Deceased Donor Workup for Solid Organ Transplantation

PROCEDURAL REVISION

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Deceased Donor Workup for Solid Organ Transplantation

I. PRINCIPLE:

The HLA Laboratory of Methodist Dallas Medical Center provides compatibility testing for deceased donor kidney, kidney/pancreas and kidney/liver transplantation for The Transplant Institute at Methodist Dallas and in association with Southwest Transplant Alliance. The series of events involved in the compatibility testing between recipients and a deceased donor is described herein.

II SPECIMEN:

Any properly labeled specimen submitted to the MDMC HLA Laboratory for transplant or cellular immunologic testing.

III. REAGENTS AND SUPPLIES:

Reagents and supplies are outlined in the specific procedures referred to throughout this document.

IV. PROCEDURE:

A. Request for Preliminary Compatibility Assessment

The laboratory or technologist on call will be notified by MDMC transplant coordinator of a potential deceased donor organ offer for a kidney or kidney pancreas recipient. The coordinator will communicate the donor's UNOS ID and Match run ID number, the recipient name, DOB/ Medical Record number and request a Preliminary Compatibility Assessment. This is performed to determine if the potential recipient has any donor directed HLA antibodies, or if they can be considered for transplant with this donor.

1. To complete this assessment, you will need to access the donor's molecular typing in DonorNet:
   a. Https://Portal.Unos.org
   b. UNET requires Multi-factor authentication (MFA) to access the system, thus, you will need to open your Authy authenticator app and approve the request to complete the log in process.
   c. Upon log in, choose DonorNet.
   d. If the donor of interest is listed on the DonorNet home page, click on the Match ID to bring up the donor information.
   If the donor is not listed, choose Donors and Search from the top tool bar. Enter the required information to access the donor of interest.
   e. Choose the D*onor Summary* tab and click on the small *Print* icon on the right side of the page. Select *Crossmatch & HLA* and click on the *Print Summary* at bottom of the page, click again to print. Use this official copy to enter the donor's type in the LIS; see B, 5 below.
   f. To view a more detailed version of the HLA type, return to the Donor Summary tab and click on the sub-tab, *Attachments*. Scroll down to find the attachment labeled HLA (ex ADFY435-HLA) and print.

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2. Looking at the donor HLA typing, determine if the intended recipient has any donor directed antibodies, listed or partial. The recipient's HLA antibodies are listed on their LIS HLA Hist report. Additionally, check the front of the folder and paperless yellow sheet to confirm if there are any partial or allele specific donor directed antibodies. Additionally, check the patient folder and LIS for any pending PRA results and evaluate for the presence of donor directed antibodies.

3. If No donor directed HLA, allele specific and or partial antibodies are present, let the coordinator know the Preliminary Assessment is negative.

4. If any HLA- A, B, C, DR, DRB3,4,5 or DQB donor directed antibodies are present, or if any DQA, DPA or DPB donor directed antibodies are present with MFIs of ≥ **10,000**, let the coordinator know the Assessment is Positive, and thus a contraindication for transplant.

   If any HLA- A, B, C, DR, DRB3,4,5 or DQB allele specific donor directed antibodies are present consult the medical director prior to reporting the assessment. If director agrees to proceed, let the coordinator know possible allelic antibody and the patient will require a final physical crossmatch.

   Note: **If there is no allele specific,** reactivity within the partial antibody, there is no need to consult the director. For example, donor is DQB1*04:01 and recipient only has reactivity to DQB1*04:02, then no donor directed allele specific or partial antibody is present.

   If any DQA, DPA or DPB partial antibodies are present whereby any one bead shows DSA with MFIs of ≥ **10,000,** consult the medical director prior to reporting the assessment. If director agrees to proceed, let the coordinator know about the partial antibody and that the patient will require a final physical crossmatch.

   Note: When reviewing partial DQA, DPA or DPB reactivity **if** there is **no** allele specific reactivity within the partial antibody, there is no need to consult the director. For example, donor is DQA1*03:01 and recipient only has reactivity to DQA1*03:02 and 03:03, then no donor directed allele specific or partial antibody is present.

   As DQ and DP antibodies are present on Luminex Single Antigen PRAs as pairs of alpha and beta antibodies, both alpha and beta forms will be considered as partial or allele specific donor directed HLA antibodies if the pattern of reactivity cannot to attributed specifically to the alpha or beta form. However, if all beads for a particular alpha form are positive and not all beads of a particular beta form are positive, the reactivity can be attributed to the specific alpha form and thus the beta form will not be considered positive in regards to partial or allele specific donor directed HLA antibodies.

5. When the Preliminary Compatibility Assessment is requested for a recipient enrolled in the ABO Intended Incompatible Transplant protocol, the following information is pertinent:

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Please NOTE Any titer results preformed with the test INDIRECT ANTIHUMAN GLOBULIN TITER [LAB275] were NOT performed using DTT and the results should NOT be assessed when determining eligibility for this protocol.

Acceptable titer results include Ref Transplant ABO Antibody DTT Titer and/ or TRANSPLANT ANTI-A DTT TITER BY GEL.

i. For deceased donor transplant, our program is only enrolling ABO B recipients in the protocol. In order to qualify and be enrolled, the recipient must have 3 Anti-A **DTT** treated titers (preferably tested monthly), and all titer results must be ≤4. Once the recipient is consented, they are enrolled, via UNET, into the protocol. To remain qualified, the UNOS requires confirmation of titer every 90 days (+/- 20 days).

ii. Upon request for preliminary compatibility assessment, complete steps 2-4 above. Additionally, verify that all recipient Anti-A **DTT** treated titers results are ≤4, and that the most recent titer is dated within UNOS required timeframe (90 days, +/- 20 days) from the day of planned transplant). **If any of the DTT titers is >4,** notify director or designee as this is a contraindication for transplant with this protocol.

iii. If most recent titer is out of date, notify the transplant coordinator that a titer must be completed when the patient presents for final crossmatch. Note in the Deceased donor log to request Blood bank to perform the TRANSPLANT ANTI-A DTT TITER BY GEL [LAB5789] on the recipient's ABO sample.

iv. Initially, verify the donor ABO in UNET to be A, non-A1. This will be verified by testing in house as outlined below.
If the donor subtype result is discrepant, immediately notify the transplant coordinator of contraindication for transplant.

Dependent on the assessment of recipient antibody status and the criteria in steps i-iv, report the preliminary compatibility assessment to the transplant coordinator.

6. Upon completion of the Preliminary Compatibility Assessment, the coordinator will provide ETA for donor harvest and recipient arrival.

7. If the recipient qualifies for Final Virtual Crossmatch, as outlined in C2 below, immediately call the HLA Medical Director for approval and then call or secure chat the on call Nephrologist and Surgeon to verify they agree to the protocol. Secure Chat requires timely acknowledgement or a follow up phone call must be made. Note all communications/ acknowledgements in the Deceased Donor

Log. This may be early in the process but agreement by treating physicians is a must. If the virtual is in the middle of the night and if the calls are not made right away, email HLA Lab and place a note in the Deceased Donor Log book so calls can be made first am.

8. Note, all information about the donor and recipient, all crossmatch and ABO results and any communication with the transplant coordinator and/or transplant clinicians must be entered into the HLAF 1.12.C Final Crossmatch Log. This must be done in a timely fashion so that any technologist working on the case has up to date information.

9. Kidney/ liver recipients do not have HLA antibodies listed in UNET. Rather upon organ offer, a Final Virtual Crossmatch is performed as outlined below in Section C, 4.

B. **Deceased Donor and Recipient Samples and LIS orders**

Note, steps 1-6 apply to Kidney and Kidney/Pancreas deceased donor and potential recipients.

Receipt of deceased donor material for ABO typing and final crossmatch

Verify each specimen is properly labeled with the UNOS number, date and time of collection and collector's identification.

1. Prior to organ harvest, the lab often receives donor blood (ACD-A tubes and red top tube) which may be used for both final crossmatch and preliminary ABO verification and subtyping where applicable.
2. Use of the ACD-A tubes for Final Crossmatch testing should occur within 48 hours of blood draw, but may exceed 48 hours if cell viability is ≥ 80%.

Preliminary ABO typing/ subtyping should occur within 3 days of draw time. If this is not the case, Blood Bank may call asking if we want the ABO, as they will have to override a flag in their LIS. Confirm yes, we do want ABO.

Upon harvest of donor organs, HLA will receive "Final" donor material that arrives with the organ and can be used for final crossmatching but must be used for final ABO verification. Blood type A donors procured for ABO intended incompatible transplant must be subtyped, however, this can be done with either preliminary blood or final donor blood. Donor material may include lymph node, spleen, ACD-A tubes and red top tube. Lymph node, spleen or blood can be used for final crossmatching; ACD-A, red top tube, EDTA tube or spleen can be used for final ABO verification.

Exception: if the donor is for transplant using the ABO Intended Incompatible Transplant protocol, only a red top or EDTA tube may be used for ABO and subtyping.

Complete the registration of the deceased donor in the LIS via Requisition Entry. Register the donor with **SWTA HLA as the Submitter regardless of the OPTN procuring the organ**. Order an HLA TYPE CLASS I AND II NO CHARGE

[LAB3429] and [LAB6965] Transplant Evaluation ABO/RH No Charge; request donor ABO subtyping when applicable, TRANSPLANT A SUBTYPE [LAB4100].

3. Any donor ABO discrepancy from that reported in UNET is brought to the immediate attention of the laboratory director. In cases where the donor has been transfused, the ABO type may not be clear. The HLA director will advise on how to proceed/ who to notify.
4. Using the HLA typing report from DonorNet; answer and verify out the HLA TYPE CLASS I AND II NO CHARGE [LAB3429] in the LIS leaving the ABO field blank as it is not applicable to deceased donors. Add a comment to the report stating 'typing information obtained from UNET'.

   Our laboratory will retype the donor only when HLA typing information is not available to laboratory personnel, the donor has a serologic typing, rather than molecular or at the discretion of the HLA laboratory director.

   NOTE: Donors may receive numerous transfusions in order to maintain their stability. In the event we retype the deceased donor, HLA typing results are acceptable only if the HLA antigens are unequivocally defined with no more than 2 antigens per locus. Equivocal typing results require repeat using lymph node or spleen cells, both of which should provide accurate results unaffected by transfusion history.
5. Make a folder for the donor that includes the LIS HLA typing and Transplant Candidate Evaluation ABO/RH and A subtype where applicable and the typing information from DonorNet report(s). Make certain to redact any donor identifying information. Submit these results to the director or designee for review.

Receipt of recipient blood for final crossmatch for kidney and kidney/pancreas:

1. When the recipient presents to the hospital, blood is drawn for ABO typing and sent directly to the Blood Bank. If the recipient is pursuing the ABO Intended Incompatible Transplant protocol and requires an updated Anti-A DTT Titer, notify Blood Bank of the 'add on' test.
2. Blood for HLA crossmatch is sent to our laboratory
   a. Kidney and Kidney/Pancreas recipients presenting to the hospital for Final Physical Crossmatch or qualifying for Final Virtual Crossmatch will have orders in the LIS for an HLA Crossmatch, Flow Allo and Flow Auto [LAB3451]. This blood draw includes yellow top ACD-A tubes, an EDTA tube and a red top tube.
   b. For recipients receiving the 3 Month Remote Sera Final Physical Crossmatch, the remote final crossmatch is performed prior to the recipient presenting to the hospital. Therefore, HLA staff will submit an order in the LIS for the HLA Crossmatch, Flow Allo and Flow Auto [LAB3451], as discussed in C, 3 below. Upon admission, blood will be drawn for HLA Crossmatch, Flow Allo and Flow Auto [LAB3451]. Store or use as discussed in E, 3 below.

c. The primary recipient for the organ, (recipient listed first on the match run), will be charged for the donor ABO retyping, both initial and final ABO. Drop the charge(s) as follows:

- Double click on the current admission for the recipient; click on the charges button on the right side of the screen; click on HLA button.
- On next screen click on BOTH the HC ABO TYPE and HC RH TYPE button.
- Edit service date to date ABO collected AND change Service Provider to the treating nephrologist.
- When/if a second ABO is performed on donor, repeat process.

3. Receipt and processing of Kidney/Liver recipient samples is discussed in section C, 4 below. Blood Bank personnel are responsible for ordering and reporting ABO typing on Kidney/ Liver and Liver donors. No donor material is required for our testing purposes (unless Final Physical Crossmatch is requested) and HLA personnel do not input donor HLA typing in the LIS.
4. Note all communication from MDMC kidney and liver transplant coordinators and physicians in the Final Crossmatch Logbook including date, time and person communicating information.

C. **Final Crossmatch Protocols for Kidney, Kidney/ Pancreas and Liver/ Kidney Recipients**

Prior to performing a Final Physical or Final Virtual Crossmatch, you will need to determine which protocol to follow as outlined below.

1. **ABO Compatible and ABO Intended Incompatible Final Physical Crossmatch for Kidney, Kidney/ Pancreas Recipients**

a. A Recipient must present to the hospital for blood draw for a Final Physical Crossmatch if their cPRA >60%, they show donor directed, including allele specific antibodies and/or they do not have a PRA within the prior 3 months. Testing will include a Flow Allo and Auto crossmatch and PRA where applicable

Exception: if the recipient does not have a PRA within the prior three months, a PRA can be performed on a sample drawn when the patient presents for final crossmatch. If the PRA shows no donor directed antibodies, shows a cPRA of ≤ 60% and shows NO **donor directed, including allele specific** antibodies, the recipient may qualify for the Final Virtual Crossmatch. See protocol 2 below to determine the qualifications.

b. Information regarding transfusion or other sensitizing event are discussed with the medical director and recorded in the Final Crossmatch logbook.

c. **When the recipient is being considered for the ABO Intended Incompatible Final Physical Transplant protocol, verify the recipient meets the titers requirements as outlined in IV**, A 5 above. In addition, verify the donor ABO subtypes as non-A1.

2. **ABO Compatible and ABO Intended Incompatible Final Virtual Crossmatch for Kidney and Kidney/ Pancreas Recipients**

a. Kidney and Kidney/Pancreas transplant recipients may qualify for these protocols as follows:
Both primary and regraft recipients may qualify for this protocol if all of criteria listed below are met. Check the recipient's HLA chart, viewing each Luminex Single Antigen PRA report or the Paperless Yellow Sheet and any outstanding PRA samples. All criteria must be met in order to proceed with the final virtual crossmatch; otherwise, the recipient must revert to a final physical crossmatch.

i. **The recipient must have a cPRA history of ≤ 60% AND all PRAs devoid of any donor directed, including allele directed, HLA antibodies.** The ≤ 60% cPRA is based on HLA antibodies identified on the Single Antigen PRA assay; the criteria for this protocol negates FCPRA results

ii. **If the donor possess an allele that is not represented on our single antigen assay, and there is no reactivity within the antigen group, the recipient qualifies for final virtual crossmatch. If the donor has allele specific reactivity within the antigen group, the recipient does not qualify for a virtual crossmatch.**

iii. **The recipient must have a minimum of three Single Antigen. PRAs tested, one of which must have been collected within the previous three months.** If the recipient has only 2 PRAs, a PRA drawn with final crossmatch samples may be tested and if the result meets all criteria, the recipient may proceed with this protocol.

iv. **To qualify for this protocol, the recipient cannot have any sensitizing events since the last qualifying PRA**. Sensitizing events include transfusion, pregnancy, and transplant with any human tissue or organ since the last qualifying PRA. Verify this with the Transplant Coordinator. Additionally, ask the coordinator if there have been any hospitalizations since the last qualifying PRA. If there has been hospitalization, consult with the HLA Medical Director, who will advise if the patient can still qualify for the protocol.

b. The three required PRAs for this protocol must be tested by Single Antigen beads and do not need to be within a particular time frame, as long as there is a minimum of three and one of these is dated within the previous three months from date of planned transplant. If no PRA has been completed within the prior three months, or the recipient has only two Single Antigen PRA samples tested thus far, a PRA must be performed on a sample drawn when the recipient presents for transplant or other qualifying sample (a serum sample that has arrived in the laboratory but has not yet been tested). If this third sample result has cPRA ≤60% and is devoid of any HLA donor directed antibodies, partial or allele specific, the patient may proceed to transplant without a Final Physical Crossmatch, assuming all criteria outlined in a-f are met.

c. If the Luminex is inoperable and the patient requires a PRA in order to meet protocol, the recipient must proceed to Final Physical Crossmatch. Notify the coordinator.

d. When the recipient is being considered for the ABO Intended Incompatible Transplant protocol, verify the recipient meets the titers requirements as outlined in IV, B 5 above. In addition, verify the donor ABO subtypes as non-A1.

e. If the recipient meets all of these criteria, you must call the HLA Laboratory Director for approval, followed by a call or secure chat to the on call surgeon and nephrologist. Secure chat must be timely acknowledged or a follow up phone call made. All persons must agree to proceed with this protocol. Document this information in the Final Crossmatch logbook, listing all persons called/ chatted, times and dates.

f. Prior to proceeding to transplant, the **HLA Sensitization History for Transplant Patients** form must be filled out and signed by the recipient and witness as outlined in Section E, 8 below.

3. **ABO Compatible and ABO Intended Incompatible 3 Month Remote Sera Final Physical Crossmatch for Kidney and Kidney/ Pancreas Recipients**

For this protocol, the date of the sample draw is Day 0.

a. To qualify for the 3 Month Remote Sera Final Physical Crossmatch protocol, the kidney or kidney/pancreas recipient, **MUST** have a serum sample dated within the prior 3 months from the day of planned transplant **AND**, have been PRA tested on a **minimum of two** Luminex Single Antigen PRA samples. Fewer than two PRA samples will require recipient to present to the hospital for Final Physical Crossmatch and PRA. The report of a sensitizing event, ie transfusion, pregnancy, transplant with any human tissue or organ within the prior 4 months or

hospitalization since the last qualifying PRA requires discussion with the medical director to determine if we can proceed with this protocol or the recipient will revert to the Final Physical Crossmatch protocol.

b. Using this protocol, the Final Physical Crossmatch will take place prior to the recipient presenting to the hospital. Once the recipient presents to the hospital for transplant, crossmatch blood will be drawn (2-4 yellow top ACD-A tubes and 1 red top tube). If the allogeneic crossmatch is negative, no further testing is needed. If the allogeneic crossmatch is positive, an autologous flow crossmatch is required and is performed using this blood **but**, using same sera used on the allogeneic crossmatch. A PRA may be performed at the discretion of the medical director.

c. When the recipient is being considered for the ABO Intended Incompatible Transplant protocol, verify the recipient meets the titer requirements as outlined in IV, A 5 above. In addition, verify the donor ABO subtypes as non-A1.

4. **Final Virtual Crossmatch for Kidney/Liver:**
This section discusses virtual crossmatching for Kidney/ Liver recipients; a Final Physical Crossmatch for Kidney/Liver recipients is available upon request.

a. Prior to transplant, a Final Virtual Crossmatch must be performed for Kidney/Liver recipient to assess the presence of any donor directed HLA antibodies. Although donor directed antibodies are not a contraindication for transplant in Kidney/Liver recipients, identifying these antibodies is necessary to manage their care post-transplant. As such, a Luminex Class I and II PRA is performed on the recipient prior to, or upon listing, and again when the patient presents for transplant.

b. A patient may proceed to transplant with the Final Virtual Crossmatch based on a prior PRA result **if,** the sample was collected within the prior 3 months of planned transplant **and** the patient has had no sensitizing events in the prior 4 months. Sensitizing events include transfusion, pregnancy and/or transplant with any human tissue or organ within the prior 4 months. If the patient has been hospitalized since the last qualifying PRA, consult HLA Medical Director to see if a current PRA is needed. If there have been sensitizing events, a PRA is performed using the sample drawn when the patient presents for transplant.

c. Upon acceptance of an organ offer, the Liver Hold test is ordered by the `transplant clinician. The Liver Hold is not a laboratory test per se, rather serves to let the phlebotomist know what tubes to draw for the final virtual crossmatch and possible post-transplant testing. With this order, we will receive 1 red top tube for PRA and 2 yellow-top ACD-A tubes for buffy coat storage (place one ACD-A tube in the DNA rack).

d. Upon receipt of the sample, pull the liver hold test into Result Entry section in the LIS, answer and finalize. Next, add on an HLA CROSSMATCH - FC ALLO AND FC AUTO [LAB3451] to the Liver Hold order. If a PRA is required for the Final Virtual Crossmatch, add on the HLA PRA CLASS I AND II BY LUMINEX SINGLE ANTIGEN [LAB3417]. The Final Virtual Crossmatch is reported as outlined in section F.

e. When the Final Virtual Crossmatch is performed using the PRA sample drawn within the prior 3 months, no PRA is required. In this case, **the patient must sign the HLA Sensitization History for Transplant Patients form and this form must be received in the HLA lab prior to release of the Final Virtual Crossmatch report.**

f. A Final Physical Crossmatch for Kidney/Liver **is required when the Luminex is inoperable and the recipient had a sensitizing event within the prior 4 months or when the Luminex is inoperable and the most recent PRA sample is greater than 3 months old**. The crossmatch may be performed concurrent with surgery. When a crossmatch is required, notify the surgeon immediately. Results of the crossmatch must be reported to the surgeon and transplant nephrologist as outlined in section E below.

g. ABO B or O Kidney/Liver recipients may receive an ABO Intended Incompatible Transplant but are not required to have anti-A DTT titers. The strength of the Anti-A titer in these recipients is not a contraindication for transplant. Blood Bank personnel are responsible for ordering and reporting ABO typing and subtyping on Kidney/ Liver and Liver donors.

D. **Testing Required for ABO Compatible and ABO Intended Incompatible Final Physical Crossmatch, 3 Month Remote Sera Final Physical Crossmatch and Final Virtual Crossmatch for Kidney and Kidney/ Pancreas Recipients**

When the Flow Cytometer is inoperable, contact the UTSWMC laboratory as outlined in in FLF 1.19.A Memorandum for Instrument Downtime in the Flow Cytometry procedure manual.
All recipients chosen for Final Physical Crossmatch will receive both Flow Cytometric allogeneic and autologous T cell and B cell crossmatches, with the exception of the 3 Month Remote Sera Final Physical Crossmatch as outlined below.

1. Each Final Physical Crossmatch will include a minimum of 2 serum samples:
   Final crossmatch sample –a serum sample drawn at the time the recipient presents to the hospital for transplant with a current donor **OR** a sample that has been collected within 3 months of planned transplant, provided the recipient qualifies as described above and by transplant/pregnancy/transfusion history.

Peak serum sample - recipient serum sample showing the highest sensitization/ most number of reactive beads for Class II followed by Class I. If multiple serum samples show equal number of antibodies, choose the one with the higher MFIs. If partial donor directed antibodies appear on a sera, choose this sample as the peak (sera with highest MFI of partial DSA must be selected).

Additional Peak serum sample – in rare circumstances a third serum sample will be used for crossmatch. For example, a recipient has allelic donor directed antibody for both Class I and II seen on separate serum samples. One sample may be used as the peak and the other as an additional peak. Consult with laboratory director/ design when other circumstances occur that may require this type of sample.

Serum sample locations are found in the LIS, or written on the requisition attached to the PRA report. For samples moved to remote R boxes, the locations are found in the LIS or the H: drive in the R box location folder.

E. Reporting Final Crossmatches

1. Unusual crossmatch results must be discussed with the HLA Medical Director who will advise how to proceed and any comments to add to the crossmatch report. These can include positive allogeneic crossmatch with positive autologous crossmatch or positive crossmatch with no known donor directed antibody, etc.

2. For recipients receiving a Final Physical Crossmatch, the treating physician will place orders in the LIS for HLA CROSSMATCH FC ALLO AND FC AUTO [LAB3451].

3. For recipients crossmatched using the 3 Month Remote Sera Final Physical Crossmatch protocol, HLA staff will place the order in the LIS for final crossmatch, as the crossmatch is performed and reported prior to the recipient presenting to the hospital. Using Requisition Entry, order HLA CROSSMATCH FC ALLO AND FC AUTO [LAB3451]. Additionally, notify the Transplant Charge Auditor, who will move the final crossmatch charges to the correct encounter.
   When the recipient is admitted for transplant, the treating physician will order the HLA CROSSMATCH FC ALLO AND FC AUTO [LAB3451]. The blood drawn in association with the physician ordered final can be used for autologous flow crossmatch and/or PRA, as needed. Regardless, the final crossmatch report is submitted using the crossmatch ordered by the HLA staff. Ultimately, the crossmatch ordered by the physician is cancelled; however, the sera drawn with this crossmatch is stored in the TXP box as described in step 13. Serum can be stored even if crossmatch is cancelled.

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4. Prior to the release of the final crossmatch report for kidney, kidney/pancreas transplant, the donor ABO must be verified using a sample drawn at the time of organ harvest and/or received with the organ. Regarding the ABO subtyping of a donor for an ABO Intended Incompatible recipient transplant – if the ABO subtyping was performed on preliminary donor blood, the subtype does not have to be repeated with the final donor blood. One subtype will suffice; however, the donor ABO must be repeated with final material. There are occasions when we do not receive blood or spleen with the organ, and therefore cannot confirm ABO with "final material". When this occurs, answer the 'ABO confirmed by Blood Bank for donor? (Y/N):' question on the final crossmatch report with comment "BLOOD WAS NOT RECEIVED WITH THE ORGAN; THE ABO WAS CONFIRMED BY BLOOD BANK FROM BLOOD THAT WAS RECEIVED PRIOR TO THE ARRIVAL OF THE ORGAN"

5. The recipient must have an ABO result from blood drawn when they present to the hospital for transplant.

6. Upon completion of the Final Physical and 3 Month Remote Sera Final Physical Crossmatches, the results must be communicated to the on call MDMC transplant coordinator, Nephrologist and Surgeon, with read back. Negative crossmatches may be communicated via the LIS Secure Chat. In this circumstance, no call is necessary unless the secure chat is not acknowledged in a timely manner. Unusual crossmatch results such as positive allogeneic crossmatch, or positive allo crossmatch with positive autologous crossmatch, must be discussed with the HLA Medical Director prior to calling results to the clinicians. Communicate these results to the coordinator, nephrologist and surgeon through a phone call, and advise them of the medical director's assessment of the result.

   When calling the results of a final crossmatch using 3 Month remote sera, report the sample date used for crossmatch.

   Calls/ Secure Chat to each person are required as is documentation in the Final crossmatch Logbook.

7. Kidney/ Liver Final Virtual Crossmatch results **must** be called or secure chatted (with acknowledgement) to the on call nephrologist, with read back.

8. Record all communication, test results, date, time and names of personnel notified in the Final Crossmatch logbook.

9. For crossmatch compatible kidney and kidney/pancreas recipients, a final crossmatch report must be present on the recipient's hospital chart prior to surgery. In addition, any recipient proceeding to transplant with the 3 Month Remote Sera Final Physical Crossmatch or Final Virtual Crossmatch **must sign the HLA Sensitization History for Transplant Patients form verifying they have had no sensitizing events. This form must be**

received in the HLA lab prior to release of the final crossmatch report. A copy of this form remains in the recipient's HLA chart and a copy of the form is sent to the transplant floor or the OR, along with the final crossmatch and ABO reports.
This form is also required when a transplant will take place greater than three days from the time of final crossmatch blood draw.

10. Kidney/ Liver Final Virtual reports are typically available prior to transplant; however, transplant may proceed prior to completion of the testing and reporting. When the patient proceeds to transplant with a Final Virtual Crossmatch based on PRA drawn within the prior 3 Months, the recipient **must sign the HLA Sensitization History for Transplant Patients form and this form must be received in the HLA lab prior to release of the final crossmatch report.**

11. Each final crossmatch is reported using the LIS Pre-Transplant-Final Crossmatch report, assessing compatibility between the recipient and donor. How the final is reported is dependent on the crossmatch protocol employed. **When Epic is unavailable for crossmatch reporting, use the downtime HLA crossmatch report as discussed in FL1.19 Flow Cytometry Cross Match for Solid Organ Transplantation.**

    a. Reporting **ABO compatible Final Physical Crossmatch or 3 Month Remote Final Physical Crossmatch for Kidney, Kidney/Pancreas Recipients:**
    Using the LIS Pre-Transplant-Final Crossmatch report, fill out as follows:

        i. Use the Current Serum date and associated Allo and Auto T and B cell result fields to report the final crossmatch serum sample or 3 Month remote sample. For the 3 Month serum sample, it is possible this sample might be the patient's peak serum; however, the crossmatch result of this sample is always considered the "current" serum. In this instance, make a note in the Comments section of the report, that the 3 Month remote sample is also the patient's peak sample.
        Fill out the result fields for Peak Serum Date and when applicable, additional Peak Serum Date and associated Allo and Auto T and B cell result(s).
        Answer No to the result for "Qualifies for Final Virtual Crossmatch".

        ii. Once crossmatch results are entered, at the HLA XM Report result line, pull in and complete the HLAFINALXM crossmatch template. Final verify the crossmatch report and send a copy of this report along with copies of the recipient and donor ABO and HLA typings to the transplant floor or the OR. In addition, for 3 Month Remote Final Physical protocol patients, the **HLA Sensitization History for Transplant Patients** form must be

received in lab prior to release of the final report. A copy of the form is sent to the transplant floor or the OR, and a copy remains in the recipient's HLA chart.

b. Reporting **ABO Intended Incompatible Final Physical or ABO Intended Incompatible 3 Month Remote Final Physical Crossmatch for Kidney, Kidney/Pancreas:**

i. Using the LIS Pre-Transplant-Final Crossmatch report, follow step a.,i above.

ii. Once crossmatch results are entered, at the HLA XM Report result line, pull in and complete the *HLAFINSUBA* crossmatch template. The *HLAFINSUBA* report contains an ABO compatibility chart for this protocol, including questions verifying ABO titer and subtyping.
Final verify the crossmatch report and send a copy of this report along with copies of the recipient HLA typing, ABO and most recent Transplant Anti-A DTT treated titer, donor HLA typing and ABO/ ABO Subtype results to the transplant floor or the OR. In addition, for 3 Month Remote Final Physical protocol patients, the **HLA Sensitization History for Transplant Patients** form must be received in lab prior to release of the final report. A copy of the form is also sent to the transplant floor or the OR, and a copy of the form remains in the recipient's HLA chart.

iii. **For recipients receiving an ABO Intended Incompatible transplant, notify Blood Bank with the recipient's name** so they can place an alert on the patient's record to give the correct type of plasma.

c. Reporting **ABO Compatible Final Virtual Crossmatch for Kidney and Kidney/ Pancreas Recipients**

i. Using the LIS Pre-Transplant-Final Crossmatch report, answer **Yes** to the result for "Qualifies for Final Virtual Crossmatch". Leave the Current, Peak and Additional Peak serum dates and crossmatch fields blank (when the report is finalized, those answer spots will not appear on the report). At the HLA XM Report result line, pull in and complete the HLAFNLNOXM template. This template has pre-printed comments discussing the Final Virtual Crossmatch requirements.

ii. Final verify the crossmatch report and send a copy of this report along with copies of the recipient and donor ABO, HLA typings and the completed **HLA Sensitization History for Transplant Patients form** to the transplant floor or the OR. A copy of this form remains in the recipient's HLA chart.

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d. Reporting the **ABO Intended Incompatible Transplant Final Virtual Crossmatch for Kidney and Kidney/ Pancreas Recipients**

i. Using the LIS Pre-Transplant-Final Crossmatch report, answer **Yes** to the result for "Qualifies for Final Virtual Crossmatch". Leave the Current, Peak and Additional Peak serum dates and crossmatch fields blank (when the report is finalized, those answer spots will not appear on the report). At the HLA XM Report result line, pull in and complete the HLAFINSUBANOXM template. This template has pre-printed comments discussing the Final Virtual Crossmatch requirement and ABO compatibility chart for this protocol, including questions verifying ABO titer and subtyping.

ii. Final verify the crossmatch report and send a copy of this report along with copies of the recipient HLA typing, ABO and most recent Transplant Anti-A DTT treated titer, and donor HLA typing, ABO/ ABO Subtype along with the completed **HLA Sensitization History for Transplant Patients form** to the transplant floor or the OR. A copy of this form remains in the recipient's HLA chart.

iii. **Notify the Blood Bank with the recipient's name** so they can place an alert on the patient's record to give the correct type of plasma.

e. Reporting **Crossmatch Incompatible Kidney, Kidney/ Pancreas** recipient:

i. Using the LIS Pre-Transplant-Final Crossmatch report, fill out the Current, Peak Sera Date and where applicable, Additional Peak Date fields along with the associated Allo and Auto T and B cell result fields.
Answer No to the result for "Qualifies for Final Virtual Crossmatch".

ii. At the HLA XM Report result line, pull in and complete the appropriate crossmatch template for your donor/ recipient pair. Do not verify out the report.

iii. Attach copies of the recipient and donor ABO and HLA typings. The laboratory director or designee will review and final out the crossmatch report.

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f. Reporting the ***Kidney/Liver Final Virtual Crossmatch protocol:***

i. Using the LIS Pre-Transplant-Final Crossmatch report, answer **Yes** to the result for "Qualifies for Final Virtual Crossmatch". Leave the Current, Peak and Additional Peak dates and crossmatch fields blank (when the report is finalized, those answer spots will not appear on the report). At the HLA XM Report result line pull in and complete the LAB HLA FINAL KL REPORT – NO XM template.

ii. If no donor directed antibodies are identified, answer as follows:
'The virtual final crossmatch using sera dated xx/xx/xx was performed and found to be Negative.'

iii. If donor directed antibodies are present:
'The final virtual crossmatch using sera dated xx/xx/xx, was performed and found to be Positive'.
List each donor directed antibody, along with the highest MFI for each antibody. When there are multiple beads for a particular antigen, report the highest MFI within that series of beads.
Lastly, add the comment 'Recipient HLA type is unknown'. (This is added because we are making the assumption that the antibodies are donor directed as we do not know recipient's HLA type.)

iv. The final report does not include HLA typing information for the recipient, as we routinely do not type kidney/ liver recipients. The ABO donor typing is reported by Blood Bank and is not included on this final report.

v. Once completed, final verify the crossmatch report. For Kidney/ Liver, the crossmatch report is not sent to the transplant floor or the OR. However, the results must secure chatted (with acknowledgement), or called to the nephrologist on call for transplant. Report the sera date, all DSA and the MFI information.

REMEMBER, when the Final Virtual Crossmatch is performed using a PRA drawn within the prior 3 Months, **the patient must sign the HLA Sensitization History for Transplant Patients form and this form must be received in the HLA lab prior to release of the Final Virtual Crossmatch report.**

vi. When a **Final Physical Crossmatch for Liver/ Kidney** is **requested or required** (i.e. when the Luminex is inoperable):
Unless otherwise requested, crossmatch may take place concurrent with transplant surgery.
In all cases below, it is not necessary to notify the laboratory director of unusual crossmatch results.

a) If crossmatching at the request of the clinician, determine if PRA is also needed (most recent PRA sample date exceeds 3 months or recipient had a sensitizing event within the prior 4 months. If the patient has been hospitalized since the last qualifying PRA, consult with the HLA Medical Director on the need for current PRA).

b) Using Requisition Entry, order HLA CROSSMATCH FC ALLO AND FC AUTO [LAB3451] and where applicable, HLA PRA CLASS I AND II BY LUMINEX SINGLE ANTIGEN [LAB3417]. Using the LIS Pre-Transplant-Final Crossmatch report, use the Current Serum date and associated Allo and Auto T and B cell result fields to report the final crossmatch serum sample and at the HLA XM Report result line, pull in and complete the HLAFINALXM crossmatch template according to step b-e below.

c) If the crossmatch is negative, answer crossmatch template per protocol, noting in the comments the recipient is receiving a liver/kidney transplant. Results of the Final Physical Crossmatch will be reported to the liver transplant coordinator, surgeon and nephrologist.
Final verify the crossmatch report and send a copy of this report to transplant floor or the OR.

d) If the crossmatch is positive and donor directed antibodies are present from in-date or remote PRA, answer the comments section of the report as follows, 'A PRA dated xx/xx/xx shows a donor directed antibody xxx, with an MFI of xxx, as such, the positive crossmatch is not unexpected. These results do not preclude kidney/ liver transplant from this donor to this patient.' In addition, add statement 'Recipient HLA type is unknown'.

Results of the final crossmatch are reported to the liver transplant coordinator, surgeon and nephrologist.
If crossmatch was performed because the Luminex was inoperable, notify the nephrologist that we will complete a PRA on the crossmatch sample when the Luminex returns in service and will report any additional donor directed antibodies/ MFIs. In this case, add an order to recipient for HLA PRA CLASS I AND II BY LUMINEX SINGLE ANTIGEN [LAB3417].
Final verify the crossmatch report and send a copy of this report to transplant floor or OR.

e) If the crossmatch is *positive* and there are ***no*** donor directed antibodies to explain positivity, answer the comments section of the report as follows:
'A PRA dated xx/xx/xx on this patient shows no donor directed antibodies to explain the positive crossmatch; however, this does not preclude kidney/ liver transplant from this donor to this recipient.
If the crossmatch was performed because the Luminex was inoperable, notify the nephrologist that we will complete a PRA on the crossmatch sample when the Luminex returns in service and will report any novel donor directed antibodies/ MFIs. In this case, add an order to recipient for HLA PRA CLASS I AND II BY LUMINEX SINGLE ANTIGEN [LAB3417].

Results of the final crossmatch are reported to the liver transplant coordinator, surgeon and nephrologist.
Final verify the crossmatch report and send a copy of this report to transplant floor or the OR.

11. For all organ types, once final crossmatch reports are sent to the transplant floor or OR, call and verify their receipt. Note all communications in the Final Crossmatch Logbook.

12. A copy of the final crossmatch reports and related documents are attached to the recipient's HLA folder/ LIS chart and must be reviewed by the laboratory director or designee during the next business day of regular laboratory operation.

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13. **All** sera used in the final crossmatch must be frozen and stored **in the TXP** (transplanted) sera box for a minimum of 5 years. Note the location of the serum sample in the LIS.

a. Recipients receiving a Final Physical Crossmatch of any type will have both the current and the peak sera stored the TXP box. If an additional peak sample was tested, store this as well.

b. Recipients receiving a Final Virtual Kidney, Kidney/ Pancreas Crossmatch of any type will have the serum sample drawn the day they present for transplant stored in the TXP box.

c. Recipients receiving a 3 Month Remote Sera Final Physical Crossmatch of any type will have three to four sera stored in the TXP box; the 3 Month remote sample, the peak sample, additional peak sample if used, and the serum sample drawn when the recipient presented to the hospital for transplant. The latter sample may be needed for future testing.

d. For Kidney/ Liver recipients proceeding to transplant based on a Final Virtual Crossmatch from a PRA drawn within the prior 3 Months: pull this serum sample from its T location and store in a TXP location along with the serum sample collected when the recipient presented for transplant.

e. For Kidney/ Liver recipients transplanted with a Final Virtual Crossmatch based on the PRA drawn when the patient presents for transplant, file this sample in a TXP location.

14. Place a sample from the donor (ACD-A tube or isolated lymph/spleen cells) in the DNA rack for buffy coat storage. This donor sample is saved for a minimum of 5 years. Note the location of the sample in the LIS.

G. **PROCEDURE NOTES:**

If there is a typing discrepancy between laboratories, a variance report describing the discrepancy is signed by laboratory director.

H. **REFERENCES:**

N/A

I. **RELATED PROCEDURES:**

FL 1.19 Flow Cytometry Cross match for Solid Organ Transplantation
FLF 1.19.G HLA Downtime Crossmatch Forms
HLA 4.11 LABScreen (One Lambda) Class I and Class II Single Antigen Assay
HLAF 1.12.C Final Crossmatch Logbook