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New York State Tissue Resources Program

Policy – Acceptability of urine specimens for Gonorrhoeae testing Effective date – February 26, 2024 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)(2) requires that semen donors be tested for infection with *Neisseria gonorrhoeae*. Part 52-8.6(b)(2) specifies that semen or a urethral specimen shall be tested using a method that meets standards generally accepted by leading authorities in laboratory medicine.

Likewise, the FDA requires semen donors to be tested for *gonorrhoeae*. The Department finds that FDA requirements regarding testing for *gonorrhoeae* and the acceptability of urine as a specimen for such testing is comparable to the requirements in 52-8.6(b)(2) and adequately protect the public health, safety, and welfare.

Henceforth, the Department will conform NYS requirements for the types of specimens to be tested for *gonorrhoeae* in semen donors to those of FDA. Therefore, the Department will allow testing of urine specimens from semen donors for *gonorrhoeae*, if urine is an acceptable specimen type for the test being used.