

Following adoption of N.J.A.C. 8:75 on May 18, 2026, the NJ Department of Health ("Department") received correspondence from some human milk banks and advocates expressing concern that the requirement that donors undergo repeat serological testing every three months is not consistent with current practice, may deter donors from donating, and therefore, may negatively impact the availability of donated human milk in the State. The Department has also received a small number of requests for waivers of this requirement.

As a result of its review of published literature and best practices in the human milk industry and following consultation with public health experts, the Department has determined that repeat serological testing of donors every six months, rather than three months, is acceptable and appropriate at this time. Accordingly, the Department is assured that waiving the three month repeat serological testing requirement by this Certificate of Waiver will not negatively impact the safety or availability of donated human milk in the State. While this waiver is in place, the Department will continue to monitor and evaluate the best practices for repeat serological testing of donors to ensure not only that the donated human milk is safe but also provides for a sufficient supply of donated human milk in New Jersey. Based upon information the Department derives from this monitoring and evaluation, it may amend this rule requirement through the rulemaking process in the near future.

CERTIFICATE OF WAIVER for Serological Testing of Human Milk Donors and Prospective Donors

Pursuant to the provisions of the New Jersey Administrative Code, specifically, N.J.A.C. 8:75-1.5(a), a waiver is issued to:

All registered and accredited human milk banks granting relief from the following provision of Chapter 75 of Title 8 of the New Jersey Administrative Code:

N.J.A.C. 8:75-4.1 (e) Donor identification, screening, and selection

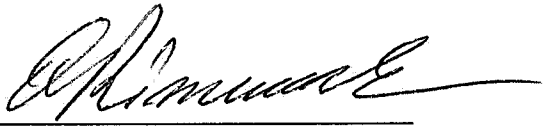
(e) An RA-HMB shall require each prospective donor, no earlier than three months prior to the donor's first milk donation and every three months thereafter, to undergo serological testing for HIV, human T-lymphotropic virus (HTLV), hepatitis B, hepatitis C, and syphilis.

This waiver is subject to the following terms and conditions:

1. A registered and accredited human milk bank (RA-HMB) shall require each prospective donor, no earlier than three months prior to the donor's first milk donation and every six months thereafter, to undergo serological testing for HIV, human T-lymphotropic virus (HTLV), hepatitis B, hepatitis C, and syphilis; and
2. The RA-HMB shall ensure that the donor's serological testing results indicate that the serological testing was conducted no earlier than three months before the donor's first DHM donation.
3. Except as waived above, the RA-HMB shall comply with all subchapters of Chapter 75 of Title 8 of N.J.A.C.

**DR. RAYNARD E. WASHINGTON
COMMISSIONER
DEPARTMENT OF HEALTH**

07/24/2026
DATE


BY: Alan Rimmer, MD
Executive Director
Clinical Laboratory Improvement Services,
Public Health and Environmental
Laboratories

Expiration Date: March 1, 2027