NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

MARY T. BASSETT, M.D., M.P.H.
Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

New York State Tissue Resources Program

Policy – Timing of testing of semen donors for infectious diseases
Effective date – December 8, 2022
Valid until – Regulatory or policy change supersedes this policy

To protect the public health and mitigate the risk of infectious disease transmission through artificial insemination and assisted reproductive procedures, 10 NYCRR Part 52-8.6(b) requires that semen donors be tested for certain infectious diseases prior to donor acceptance and initial collection of semen for clinical use. However, 52-8.6(b) does not specify a window of time within which such testing must be performed.

In contrast to 52-8.6(b), US FDA, in Title 21 Code of Federal Regulations part 1271, requires that blood specimens for testing of semen donors be collected within seven days before or after initial collection of semen for clinical use. To remain in compliance with both sets of requirements, the tissue bank must collect blood specimens and test semen donors within seven days prior to initial collection of semen, which can be impractical and present a hardship for tissue banks and donors while providing no public health benefit.

The Department finds that FDA requirements regarding the timing of testing for infectious diseases are comparable to the requirements in 52-8.6(b) and adequately protect the public health, safety, and welfare. Henceforth, the Department will conform NYS requirements for the timing of specimen collection and testing of semen donors to those of FDA. Therefore, the Department will enforce the testing requirement consistent with the parameters established by the FDA and allow for the collection of specimens for testing from semen donors up to seven days after collection. The Department will continue to enforce the requirements in 52-8.5 that semen donor screening based on physical examination and social and medical history be completed prior to initial collection of semen for clinical use.

Any tissue bank that collects donor semen for clinical use prior to finding the donor acceptable shall immediately quarantine the semen. In such a case, the tissue bank's medical director shall review the results of clinical testing in accordance with the requirements in 52-3 and 52-8 and shall find the semen donor acceptable based on initial and repeat testing, as required in 52-8.6(e), prior to release of the semen from quarantine.