Oil

Mineral oil is used in the microcytotoxicity assay to prevent the evaporation of antisera dispensed onto a Terasaki Typing Tray. One Lambda offers a heavy mineral oil that prevents evaporation and facilitates the mixing of reagents in each well.

Product Name	Cat Id	Package
Heavy Mineral Oil, 1 gallon	MO	bottle

Product Specifications Mineral Oil

Storage Temperature:	20° to 25° C
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Shipping Considerations:	Ambient temperature
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Packaging:	1 gallon bottle
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For General Laboratory Use.

Dynabeads

Gentle, tube-based magnetic separation with Dynabeads is the technology of choice when you want to isolate high yields of pure, viable and functional cells. Your cells are not exposed to the stress of going through a dense column, and there's no risk of your results being affected by the isolation method.

Reduce variability and get truly reliable and reproducible lab results on which to build your studies, diagnostic assays and therapeutic protocols.

Product Description	Cat Id
Dynabeads HLA Class II - 20 isolations	21903
Dynabeads HLA Class II - 50 isolations	21904

For In Vitro Diagnostic Use.

Product Name	Cat Id
Dynabeads HLA Class I - 20 isolations	21001D
Dynabeads HLA Class I - 50 isolations	21002D
Dynabeads HLA Class II - 20 isolations	21003
Dynabeads HLA Class II - 50 isolations	21004D

For In Vitro Diagnostic Use. (Limited to distribution in EU only).

Dynabeads for Transplant research

Product Description	Cat Id
Dynabeads HLA Class I - 20 isolations	21901BD
Dynabeads HLA Class I - 50 isolations	21902BD

For Research Use Only. Not for use in diagnostic procedures.

Product Specifications	Dynabeads HLA Class I & II
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Storage Temperature:	2° to 8° C
Shipping Considerations:	Cold Pack
Amount:	20, 50 isolations

B27 Monoclonal Antibody

Product Name	Cat Id	Tests	Sale Unit
HLA Class I Fluorescein Isothiocyanate (FITC) Conjugated Monoclonal Antibody	HLA1F50X	50 test	vial
HLA-B27 Fluorescein Isothiocyanate (FITC) Conjugated Monoclonal Antibody	B27F50X	50 test	vial
Mouse IgG2b Fluorescein Isothiocyanate (FITC) Conjugated Monoclonal Antibody	G2BF50X	50 test	vial

For In Vitro Diagnostic Use.

B27 Monoclonal antibody for transplant research

HLA B7, 27 IgG Biotinylated Conjugated Monoclonal Antibody	BIH1453	25 test	vial
HLA B7, 27 IgG Fluorescein Isothiocyanate (FITC) Conjugated Monoclonal Antibody	FH1453	25 test	vial

For Research Use Only. Not for use in diagnostic procedures.



Serology Reagents for Transplant Research

Cytotoxic Controls

Designed for the microcytotoxicity assay, One Lambda cytotoxic controls are used to test various conditions from the purity of a lymphocyte preparation to the reactivity of complement. One Lambda cytotoxic controls are provided in frozen form in 1 ml aliquots. The negative control is from a nontransfused AB male donor(s).

Product Name	Cat Id	Package
Class I		
Anti-T Lymphocyte, IgG (Not for use with FluoroBeads cell preparations)	ATSG	bottle
Anti-T Lymphocyte, IgM (Not for use with FluoroBeads cell preparations)	ATSM	bottle
Anti-T Lymphocyte, IgM (For use with FluoroBeads cell preparations)	ATSMX	bottle
Class II		
Anti-B Lymphocyte, IgG	ABSG	bottle
Anti-B Lymphocyte, IgM	ABSM	bottle
Class I & II		
Anti-Monocyte, IgM	AMSM	bottle
Anti-Granulocyte, IgM	AGSM	bottle
Anti-Lymphocyte, IgG	ALSG	bottle
Anti-Lymphocyte, IgM	ALSM	bottle
Negative Control	NS	bottle

Product Specifications

Controls

Storage Temperature:	-20° C
Shipping Considerations:	Dry ice
Packaging:	1 ml bottle

For Research Use Only. Not for use in diagnostic procedures.

Goat IgG Anti-Human Kappa

Goat IgG Anti-Human Kappa augments the cytotoxic reactivity of HLA antibodies, cytotoxic negative absorption positive (CYNAP) reactive antibodies, by at least 4 to 8-fold, depending on the titer of HLA serum.

Product Name	Cat Id	Package
Class I & II		
Goat IgG Anti-Human Kappa - 1 ml	AHG1	tube
Goat IgG Anti-Human Kappa - 50 ml	AHG50	tube

Product Specifications

IgG

Storage Temperature: -65° C or below

Shipping Considerations: Dry ice

Packaging: IgG: 1 ml or 50 ml tube

For Research Use Only. Not for use in diagnostic procedures.

FITC Conjugated Monoclonal Antibodies

Product Name	Isotype	Cat Id	Tests
HLA A2,A28 IgG2a Fluorescein Isothiocyanate (FITC) Conjugated Monoclonal Antibody	IgG2a	FH0037	25 tests
HLA A9 IgG2b Fluorescein Isothiocyanate (FITC) Conjugated Monoclonal Antibody	IgG2b	FH0964	25 tests
HLA B7,27 IgG Fluorescein Isothiocyanate (FITC) Conjugated Monoclonal Antibody	IgG	FH1453	25 tests
HLA B8 IgG2b Fluorescein Isothiocyanate (FITC) Conjugated Monoclonal Antibody	IgG2b	FH0536A	25 tests
HLA B12 IgG2b Fluorescein Isothiocyanate (FITC) Conjugated Monoclonal Antibody	IgG2b	FH0066	25 tests
HLA Bw4 IgG2a Fluorescein Isothiocyanate (FITC) Conjugated Monoclonal Antibody	IgG2a	FH0007	25 tests
HLA Bw6 IgG3 Fluorescein Isothiocyanate (FITC) Conjugated Monoclonal Antibody	IgG3	FH0038	25 tests
HLA Class II IgG2a Fluorescein Isothiocyanate (FITC) Conjugated Monoclonal Antibody	IgG2a	FH0002	25 tests

Conjugated HLA Monoclonal Antibodies are supplied in liquid form.

For Research Use Only. Not for use in diagnostic procedures.

Biotinylated Monoclonal Antibodies

Product Name	Isotype	Cat Id	Tests
HLA A1,36 IgM Biotinylated Conjugated Monoclonal Antibody	IgM	BIH0331	25 tests
HLA A2 IgM Biotinylated Conjugated Monoclonal Antibody	IgM	BIH0648	25 tests
HLA A2, 28 IgG2a Biotinylated Conjugated Monoclonal Antibody	IgG2a	BIH0037	25 tests
HLA A3 IgM Biotinylated Conjugated Monoclonal Antibody	IgM	BIH0269	25 tests
HLA A9 IgG2b Biotinylated Conjugated Monoclonal Antibody	IgG2b	BIH0964	25 tests
HLA A11 IgM Biotinylated Conjugated Monoclonal Antibody	IgM	BIH0084	25 tests
HLA A25, 26 IgM Biotinylated Conjugated Monoclonal Antibody	IgM	BIH0048	25 tests
HLA A29 IgM Biotinylated Conjugated Monoclonal Antibody	IgM	BIH0155	25 tests
HLA A30,31 IgM Biotinylated Conjugated Monoclonal Antibody	IgM	BIH0087	25 tests
B7, 27 Biotinylated Conjugated Monoclonal Antibody	IgG	BIH1453	25 tests
B51, 52, 7801 IgM Biotinylated Conjugated Monoclonal Antibody	IgM	BIH0209	25 tests
B8 IgG2b Biotinylated Conjugated Monoclonal Antibody	IgG2b	BIH0536A	25 tests
HLA B13 IgM Biotinylated Conjugated Monoclonal Antibody	IgM	BIH0261	25 tests
HLA B13,15 IgM Biotinylated Conjugated Monoclonal Antibody	IgM	BIH0129	25 tests
HLA B15,57 IgM Biotinylated Conjugated Monoclonal Antibody	IgM	BIH0507	25 tests
HLA B57,58 IgM Biotinylated Conjugated Monoclonal Antibody	IgM	BIH0243	25 tests
HLA Bw4 IgG2a Biotinylated Conjugated Monoclonal Antibody	IgG2a	BIH0007	25 tests
HLA Bw6 IgG3 Biotinylated Conjugated Monoclonal Antibody	IgG3	BIH0038	25 tests
HLA DR4 IgM Biotinylated Conjugated Monoclonal Antibody	IgM	BIH0453B	25 tests

Biotinylated Monoclonal Antibodies (continued)

Product Name	Isotype	Cat Id	Tests
HLA DR7 IgM Biotinylated Conjugated Monoclonal Antibody	IgM	BIH0108	25 tests
HLA Class I IgG1 Biotinylated Conjugated Monoclonal Antibody	IgG1	BIH1112	25 tests
HLA Class II IgG2a Biotinylated Conjugated Monoclonal Antibody	IgG2a	BIH0002	25 tests

Conjugated HLA Monoclonal Antibodies are supplied in liquid form.
For Research Use Only. Not for use in diagnostic procedures.

Unconjugated Lyophilized Monoclonal Antibodies

These antibodies are supplied in lyophilized form (reconstitute to 100ul with distilled water). Specificity was determined at a 1:10 dilution by the microcytotoxicity assay using standard NIH conditions.

Product Name	Isotype	R-Value	Cat Id
HLA Class I			
Bulk Monoclonal Antibody A1,11,26+ IgM	IgM	1.000	0544HA
Bulk Monoclonal Antibody A1,36 IgM	IgM	0.969	0289HA
Bulk Monoclonal Antibody A2 IgM	IgM	0.966	0397HA
Bulk Monoclonal Antibody A2 IgM	IgM	0.982	0475HA
Bulk Monoclonal Antibody A2 IgG	IgG	0.937	0791HA
Bulk Monoclonal Antibody A2,3,29+ IgM	IgM	0.818	0887HA
Bulk Monoclonal Antibody A2,24 IgM	IgM	0.843	0138HA
Bulk Monoclonal Antibody A2,25,32+ IgM	IgM	1.000	0578AHA
Bulk Monoclonal Antibody A2,28+ IgM	IgM	0.934	0189HA
Bulk Monoclonal Antibody A2,69 IgG	IgG	0.949	0131HA
Bulk Monoclonal Antibody A2,+/-69 IgM	IgM	0.931	0335HA
Bulk Monoclonal Antibody A2,B5 IgM	IgM	0.932	0840AHA
Bulk Monoclonal Antibody A2,B17 IgM	IgM	0.967	0543HA
Bulk Monoclonal Antibody A2,B17 IgM	IgM	0.886	0580BHA
Bulk Monoclonal Antibody A3 IgM	IgM	0.900	0141HA
Bulk Monoclonal Antibody A3 IgM	IgM	0.949	0170HA

Unconjugated Lyophilized Monoclonal Antibodies (continued)

Product Name	Isotype	R-Value	Cat Id
HLA Class I			
Bulk Monoclonal Antibody A3 IgM	IgM	1.000	0378HA
Bulk Monoclonal Antibody A9,25,32 IgM	IgM	0.966	0341HA
Bulk Monoclonal Antibody A9,32,B13+ IgM	IgM	0.745	0549HA
Bulk Monoclonal Antibody A10,11+ IgM	IgM	0.942	0553HA
Bulk Monoclonal Antibody A10,28,B75+ IgM	IgM	0.803	0660HA
Bulk Monoclonal Antibody A10,B62,71+ IgM	IgM	0.840	0662HA
Bulk Monoclonal Antibody A11, +/-3 IgG	IgG	0.805	0284HA
Bulk Monoclonal Antibody A23,24 IgG2b	IgG2b	0.982	0041HA
Bulk Monoclonal Antibody A23,24 IgM	IgM	0.765	0497HA
Bulk Monoclonal Antibody A24,11,2403+ IgM	IgM	0.783	0586AHA
Bulk Monoclonal Antibody A25,26,34 IgM	IgM	0.886	0514AHA
Bulk Monoclonal Antibody A25,32 IgM	IgM	1.000	0136HA
Bulk Monoclonal Antibody A25+ IgG	IgG	0.768	0473HA
Bulk Monoclonal Antibody A25,26,34,B71,62 IgM	IgM	0.808	0102HA
Bulk Monoclonal Antibody A29 IgM	IgM	0.722	0334HA
Bulk Monoclonal Antibody A30,31 IgM	IgM	0.927	0273HA
Bulk Monoclonal Antibody A30,31 IgM	IgM	0.876	0361HA
Bulk Monoclonal Antibody A33,B8 IgM	IgM	0.740	0612HA
Bulk Monoclonal Antibody A34,B71,-/+A26 IgM	IgM	0.660	0119HA
Bulk Monoclonal Antibody B5,49,56+ IgM	IgM	0.702	0070HA
Bulk Monoclonal Antibody B7,27,42+ IgM	IgM	0.860	0884HA
Bulk Monoclonal Antibody B8 IgM	IgM	1.000	0059HA
Bulk Monoclonal Antibody B8 IgM	IgM	1.000	0201HA
Bulk Monoclonal Antibody B8 IgM	IgM	1.000	0404HA
Bulk Monoclonal Antibody B8,14 IgM	IgM	0.953	0332HA
Bulk Monoclonal Antibody B12,76+ IgG	IgG	0.691	0735AHA
Bulk Monoclonal Antibody B13 IgM	IgM	1.000	0211BHA
Bulk Monoclonal Antibody B13,62,15 IgG	IgG	0.554	0044HA

For Research Use Only. Not for use in diagnostic procedures.

Unconjugated Lyophilized Monoclonal Antibodies (continued)

Product Name	Isotype	R-Value	Cat Id
Bulk Monoclonal Antibody B14+ IgM	IgM	0.684	0833HA
Bulk Monoclonal Antibody B14 IgM	IgM	0.631	0277HA
Bulk Monoclonal Antibody B17 IgM	IgM	1.000	0196HA
Bulk Monoclonal Antibody B17,35,44+ IgM	IgM	0.823	0786BHA
Bulk Monoclonal Antibody B21,70,55+ IgM	IgM	0.803	0495HA
Bulk Monoclonal Antibody B27,44,47+ IgG	IgG	0.614	0792AHA
Bulk Monoclonal Antibody B35,57,75,77+ IgM	IgM	0.609	0789AHA
Bulk Monoclonal Antibody B44,75,17+ IgM	IgM	0.754	0601HA
Bulk Monoclonal Antibody B48,60+ IgM	IgM	0.740	0831HA
Bulk Monoclonal Antibody Bw4,A9,32 IgM	IgM	1.000	0548HA
Bulk Monoclonal Antibody Bw6,B77	IgM	0.935	0149AHA
HLA Class II			
Bulk Monoclonal Antibody DR3,6+ IgM	IgM	0.750	0260HA
Bulk Monoclonal Antibody DR3,6 IgG	IgG	–	0219HA
Bulk Monoclonal Antibody DR4+ IgM	IgM	–	0222HA
Bulk Monoclonal Antibody DR7+ IgM	IgM	0.740	0757AHA
Bulk Monoclonal Antibody DR8,12+ IgM	IgM	0.900	0834AHA
Bulk Monoclonal Antibody DR8,12+ IgM	IgM	0.830	0861HA
Bulk Monoclonal Antibody DR9+ IgM	IgM	0.860	0399HA
Bulk Monoclonal Antibody DR11 IgG	IgG	0.820	0845HA
Bulk Monoclonal Antibody DR11 IgM	IgM	0.900	0854HA
Bulk Monoclonal Antibody DR13+ IgG	IgG	0.750	0258HA
Bulk Monoclonal Antibody DR15,16 IgG	IgG	0.700	0218HA
Bulk Monoclonal Antibody DR15,16 IgM	IgM	0.920	0435AHA
Bulk Monoclonal Antibody DR17,18 IgM	IgM	0.900	0356HA
Bulk Monoclonal Antibody DR17,18 IgM	IgM	0.870	0500HA
Bulk Monoclonal Antibody DR52 IgM	IgM	0.840	0635HA
Bulk Monoclonal Antibody DR52+ IgM	IgM	0.760	0781HA
Bulk Monoclonal Antibody DR53+ IgG	IgG	0.610	0275HA

For Research Use Only. Not for use in diagnostic procedures.

Unconjugated Lyophilized Monoclonal Antibodies (continued)

Product Name	Isotype	R-Value	Cat Id
Bulk Monoclonal Antibody DQ1,7 IgM	IgM	0.850	0265HA
Bulk Monoclonal Antibody DQ3+ IgM	IgM	0.830	0782HA
Bulk Monoclonal Antibody DQ4+ IgM	IgM	0.840	0736HA
Bulk Monoclonal Antibody DQ6+ IgM	IgM	0.750	0237HA
Bulk Monoclonal Antibody DQ7 IgM	IgM	0.910	0248HA
Bulk Monoclonal Antibody DQ7 IgM	IgM	0.870	0249AHA
Bulk Monoclonal Antibody DQ7 IgM	IgM	0.870	0267HA
Bulk Monoclonal Antibody DQ7 IgM	IgM	0.910	0280HA
Bulk Monoclonal Antibody DQ7+ IgM	IgM	0.880	0769AHA
Bulk Monoclonal Antibody DQ7 IgM	IgM	0.880	0778HA

Product Specifications FITC/Biotinylated

Unconjugated/Lyophilized

Storage Temperature:	2° to 5° C	2° to 5° C
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Shipping Considerations:	Cold Pack	Ambient temperature
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Packaging:	Vial in foil bag	Vial in foil bags
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For Research Use Only. Not for use in diagnostic procedures unless specified otherwise.

Ancillary

Terasaki Cover Slides

FluoroSeal™ and InstaSeal™ Cover Slides are designed specifically for One Lambda's 60- and 72-well Terasaki Typing Trays. When applied to the Terasaki Typing Tray, a barrier is formed over the reaction area to prevent skin contact with reagents.

FluoroSeal™ Cover Slides: Used in fluorescence testing, black plastic cover slides minimize photo-bleaching.

InstaSeal™ Cover Slides: Used in standard dye exclusion testing, clear plastic covers provide a clear, distortion-free view of live and dead cells.

Product Name	Cat Id	Package
Insta-Seal™ Cover Slides - 250 slides	TIS-250U	box
IFluoroSeal™ Cover Slides - 250 slides	TFS-250U	box

For General Laboratory Use.

Product Specifications Terasaki Cover Slides

Storage Temperature:	20° to 25° C
Shipping Considerations:	Ambient temperature
Packaging:	250 slides per box

Terasaki Trays

Terasaki Typing Trays are available with in 60-, 72-, and 96-well sizes, in packages of 100 each. The plastics used in producing these trays are the same materials used by One Lambda for Terasaki Tissue Typing Trays and other One Lambda products.

Product Name	Cat Id	Package
Terasaki Tray (STD) 60 well - 100 trays	TH60-100	box
Terasaki Tray (STD) 72 well - 100 trays	TH72-100	box
Terasaki Tray (STD) 96 well - 100 trays	TH96-100	box

For General Laboratory Use.



Transfusion & Transfusion Research

Antibody Detection For Transfusion Diagnostics

LABScreen Multi

LABScreen Multi is used for screening for antibodies against both HLA Class I, Class II, and HNA3a (Human Neutrophil Antigens). Antibodies against HNA are implicated in a variety of clinical conditions, including TRALI (Transfusion Related Acute Lung Injury). All LABScreen products qualitatively measure the presence of specific antibodies in a human serum or plasma sample.

Product Description	Cat Id	Sale Unit	Tests
LABScreen Multi	LSMUTR	pkg	100 tests

For In Vitro Diagnostic Use.

Molecular Typing For Transfusion Diagnostics

HNA Genotyping Tray

Human Neutrophil antigens (HNA) are involved in a variety of clinical conditions, including immune neutropenias, transfusion related acute lung injury (TRALI), refractoriness to granulocyte transfusions, and febrile transfusion reactions. Due to the unavailability of certain HNA antibodies and type specific neutrophil antigens, serological methods are time consuming and limited in detection. With One Lambda's sequence specific primer PCR based genotyping tray, blood centers can effectively assign HNA alleles, including HNA-3a.

Product Description	Cat Id	Sale Unit	Tests
HNA Genotyping Tray	HNAGEN	4 trays	8 tests

For In Vitro Diagnostic Use.

Storage HNA Genotyping Tray

Storage Temperature:	-80° to -20° C
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Shipping Considerations:	Cold Pack
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Packing:	4 Trays in a Box
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LinkSeq™ Typing Kits

Fast and Easy Real-time PCR Genotyping

LinkSeq is a rapid genotyping method with a simple workflow that prevents post-amplification contamination. With a fast turnaround time of only 90 minutes, and minimal hands-on time, your lab's productivity will greatly increase.

With LinkSeq, you can achieve high throughput. By using inexpensive thermal cyclers for the first 60 minutes of the amplification step and only 10 minutes on a real time PCR instrument, you can type multiple samples per hour with unmatched simplicity. Products include HPA and ABO.

Features and Benefits

- More productivity with less effort
- Fewer repeats with less steps and reproducible results
- SureTyper software for robust and automated analysis

LinkSeq™ HPA Typing Kits

Human Platelet Antigens (HPA) are glycoproteins expressed on platelet membranes. These HPAs can stimulate the production of alloantibodies after transfusion. In subsequent blood transfusions, alloantibodies against donor HPA may cause immunological reactions in the recipient's blood, resulting in the lysis of the transfused platelets and thrombocytopenia. The LinkSeq HPA kits provide HPA typing for HPA-1 through HPA-11, and HPA 15.

Product Description	Tray Type	Tests per Kit	Cat ID
LinkSeq HPA Kit (1 Sample per Tray)	96 Well	10	6001C
LinkSeq HPA Kit (2 Sample per Tray)	96 Well	20	6002C
LinkSeq HPA 384 Kit (2 Sample per Tray)	384 Well	20	6302C
LinkSeq HPA 384 Kit (8 Sample per Tray)	384 Well	80	6308C

For In Vitro Diagnostic Use. European Union Only

Product Description	Tray Type	Tests per Kit	Cat ID
LinkSeq HPA Kit (1 Sample per Tray)	96 Well	10	6001R
LinkSeq HPA Kit (2 Sample per Tray)	96 Well	20	6002R
LinkSeq HPA 384 Kit (2 Sample per Tray)	384 Well	20	6302R
LinkSeq HPA 384 Kit (8 Sample per Tray)	384 Well	80	6308R

For Research Use Only. Not For Use in Diagnostic Procedures.

Molecular Typing For Transfusion Research

LinkSēq™ ABO

ABO alleles encode the enzyme Glycosyltransferase, which adds sugar groups to the surface of red blood cells (RBC) and other cells. ABO has been implicated in tissue rejection as well as adverse transfusion reactions. Many A subgroups involve a weakly expressed A antigen, which can cause discordant serological reactions in forward and reverse typing. Our ABO products enable you to get results from problematic samples, and to resolve A, B and O subgroups.

Features and Benefits

- Identify weakly expressed phenotypes
- Identify possible Bombay phenotype
- Get results from problem samples”

Product Description	Tray Type	Tests per Kit	Cat ID
LinkSēq ABO Kit (1 sample per tray)	96-well	10	6021R
LinkSēq ABO Kit (2 samples per tray)	96-well	20	6022R
LinkSēq ABO 384 Kit (1 sample per tray)	384 well	10	6321R
LinkSēq ABO 384 Kit (8 samples per tray)	384 well	80	6328R

For Research Use Only. Not for use in diagnostic procedures.

A white, boxy laboratory instrument with a control panel on top and a sample compartment on the right. The front panel features the One Lambda logo and the model name. A vertical window on the right shows internal components with blue lights.

ONE LAMBDA
LABSCAN3D™

THE
POWER
INSIDE
One Lambda

XMA
TECHNOLOGY
www.onelambda.com

INSTRUMENTS & SOFTWARE

Simplify laboratory procedures and diagnostic analysis with One Lambda's automation and software solutions.

Automation and Software Flexibility

Workflow, effectiveness and the optimal use of resources are central to modern laboratory operations. One Lambda's automation and software products help managers to streamline processes for increased efficiency. Designed with function and cost effectiveness in mind, our technology supports the automation of tasks in the HLA laboratory. When well-designed automation and robust software solutions are at work, laboratories can deliver test results with greater confidence and ease.

One Lambda's state of the art equipment provides optimal support for high and low through-put laboratories. The LABScan™ 100 and LABScan3D, based on Luminex® xMAP® technology, can rapidly process up to 96 samples. Bring automation to new a level with the LABXpress™ Pipettor—supports faster processing time, performance uniformity, and is optimal for high throughput testing.

Page

00 Automated Pipettors/Dispensers

Featuring the One Lambda LABXpress Pipettor.

Page

00 Readers/Analyzers

Featuring the LABScan100, LABScan3D, and Ion S5™ and S5™ XL Systems.

Page

00 Software

Designed for use with One Lambda assays.

Automated Pipettors/Dispensers

LABXpress™ Pipettor

The LABXpress Pipettor handles dispensing and mixing with precision and ease. Perfect for high throughput testing, LABXpress reduces turnaround time and enhances automation. With worry-free tracking and walk-away capability, it frees technicians for other essential tasks. LABXpress aspirates and dispenses precise volumes from test wells of a 96-well reaction plate and reagent vials. It features a barcode reader for sample tubes and reagent reservoirs allowing for easy tracking. Eight pipetting channels facilitate quick processing. With a short set-up time of 30 minutes to one hour, (depending on the assay), LABXpress can improve laboratory efficiency.

Product Description	Cat Id	Package
LABXpress Pipettor	LXPRP	each

For general laboratory use.

LinkSēq™ VIAFLO ASSIST Liquid Handler Kit

The LinkSēq VIAFLO ASSIST Liquid handler is a personal pipetting assistant. LinkSēq VIAFLO ASSIST Liquid handler delivers simplicity to the laboratory.

Add product ordering table

Product Description	Cat Id	Package
LinkSēq VIAFLO ASSIST Liquid Handler Kit	AC-300	each

For general laboratory use.



Readers/Analyzers

LABScan™ 100

LABScan 100 is a sensitive flow analyzer capable of rapidly processing up to 96 samples. When used with One Lambda's LABType™ and LABScreen™ family of products, this system allows the user to make assignments of HLA antibodies as well as HLA typing with the analysis support of HLA Fusion™ Software.

Note: The LABScan 100 flow analyzer is equivalent to the Luminex® 100 or 200 systems.

Product Description	Cat Id	Package
LABScan 100 System (Includes LX200, XY Platform, and Sheath Delivery System)	LABSCNXS3	each
LABScan 100 Calibration Kit	LX3CALKT	each
LABScan 100 Performance Verification Kit	LX3VERKT	each
Automated Maintenance Plate	LX3-AMP	each

LABScan3D™

Designed to provide breakthrough performance, higher throughput and increased multiplexing capabilities, the LABScan3D is the most advanced Luminex®-based flow analyzer available. When used with LABType XR and CWD products, exclusively designed for the LABScan3D, 500 beads can be simultaneously multiplexed in a single reaction, significantly increasing the pool size of screenable analytes. This advanced instrument is compatible with all LABType and LABScreen products.

Product Description	Cat Id	Package
LABScan 3D System (Includes internal, XY Platform and Sheath Delivery System)	LABSCNXS4	each
LABScan3D Calibration Kit	LX4CALKT	each
LABScan3D Performance Verification Kit	LX4VERKT	each
LABScan3D Utility Stand	LXPLX4SYS	each

Luminex Microspheres & Sheath Fluid

Product Description	Cat Id	Sale Unit
For use with xPONENT 4.2-LABScan 100		
Luminex Calibration Kit (Classification and Reporter)	LX3CALKT	Set
Performance Verification Kit (Classification, Reporter, and Fluidics)	LX3VERKT	Set
Accessory: Automated Maintenance Plate	LX3-AMP	Each
For use with xPONENT 4.2-LABScan3D		
LABScan3D Calibration Kit	LX4CALKT	Each
LABScan3D Verification Kit	LX4VERKT	Each
For use with Luminex Systems-LABScan 100 or LABScan		
Luminex Sheath Fluid - 20 liters	LXSF20	box
Luminex Sheath Fluid - 100 liters	LXSF20X5	5-20L boxes
Luminex Sheath Fluid Concentrate Pack (20x) – 1 Liter	LXSFC	box

For In Vitro Diagnostic Use.

Product Specifications	Calibration and Control Microspheres	Sheath Fluid
Storage Temperature:	2° to 8° C	Room Temp
Shipping Considerations:	Cold Pack	Room Temp
Packaging:	5ml per bottle	20 L bottle

QuantStudio™ 5

The QuantStudio 5 Real-Time PCR System is a high-performance benchtop instrument giving you greater control of your experiment data. Interact with the latest advancements in touch screen usability, access your data more easily than ever before and securely share your results with collaborators around the world.

Features and Benefits

- Multiplex with ease
- Connect to the cloud
- Precise temperature control
- Confidence in your records
- Protection of your work

Product Description	Cat Id	Package
QS 5 RT-PCR System,384-well, Laptop	QS5L	each
QS 5 RT-PCR System,384-well, Desktop	QS5D	each

QuantStudio™ 6

The QuantStudio 6 Flex Real-Time PCR System is ideal for laboratories with multiple applications or changing throughput needs. With an upgradable path to a QuantStudio 7 Flex System to accommodate automation or TaqMan Array cards, the QuantStudio 6 Flex System is the ideal qPCR platform if your needs change in the future.

Features and Benefits

- Flexibility that minimizes large up-front capital investment
- Skip the learning curve
- Performance you can trust.
- Upgrade capabilities when you need it.

Product Description	Cat Id	Package
QS 6 Flex RT-PCR System,384-well, Laptop	QS6FL	each
QS 6 Flex RT-PCR System,384-well, Desktop	QS6FD	each

For research use only. Not for use in diagnostic procedures.

QuantStudio™ Dx Real-Time PCR Instrument with 96-well fast block

The QuantStudio™ Dx Real-Time PCR Instrument is a real-time PCR platform that delivers the proven performance, flexibility, expandability, and support needed to meet the evolving needs of the clinical laboratory today and tomorrow. In Test Development Mode, the QuantStudio™ Dx Real-Time PCR Instrument offers easy-to-change blocks that can also accommodate array cards, as well as 96-well standard, 96-well Fast, and 384-well plates, allowing you to select the format that is right for your throughput needs.

Features and Benefits

- Results you can trust
- Flexibility you want, Security you need
- Efficient Workflows and Assays
- QuantStudio Dx Software

Product Description	Cat Id	Package
QuantStudio Dx RT-PCR 96w Fast Block	QSDXR-96FB	each

For In Vitro Diagnostic use.

Ion GeneStudio S5™ Sequencing Systems

The AllType HLA Sequencing assay together with the Ion GeneStudio S5 Sequencing System enables first pass, high- resolution genotyping of all the Class I and Class II loci of the Histocompatibility Leukocyte Antigen (HLA) genes.

The S5 platform uses cartridge-based consumables to enhance consistency and significantly shorten setup time. Sequencing data generated on the Ion GeneStudio S5 system is downloaded in real time onto the Torrent Server™ and automatically processed after each run using TypeStream Visual™ NGS Analysis Software. This process is optimized for speed and accuracy to deliver the highest level of performance from an NGS workflow to date. The S5 system is available in two configurations intended to meet the specific reporting requirements of your laboratory.

Ion GeneStudio S5™ System

- Sequencing in less than 5 hours
- Includes internal server for smaller footprint
- Can complete **one** sequencing run per day

Ion GeneStudio S5™ Plus System

- Sequencing in less than 5 hours
- Includes internal server for smaller footprint
- Can complete **three** sequencing runs per day

Features and Benefits

- Affordable entry into NGS
- Suitable for low to high volume laboratories
- HLA sequencing in less than 5 hours
- Complete up to 3 NGS sequencing runs per day (S5 Plus)

Ion Chef System

The Ion Chef System compliments the S5 by bringing walk-away convenience to template preparation with cartridge-based reagents and push-button simplicity. Clonal amplification, enrichment and loading of a single sequencing chip has never been so easy.

Features and Benefits

Automate Template Preparation

- Isothermal Amplification
- Enrichment
- Chip loading

Reduce labor

- Complete instrument set up in less than 10 minutes with cartridge-based reagents

Standardize results

- Eliminate variability with automation and on-board reagent tracking

Product Description	Cat Id	Package
Ion GeneStudio S5	IONGSS5	each
Ion GeneStudio S5 Plus	IONGSS5PL	each
Ion S5 System	IONS5	each
Ion S5 XL System	IONS5XL	each
Ion Chef System	IONCHEF	each

For research use only. Not for use in diagnostic procedures.

Software

HLA Fusion™ Software

HLA Fusion Software is a companion product to our HLA antibody detection and molecular typing products. HLA Fusion allows you to import raw data from our flow analyzers (LABScan 100 or LABScan3D), manually enter reactions, and read ELISA results for LAT products. Analysis results can be reviewed in graphical form and compared to One Lambda's quality control data, allowing easy adjustment of cut-off values to clarify results.

Users can also search for specific data and create standard or customized reports. Data can be exported in multiple formats. This software runs in both stand-alone and network environments.

HLA Fusion Software is for clinical diagnostics and features analysis modules for One Lambda's IVD products such as FlowPRA™, LABScreen, LABType, LCT™, LAT, Micro SSP™ and more.

Product Description	Cat Id	Package
HLA Fusion Software (IVD) For In Vitro Diagnostic Use.	FUSPGR	Software

HLA Fusion™ Research Software

The HLA Fusion Research Software for research sciences features modules for our RUO products such as KIR, Quantiplex, and more. HLA Fusion Research Software also now supports Non-HLA analysis for LABScreen Autoantibody.

Product Description	Cat Id	Package
HLA Fusion Research Software (RUO) For Research Use Only. Not for use in diagnostic procedures.	FUSREPGRX	Software

TypeStream Visual™ NGS Analysis Software

TypeStream Visual is a standalone NGS software solution that supports the analysis of both single read and paired-end sequencing data produced using AllType™ NGS assays.

Upon completion of sequencing, TypeStream Visual automatically aligns unmapped barcode sequences to the IMGT reference library to generate individual allele assignments. In addition to genotyping, TypeStream Visual provides the analyst with a wide range of analytical tools, run statistics and quality metrics to facilitate examination and reinforce decision making.

Results are seamlessly integrated with the HLA Fusion Research database, allowing you to combine high resolution typing data with antibody information for a more complete sample profile.

Features and Benefits

- Fully automated analysis
- No required network access
- Supports analysis of single read and paired-end sequencing

Flexible

- Compatible with multiple platforms

Automatic

- HLA typing initiates automatically to reduce time to results.

Concordant

- Genotyping and variant calling algorithms exceed 99.7% concordance

Integrated

- Data integration with HLA Fusion™ Research combines high resolution genotyping with:
 - Sample Records
 - Antibody Tracking
 - Combined Analysis
 - Reporting

Product Description	Cat Id	Package
TypeStream Visual NGS Analysis Software For Research Use Only in the USA and Canada. Not for use in diagnostic procedures. For In Vitro Diagnostics in the European Union only.	TSVPGR	Software

SureTyper™ Software

SureTyper is the software platform used with LinkSeq™ Real Time PCR products for automated and simplified genotype and phenotype reporting. With an easy to use interface, transparency of raw data, and flexible reporting options, SureTyper for simplified data interpretation and analysis.

Features and Benefits

The simple, fast, automated SureTyper software requires minimal training.

- No contamination control needed
- Less than 10 minutes of hands-on time per tray
- Genotyping results of Class I and II loci in 90 minutes
- Fewer repeats with less steps and reproducible results

Product Description	Cat Id	Package
SureTyper™ HLA*	STTPGRX	Software
SureTyper™ Blood **	STBPGRX	Software

*For In Vitro Diagnostic Use. (European Union Only)

For research use only in U.S. and Canada

**For research use only. Not for use in diagnostic procedures.

uTYPE™ HLA Sequence Analysis Software and uTYPE™ Dx HLA Sequence Analysis Software

uTYPE processes DNA sample data files of HLA Class I and Class II to determine allele assignment by comparison to the IMGT/HLA database. The sample data files are generated from samples processed with SeCore™ SBT Sequencing kits or SeCore GSSP SBT Sequencing kits and the Applied Biosystems Genetic Analyzer 3500 or 3500DX.

The software combines rapid data analysis with effective results management. Interpret data from a single user interface and navigate easily through key positions. Use single-click editing without compromising your original data file. A unique filter function eliminates mismatched allele combinations from consideration, while customizable reports containing interpreted results are available for convenient review.

Features and Benefits

- Stacked forward and reverse sequence display for easy comparison of a position or region of interest
- Use of color-coded markers that allow for easy identification and navigation across sequencing positions requiring user interrogation
- Includes accessory functionality such as a Plate Record Generator, Sequence Alignment Tool, and Customizable Reports to enhance the user experience

Product Description	Cat Id	Package
uTYPE HLA Sequencing Analysis Software (CE-IVD) CE/IVD: For In Vitro Diagnostic Use. European Union Only	539992	Software
uTYPE Dx HLA Sequence Analysis Software (IVD) For In Vitro Diagnostic Use.	539993	Software

uTYPE™ HLA Sequence Analysis Software for Research

Product Description	Cat Id	Package
uTYPE HLA Sequencing Analysis Software (RUO) For Research Use Only. Not for use in diagnostic procedures.	539991	Software



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