



Additional Agreement to Use Donor Sperm from Donor LX 2064

I, _____ (Recipient), and _____ (Partner, if applicable), specifically request and accept frozen semen from Cryobio donor LX 2064. I understand that this Additional Agreement is an additional part of the Sperm Use Agreement specific to donor LX 2064. LX 2064's cytomegalovirus (CMV) status changed from negative to positive during his time in the donor program. Any vials available after September 14, 2023, are from when he is positive CMV total. Health care providers differ on how they counsel their patients about CMV. Some health care providers want their patients to consider a donor's CMV status relative to their own and have them pick a donor with the same CMV status, but not all do. Since all health care providers differ on this, and since Cryobio cannot give you medical advice, you must consult with your health care provider and determine whether LX 2064's CMV status matters to you.

Information about CMV:

CMV is a common virus that affects people of all ages. Most healthy people who are infected do not show symptoms and do not experience any lasting effects. The most common way CMV is spread is through saliva or urine from young children who are infected with the virus. CMV can also be transmitted by other bodily fluids, including semen, but this is not as common. People who have children, work with young children, or have interactions with young children are most at risk of infection. Generally, in the U.S., over half of adults have been infected by age 40, but some studies have shown that globally, in women of reproductive age, between 45-100% show past infection with CMV.

CMV stays in the body for life once a person is infected and can reactivate, or an individual can be infected by a different strain. An active CMV infection can cause serious illness or other problems in people who are immunocompromised. If a fetus is exposed in utero through an infection in the pregnant person, they may be born with congenital CMV. Congenital CMV is more common during the first (primary) infection a person experiences but may also occasionally happen during later infections. CMV can also be passed through the birthing process or through breast milk.

The effects of congenital CMV are widely variable and range from no lasting effects to effects such as sensorineural hearing loss, vision impairments, developmental or learning challenges, seizures, or more serious issues. Symptomatic infants tend to have more serious long-term complications, while asymptomatic infants usually have no complications, however hearing loss may develop in these children as they get older. While congenital CMV is the leading cause of non-genetic deafness in children, asymptomatic newborns who have no signs of hearing loss by age 2 will generally not develop any hearing losses. Monitoring and early interventions can help with some of the challenges children with congenital CMV may have. Some hospitals have started screening for congenital CMV at birth, and all states have some form of a hearing assessment that infants should undergo to help identify hearing loss.

Please see the CDC's website for more CMV information. And as always with any medical information, please ask your health care provider for more information about CMV and whether you should consider a donor's CMV status when deciding which donor to use.

Sperm Donors and CMV:

As required by the FDA, all Cryobio donors are screened and tested for relevant communicable diseases multiple times while they are in the donor program. Donors are tested when they first enter the donor program, they are tested on a quarterly basis while in the program, and they are tested at least 6 months after their last collection. All donor vials are collected at least 6 months before they are released to the public. The FDA requires CMV testing for sperm donors and this testing occurs on a frequent basis while the donor is in the program. Cryobio donors are tested initially for CMV total antibodies to determine whether the donor has ever been infected with CMV. A donor that has not been infected with CMV will test negative. A positive CMV total test means the donor has previously been infected or has a current infection. A donor with a positive CMV total result has further testing that looks at IgG and IgM separately. IgG and IgM indicate whether the positive CMV total result means the donor has an active infection or whether they have just been exposed to CMV in the past. A positive IgG indicates they have been exposed to CMV in the past. A positive IgM indicates an active infection.

Cryobio follows FDA regulations and ASRM guidance and donors are not disqualified from donating for being CMV positive as long as further testing shows that the positive result does not indicate an active infection. Cryobio's policy is that if the donor's IgM results indicate an active CMV infection, then they do not collect any sperm samples until the active infection resolves, and their test results indicate that they have history of past infection but not an active infection. Any vials collected during the time a donor has an active infection are discarded.

Donors who are positive CMV total are tested for IgM monthly to determine if they have an active infection. Donors with a history of past CMV infection will be labeled CMV positive on our website. Donors with no history of past infection will be labeled CMV negative on our website. A CMV positive donor's accompanying paperwork will show positive CMV total, positive IgG, and negative IgM. Because CMV is such a common infection, some donors who were CMV negative when they started the donor program end up becoming a CMV positive donor while they are in the program. The donor's CMV status is always available on our website and in the paperwork accompanying the vials.

LX 2064 and CMV:

Based on initial CMV testing, LX 2064 was originally labeled as a CMV negative donor. During his time in the donor program, LX 2064 tested positive on a routine CMV total test. He underwent further IgG and IgM testing to determine if he had an active infection, and testing indicated he did. All collections from the time he first tested positive back to his last negative CMV total test were discarded and were never put on the website for purchase. LX 2064 resumed collecting samples after testing showed his original infection had passed, and his IgG and IgM showed past evidence of CMV infection but did not indicate active infection.

Any previously purchased vials from LX 2064 were from when he was CMV negative. Any vials purchased after September 14th, 2023, are from when he is CMV positive. Out of an abundance

of caution, we paused the ability to purchase vials of LX 2064 for a few months to make sure that people were aware of the change in LX 2064's CMV status, and we are requiring all recipients to sign this consent, whether they used LX 2064 in the past or not.

I specifically request and accept donor sperm from Donor LX 2064 with the understanding that:

Based on testing during his time in the donor program, LX 2064 was originally labelled as a CMV negative donor, and he is now labelled as a CMV positive donor. CMV positive status on our website is based on past infection, it does not mean the donor has an active infection, we do not offer vials from donors with an active infection.

All vials of LX 2064 purchased after September 14, 2023, are vials that are from when he is CMV positive. LX 2064's website profile and the paperwork accompanying the sperm will now label him as CMV positive.

Cryobio offers CMV positive donors, based on FDA regulations, ASRM guidance, and Cryobio's policies, as long as the donor's IgM results indicate no evidence of active infection.

Cryobio cannot give medical advice and we strongly recommend that all recipients consult with their health care provider about CMV in general, their CMV status, if they should be tested for CMV, and whether they should consider the donor's CMV status while attempting pregnancy.

I have read and had the chance to ask questions, and I understand and agree to the terms of this Additional Agreement to use donor LX 2064.

Recipient	Date
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Partner, if applicable	Date
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<i>William C. Baird, PhD.</i>	09-14-2023
Cryobio	Date