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Form 18: Donor Derived Cell-free DNA Collection

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Not Started

1 **Date of collection**

CollectionDate

2 **Indication for test**

- Routine surveillance
- Follow-up of treated rejection
- Follow-up of elevated dd-cfDNA result
- Clinical indication/for cause

Indication

2a **Rejection date** **Missing Reason:** Unknown

RejectionDateCode

2b **Elevated dd-cfDNA result date** **Missing Reason:** Unknown

ElevatedResultDateCode

2c **Clinical indication/for cause**

- Clinical symptoms/exam findings ClinicalIndicationClinicalSymptomsExamFindings
- Echo concern ClinicalIndicationEchoConcern
- Suspected medication nonadherence (e.g. by history, fluctuating levels, etc.) ClinicalIndicationSuspectedMedicationNonadherence
- New or increased donor specific antibody ClinicalIndicationNewOrIncreasedDonorSpecificAntibody
- Isohemagglutinin against ABOi graft ClinicalIndicationIsohemagglutininAgainstAboiGraft
- Change in biomarker ClinicalIndicationChangeInBiomarker
- Change in immunosuppression ClinicalIndicationChangeInImmunosuppression

2c.i **New or increased donor specific antibody detail**

- HLA antibody DonorAntibodyHlaAntibody
- Non-HLA antibody DonorAntibodyNonHlaAntibody

2c.ii **Change in biomarker detail**

- BNP/NT-pro-BNP
- hs-troponin
- Other, specify

BiomarkerChangeSpecify

BiomarkerChange

2c.iii

Was this patient changed to CNI-free maintenance immune suppression (i.e., no tacrolimus AND no cyclosporine?)

- Yes
- No

ImmunosuppressionChange

3 Donor-derived cell-free DNA result (%)

Range Information
 Too Low: < 1
 Normal: Between 1 and 100
 Question Zone: > 101
 Red Flag Zone: > 101

Missing Reason:
 Failed Test

DNAResultPercentCode

3 Donor-derived cell-free DNA result (Absolute value)

Missing Reason:
 Failed Test

DNAResultAbsCode

3a

Indicate Test Manufacturer

- Allosure (CareDx)
- Prospera (Natera)
- MyTAI
- Other, specify

ManufacturerSpecify

Manufacturer

4 Additional testing obtained within 30 days / closest to obtaining the dd-cfDNA

- Cardiac biomarkers AdditionalTestingPre30CardiacBiomarkers
- Antibody testing performed AdditionalTestingPre30AntibodyTestingPerformed

4a

Cardiac Biomarkers

- BNP CardiacBiomarkersBnp
- NT-pro-BNP CardiacBiomarkersNTProBnp
- High Sensitivity Troponin CardiacBiomarkersHighSensitivityTroponin
- Gene expression profile CardiacBiomarkersGeneExpressionProfile

4a.i

BNP

Missing Reason:
 Unknown

AdditionalBNPCode

4a.ii

BNP Date

Missing Reason:
 Unknown

AdditionalBNPDateCode

4a.iii

NT-pro-BNP

Missing Reason:
 Unknown

AdditionalNTPBNPCode

4a.iv NT-pro-BNP Date Missing Reason: Unknown

AdditionalNTBNPDateCode

4a.v High Sensitivity Troponin Missing Reason: Unknown

AdditionalTropCode

4a.vi High Sensitivity Troponin Date Missing Reason: Unknown

AdditionalTropDateCode

4a.vii Gene expression profile Missing Reason: Unknown

AdditionalGeneProfileCode

4a.viii Gene expression profile Date Missing Reason: Unknown

AdditionalGeneProfileDateCode

4a.ix Gene expression profile - specify manufacturer Allosure Eurofins-Viracor

AdditionalGeneProfileSpecify

4b Antibody testing performed HLA antibody (DSA) AdditionalAntibodyPre30HlaAntibody
 Non-HLA antibody AdditionalAntibodyPre30NonHlaAntibody
 Isohemagglutinin (A and/or B Ab) to ABO-I graft AdditionalAntibodyPre30Isohemagglutinin

4b.i HLA antibody (DSA) Positive Negative Unknown

HSAAntibodyPre30

4b.i.1 HLA antibody (DSA) Detail Class I HSAAntibodyDetailPre30ClassI
 Class II HSAAntibodyDetailPre30ClassII

4b.i.1.a HLA antibody (DSA) Class I Detail New Present And Stable Present And Increased Unknown

HSAAntibodyDetailClassIPre30

4b.i.1.b C1q binding (Class I) Yes No Unknown

C1qBindingClassIPre30

4b.i.1.c If Class I Positive, Present at dilution >=1:16 (Class I) Yes No Unknown

PresentConcentrationClassIPre30

4b.i.1.d HLA antibody (DSA) Class II Detail New Present And Stable Present And Increased Unknown

HSAntibodyDetailClassIIPre30

4b.i.1.e C1q binding (Class II) Yes No Unknown

C1qBindingClassIIPre30

4b.i.1.f If Class II Positive, Present at dilution >=1:16 (Class II) Yes No Unknown

PresentConcentrationClassIIPre30

4b.ii Non-HLA antibody Positive Negative Unknown

NonHLAAntibodyPre30

Non-HLA antibody Detail

4b.ii.1

- MICA NonHLAAntibodyDetailPre30Mica
- MICB NonHLAAntibodyDetailPre30Micb
- Antiendothelial cell Abs NonHLAAntibodyDetailPre30AntiendothelialCellAbs
- Vimentin NonHLAAntibodyDetailPre30Vimentin
- Anti-myosin NonHLAAntibodyDetailPre30AntiMyosin
- Angiotensin receptor (AT1R) NonHLAAntibodyDetailPre30AngiotensinReceptor
- Other non-HLA Ab NonHLAAntibodyDetailPre30OtherNonHlaAb

4b.ii.1.A MICA Stable New Present But Increased Unknown

MICAPre30

4b.ii.1.B MICB Stable New

- Present But Increased
- Unknown

MICBPre30

4b.ii.1.C
Antiendothelial cell Abs

- Stable
- New
- Present But Increased
- Unknown

AntiendoCellAbsPre30

4b.ii.1.D
Vimentin

- Stable
- New
- Present But Increased
- Unknown

VimentinPre30

4b.ii.1.E **Anti-myosin**

- Stable
- New
- Present But Increased
- Unknown

AntiMyosinPre30

4b.ii.1.F
Angiotensin receptor (AT1R)

- Stable
- New
- Present But Increased
- Unknown

AT1RPre30

4b.ii.1.G **Other non-HLA Ab**

- Stable
- New
- Present But Increased
- Unknown

OtherNonHLAAbDetailPre30

4c.iii Isohemagglutinin - Present at >=1:16 dilution

- Present at >=1:16 dilution
- Present at <1:16 dilution
- Negative
- Unknown

IsohemagConcentrationPre30

5 Was a biopsy obtained within 14 days of the dd-cfDNA assessment

- Yes
- No
- Unknown

BiopsyObtained

5a

Biopsy date

Missing Reason:
 Unknown

BiopsyDate

5b

ACR grade

- 0R
- 1R

- 2R
- 3R
- Unknown

ACRGrade

5c

AMR grading

- Both histology and immunofluorescence/immunohistochemistry performed (ie. C4d or C3d)
- Did not access biopsy for evidence of AMR
- Only assessed histology/ did not perform immunofluorescence/immunohistochemistry (ie. C4d or C3d)
- Unknown

AMRGrade

pAMR Grading

2013 revised ISHLT grading system for pAMR:
J Heart Lung Transplant 2013 Dec 32(12):1147-62.)
pAMR: pathologic antibody mediated rejection (0, 1h, 1i, 2, 3)

- 0 (negative)
- 1h
- 1i
- 2
- 3
- Positive for AMR but pAMR score not known

PAMRSCOR

AMR Findings

- No histologic features AMR
- Positive histologic features AMR (ie. Vasculitis/pericapillaritis)

BIOPAMR

5d

Was EMB gene expression profiling done (i.e., MMDx)

- Yes
- No
- Unknown

GeneExpProfile

5d.i

Was MMDx normal/abnormal?

- Normal
- Abnormal

MMDxNormAb

5d.i.1

TCMR?

- TCMR present
- TCMR absent
- TCMR-like changes not meeting threshold for TCMR

TCMR

5d.i.2

ABMR?

- ABMR present
- ABMR absent
- ABMR-like changes/not meeting threshold for ABMR

ABMR

5d.i.3

Injury

- None
- Mild
- Some
- Moderate
- Severe

Injury

5d.i.4 Parenchymal dedifferentiation

- None
- Mild
- Some
- Moderate
- Severe

ParenDediff

6a

Immune suppression

- No change made
- Decreased dose or target trough levels
- Increased dose or increased target trough levels
- Treatment for rejection (complete rejection form)
- Other, specify

ImmuneSuppressionSpecify

ImmuneSuppression

6b

Biopsy

- No biopsy ordered
- Biopsy ordered as planned per protocol
- Biopsy ordered outside of protocol
- Other, specify

BiopsySpecify

Biopsy

6c

Next surveillance (only if no biopsy obtained)

- No change to protocol based surveillance
- Earlier than planned surveillance (example labs, clinic visit, echo)
- Other, specify

NextSurveillanceSpecify

NextSurveillance

6d

Were there any additional management strategies in reponse to cell free DNA result?

Missing Reason:

- No other strategies

AddMgmtStrategyCode

7

Antibody testing performed (Post 30-days)

- HLA antibody (DSA) AdditionalAntibodyPost30HlaAntibody
- Non-HLA antibody AdditionalAntibodyPost30NonHlaAntibody
- Isohemagglutinin (A and/or B Ab) to ABO-I graft AdditionalAntibodyPost30Isohemagglutinin

7a

HLA antibody (DSA) (Post 30-days)

- Positive
- Negative
- Unknown

HSAntibodyPost30

7a.i

HLA antibody (DSA) Detail

- Class I
- Class II

HSAntibodyDetailPost30ClassI

HSAntibodyDetailPost30ClassII

7a.i.1 HLA antibody (DSA) Class I Detail (Post 30-days)

- New
- Present And Stable
- Present And Increased
- Unknown

HSAntibodyDetailClassIPost30

7a.i.2 C1q binding (Class I) (Post 30-days)

- Yes
- No
- Unknown

C1qBindingClassIPost30

7a.i.3 Present at dilution > =1:16 (Class I) (Post 30-days)

- Yes
- No
- Unknown

PresentConcentrationClassIPost30

7a.i.4 HLA antibody (DSA) Class II Detail (Post 30-days)

- New
- Present And Stable
- Present And Increased
- Unknown

HSAntibodyDetailClassIIPost30

7a.i.5 C1q binding (Class II) (Post 30-days)

- Yes
- No
- Unknown

C1qBindingClassIIPost30

7a.i.6 Present at dilution > =1:16 (Class II) (Post 30-days)

- Yes
- No
- Unknown

PresentConcentrationClassIIPost30

7b Non-HLA antibody (Post 30-days)

- Positive
- Negative
- Unknown

NonHLAAntibodyPost30

7b.i Non-HLA antibody Detail (Post 30-days)

- MICA NonHLAAntibodyDetailPost30Mica
- MICB NonHLAAntibodyDetailPost30Micb
- Antiendothelial cell Abs NonHLAAntibodyDetailPost30AntiendothelialCellAbs
- Vimentin NonHLAAntibodyDetailPost30Vimentin
- Anti-mysin NonHLAAntibodyDetailPost30AntiMyosin
- Angiotensin receptor (AT1R) NonHLAAntibodyDetailPost30AngiotensinReceptor
- Other non-HLA Ab NonHLAAntibodyDetailPost30OtherNonHlaAb

NonHLAAntibodyDetailPost30Specify

7b.i.1 MICA (Post 30-days)

- Stable
- New
- Present But Increased
- Unknown

MICAPost30

7b.i.2 MICB (Post 30-days)

- Stable
- New
- Present But Increased
- Unknown

MICBPost30

7b.i.3 Antiendothelial cell Abs (Post 30-days)

- Stable
- New
- Present But Increased
- Unknown

AntiendoCellAbsPost30

7b.i.4 Vimentin (Post 30-days)

- Stable
- New
- Present But Increased
- Unknown

VimentinPost30

7b.i.5 Anti-myosin (Post 30-days)

- Stable
- New
- Present But Increased
- Unknown

AntiMyosinPost30

7b.i.6 Angiotensin receptor (AT1R) (Post 30-days)

- Stable
- New
- Present But Increased
- Unknown

AT1RPost30

7b.i.7 Other non-HLA Ab (Post 30-days)

- Stable
- New
- Present But Increased
- Unknown

OtherNonHLAAbDetailPost30

7c Isohemagglutinin - Present at \geq 1:16 dilution (Post 30-days)

- Present at \geq 1:16 dilution
- Present at $<$ 1:16 dilution
- Negative
- Unknown

IsohemagConcentrationPost30

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