

Newsletter



ISSUE #13

WINTER 2019

Dear colleagues,

In this winter edition you will again find information on the introduction of virtual PRA (vPRA). It is of the utmost importance that for all sensitized patients the unacceptable antigens are registered in ENIS and that for the appropriate patients on the active kidney waiting list sera are shipped to the donor centers. Furthermore, some changes in the Eurotransplant EPT will be introduced at January 1st, 2020. Finally, we wish you all a Merry Christmas and a great 2020!

Towards virtual crossmatching

The first step towards virtual crossmatching is the introduction of the vPRA, based on unacceptable antigens, with patients having a vPRA >0% being regarded as immunized. As for the time being the physical donor-center crossmatch will remain, the quarterly serum exchange is still required. Sera that must be shipped are those that have a vPRA>0% from patients on the active kidney waiting list with known CDC reactivity. Please be aware of the vPRA introduction timeline:

- From November, 2019: bulk unacceptable antigen transfer to the ET office by CSV file is already possible, as specified by ET (to be found at the membersite and attached to this newsletter). This transfer must be tested on a per center basis.
- January 28th, 2020: transition to the vPRA and cessation of the %PRA as a parameter of sensitisation. On this date, for all patients on the waiting list the vPRA will be recalculated using the ETRL reference database 3.0.
- In the transition period we strongly advise to include sera from all patients on the active kidney waiting list with either vPRA>0% and known cytotoxic HLA antibodies and/or a %PRA>5% in the serum shipment. This is of importance since from January 28th 2020 onward all crossmatch requests will be based on the vPRA status (together with known CDC reactivity). In the absence of a serum sample in the donor center for a patient with vPRA>0% and know CDC reactivity, the organ offer will not be made. This is not the case for the AM program where no crossmatch at the donor center is performed. Information on adaptations of the ENIS screens involved will be provided in the beginning of January 2020.

External Proficiency testing update

Next year, a number of changes will be made to the Eurotransplant EPT, both in the materials that are shipped, the appearance of the EPT website, as well as the way some of the results should be entered.

- Screening detection and identification of HLA antibodies will be separated from crossmatching. The reason is that crossmatches must be interpreted independently from data obtained by screening to mimic the donor center crossmatch. This means that you will receive a separate set of sera for crossmatching, different than the one for screening detection/identification of antibodies. Sera for these two purposes will be shipped following the table below. All numbering will be made clearly visible in the accompanying information to the sera and on the EPT website.
- Reporting of screening detection of HLA antibodies will change. Due to changing policies within Eurotransplant, CDC%PRA and Flow%PRA will change. At this moment there are three categories: non-immunized (<6% PRA), immunized (≥6 and <85% PRA) and highly immunized (≥85% PRA). This will change to the following classification: negative (non-immunized) or positive (immunized). You also will have the possibility to enter the vendor of the CDC/Flow test used. It remains possible to enter panel number.
- HLA typing EPT: When a locus is found to be homozygous, please give only one entry to comply to EFI standards. E.g. when a sample is found to be A1, B8. Enter A1, B8, and not A1, A1, B8, B8. Deviations will be marked in the analysis, but will not be counted as discrepancy for the time being.

Shipping date	Typing dispatch (n)	Deadline typing/ xm report	screening dis- patch (n)	Crossmatch dispatch (n)	Deadline screening report
04-02-2020	3	18-02-2020	2020-SCr-A-L (12)	2020-XM-A, B, C (3)	07-07-2020
24-03-2020	3	07-04-2020		2020-XM-D, E, F (3)	
26-05-2020	3	09-06-2020		2020-XM-G, H, I (3)	
15-09-2020	3	29-09-2020		2020-XM-J, K, L (3)	

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Version dd 30.10.2019 General

UNACCEPTABLES

Specification for import of unacceptables

If the number of unacceptables results to be processed is over 50, bulk results may also be sent to datamanager@eurotransplant.org via secure email https://app.zivver.com/l/start/2582e30c-036a-4f0f-bd70-d822ab53a09d. However, please bear in mind that the files will be processed manually, so processing the data may takeup to a week, and will only take place during office hours. Before starting an import on the production database you should send a testfile to datamanager@eurotransplant.org, after a successfull test the center can start sending data files for production.

The unacceptables data from your system have to be converted to these two files:

UNACC_REC.DAT Unacceptable records per recipient
UNACC_AG.DAT Specification of the unacceptable antigens

Layout of UNACC REC.DAT

*ENTRY DATE	VARCHAR2(8)->	DATE [DDMMYYYY]
*ETNUMBER	VARCHAR2 (6)	[123456]
*BIRTH DATE	VARCHAR2(8)->	DATE [DDMMYYYY]
*TTLAB	NUMBER (4)	CENTERCODE [0000] (request from datamanager)
*ADD REPLACE	VARCHAR2(1)->	A=add to existing unacceptables
_		R=replace all existing antigens with this
result		
		N= No unacceptables, replace existing antigens
		with a record not containing unacceptables
		(removing existing unacceptables)
COMMENTS	VARCHAR2(240)	comments on unacceptable result

Layout of UNACC_AG.DAT

```
*ENTRY_DATE VARCHAR2(8)-> DATE [DDMMYYYY]

*ETNUMBER VARCHAR2(6) [123456]

*BIRTH_DATE VARCHAR2(8)-> DATE [DDMMYYYY]

*ANTIGEN_NR NUMBER 1 = "A1", 116 = "DR16" (see separate file)
```

Only unacceptables of the types Broad, Split or Public are allowed. If a Split is entered its associated Broad should be omitted, and vice versa. The existing antigens cannot be replaced partially. If only some existing antigens must be replaced, you have to enter all remaining antigens.

UNACC REC.DAT Example:

```
12102015,080284,17071930,8052,A,test

12102015,088629,17041943,8052,A,test 2

12102015,095597,22051934,8052,R,

12102015,094408,14031948,8052,A,

12102015,024123,01061978,8052,R,test 3

12102015,030599,25021940,8052,N,test 4
```

UNACC AG.DAT Example:

```
12102015,080284,17071930,1
12102015,080284,17071930,2
12102015,088629,17041943,5
12102015,088629,17041943,25
12102015,088629,17041943,46
12102015,095597,22051934,1
12102015,094408,14031948,8
12102015,024123,01061978,64
12102015,024123,01061978,70
```

^{*=}Mandatory item

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Attached is a list of allowed unacceptables of the types Broad, Split or Public.

SORT	CODE	TYPE	50	B77	Split	104	CW6	Broad
1	A1	Broad	51	B16	Broad	105	CW7	Broad
2	A2	Broad	52	B38	Split	106	CW8	Broad
3	A3	Broad	53	B39	Split	113	DR1	Broad
4	A9	Broad	54	B17	Broad	114	DR2	Broad
5	A23	Split	55	B57	Split	115	DR15	Split
6	A24	Split	56	B58	Split	116	DR16	Split
8	A10	Broad	57	B18	Broad	117	DR3	Broad
9	A25	Split	58	B21	Broad	118	DR17	Split
10	A26	Split	59	B49	Split	119	DR18	Split
11	A34	Split	60	B50	Split	120	DR4	Broad
12	A66	Split	61	B22	Broad	121	DR5	Broad
13	A11	Broad	62	B54	Split	122	DR11	Split
14	A19	Broad	63	B55	Split	123	DR12	Split
15	A29	Split	64	B56	Split	124	DR6	Broad
16	A30	Split	65	B27	Broad	125	DR13	Split
17	A31	Split	66	B35	Broad	126	DR14	Split
18	A32	Split	67	B37	Broad	127	DR7	Broad
19	A33	Split	68	B40	Broad	128	DR8	Broad
20	A74	Split	69	B60	Split	129	DR9	Broad
21	A28	Broad	70	B61	Split	130	DR10	Broad
22	A68	Split	71	B41	Broad	133	DR51	Public
23	A69	Split	72	B42	Broad	134	DR52	Public
24	A36	Broad	73	B46	Broad	135	DR53	Public
25	A43	Broad	74	B47	Broad	145	DQ1	Broad
28	A80	Broad	75	B48	Broad	146	DQ5	Split
33	B5	Broad	76	B53	Broad	147	DQ6	Split
34	B51	Split	77	B59	Broad	148	DQ2	Broad
35	B52	Split	78	B67	Broad	149	DQ3	Broad
36	B7	Broad	79	B70	Broad	150	DQ3	Split
37	B8	Broad	80	B71	Split	151	DQ8	Split
38	B12	Broad	81	B72	Split	152	DQ9	Split
39	B44	Split	82	B73	Broad	153	DQ4	Broad
40	B45	Split	84	B78	Broad	325	B81	Broad
41	B13	Broad	85	BW4	Public	327	B82	Broad
42	B14	Broad	86	BW6	Public	328	B83	Broad
43	B64	Split	97	CW1	Broad	329	CW12	Broad
44	B65	Split	98	CW1	Broad	330	CW 12	Broad
45	B15	Broad	99	CW2	Broad	331	CW13	Broad
46	B62	Split	100	CW9	Split	332	CW 14	Broad
40 47	B63	Split	100	CW9 CW10	Split	333	CW15 CW16	Broad
48	Б03 В75		101	CW10	Broad	334	CW16 CW17	Broad
48 49	в75 В76	Split Split	102	CW4 CW5	Broad	335	CW17 CW18	Broad
+7	D /0	Spiit	103	CWJ	Divau	333	C W 10	Divau