STAMP guideline version 7.0 – 23 June 2016

Scandiatransplant Acceptable Mismatch Program (STAMP) and
Local Acceptable Mismatch Program (LAMP)

STAMP

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1. General STAMP guidelines

Purpose
To increase the likelihood of offering a suitable kidney graft to highly immunized (HI) recipients, thus reducing their time on the waiting list.

Success criteria
- Reduced waiting time for highly immunized patients.
- Acceptable frequency of when a shipped kidney is not transplanted to the indicated STAMP patient (< 10 %?).
- Survival of grafts comparable to graft survival in PRA-negative patients.

Acceptance criteria
1. On waiting list > 1 year (Not necessary for paediatric patients)
2. HI status PRA ≥ 80% reactivity based on CDC and/or solid phase assay
   2.1 Must be identified in two consecutive samples over a period of more than 3 months (calculated from last tested sample)
   2.2 With proven reactivity against HLA class I or II antigens OR both HLA class I and II antigens.
3. The last tested sample drawn less than 3 months before acceptance

Recipient HLA typing
Recipient HLA-antigens must be assigned at split level, by serology or molecular typing.

Recipient acceptable HLA-antigens
Definition of acceptable HLA-mismatches is performed by laboratory at recipient center. Acceptable mismatches may be HLA-A, -B, -C, -DR, -DQ antigens. Acceptable mismatches may include repeated mismatches from previous transplantations. Definition of acceptable mismatches may be based on CDC and/or solid phase assays.

Wait listing and matching:
Recipients own antigens and the defined acceptable mismatches are treated like. Recipients in the program must be regularly screened at least every 3 months; PRA reactivity must be re-evaluated at least once a year. Once accepted, patients will stay included even if PRA drops below 80%.

For each donor search, a special search among AM-recipients based on split level HLA typing is performed. Exchange obligation is marked when the donor only has HLA-A,-B, -C, -DR, -DQ antigen specified in the recipient as own or acceptable. Exchange priority will follow Scandiatransplant rules and placed as priority number 2: *Patient with STAMP-status when all donor HLA-A, -B, -C, -DR, -DQ antigens are either shared with the recipient or are among those defined as acceptable.* Return obligation as for other exchange rules. Exchanged organ may be used for other local recipient if the indicated STAMP patient for any reason not can be transplanted. Only the centers joining STAMP have an obligation to exchange kidneys to a STAMP recipient.
Re-evaluation by the steering committee

- A STAMP patient not transplanted with a shipped kidney because of a positive cross-match should be temporarily withdrawn from STAMP, re-evaluated and eventually re-admitted.
- When removing defined antibodies and adding them as acceptable mismatches the patient must be re-evaluated by the committee. The responsible laboratory is obliged to inform the committee in such cases. Re-evaluation is not needed when adding new antibodies and removing them as acceptable mismatches.

Event reporting
Recipient centers must notify Scandiatransplant if the kidney is transplanted to somebody else than the indicated STAMP patient.
Recipient center must give detailed follow-up information on performed transplantations.

Steering committee:
A steering committee (SC) for the project must be appointed by the board of Scandiatransplant.
SC shall be composed by one tissue typer from each of the countries Denmark, Finland, Norway and Sweden together with two representatives from the Nordic Kidney Group.
Proposals of STAMP candidates from individual centers must be evaluated and accepted by the tissue typers in the SC.

SC must keep updated on all effects of the program, including:
- Number of exchanged organs.
- Changes in waiting time for STAMP recipients and for other waiting patients.
- Changed reactivity in individual waiting recipients
- Positive cross matches at donor center.
- Fate of performed transplants.

SC may decide to withdraw STAMP-status if antibody reactivity changes.

SC must give yearly status reports to Scandiatransplant.

2. Finding the menu for entering STAMP-data
Enter patient identification (Scandia No./birth day) and press search
Click on the relevant patient on the search result list

Click on the waiting list tab (1) followed by the active kidney waiting list record (2)

Any patient with a kidney treatment record will have the STAMP tabs available.
3. Selection of patients

3.1 Potential candidates

Potential candidates are found by entering the list from the menu entrance ‘Quality Control’ -> ‘STAMP - HI immunized KI patients with no STAMP record’. This list contains patients that have been highly immunized for more than a year and highly immunized pediatric patients.

From the list, select local patients who fulfill the rest of the STAMP acceptance criteria:

- PRA ≥ 80% must be identified in two consecutive samples over a period of more than 3 months (calculated from last tested sample).
- With proven reactivity against HLA class I or II antigens OR both HLA class I and II antigens.
- The last tested sample drawn less than 3 months before acceptance.

3.2 Good candidates?

Evaluate if these potential STAMP eligible patients may have difficulties in getting kidneys from local donors.

- Good candidates usually have a reason for immunization (previous transplants, pregnancies, or blood transfusions).
- Good candidates usually have both CDC and solid phase reactivity (although both do not have to fulfill HI criteria).
- Good candidates usually have high-level reactivity in antibody testing.
- Good candidates occasionally have a history of positive cross matches.

3.3 Consult clinician

Consult clinician about the need for STAMP or any other type of prioritizing. Consider both STAMP and LAMP and decide together which one is better for particular patient.
4. STAMP initial preparation

4.1 Registration of relevant HLA antibodies

All registered antibodies can be viewed in the ‘STAMP Aux’ tab

- Include all antibodies that are positive according to local rules (e.g. all with Luminex MFI level > 1000)
- If allele specific antibodies are detected, consider adding them at serological level if the allele is not extremely rare. Remember that you do not know ethnical background of potential donor beforehand!

If list of antibodies needs to be updated, you need to go back

And enter the ‘Antibody screen test’ tab, further procedure is described in the ‘All recipient’ manual.
4.2 Entering STAMP data

4.2.1 Determination method
Click on the field 'Determination method' and select one to many from the list

4.2.2. Acceptable mismatches
Acceptable mismatches are selected from the lists or entered one by one.

Deselect by clicking on the antigen specificity again

How to select antigens to be listed as acceptable mismatches (AMM)

- All antigens that the patient has no antibodies against could usually be added to the AMM list. These may also include possible previous mismatches.
  - If you add DR17 remember to add DR3 also.
  - If you add both Cw9 and Cw10 add Cw3 also.
  - Other broad serological level antigens may be added if all splits are on the AMM list, but usually are not necessary since laboratories type these at split level.
Own known antigens should not be added to the AMM list. Add most likely own (according to haplotype analysis) C/DQ antigens to the AMM list if these are not typed and reported.

Do not add antigens that are strongly linked with other antigens that patient have antibodies against, if particular antigens are not analyzed from donors (DRB3-5 and all allele specific antibodies).

DP and DQA-antigens are neither added to the AMM list nor analyzed from donor. Therefore consider LAMP or other options for patients with multiple strong DP antibodies.

4.2.3 Date of acceptance
Date of acceptance is automatically inserted when saving data the first time

4.2.4 Status
When you are preparing the patient set the status to Inactive

4.2.5 Comments
Write all relevant information to comments field. At least the following information should be added:

- List of all detected DRB3-5 antibodies.
- List of all detected allele specific antibodies that are not added at serological level to the antibody list.
- List of all antigens that are not included to antibody or the AMM list, for instance due to strong linkage to detected allele specific or DRB3-5 antibodies.
- Other relevant explanations for NO in the ‘STAMP QC’ tab
**TIP!**

You can always start entering data on the patient – leave the patient – with status inactive and return to enter more data later.

5. Quality check of STAMP data

When all data have been entered on the patient a quality check must be performed. Go to the tab ‘STAMP check’

The STAMP QC will give you an indication of the quality of the registered data.  
Green colour = quality check passed
Red colour = quality check did NOT passed, mandatory according to the STAMP guidelines, please check and/or add explanation to comment field
Orange colour = quality check NOT passed, please check and/or add explanation to comment field

The STAMP check is a quality control and is meant as a help, it does not inflict with the activation of patients to STAMP. If you have an explanation of why a criteria is not fulfilled, please enter a message to the STAMP committee, in the field for comments.

The quality check and calculations are done on all the following variables:
5.1 Wait time > 1 year or child
The total waiting time on kidney waiting list and present age on the patient is calculated. Total waiting time on kidney waiting list must be more than one year. (Excepted are children they do not have to wait one year before acceptance).

5.2 HI PRA >= 80% at present
Defines if the patient is highly immunized (PRA ≥ 80%) in last registered antibody screen test

5.3 Most recent PRA < 3 months
Checks if the last registered antibody screen test is done within the last 3 months

5.4 HI >= x2 > 3 months
Identifies if highly immunized test result is identified in two consecutive samples over a period of more than 3 months.

5.5 A, B, C, DR, DQ splits
A check is done weather the recipient HLA-antigens are assigned at split level. A '*' in front of an allele indicates that the assigned HLA type contains a broad type which is serological typed. A '!' in front of an allele indicates that the problematic broad type is genomic typed.
Result of the QC check may be No, if so check carefully that the reason for NO is something you have intended.

5.6 Acc. mm. splits
Checks if all acceptable mismatches are registered as splits
Result of the QC check May be No, if so check carefully that the reason for NO is something you have intended.

5.7 Id. antib. splits
Checks if all identified antibodies are registered as splits
Result of the QC check may be No, if so check carefully that the reason for NO is something you have intended.

5.8 Patient DQ in Acc. mm.
Checks if patients own DQ is entered as acceptable mismatch.

5.9 No identif. AB in Acc. mm.
Compares one to one if any identified antibodies by mistake are given as acceptable mismatches.

5.10 Consistent Sero/Geno HLA
Compares the patient’s own serological and genomic HLA as it is registered in the database

5.11 All HLA checked
Listing all antigens not given as own HLA antigens, acceptable mismatches or identified antibodies.
Result of the QC Check may be No. If so, check carefully that you have mentioned not to include some antigens and that you have explained reasons not to include some antigens (for instance if antigens are left out due to linkage or if these are considered as “grey zone”).
6. Patients being prepared for STAMP

Finding the patients being prepared for STAMP, enter the menu ‘All recipients’ and register the search parameters below.

- Enter the Scandia number, Person number, Surname, First name, Transplant center, ABO blood group, waiting list status, and urgency.
- Set the sign up as ‘N: No’ and status as ‘I: Inactive’.
- Termination: Leave blank.

7. Patients ready to go on STAMP

When you have done the quality check and you believe that sufficient data has been entered you have to change “Status” from I = Inactive to A = Active and save data.

- An Email will now be sent to the committee and they will go through the patient to see if it is valid for the program.
- The results of the STAMP quality check will automatically be included in this message.
Example of part of an email message

Scand updated 05/19/2015 00:00:00 by IDW: Not signed up, changed status to Active
Ser. equiv. HLA: A 11,26;B 7,8;Cw 1,7;DR 17,15;DQ 2,6;
Identif. Antib: A1,2,23,24,25,32,68,69; B13,27,35,37,38,44,45,46,47,49,50,51,52,53,56,57,58,59,62,63,71,72,75,76,77,78; Cw 10,9;
Calc. comb. PRA: 98 (19-MAY-2015)
Acc. Mism:
Waiting time > 1 year or child: Yes (Age: 48 years Wait time: 26 months)
PRA < 3 months: Yes (11-MAY-2015 0 months 8 days)
Present immunization status HI: No (NI Non immunized)
Repeated immunization status HI > 3 months: No (samples over 0 months 0 days)
AB,Cw,DR,DQ splits: Yes (A 11,26; B 7,8; Cw 1,7; DR 15,17; DQ 2,6)

STAMP patients ready for evaluation is found by entering the menu ‘All recipients’ and register the parameters below:
8. Patients on STAMP

In the menu 'All recipients' enter the search parameters below and you will find all patients on STAMP. If you only wish to see patients belonging to a specific tx. Center you can add it as a search parameter.

9. Quality control of antibody screening

Patients on STAMP must be HLA antibody screen tested at least every 3 months. To ensure that all active STAMP patients complies with this rule go to the menu Quality Control -> 'STAMP - PRA older than 3 months'.

By entering this menu, you get a display of patients missing the regular antibody screen test. To the right is a count of months and days since last registered screen test.

- Immunization status of STAMP listed patients must be screened at least every 3 months, and antibody specifications must be re-evaluated at least yearly. However, it is recommended to perform the AMM list re-evaluation immediately when you
notice significant changes in patient’s immunization status, although the patient may have been previously evaluated less than a year ago.

- Add all new antibodies into the detected antibodies list and remove the same antigens from the AMM list. This does not necessitate steering group re-evaluation.
  - If the new antibody is allele specific, add it to antibody list at serological level if it is not extremely rare and remove the antigen from the AMM list. Information of very rare new allele specific antibody could be only added to the comments field without changing the AMM list.
  - If the new antibody is DRB3-5, add this information to comments field and remove all strongly associated antigens from the AMM list.
  - If detected new antibody is DP antibody and you think it is relevant, consider changing the patient’s status form STAMP to LAMP

- If your patient’s immunization status has improved, you may consider registering previously detected antibodies as allowable antibodies and adding them into the AMM list.
  - Change the patient’s status from A to I
  - After all modifications to the antibody and the AMM lists, write the information of all changes into comments field
  - Finally change the status back to A
  - Case will be re-evaluated by the steering group.

10. Patients temporary off STAMP

After acceptance to STAMP, the center responsible for the patient, has the possibility to remove the patient temporary from the program (for instance after a positive X-match). If you want to do so, you have to change "Status" from A = Active to I = Inactive.
When you change the status a new window appears where you should register cause of temporary withdrawal.

**Note**
The patient will of cause still be searchable in Kidney-search only the STAMP exchange obligation will be suppressed.

To find “Patients temporarily off STAMP”

Perform thorough re-evaluation of the case and change the antibody/ the AMM list accordingly.
Write the information of all changes and your opinion of the reason for positive cross match into comments field.
Finally change the status from I = Inactive to A = Active and the patient will be re-evaluated by the steering group.
11. Patients permanent off STAMP
Patients no longer eligible for STAMP, must be permanently withdrawn from STAMP.

Select cause from list of value and save data.
12. STAMP reports

12.1 Patient STAMP details

When you have a STAMP-patient (active/on hold/withdrawn) on screen you can press the STAMP print button to display STAMP data on the screen.

A typical printout will look like this

```
SCANDIATRANSPLANT                                                 stamp_details
Report produced: 23-JUN-2016  12:09 requested by user:           Page  1
*------------------------------------------------------------------*
| STAMP details          |                                  |
------------------------------------------------------------------*
Scandianumber:              123         Person number: 123456-7891
Gender:                     F Female     Name:        Test, test
Country:                    S Sweden      Tx-Center:    
Dialysis/Treatment center:  KI Kidney    Waiting list:
Date of entry on waiting list: 23-JAN-2012
Waiting list status:        N Notified
Waiting for tx number:      1
Blood group:                AB
Narrow HLA:                 A 2,3;B 7, 62;Cw 7;DR 15;DQ 6, 5;
Identified antibodies:      A23,24,25,26,32,33,34,66,68,69; B13,18,27,35,37,  
                            38,39,41,44,45,46,47,48,49,50,51,52,53,56,57,58,  
                            59,60,61,63,64,65,71,72,75,76,77,78,8,82;  
                            DR11,12,13,14,17,18,7,8,9;
Antibody Screen Test:       20-APR-2016 I% 99 FLOW II% 85 FLOW  
                            21-JAN-2016 I% 99 FLOW,LUMI II% 83 FLOW,LUMI
Identified antibodies:      A23,24,25,26,32,33,34,66,68,69; B13,18,27,35,37,  
                            38,39,41,44,45,46,47,48,49,50,51,52,53,56,57,58,  
                            59,60,61,63,64,65,71,72,75,76,77,78,8,82;  
                            DR11,12,13,14,17,18,7,8,9;
Date of entry on STAMP:     23-FEB-2016   Date of acceptance on STAMP: 17-MAR-2016
Signed up:                  Y Yes
STAMP status:               A Active      Determination methods: LUMI
Acceptable mismatches:      A1,11,29,30,31,36,43,74,80;B42,54,55,67,73,81;
```
Waiting time > 1 year or child: Yes
Age: 35 years
Wait time: 14 months
Most recent PRA < 3 months: Yes
HI PRA >= 80% at present: Yes
HI >= x2 > 3 months: Yes
A,B,Cw,DR,DQ splits: Yes A 2,3; B 7; Cw 7; DR 15; DQ 6;
Acc. mm. splits: Yes
Id. antib. splits: Yes
No identif. AB in Acc. mm.: No
Consistent Sero/Geno HLA: Yes
All HLA checked: Yes
First registered: 01-FEB-2016
Last changed: 01-MAR-2016

12.2 Reports
A variety of STAMP reports are available in Reports -> More:.

Selecting STAMP notifications or withdrawals

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Notifications all STAMP patients</td>
</tr>
<tr>
<td>N</td>
<td>Notifications only active on waiting list</td>
</tr>
<tr>
<td>PM</td>
<td>Permanent withdrawals from STAMP</td>
</tr>
<tr>
<td>TW</td>
<td>Temporary withdrawals from STAMP</td>
</tr>
<tr>
<td>W</td>
<td>Withdrawals</td>
</tr>
</tbody>
</table>
A: Notifications all STAMP patients
If you choose this report you will get all patients with a STAMP record. In other words, the report will contain patients that are: Preparing to go on STAMP, active/on hold on STAMP, transplanted, permanently withdrawn and dead.

N: Notifications only active on waiting list
Gives you patients with a STAMP record active/on hold in the specified period

PW: Permanent withdrawals from STAMP
This extraction contains patients permanent withdrawn from STAMP together with cause and date.

TW: Temporary withdrawals from STAMP
If you choose this report you will get a list of patients that have been temporary off STAMP along with cause and date.

W: Withdrawals
Consist of all patients with a STAMP record that have been permanent withdrawn from the main kidney waiting list.

Selecting STAMP notifications or withdrawals

If you choose this report you will get a list of patients transplanted while they we signed up on STAMP waiting list.

It is possible to do the extraction for a specific period just enter starting and/or ending date.
LAMP

13. Introduction

Purpose
This program is a local alternative for patients that do not meet STAMP criteria. At recipient search the patients are matched the same way as STAMP patients, due to defined acceptable mismatches. The program does not result in any exchange obligations between centers.

Acceptance criteria
Each center defines the acceptance criteria themselves and there is no approval for inclusion to the program from the committee. Patients can both go directly on LAMP and no matter their STAMP status be 'transferred' to LAMP.

14. Menus for entering LAMP-data and LAMP pre transplantation information

You use the same menus, facilities and screens as described for STAMP patients. Methods of determination, acceptable mismatches and comments are registered the same way as for STAMP patients.

15. Patients ready to go on LAMP

When you have done the quality check and you believe that sufficient data has been entered you have to change "Status" from I = Inactive to L = Local program and save data.

The patient is now on LAMP

Please note that no matter what STAMP status a patient has it can always become a LAMP patient.
16. Patients on LAMP
To find patients on LAMP enter the menu ‘All recipients’ and make a search on ‘Local program’.

17. Kidney search result LAMP
In the kidney search result screen a LAMP match will appear as a priority 6 match.
18. Calculated combined PRA and transplantability

A donor pool, based on 1000 recently HLA typed deceased donors registered in Scandiatransplant, has been made. The pool forms the basis of the following calculations.

18.1 Calculated combined PRA

The calculated PRA is based on the antibody summary and is updated automatically when list of identified antibodies are changed.

This feature is accessible from two places:
1. From the ‘STAMP Aux’ tab

2. From the menu ‘All recipient’, make a query on the specific patient and enter the antibody screen test tab.
18.2 Calculated transplantability

In STAMP it is possible to get a calculated transplantability on

- ‘Normal match’ based on the patient HLA type and a ‘normal’ broad level A, B and DR match
- ‘STAMP match’ based on split level typings on patient and defined acceptable mismatches.

The calculation is based on the HLA and AB0 blood types represented in the donor pool. The calculation is done by clicking on the ‘STAMP Recalc’ button.

If you make changes to patient HLA and/or defined acceptable mismatches you recalculated by pressing the ‘STAMP recalc’ button.