STAMP guideline version 9.2 - January 31, 2023

Scandiatransplant Acceptable Mismatch Program (STAMP) and

Local Acceptable Mismatch Program (LAMP)

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STAMP

1. General STAMP guidelines

Purpose

To increase the likelihood of offering a suitable kidney graft to broadly sensitized recipients, thus reducing their time on the waiting list.

Acceptance criteria

- 1. Transplantability score (TS) ABO compatible ≤ 2%
- 2. The last tested sample drawn less than 3 months before acceptance

Recipient HLA typing

Recipient HLA-antigens must be assigned at split level by molecular (and serology) 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, -DRB1, -DRB3/4/5, -DQA1, -DQB1, -DPA1, -DPB1 antigens.

Acceptable mismatches may include repeated mismatches from previous transplantations, but should mainly reflect the current immunization and not historical antibodies.

Definition of acceptable mismatches may be based on CDC and/or solid phase assays.

Wait listing and matching

Recipients in the program must be regularly screened at least every 3 months, antibody specificities must be re-evaluated at least once a year.

Once accepted, patients will stay included even if sensitization decreases.

For each donor search, a specific search among STAMP-recipients based on split level HLA, is performed. Exchange obligation is marked when the donor only has HLA-A, -B, -C, -DRB1, -DRB3/4/5, -DQA1, -DQB1, -DPA1, -DPB1 antigens specified as recipient`s own or acceptable.

If there is more than one STAMP candidate when doing the search for kidney exchange obligations the recipients must be prioritised in the following order

- 1. Lowest TS, ABO compatible
- 2. ABO identical recipients
- 3. Same country as donor
- 4. Longest waiting time

The search result list is sorted by a calculated AMP-score, which is a weight score based on these priorities.

Re-evaluation by the steering committee

A STAMP patient not transplanted with a shipped kidney because of a positive crossmatch must be temporarily withdrawn from STAMP, re-evaluated and eventually readmitted.

Event reporting

Exchanged organ may be used for other local recipient if the indicated STAMP patient for any reason cannot be transplanted, reason must be recorded.

Recipient center must give detailed follow-up information on performed transplantations.

Steering committee:

The STAMP steering committee (SC) is a scientific subgroup of the Tissue Typers Group, which is an expert advising committee for the Nordic Kidney Group.

SC shall be composed of one tissue typer from each of the countries within

Scandiatransplant together with a clinical representative from each country represented in the Nordic Kidney Group.

Proposals of STAMP candidates from individual centers must be evaluated and accepted by two of the tissue typers in the SC from which the candidate does not originate from. The evaluation by the SC is performed within four weeks from the date that recipient center has activated the patient for evaluation.

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.

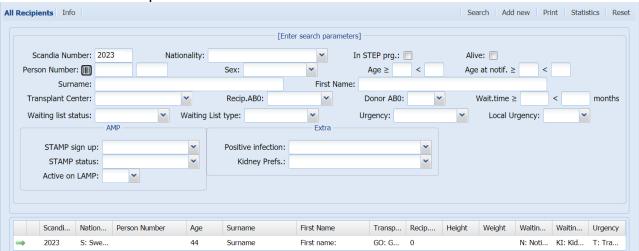
SC must give yearly status reports to Scandiatransplant.

At the annual Scandiatransplant Tissue Typer Group meetings, individual cases on patients who have been waiting for years on the STAMP list can be brought up for discussion.

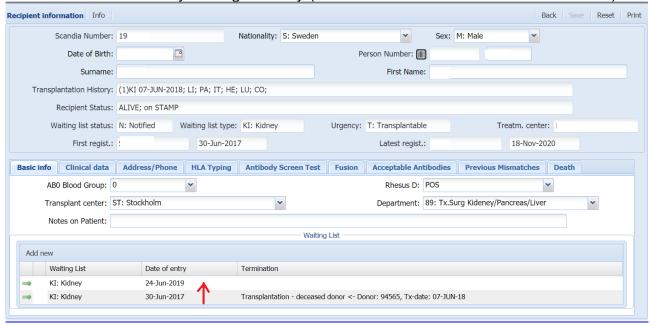
2. Finding the menu for entering STAMP-data



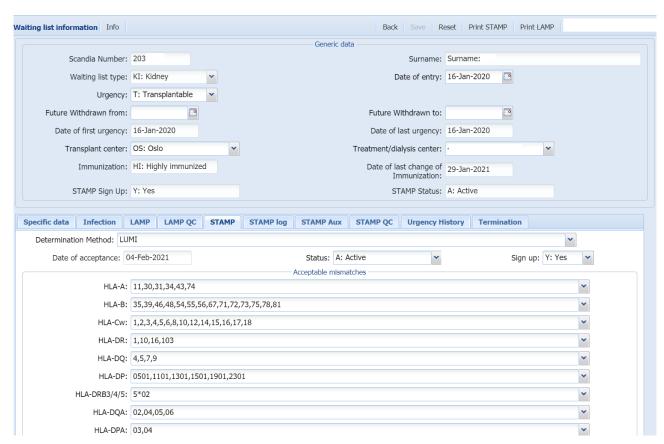
Enter patient identification (Scandia no. / date of birth) and press search Click on the relevant patient on the search result list



Click on the active kidney waiting list entry (no information in the 'Termination' column):



Any patient with a kidney treatment record will have the STAMP tabs available.



3. Selection of patients

3.1 Potential candidates

Potential candidates can be found by entering the list from the menu entrance 'Quality Control' -> 'Estimated TS ≤ 2% with no STAMP record'. This list contains patients that are highly sensitized and have antibody specificities recorded in the system.

3.2 Good candidates?

Evaluate if the potential <u>STAMP eligible patient have difficulties in getting a kidney from a</u> local donor.

- Good candidates usually have a reason for sensitization(previous transplants, pregnancies, or blood transfusions).
- Good candidates often have both CDC and solid phase reactivity.
- 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 what is best for the particular patient.

4. STAMP initial preparation

4.1 Registration of relevant HLA antibodies

A summary of all registered antibodies can be viewed in the 'STAMP Aux' tab.



Antibodies with () are no longer clinical relevant, these can be given by selecting them through the 'Acceptable Antibodies' tab on the recipient.

- 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!

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

'Select all' will select all antigens on the list as acceptable mismatches

'Select calculated' will select all antigens that the recipient has no HLA antibodies against.

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

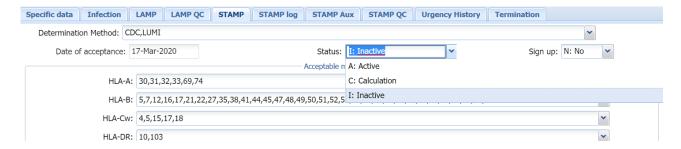
- All antigens that the patient has no antibodies against could usually be added to the AMM list. These may also include possible previous mismatches.
 - o If you add DR17 remember to add DR3 also.
 - o If you add both Cw9 and Cw10 add Cw3 also.
 - Other broad serological level antigens may be added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

4.2.3 Date of acceptance

Date of acceptance is automatically inserted when the recipient has been accepted and 'Sign up' is changed to 'Yes'.

4.2.4 Status

When you are preparing the patient set the status to Inactive/calculation



4.2.5 Comments

Write all relevant information in the comments field. At least the following information should be added:

- 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 the antibody or AMM list for any reason.
- All other relevant information that SC should know

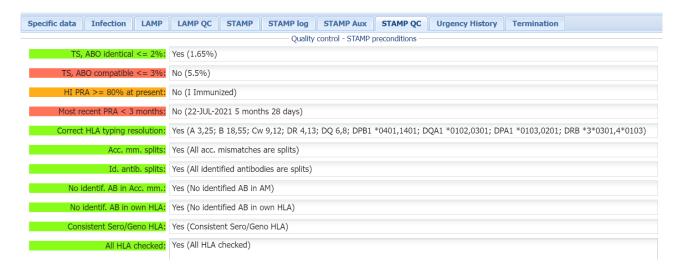


TIP!

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 QC'



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 pass, <u>mandatory</u> 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 criteria are not fulfilled, please enter it in the comment field.

The quality check and calculations are done on the following variables:

TS, ABO compatible ≤ 2% (obligatory to fulfil)

Checks if the current ABO compatible transplantability score is ≤ 2%

HI PRA ≥ 80% at present

Defines if the patient is highly immunized (PRA ≥ 80%) in last registered antibody screen test

Most recent PRA < 3 months (obligatory to fulfil)

Checks if the last registered antibody screen test is done on serum drawn within the last 3 months

A, B, C, DR, DQ splits

A check is done whether the recipient HLA-antigens are assigned at split level. A '*' in front of an allele indicates that the assigned HLA type contains a broad serological type. A '!' in front of an allele indicates that there is a broad genomic type.

Result of the QC check may be No, if so check carefully that the reason for No is something you have intended.

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.

ld. 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.

No identif. AB in Acc. mm.

Compares one to one if any identified antibodies by mistake are given as acceptable mismatches.

Own HLA typing as Acc. mm.

That checks if all own HLA types have been added as acceptable mismatches.

Consistent Sero/Geno HLA

Compares the patient's own serological and genomic HLA as it is registered in the database

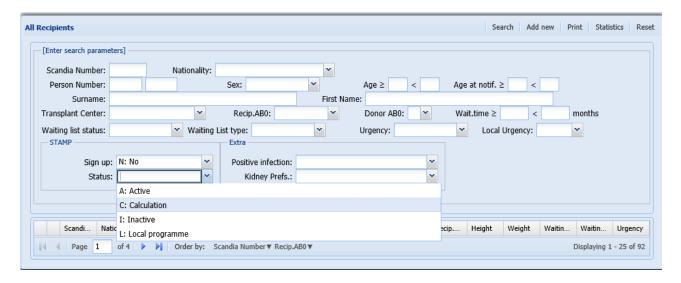
All HLA checked

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").

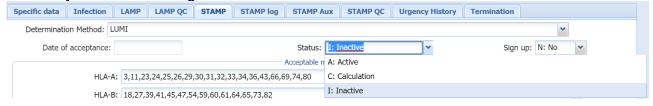
6. Patients being prepared for STAMP

Finding the patients being prepared for STAMP, enter the menu 'All recipients' and register the search parameters below (Status should be either Inactive or calculation)



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/C to A and save data.



An e-mail 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 the email message.

Example of part of an email message

Scand 181 updated 2/4/2021 7:48:56 AM by

Not signed up, changed status to Active

Serological HLA: A2,11;B13,53;Cw4,6;DR7,13;DQ2,6;Bw4

Genomic HLA: A*0201,1101;B*1302,5301;C*0401,0602;DRB1*0701,1302;DPB1*0401,1701;DQB1*

Identif. Antib.: A:1,23,24,(80)

B:(7),(8),(18),(35),(39),(41),(42),44,45,(46),(48),(49),(50),(54),(55),(56),(60),(61),(62),

(64),(65),(67),(71),(72),(75),76,(78),(81),82

Cw:(1),(8),(10)

DQ:4,7,8,9

DQA:03,04,05

DR:1,4,(14),15,(18)

Calc. comb. PRA: 98

Acc. Mism.: A3,25,26,29,30,31,32,33,34,36,43,66,68,69,74,80

B7,8,18,27,35,37,38,39,41,42,46,47,48,49,50,51,52,54,55,56,57,58,59,60,61,62,63,64,65,67,71,72,

Cw1,2,5,7,8,9,10,12,14,15,16,17,18

DP0101,0201,0301,0402,0501,0601,0901,1001,1101,1301,1401,1501,1801,1901,2001,2301,2801

DPA03,04

DQ5

DR103,8,9,10,11,12,14,16,17,18

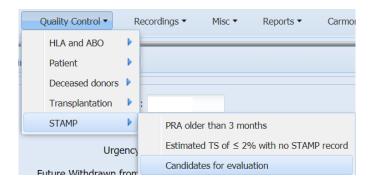
DRB3*01,3*02,5*01,5*02

TS <= 2%: Yes (.75%)

PRA < 3 months: Yes (18-NOV-2020 2 months 17 days)

8. Patients for evaluation

STAMP patients ready for evaluation is found by entering the 'Quality Control' menu and selecting 'Candidates for evaluation':



9. Communication during evaluation

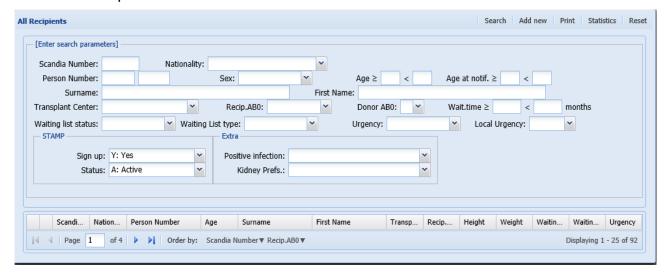
Approval/disapproval and communication about each specific patient must be done on the related waiting list record in the 'STAMP log' tab. To add information in the table, click below the 'Comments' column header.



Each time information is added in the STAMP evaluation table an e-mail with updated information will be sent to the STAMP committee and persons working on the patient record.

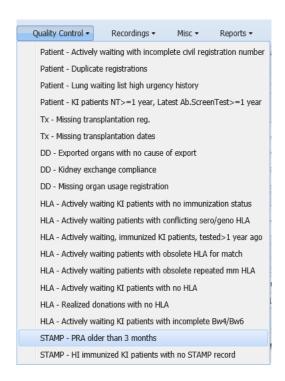
10. Patients on STAMP

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 is as a search parameter.



11. 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'.

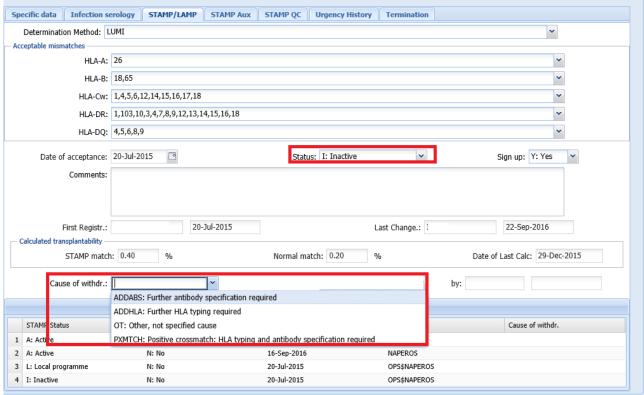


By entering this menu, you get a display of patients missing the regular antibody screen test. To the right is a count of months and days since last registered screen test.

- STAMP listed patients must be screened at least every 3 months, and antibody specificities must be re-evaluated at least yearly. However, it is obligatory 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 nor 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 your patient's immunization status has improved, you may consider register previously detected antibodies as allowable antibodies and adding them into the AMM list.

12. 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.

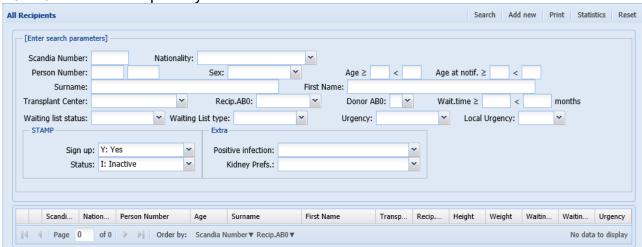


Please select cause of temporary withdrawal.

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"



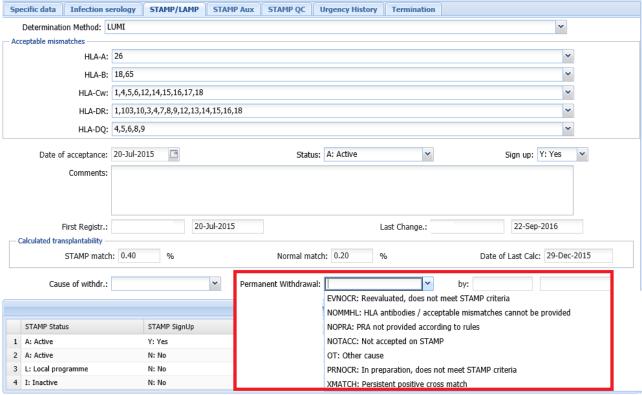
Perform thorough re-evaluation of the case and change the antibody/ the AMM list accordingly

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 reevaluated by the steering group.

13. 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.

14. STAMP reports

14.1 Patient STAMP details

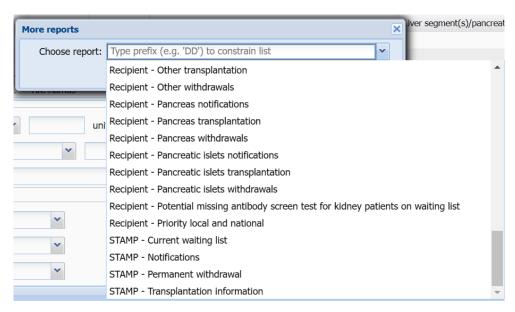
When you have a STAMP-patient (active/on hold/ withdrawn) on screen you can press the STAMP print button to display STAMP data on the screen.



14.2 Reports

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





STAMP – Current waiting list

Brings forward the recipients from your center that have an active STAMP record on the waiting list

STAMP - Notifications

Gives you all recipients that have been accepted on STAMP from your center in the period specified.

STAMP - Permanent withdrawal

This extraction contains patients from your center that have been permanent withdrawn from STAMP together with cause and date.

STAMP - Transplantation information

This extraction brings forward recipients transplanted through STAMP from your center in the specified period

LAMP

15. Introduction

Purpose

This program is a local version of STAMP. 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.

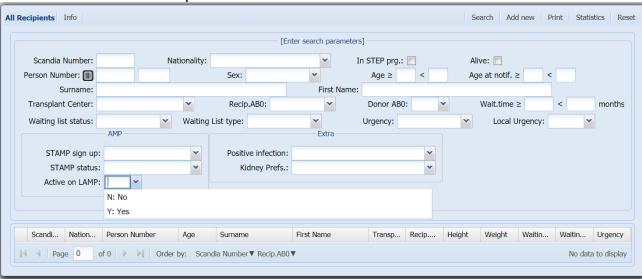
Acceptance criteria

Each center defines the acceptance criteria themselves and there is no approval for inclusion to the program from the committee, patients can go directly on LAMP.

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

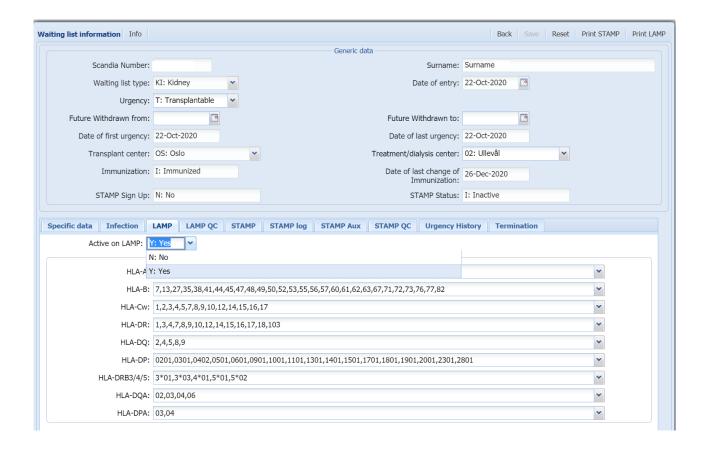
To create a new LAMP-record search forward the recipient the same way as described for STAMP point 2.

To find patients with an existing LAMP record you can search on patient ID or you can use the 'Active on LAMP' search option:



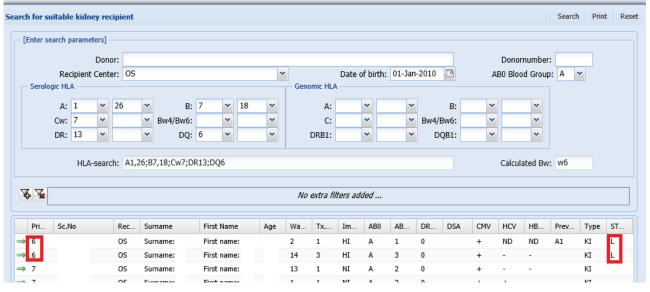
17. Patients ready to go on LAMP

Enter LAMP information in the dedicated tab and select 'Yes' when you want to activate the patient on LAMP:



18. Kidney search result LAMP

In the kidney search result screen a LAMP match will appear as a priority 6 match and marked with a 'L' in the STAMP status column.



STAMP & LAMP

19. Calculated combined PRA and transplantability

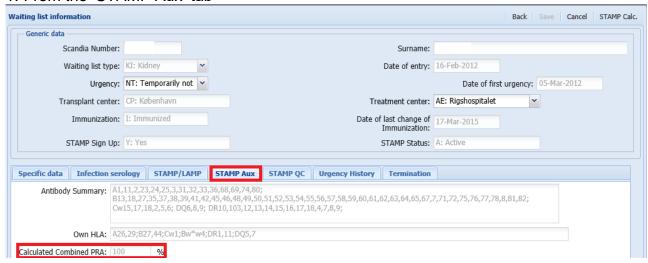
A donor pool, based on 2000 recently HLA typed deceased donors registered in Scandiatransplant, has been made. The pool forms the basis of the following calculations.

19.1 Calculated combined PRA

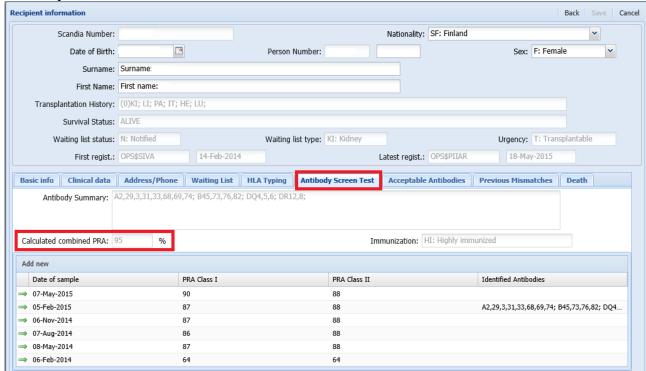
The calculated PRA is based on the antibody summary and is updated automatically when list of identified antibodies is changed. Antibodies that are no longer clinical relevant and set as acceptable () are not included in the calculation.

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.



19.2 Estimated transplantability score

There are two sets of estimated transplantability scores, one set is based on the latest antibody screen test result where HLA specificities have been defined and the other includes all antibody screen test results within the last year.

HLA-antigens to which the patients has no antibodies against are regarded as acceptable mismatches.

Based on split level HLA typing it gives you the percentage of donors in the pool which are ABO identical or compatible and have HLA split level antigens that are acceptable to the recipient (recipient HLA + Acceptable mismatches)

Recipient information Info Nationality: N: Norway Sex: F: Female Scandia Number: Date of Birth: Person Number: IIII Surname: Surname: First Name: First name: Transplantation History: (0)KI; LI; PA; IT; HE; LU; CO; Recipient Status: ALIVE; on STAMP; on LAMP Treatm. center: Haukeland Waiting list status: N: Notified Waiting list type: KI: Kidney Urgency: T: Transplantable 08-Oct-2020 First regist.: Latest regist.: 18-Nov-2020 Basic info | Clinical data | Address/Phone | HLA Typing | Antibody Screen Test | Fusion | Acceptable Antibodies | Previous Mismatches | Death Antibody Summary A:2,24,33,34,68,69 B:7,8,18,27,37,38,39,41,42,46,54,55,56,59,60,63,64,65,67,73,75,81,82 Cw:1,4,5,6,7,8,9,10,12,14,15,16,17,18 Q:2 DR:7,9 DRB3/4/5:3*02 equivalent): Calculated combined PRA: 100 Immunization: HI: Highly immunized Estimated Transplantability score

Identical ABO: 0.00

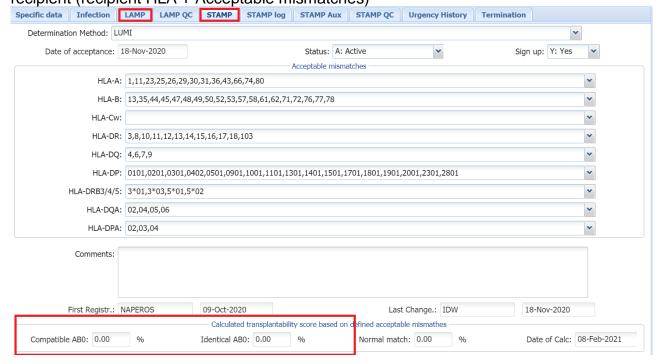
%

19.3 Transplantability score

%

Compatible ABO: 0.00

The transplantability scores are based on split level HLA typing on the patient and defined acceptable mismatches. It gives you the percentage of donors which are AB0 identical or compatible and have HLA split level antigens that are acceptable to the recipient (recipient HLA + Acceptable mismatches)



19.3 Normal match

'Normal match' is based on the patient HLA type and a 'normal' broad level A, B and DR match. It gives you the percentage of donors which are AB0 identical and have no mismatches on HLA broad level A, B and DR with the recipient, similar to a priority 2 kidney exchange obligation.