



Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, M.D., M.P.H.
Commissioner

JOHANNE E. MORNE, M.S.
Executive Deputy Commissioner

August 22, 2024

Dear Colleague,

10 NYCRR Part 52-8.6 requires that all semen donors be tested for Hepatitis B and precludes the use of semen from donors who test positive.

The United States Centers for Disease Control and Prevention (CDC) provides guidance for interpreting Hepatitis B serology results that indicates not all donors who test positive for Hepatitis B present a risk of infection to recipients¹.

Under Part 52-3.8, the Department may exempt a tissue bank from specific requirements in Part 52 under limited circumstances. Requests for exceptions to allow inseminations or other assisted reproductive procedures using semen from directed (known) donors² who test positive for antibodies to Hepatitis B core antigen (anti-HBc) may be allowed if:

- The directed donor tests negative for Hepatitis B surface antigen (HBsAg);
- The directed donor tests positive for Hepatitis B surface antibody (anti-HBs); and
- Based on the CDC's guidance and the policies and procedures in place at the tissue bank, the Medical Director has determined, and documented, that the directed donor is "immune due to natural infection".

Requests for exceptions for the use of semen from anonymous donors testing positive for Hepatitis B, or for the use of semen from donors testing positive for other infectious agents, will not be considered at this time.

Please contact the Department with any questions at tissue@health.ny.gov or 518 485-5341.

Sincerely,

Matthew Kohn, Ph.D.
Director
Tissue Resources Program

¹ <https://www.cdc.gov/hepatitis/hbv/pdfs/SerologicChartv8.pdf>

² In this circumstance, a "directed donor", as defined in Part 52-8.1(e), means a semen donor who is known to the recipient and who directs his semen for use by the particular recipient.