

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Ron DeSantis
Governor

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Vision: To be the Healthiest State in the Nation

Voluntary Recall Alert for Chlorhexidine Gluconate Oral Rinse Due to Microbial Contamination and Call for Cases

The Florida Department of Health (DOH) is investigating a cluster of *Burkholderia lata* (*B. lata*) infections reported by a health care system in Florida that identified clinical infections of *B. lata* among 15 patients since September 2020, from multiple facilities. The U.S. Food and Drug Administration (FDA) posted a voluntary nationwide recall of Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% on October 28th, 2020, due to potential microbial contamination with *B. lata*, a gram-negative organism that causes opportunistic infection in susceptible individuals. Not all health care laboratories are able to perform species identification needed to detect *B. lata*. Without validated tools like Matrix-Assisted Laser Desorption/Ionization Time-of-Flight mass-spectrometer (MALDI-TOF), most laboratories will identify this organism as either *Burkholderia cepacia* (*B. cepacia*) or *Burkholderia cepacia* complex (BCC).

FDOH is requesting health care facilities to perform a laboratory lookback and notify their county health department of any potential cases that meet the following criteria:

- An increase above baseline in cases of *B. cepacia* or BCC in non-cystic fibrosis patients from any specimen source (e.g., blood, respiratory, and other tissues) since January 1, 2020,
or
- Any cases of *B. lata* from any specimen source since January 1, 2020

Please refer to the contact information for your county health department to report potential cases related to this investigation: www.FLhealth.gov/chdepcontact.

Products implicated in the announcement include Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12%, 4 oz and 16 oz, bearing expiration dates from June 30, 2020–September 30, 2022. Specific lot numbers may be found on the FDA’s website. This product was distributed nationwide to health care facilities including acute care facilities, dental offices and dental distributors, as well as pharmaceutical wholesalers and pharmacies. This product is often used in dental offices and for routine oral care in acute care hospitals and long-term care facilities. Additional details related to the announcement may be found on the FDA’s website: www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sunstar-americas-inc-issues-voluntary-nationwide-recall-paroexr-chlorhexidine-gluconate-oral-rinse.

Health care facilities, patients, and pharmacies in possession of the implicated product should stop use and coordinate return of all the recalled products per the voluntary recall (www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sunstar-americas-inc-issues-voluntary-nationwide-recall-paroexr-chlorhexidine-gluconate-oral-rinse). Please do not destroy it as product may be requested for sampling. Similarly, please save any clinical isolates of *B. cepacia*, BCC, and *B. lata* as these may be requested for additional testing as well.

For any questions, please contact the Health Care-Associated Infections Program at 850-845-4401 or HAI_Program@flhealth.gov.