

Federal Select Agent Program

SA-Grams

Date of issuance: 8/16/2011

Title: Botulinum neurotoxin producing species of Clostridium

Text: Botulinum toxin (serotypes A through G) is produced by Clostridium botulinum (phenotypically classified into 4 Groups -I, II, III, IV) and some isolates of Clostridium baratii (serotype F only), Clostridium butyricum (serotype E only), and Clostridium argentinense (serotype G only). Some strains of C. botulinum have been identified that produce 2 botulinum serotypes (e.g. both A and B).

Demonstration of the production of botulinum neurotoxin, through a toxin detection test, in a suspect culture is critical to the characterization of a Botulinum neurotoxin producing species of Clostridium. Most isolates of C. baratii, C. butyricum, and some isolates of C. argentinense do not contain the genes necessary to produce botulinum toxin. Some non-toxigenic clostridia species (e.g. C. sporogenes) are phenotypically identical to C. botulinum but may result in an identification of C. botulinum on some rapid biochemical identification methods (i.e., 16sRNA sequencing may misidentify a non-toxin producing clostridia as a C. botulinum, particularly Group II strains).

If a laboratory detects botulinum neurotoxin from a culture of any suspected Clostridium species (such as C. botulinum, C. baratii, C. butyricum, and some isolates of C. argentinense), the laboratory will need to report the identification of Botulinum neurotoxin producing species of Clostridium by completing Section 1 of the APHIS/CDC Form 4 within seven calendar days of identification. In addition, if the laboratory is not registered with the Federal Select Agent Program for possession of Botulinum neurotoxin producing species of Clostridium, the laboratory must destroy or transfer the isolate within seven calendar days after identification.

General information about reporting the identification of a Select Agent or Toxin including frequently asked questions are available at: http://www.selectagents.gov/FAQ_ReportingForm4.html.