

Sterile products potentially contaminated with *Rhodococcus equi*.

Target audience: Clinical laboratories

Monday, Aug 12, 2013

Background:

Specialty Compounding, LLC, a subsidiary of Peoples Pharmacy Inc., is voluntarily recalling all lots of sterile medications within expiry. The recall applies to all unexpired sterile compounded products dispensed since May 9, 2013, including all strengths and dosage forms.

The recall was initiated after reports of bacterial infection affecting 15 patients at two Texas hospitals, Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area, whose treatment included IV infusions of calcium gluconate from Specialty Compounding. There is a potential association between the infections and the medication at this time. Details are available at

<http://www.fda.gov/Safety/Recalls/ucm364643.htm?source=govdelivery>

Recalled products were distributed directly to hospitals and physician offices in Texas. **Recalled products were also sent directly to patients located nationwide with the exception of North Carolina.**

Adverse reactions experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program. www.fda.gov/medwatch/report.htm

Details:

Steps for laboratories to take now:

Report all *Rhodococcus equi* infections from sterile sites to the MDCH and save isolates until further notice. Of note, the organism can range from coccoid to bacillary in appearance, and could be easily mistaken for coryneform bacteria.

Also, please check records of sterile sites back to May 9, 2013 for additional possible cases of *Rhodococcus equi*.

If other organisms are isolated from sterile sites that may be connected to a product from this pharmacy, please notify public health and save those isolates also.

Questions and Additional Information

For laboratory related questions, please contact
Dr. Jim Rudrik, Microbiology Section Manager
RudrikJ@michigan.gov (517) 335-9641