

*E. coli* O145/(b)(4)

Apr 2025 - CARA ID 1303

On 4/28/2025, CDC notified CORE Signals of a cluster of *E. coli* O145:H28 illnesses (PulseNet ID: 2504MLENM). At the time of transfer to CORE Response, this cluster includes 11 cases from (b)(4) states: (b)(4) (b)(4). Isolation dates range from 3/25/2025 - 4/9/2025 and symptom onset dates range from 3/21/2025 - 4/1/2025. Cases ranged in age from 12 - 45 years (median: 21) and 73% (8/11) were female. Three cases were hospitalized. One case of HUS, and 1 death, were reported and attributed to STEC. Isolates are related within 0-2 (average: 1) SNPs by WGS and 0-1 alleles by cgMLST. HFPs Office of Surveillance Strategy and Risk Prioritization, Signal Detection and Bioinformatics Branch conducted an expanded genetic analysis and noted there are no other outbreak clusters or non-clinical isolates within approximately 300 SNPs of the cluster. CORE issued one assignment for traceback record collection at (b)(4) and one assignment for a preventive controls inspection at (b)(4) (b)(4) to FDA Office of Inspections and Investigations (OII)

Office of Human Food Inspectorate (OHFI) for this incident. No FDA Form 483 was issued. There were no public communications related to this outbreak. (b)(4) sample ((b)(4)) ; env. swabs) was collected by FDA. Neither *Listeria* spp. nor the outbreak strain were detected in any retail or inspectional samples collected during this response. Three traceback legs were investigated, which encompassed (b)(4) POS in (b)(4) (b)(4). No firms were implicated in this traceback investigation due to limited purchase information and lack of commonalities for the component ingredients used in the (b)(4) . This outbreak investigation did not yield sufficient evidence to identify a definitive source or route of contamination. Although epidemiologic data were suggestive, the absence of supporting laboratory, traceback, and inspectional evidence limited the team's ability to confirm (b)(4) as the vehicle. Therefore, (b)(4) remained the suspect vehicle for this outbreak investigation based on epidemiologic evidence alone. Due to the lack of sufficient laboratory, traceback, and inspectional evidence, there were no indicators to formulate a hypothesis as to source or route of contamination for this outbreak. This investigation was closed on June 27, 2025, with (b)(4) as the suspected source of illnesses. As of the closeout of this incident on 8/12/2025, eleven ill people from (b)(4) states (b)(4) (b)(4) including three hospitalizations, one HUS, and one reported death attributed to *E. coli*, were included in the outbreak.