

**NATIONAL  
PHYSICIANS  
COOPERATIVE**



**GLOBAL  
ONCOFERTILITY  
NETWORK**

**National Physicians Cooperative of the Oncofertility Consortium®**  
**Section 5. Infectious Disease Testing:** Establishing an account with Memorial Blood Centers (MBC) and performing infectious disease testing and plasma archiving.

*\*If your institution is registered with the FDA to perform infectious disease testing for living donors (see sample requisition and confirm with your lab), you may have ID testing done on-site. Always retain a purple-top tube for future testing and keep with the patient's tissue (see section titled Plasma Sample Archive).*

**Estimated Time to Complete (through MBC): 2 Weeks**

### **Background:**

1. Patients undergoing cell or tissue cryopreservation will be tested as anonymous donors of leukocyte rich tissue which does not come into contact with the genitourinary tract.
2. While some patients may use their tissue for transplant or IVF themselves, based on the type of cancer they have and/or their treatment, it may be necessary for them to make use of gestational carrier to establish a pregnancy. Therefore, these patients will be tested as though they might be donors of leukocyte rich tissue.
2. **Current FDA regulations require screening and testing of donor of sperm, testicular or ovarian tissue within 7 days of tissue procurement and oocyte donors within 30 days prior to or 7 days after retrieval. Retrospective testing beyond this window is not permitted.**
3. Because you cannot anticipate how your patients may ultimately use their ovarian tissue, you should test all of them within 7 days of their surgery to maintain maximum flexibility for the patient.
4. Logistically, we recommend drawing blood for infectious disease testing on the day of surgery (even intraoperatively). In this way, the blood is ONLY drawn and sent out for testing if there is actually tissue available for testing.
5. The Oncofertility Consortium recommends that this testing be performed at Memorial Blood Centers in St. Paul, MN or at an FDA-approved site for infectious disease testing.

### **Why Memorial Blood Center?**

1. FDA regulations require testing in an FDA registered lab using FDA cleared kits that are appropriate for low prevalence donor populations.
2. This testing is NOT generally performed at most medical centers since the testing they do is for diagnostic purposes. (For example, the diagnostic HIV

- test done by most hospital labs does not make use of the kit required by the FDA).
3. FDA regulations also require that you audit the lab that is performing your testing (in fact, you must audit all significant vendors of products and services involved with processing donor cells and tissues.). Having all sites performing OTC use the same lab for infectious disease testing simplifies this process and the number of audits that must be conducted. However, you may use your home institution **if you have a FDA registered lab using FDA cleared kits appropriate for this situation.**
  4. Memorial Blood Center's pricing is generally significantly cheaper than that available from diagnostic labs (approximately \$150 for the full battery of tests).

### **Timing, Turnaround and Practical Considerations**

1. Infectious disease testing must be **drawn** within 7 days (**30 days prior for oocytes**) of tissue procurement (either before or after surgery).
2. For practical reasons, we have found that it works best to **draw the blood on the day of surgery---even intra-operatively.** In this way, if the patient's surgery day gets changed for *any* reason, you are not in the position of potentially having to draw the blood a second time because the surgery falls outside the acceptable window. We have also seen situations where unexpected surgical findings meant that no ovarian tissue was available for freezing (i.e. pathology decided they needed the entire ovary based on unanticipated surgical findings). Drawing the blood once you are sure you have tissue for freezing eliminates unnecessary testing with its associated costs.
3. A **sample requisition** for the blood testing required under current FDA regulations is available on the Oncofertility Consortium website. While you can order additional tests, this is the required minimum. Memorial Blood Center will provide you with requisitions that contain your unique account number so please just use this one as an **EXAMPLE. You should keep abreast of any changes in these regulations.**
4. **NOTE: If the tissue is removed vaginally** (e.g. vaginal TAH/BSO), you **MUST** also perform GC and Chlamydia. If the tissue is removed laparoscopically and does not come into contact with the genitourinary tract these tests are **NOT** required.
5. You can also add a test after results are available if you need a confirmatory test.
6. **You will draw 3 purple top tubes and one red top tube.** Memorial Blood Center will provide all supplies and the shipping boxes. (**Two purple and one red for Memorial blood center and one purple for plasma archiving**). If GC and Chlamydia are performed urine sample or vaginal swab is required.
7. **You will retain one purple top tube for Plasma Archiving (see below).**
8. Samples should be over-nighted to Memorial Blood Center the **on the day drawn!** MBC usually turns around results in 2-3 business days (depending upon the day of the week). However, samples must be processed within a time frame specified and validated by the kit manufacturer. Therefore, you should **NOT** hold on to these samples over a weekend, etc.
9. Samples being shipped to MBC should be labeled with the patient's name and appropriate study identification information. Use of a hospital label is acceptable.
10. **NOTE:** Patients will **not** be excluded from banking ovarian tissue based on

infectious disease status so test results are not required before tissue processing. However, test results **MUST** be available before the tissue can be shipped to Reprotech for storage (see Reprotech instructions in a separate section).

## **Plasma Sample Archive**

1. A sample of the patient's plasma (drawn within 7 days of tissue procurement) will be stored with her **own tissue**.
2. FDA can change its requirements for infectious disease testing at any time, usually by adding additional tests, to minimize the spread of new diseases. Historically, they have not allowed retrospective re-testing of a patient when they have added additional test requirements.
3. Storing a plasma sample drawn within 7 days of tissue procurement is the best way to ensure that future changes in FDA testing requirements will not render the tissue unusable.
4. **Plasma** (not serum) is required for this testing.
5. The protocol for ovarian tissue freezing (separate section) gives a detailed description of how to process and store this plasma sample.

## **Billing and Finances**

1. The infectious disease testing performed on patients banking ovarian tissue is required to ensure that patients can use the portion of their tissue that is stored **for their own use; *Jhis being done to meet FD5 fYei JfYa Yblg`Zf` H YdUjYbhic i gY\ Yf`ck b tissue in the future.***
2. Costs of infectious disease testing is the patient's responsibility. You should bill her or her insurance. In most cases, insurance will cover this testing.
3. Memorial Blood Center will bill you (your practice or division) for this testing. You should bill the patient or her insurance.
4. You should always use the correct CPT codes to denote these tests and diagnosis codes for the patient's medical diagnosis. These patients are not infertile so infertility should **NOT** be used as diagnosis code.

## **Establishing your account with Memorial Blood Center (MBC)**

1. Contact Tracy Hanks at Memorial Blood Center to set up your account:

Tracy Hanks  
Customer Service Team Lead  
Memorial Blood Center  
Phone: (651)332-7115  
Fax: (651) 332-7007  
thanks@mbc.org

**If Tracy is unavailable**, her voicemail will instruct you about alternate phone numbers to use.

2. MBC will provide you with a very extensive packet of logistical information that including: requisitions, supplies and shipping containers, shipping procedures, blood drawing requirements, pricing, CPT codes for billing, etc. etc.
3. This process of establishing and account and obtaining blood drawing kits, requisitions, having materials shipped, etc, takes time to complete (please allow up to 2 weeks unless you are willing to pay premium shipping costs).
4. **Remember, you will always be drawing an additional purple top tube for plasma archiving! Keep it with the patient's tissue, DO NOT send it to Memorial Blood Centers.**
5. Testing performed at MBC is appropriate for any of donor testing needs (egg donors, donor embryos, etc.). You are required to send the testing of your ovarian tissue patients to MBC.
6. It is never too early to get this account set up and to start working through your logistics.