

# Frequently Asked Questions pertaining to storage of Potentially Infectious Reproductive Tissue

ReproTech provides storage services for patients who have tested reactive for any communicable disease, such as HIV, Hepatitis B, Hepatitis C, Syphilis or COVID-19/SARS-CoV-2. ReproTech can help eliminate potential cross- contamination issues with this program. The extra steps detailed below help ensure the safe storage of reproductive tissue for all clients.

### How are embryos, oocytes and sperm (reproductive tissue) stored?

Cryopreserved reproductive tissue is stored either in liquid nitrogen or nitrogen vapor.

### What are the temperatures of liquid nitrogen or nitrogen vapor?

The temperature of liquid nitrogen is -196 degrees Celsius at sea level. Specimens stored in our vapor tanks are in canisters which sit above liquid nitrogen and are maintained at -194 degrees Celsius.

### Is vapor storage safe?

Yes, as stated above, the temperature differential between liquid and vapor is minimal, approximately 2 degrees. The critical temperature for cryopreserved specimens is approximately -130 degrees Celsius, so specimens maintained at temperatures below -130 degrees Celsius would be safe. Studies show that vapor storage of vitrified samples is as effective as liquid storage.

# Why are embryos and gametes from people who have a reactive test segregated?

There is a theoretical risk of cross contamination between specimens stored in liquid nitrogen. We say theoretical because there are no documented cases of disease transmission between cryopreserved human reproductive tissue. There is a documented case of Hepatitis transmission between blood bags stored in liquid nitrogen. That case is what prompted the concern, and resulting protocols, for segregating specimens from people who have tested reactive for various communicable diseases.

# How are reproductive tissues from people who have a reactive test segregated?

ReproTech stores reproductive tissue from individuals who have had a reactive test to a communicable disease in vapor to eliminate the possibility of cross contamination from liquid nitrogen. Further segregation occurs by disease, meaning specimens from individuals who have tested reactive for "Disease A" are only stored in a canister with specimens from other individuals who have tested reactive for "Disease A." Likewise, specimens from individuals who have tested reactive for "Disease A." Likewise, specimens from individuals who have tested reactive for "Disease B."

# What if I have a reactive test result for Hepatitis B Core Antibody but I am Antigen non-reactive? I do not want my specimens stored with those from people who have confirmed infectious status.

ReproTech provides another level of segregation in this instance. We further segregate the specimens of individuals who have antibodies to a disease, but have confirmatory testing indicating they are no longer infectious, from specimens of individuals who have confirmed infectious status.

# If I have been confirmed to be non-infectious, why am I being stored as potentially infectious?

The FDA regulations for tissue donors, as well as the American Association of Tissue Banks Standards, require this type of designation. We simply are providing the safest storage possible. While you may have confirmatory testing indicating you are no longer infectious, this cannot be confirmed to a 100% certainty. While you will experience an increased shipping fee, ReproTech does not apply the potentially infectious storage rate to this group of patients.

# I traveled to an area under a Travel Advisory for Zika virus transmission, but have not been tested reactive for Zika, why is my specimen segregated in a potentially infectious tank?

Simply traveling to an area of risk for Zika virus or other emerging diseases does create a risk that you may be infective and therefore your stored reproductive tissue may be infectious. Further, in the case of Zika, there is a potential risk to the developing fetus should the reproductive tissue be infected.

However, since there currently is no testing to confirm that you or your tissue are infectious, you will not see an increased fee for storage or shipping of your reproductive tissue.

### I have tested positive for COVID-19, how will my specimens be stored?

Research about the transmissibility of COVID-19 in reproductive tissue is ongoing and ReproTech is focused on providing the safest storage possible for our clients with the information that is currently available. We separate the storage and shipping of specimens depending on your testing and screening status as follows:

### Positive COVID-19 test <u>without</u> a follow-up Negative COVID-19 result:

If you tested positive for COVID-19 in the 60 days before or after the collection/retrieval of your specimens, and you did not receive a Negative test result before your collection/retrieval, we will transport and store your specimens as Potentially Infectious. You will need to pay shipping fees and we will assess Potentially Infectious storage fees.

#### Positive COVID-19 test result with a follow-up Negative COVID-19 result:

If you tested Positive for COVID-19 in the 60 days before your collection/retrieval, but you had a Negative test result before your collection/retrieval, we will transport and store your specimens as Potentially Infectious. You will need to pay shipping fees, however we will assess our regular storage fees. ReproTech still considers these specimens to be Potentially Infectious because some research has indicated that COVID-19 virus may still be present in reproductive tissues even after a negative test result.

# Positive COVID-19 test result or screening indicates <u>active COVID-19 infection at the time of</u> <u>collection/retrieval:</u>

If your clinic considers your specimens to be Potentially Infectious for COVID-19 based on testing or screening, ReproTech will transport and store your specimens as Potentially Infectious. You will need to pay shipping fees and we will assess Potentially Infectious storage fees.

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The Cryostorage Experts