

MACS Specimen Requests and Repository Information

Investigators with an EC-approved concept sheet are able to request access to MACS specimens. The MACS collects and stores a variety of biological specimens, including serum, plasma, and cells.

MACS Repositories

- Precision Bioservices (Frederick, MD)
 - MACS central repository
 - CAMACS coordinates/completes repository requests
 - Specimen types available:
 - Collected every visit:
 - Serum
 - Plasma
 - PBMC viable
 - PBMC Pellets
 - Not collected on a regular basis:
 - Semen
 - Stool
 - Urine
 - Throat Wash
 - Anal Swab
- Local Repositories
 - Site coordinates/completes repository requests
 - Site maintains specimen inventory
 - Requests to use local repository specimens go through CAMACS
- Fisher Bioservices (Rockville, MD)
 - Additional B-cell pellets and non-viable PBMC pellets are stored at Fisher BioServices for the purpose of conducting host genetic studies. These samples are comprised of B-cell pellets created from immortalized lines of viable PBMC, and of non-viable PBMC pellets, respectively, created by the MACS laboratories on a limited basis. Unlike other specimens, the time point (visit/date) at which the specimen was collected is not required for host genetic studies and is therefore not recorded.
 - Immortalized B-cell lines
 - Program ended 2004
 - Each participant started with 3 vials of viable B-cells and 10 vials of cell pellets
 - 56% of MACS participants have at least one established B-cell line

Before Submitting Request

- Make sure you have:
 - Funding
 - Freezer space
 - Personnel and materials necessary for testing
 - IRB approval to receive specimens

Additional Specimen Requirements:

- Specimens obtained may not be used for anything other than the approved project without prior consultation and permission from the MACS EC.

- Storage of plasma collected with EDTA started April 1, 2006. Specimens previously thawed for other initiatives will most likely be shipped. If unacceptable, give a reason in the concept sheet for requiring specimens not previously thawed. Leftover material cannot be returned to the National Repository without prior approval from EC.
- Use of MACS specimens requires submission of a signed MACS Materials Transfer Agreement (MTA).
- If specimens are being shipped to multiple locations, please copy and complete the information in the concept sheet (E.6.a-c. above) for all locations. An MTA will need to be completed for all locations receiving specimens.
- If you are requesting lymphoblastic cell lines, the NIH AIDS Research and Reference Reagent Program requires all investigators to be registered prior to receiving samples. Registration materials and instructions can be found on the Reagent Program web site located at www.aidsreagent.org

How to Request Specimens: Choosing ID-VISITS

- CAMACS:
 - selects person-visits according to study design and in collaboration with investigator
 - determines specimen availability
 - obtains final approval of person-visits and specimens from the investigator
 - creates data file of specimens for repository request

Restricted time periods	Definition	Restricted Visits
1 st visit	specimens collected in first visit period 4/1/84 – 9/30/84	Visit 1
HIV Seroconverters	All men who have become HIV+ during the study	If specimen is within 18 months of seroconversion
ART-Naïve HAART Initiators	ART-naïve HAART initiator; Cannot occur at baseline visit	If specimen is within 18 months of HAART initiation
Deaths	All men who died during the study	If specimen is within 18 months of Death
Last specimen	Last specimen at person-visit	Varies
Rapid Progressors	All men who have less than 3 years between seroconverting and first AIDS diagnosis	All

Fast Progressors	All men who have 3 to less than 5 years between seroconverting and first AIDS diagnosis	All
Intermediate Progressors	All men who have 5 to less than 12 years between seroconverting and first AIDS diagnosis	All
Slow Progressors	All men who have 12 to less than 15 years between seroconverting and first AIDS diagnosis	All
Long-Term Non-Progressors	Defined two ways: 1) Remaining AIDS-free without therapy for 15 or more years 2).CD4 >500 for 5+ years; No ART; A single CD4 measurement between 350-500 is allowed during that time period	All pre-HAART and first post HAART visit restricted
Elite Controllers	Less than 50 HIV RNA copies/ml on 2 or more occasions within 1.5 years in absence of therapy; 1 detectable measurement less than 1000 copies/ml was allowed between two suppressed values	All pre-HAART and first post HAART visit restricted

Specimen Selection/Submittal

- Specimens are requested using final list of id-visits
- CAMACS works with investigator regarding:
 - Vial warnings
 - Alternate id-visits (if no specimens remain)
 - Volume concerns
- Specimen selection takes approximately 1-2 weeks
- Discrepancy reports
 - CAMACS handles all discrepancy reports emailed to CAMACS staff from repository
 - In some cases:
 - Alternate id-visits may be selected
 - Id-visits may need to be dropped
- Once complete, CAMACS provides investigator with:
 - Requisition number for request
 - Excel spreadsheet of final id-visits requested
 - List of any id-visits dropped or replaced
 - List of any transfer id-visits in request

Specimens are usually shipped by the repository within 10 business days from submittal of request by CAMACS

Unused Material

Once specimens have left the repository, been thawed, and/or used for testing, they cannot be returned to the repository. Left-over materials cannot be used for other studies not described in the EC-approved concept sheet.

Repository Files

- Bi-annually, following central edits and summary file:
 - CAMACS Programmer downloads inventories of BSI and Fisher databases.
 - The inventories are matched to assure the repository specimens are correctly linked to all other visit information
 - Programmer works with CAMACS coordinator to correct any inconsistencies in repository database
 - Data files are defined by macsid/visit/date/vial

Restrictions on Samples

- Use of last vial for any id-visit:
 - CAMACS asks investigator to select alternate id-visit
 - If no alternates exist, investigator can:
 - Contact local repositories to obtain specimens
 - Petition the EC for approval to use the last vial
 - Restricted time period specimens:
 - Use of restricted specimens must be approved by EC

Transfer of Results

The MACS releases specimens to investigators with the understanding that the MACS is entering into a full collaboration with the study investigator. All data generated from testing of MACS specimens must be submitted to CAMACS before release of any visit data for analysis.

Results should be sent to CAMACS with the following information (in Excel or ASCII):

- README#
- Brief synopsis of project and type of testing performed
- Codebook detailing result ranges and full test names
- Include (at the very least): macsid, visit, specimen collection date, test(s) result(s)