



Public Health Division  
122 West 25th Street, 3rd Floor West  
Cheyenne, WY 82002  
(307) 777-6004 • 800-599-9754  
Fax (307) 777-8687 • [www.health.wyo.gov](http://www.health.wyo.gov)



---

Stefan Johansson  
Director

Mark Gordon  
Governor

---

## State Health Advisory

### Infant Botulism Linked to Infant Formula

### Wyoming Department of Health

### November 14, 2025

#### Summary

The Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), and state health officials are investigating a multistate outbreak of infant botulism linked to infant formula. All ByHeart Whole Nutrition infant formula has been recalled and should not be consumed. ByHeart Whole Nutrition infant formula was distributed in Wyoming. **Providers who suspect infant botulism in patients less than 15 months old based on clinical presentation should immediately consult the Infant Botulism Treatment and Prevention Program by calling 510-231-7600. The decision to treat with BabyBIG should be based on clinical presentation and findings and should not be delayed by waiting for results of laboratory confirmatory testing.** This Health Advisory provides recommendations to providers on evaluating potential cases of infant botulism in Wyoming.

#### Epidemiology

As of November 10, 2025, this outbreak includes 15 infants with suspected or confirmed infant botulism from 12 states. For 14 cases with known illness onset, illnesses started on dates ranging from August 9 to November 10, 2025. All 15 infants were hospitalized and treated with BabyBIG. No deaths have been reported. For 14 infants with age and sex information available, they range in age from 16 to 157 days, and 7 (50%) are female. All 15 infants consumed ByHeart Whole Nutrition infant formula prior to illness onset. Testing by the California Department of Public Health suggested the presence of *Clostridium botulinum* in an open can of ByHeart infant formula that was consumed by an infant with infant botulism.

CDC and FDA suspect that multiple lots of ByHeart Whole Nutrition infant formula may be contaminated. All ByHeart Whole Nutrition infant formula has been recalled and should not be sold or consumed. ByHeart Whole Nutrition infant formula was distributed and sold in Wyoming.

Infant botulism is an intestinal toxemia that results after spores of the bacterium *Clostridium botulinum* or related species are consumed by infants. Infant botulism occurs predominantly in infants younger than 6 months of age (range 1 day-14 months). The spores temporarily colonize

an infant's large intestine and produce botulinum neurotoxin. The incubation period for infant botulism is estimated to be 3 to 30 days from the time of spore ingestion, indicating that infants could develop symptoms weeks after ingestion of contaminated formula. Infant botulism is rare, and not all infants who have consumed potentially contaminated formula will develop illness.

Updates from CDC and FDA on this outbreak can be found at the following links:

<https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/index.html>

<https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025>

## **Clinical Presentation**

Infant botulism is preceded by or begins with constipation and manifests as decreased movement, loss of facial expression, poor feeding or poor suck, ptosis, weak cry, diminished gag reflex, ocular palsies, loss of head control, and progressive descending generalized weakness and hypotonia. The progressive flaccid paralysis can lead to respiratory depression and failure. Symptoms of infant botulism can take as long as several weeks to develop after consumption of *Clostridium botulinum* spores.

## **Management**

**Providers who suspect infant botulism in patients less than 15 months old based on clinical presentation should immediately consult the Infant Botulism Treatment and Prevention Program by calling 510-231-7600.** Consultation is available 24 hours a day, 7 days a week (<https://www.infantbotulism.org/physician/obtain.php>). If, through consultation, it is determined that treatment with BabyBIG (human botulism immune globulin for intravenous use or BIG-IV) is warranted, the on-call consultant will instruct providers on how to order it. BabyBIG is only available through this consultation line.

**The decision to treat with BabyBIG should be based on clinical presentation and findings and should not be delayed by waiting for results of laboratory confirmatory testing.** Prompt treatment of infant botulism patients immediately ends their toxemia and enables motor nerve regeneration to begin.

Testing or treatment of asymptomatic infants who have consumed ByHeart Whole Nutrition Infant Formula is not recommended. Parents whose asymptomatic infants have consumed ByHeart formula should observe their infants and seek medical care immediately if any symptoms consistent with infant botulism develop.

Clinicians who suspect botulism in patients older than 15 months of age should call the WDH 24/7 public health emergency line at 888-996-9104.

## **Laboratory Diagnosis**

Clinical consultation with the Infant Botulism and Prevention Program and acquisition and administration of BabyBIG should be the first priority when infant botulism is suspected. Once

consultation occurs and BabyBIG is ordered, clinicians should notify the Wyoming Department of Health (WDH) at 888-996-9104 and request diagnostic testing. A raw stool or enema specimen is required for definitive diagnosis of infant botulism. Fecal specimens for infant botulism diagnostic testing can be collected before or after antitoxin administration. The best container in which to collect, store, and submit fecal specimens is a sterile urine container with a tight, screw-capped lid. The CDC requires the collection of at least a pea-sized amount of raw stool. Do not use containers with fixatives or preservatives. If stool cannot be obtained, an enema collection procedure using non-bacteriostatic water can be used. Glycerin suppositories will yield an unsatisfactory specimen and should not be used. Specific instructions for enema collection can be found here: <https://www.infantbotulism.org/laboratorian/collection.php>

The WDH recommends submitting specimens directly to the CDC. Prior authorization by the WDH is required prior to shipping specimens to the CDC or, alternatively, to the Wyoming Public Health Laboratory (WPHL) for reference to CDC. Prior authorization may be obtained by calling the 24/7 public health emergency line at 888-996-9104. Specimen storage, ordering, and shipping information from the CDC can be found attached to this Health Advisory and here: [https://health.wyo.gov/wp-content/uploads/2025/11/BotulismConfirmTesting\\_Updated\\_2025\\_WPHL.pdf](https://health.wyo.gov/wp-content/uploads/2025/11/BotulismConfirmTesting_Updated_2025_WPHL.pdf). Additional information may be found on the CDC website: <https://www.cdc.gov/botulism/php/submit-specimen/index.html>.

The WPHL can also provide guidance or assistance with specimen submission. Providers and laboratorians may contact the WPHL Microbiology Program at 307-777-7431 or by email at [danielle.mcafee@wyo.gov](mailto:danielle.mcafee@wyo.gov).

If a toxin-producing *Clostridium botulinum* is isolated in a clinical laboratory, refer to <https://www.aphl.org/aboutAPHL/publications/Documents/PHPR-Select-Agent-Decontamination.pdf> for procedures on the safe and compliant disposal of toxin-producing isolates.

## Prevention

Families should immediately cease using any remaining ByHeart Whole Nutrition infant formula, including any formula sold in cans and single-serve packets. If possible, parents can take a picture or record the lot number and best by date of any remaining formula. Leftover formula should be clearly labeled “DO NOT USE” and kept stored in a safe place for at least a month. Families are recommended to wash items and surfaces that have touched the formula using hot soapy water or a dishwasher. In the case of a Wyoming infant developing infant botulism, WDH may request the remaining formula for testing. If no symptoms develop after a month, families should discard the remaining formula.

Additional information from the Wyoming Department of Agriculture can be found here: <https://agriculture.wy.gov/index.php?section=news&prid=150>.

**Contact Information:** Botulism is an immediately notifiable disease in Wyoming. After consultation with the Infant Botulism Treatment and Prevention Program, clinicians should call 888-996-9104 to notify WDH of suspected cases of infant botulism. For questions or additional information, providers can contact WDH epidemiology at 877-996-9000 or email [matthew.peterson@wyo.gov](mailto:matthew.peterson@wyo.gov).