

Emerging Infections Program *Clostridium difficile* Infection Surveillance Isolate Bank

Overview

The *C. difficile* isolate bank is a collection of isolates obtained through the Emerging Infections Program's *C. difficile* infection (CDI) surveillance. This population- and laboratory-based surveillance system operates in ten states, drawing from a population of approximately 11.7 million people. Isolates represent a convenience sample of both community- and healthcare-associated strains obtained from cases of CDI in the population under surveillance.

Stool aliquots or stool swabs are sent to partner reference labs for toxigenic culture and then sent to CDC for molecular characterization including detection of *tcdA*, *tcdB*, *cdtA* and *cdtB* toxin genes by polymerase chain reaction (PCR) and assessment of deletions in *tcdC* gene by fragment analysis. Strain typing is also performed using capillary-based PCR-ribotyping and results are analyzed against a library of standard profiles using BioNumerics.

On this website you will find further information about the available isolates, as well as the proper procedure for requesting them.

Isolates Currently Available

- *C. difficile* isolates available through the Emerging Infections Program (EIP) have been collected from the following 10 US states during the specified period:

2009 to present	Colorado, Minnesota, and New York
2010 to present	California, Connecticut, Georgia, Oregon and Tennessee
2011 to present	Maryland
2012 to present	New Mexico

A nationally representative sample of *C. difficile* isolates (based on geographic distribution across the EIP sites) collected during 2010-2011 were submitted to BEI Resources, a research material repository established by the National Institutes of Health / National Institute of Allergy and Infectious Disease and currently managed by the American Type Culture Collection (ATCC). Accompanying metadata include basic demographic information, year of specimen collection, geographical region, hospitalization, outcome, epidemiologic classification, and molecular data.

Procedure for Requesting Isolates

A) Request for EIP *C.difficile* Isolates:

Requests for EIP C. difficile isolates that are currently available through BEI Resources should be made directly to ATCC (http://www.atcc.org/en/About/Grants_and_Contracts/BEI_Resources.aspx).

Requests for other EIP C. difficile isolates should come directly to CDC by interested institutions according to the follow procedure:

Initiating a Request:

- Requestor will be required to prepare a short request (3-5 sentences) which states the number of isolates needed and associated specific epidemiologic data requested. The request should be sent to Maria Karlsson by email, fwt4@cdc.gov
- CDI surveillance staff will notify requestor if the isolates are available. If isolates are available, requestor will submit a formal request using official letterhead with the following information:

Brief summary of the proposed project, no longer than 2 pages, which includes the following:

- Objective of the project
- Public health importance
- Scientific methods
- Authorship plans
- Confidentiality
- Biohazard issues
- Projected timelines
- Requestor's current association/affiliation and complete contact information
- Number of isolates needed and associated specific epidemiologic data
- Shipping account number

CDC Evaluation:

In order to avoid duplication, the scientific work proposed must not already be part of 'core' CDI surveillance project activities or contained within a proposal for which permission was already granted to another investigator. CDC will ensure this through the following process:

- All requests will be shared with the CDI Pathogen Group for approval by email.
- CDI surveillance staff will notify the requestor if the request has been approved or denied within 14-21 days of receipt of formal request.

- Any modifications to the initially proposed use of isolates by receiving institutions should be submitted for approval by the CDI Pathogen Group.

User Fee Agreement:

- If the request is approved, for-profit institutions will be charged \$150 per isolate requested and non-profit institutions will be charged \$50 per isolate requested if over 10 isolates are requested. Isolates will be free of charge for non-profit institutions requesting ≤ 10 isolates. CDC will send a User Fee agreement for completion. The document requires a limit on dissemination of isolates and includes an agreement to acknowledge the source of these isolates and to limit isolate use to what was proposed in the original request. Acknowledgment for CDI surveillance will be in the following standardized format: Clostridium difficile infection (CDI) surveillance/Emerging Infections Programs (EIP) Network. In addition, requestor will be required to share any abstracts or manuscripts containing EIP isolates data with CDC prior to submission to scientific conferences or peer-reviewed journals to ensure that the source of isolates has been appropriately acknowledged and that the presentation/publication reflects what was proposed by the requestor.

Note: At least scientist from the CDI Pathogen Group should review the abstract or manuscript, even when lead authors are not members of the CDI Pathogen Group (refer to CDI Authorship Guidelines).

Contracts:

- Shipping questions should be directed to: Maria Karlsson (email: fwt4@cdc.gov).
- All other questions should be directed to: Alice Guh (email: ggt4@cdc.gov)