

# MLS Laboratory Update: National Infant Botulism Outbreak Linked to Powdered Infant Formula

NOVEMBER 10TH, 2025

## Purpose of this Message:

To inform laboratories of an ongoing, multi-state outbreak (including one case in Minnesota) of infant botulism cases linked to ByHeart Whole Nutrition infant formula.

## Action Item:

Please forward to relevant clinical, infection prevention, and laboratory staff in your organization, as appropriate.

## Background:

CDC and public health officials in several states, the Infant Botulism Treatment and Prevention Program, and FDA are investigating a multistate outbreak of infant botulism linked to **ByHeart Whole Nutrition infant formula**. One case has been reported in Minnesota.

Infant botulism occurs when swallowed *Clostridium botulinum* spores germinate in an infant's large intestine and produce toxin. Infant botulism often starts with constipation but is usually first noticed as difficulty feeding (sucking and swallowing), a weak and altered cry, and lack of head control.

As of November 8, 2025, 13 infants with suspected or confirmed infant botulism have been reported from 10 states: Arizona, California (2), Illinois (2), Minnesota, New Jersey, Oregon, Pennsylvania, Rhode Island, Texas (2), and Washington. Laboratory confirmation for some cases is ongoing. Illness dates range from mid-August to November 2025. All 13 infants were hospitalized and treated with BabyBIG (Botulism Immune Globulin). No deaths have been reported. Infants ranged in age from 16 to 157 days.

On November 8, 2025, ByHeart Inc. recalled two lots of Whole Nutrition Infant Formula:

- Lot: 206VABP/251261P2 ("Use by 01 Dec 2026")
- Lot: 206VABP/251131P2 ("Use by 01 Dec 2026")

Parents/caregivers should not use recalled infant formula and should throw it away or return it to where it was purchased. ByHeart Whole Nutrition Infant Formula is available for sale online and at major retailers nationwide.

## Laboratory testing

- If clinical consultation supports infant botulism, begin treatment with BabyBIG® as soon as possible. Do not wait for laboratory confirmation.
- The MDH Public Health Laboratory (MDH PHL) is the regional botulism laboratory. Confirmatory testing for infant botulism uses the mouse bioassay to identify toxin in feces and can take up to two weeks to get results. Contact MDH at 651-201-5414 to get approval for testing prior to sending clinical specimens. Ideally, 10g of feces should be collected. If an enema is needed, use sterile, non-bacteriostatic water.

## Additional Information:

- [FDA Outbreak Investigation of Infant Botulism: Infant Formula \(November 2025\)](https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025)  
(<https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025>)
- [CDC Infant Botulism Outbreak Linked to Infant Formula, November 2025](https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/index.html)  
(<https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/index.html>)
- [CDC Clinical Overview of Infant Botulism](https://www.cdc.gov/botulism/hcp/clinical-overview/infant-botulism.html) (<https://www.cdc.gov/botulism/hcp/clinical-overview/infant-botulism.html>)
- [Botulism \(\*Clostridium botulinum\* toxin\) - MN Dept. of Health](https://www.health.state.mn.us/diseases/botulism/index.html)  
(<https://www.health.state.mn.us/diseases/botulism/index.html>)
- [Clostridium botulinum testing – MDH-PHL Test Catalog](https://labinventory.web.health.state.mn.us/#/html?id=884)  
(<https://labinventory.web.health.state.mn.us/#/html?id=884>)

**Questions:** Please contact: Aaron Barnes, MD/PhD, EPR Lab Unit Supervisor, 651-201-4184, [aaron.m.t.barnes@state.mn.us](mailto:aaron.m.t.barnes@state.mn.us)

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*To obtain this information in a different format, call: 651-201-5200.*