

**United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Microbiological Data Program**

SOP No.: MDP-SHIP-03		Page 1 of 8
Title: Procedures for Packaging, Shipping, and Archiving Microbiological Cultures		
Revision: 01	Replaces: Original	Effective: 11/01/04

1. Purpose:

To provide standard procedures that ensure that all shipments of microbial cultures isolated in USDA/AMS Microbiological Data Program (MDP) laboratories are properly prepared and documented in accordance with applicable U.S. Department of Transportation (DOT), U.S. Public Health Service, the Centers for Disease Control and Prevention (CDC), and the International Air Transport Association (IATA) regulations. To ensure proper packaging of microbial cultures. To provide destination addresses and contacts as well as shipment schedules. To communicate MDP requirements and/or standard procedures regarding the archival of microbiological isolates.

2. Scope:

This standard operating procedure (SOP) shall be followed by all laboratories conducting microbiological studies for MDP, including support laboratories conducting non-routine activities that may impact the program.

3. Outline of Procedures:

Shipments by MDP Participating Laboratories	5.1
Shipments by Culture Repository (located at the NSL)	5.2
Packaging Requirements	5.3
Shipping Requirements	5.4
Documentation Requirements	5.5
Requirements of the Culture Repository	5.6

4. References:

- 4.1 International Air Transport Association (IATA). 2004. Infectious Substances and Diagnostic Specimens Shipping Guidelines, 5th Edition, IATA publication, Montreal, Quebec, Canada.
- 4.2 U.S. Department of Transportation (DOT), Transport Canada, and the Secretariat of Transport and Communications of Mexico (SCT), 2000. 2000 Emergency

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Response Guidebook (ERG2000), U.S. Government Printing Office. <http://hazmat.dot.gov/gydebook.htm> (last accessed 9/01/04).

- 4.3 Bureau of Industry and Security, U.S. Department of Commerce, "Introduction to Commerce Department Export Controls", <http://www.osec.doc.gov/> last accessed October 7, 2004.
- 4.4 Bureau of Industry and Security, U.S. Department of Commerce, Rules and Regulations Amendments to the Export Administration Regulations (EAR), Federal Register/Vol 69, No. 53/Thursday, March 18, 2004.
- 4.5 Importation Permits for Etiologic Agents, Office of Health and Safety, CDC, <http://www.cdc.gov/od/ohs/biosfty/impptper.htm>, last accessed October 7, 2004.
- 4.6 Pro-Lab Diagnostic (Microbank[™]) Storage System, Product Insert
- 4.7 SOP MDP-MTH-01, Enumeration of *E. coli*
- 4.8 SOP MDP-DATA-01, Microbiological Record Keeping and Results Reporting
- 4.9 Attachment 01: Shipping Destinations, Contacts and Schedules
- 4.10 Attachment 02: Participating Laboratories Addresses and Contact Staff for Shipment of Cultures
- 4.11 Attachment 03: Flowcharts of Shipments
- 4.12 Attachment 04: MDP Shipping Form

5. Specific Procedures:

This SOP represents minimum MDP requirements and is presented as a general guideline. Each laboratory shall have written operating procedures that provide specific details concerning the manner in which the procedures have been implemented in that laboratory.

5.1 Shipments by MDP Participating Laboratories

- 5.1.1 Positive samples (mixed cultures) resulting from MDP-MTH-01 that require testing for pathogenic *E. coli* by the Florida Department of Agriculture and Consumer Services (FDACS), shall be preserved according to MDP-MTH-01.

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One of two (1 of 2) cryovials shall be retained at the participating laboratory as a backup. The second cryovial (2 of 2) shall be shipped to FDACS for testing.

5.1.2 Target organisms that have been isolated and identified shall be preserved and stored in Microbank™ vials according to the manufacturer's instructions.

5.1.2.1 For isolates of pathogenic *E. coli* (resulting from mPCR testing), three Microbank™ vials shall be shipped to the MDP Culture Repository (NSL).

5.1.2.2 For all other target organisms (including *E. coli* O157), two Microbank™ vials per organism shall be shipped to the NSL.

NOTE: Laboratories are encouraged to archive a vial of the isolates in their laboratories in case further analysis is required by their State or laboratory.

5.1.2.3 Inoculate Microbank™ vials following the manufacturer's instructions. Select the number and type of vials according to Attachment 1 and the color coding scheme below (matching cap & bead color):

RED	<i>Salmonellae</i>
GREEN	Pathogenic <i>E. coli</i> (other than O157)
YELLOW	<i>E. coli</i> O157
LIGHT BLUE	<i>Shigella</i>

5.1.3 Labeling of vials:

5.1.3.1 Cryovials (from MDP-MTH-01) and Microbank™ vials (of target organisms from all other methods) shall be identified by accessing the Tools section of the Remote Data Entry (RDE) system and entering the future shipment date to the various destinations. An identification number will automatically be provided by RDE for use in labeling the vials prior to freezing. The number generated will consist of the last two digits of the calendar year, followed by a dash and the next available number consisting of five digits. (i.e. 04-00001)

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5.1.3.2 After mPCR testing has been completed, isolated pathogenic strains of *E. coli* shall be inoculated into Microbank™ vials and sent to NSL. The vials shall be identified prior to shipment by assigning sequential letters as needed after the identification number of the LST glycerol vial. (i.e. 04-00001a, 04-00001b, etc.)

5.1.4 Store glycerol cryovials and Microbank™ vials in a -70°C or lower freezer. See Attachment 1 for shipping addresses and schedules.

5.2 Shipments by Culture Repository (located at the NSL)

5.2.1 One Microbank™ vial of each isolate received from participating and reference laboratories shall be shipped to the Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), Laurel, MD for additional testing.

5.2.2 Additionally, one Microbank™ vial of pathogenic *E. coli* shall be shipped to Penn State for further analyses.

5.2.3 One Microbank™ of each isolate received from participating and reference laboratories shall be archived according to the internal procedures established by the culture repository.

5.3 Packaging Requirements

5.3.1 Laboratories shall follow the IATA regulatory requirements for classification, documentation, packaging, and labeling of the materials to be shipped. Laboratories shall follow the IATA regulatory requirements for emergency response procedures and contacts for notification as well as training requirements for personnel involved in the preparation of shipments.

5.3.2 MDP cultures, including *E. coli* in mixed or pure culture, shall be considered infectious bacteria.

5.3.3 MDP laboratories will ship only microorganisms of Biosafety Level (BSL) 2 or lower.

5.3.4 The CDC and Department of Transportation do not currently require any permit to transport *Salmonella*, *E. coli*, *E. coli* O157:H7, or *Shigella* within the U.S.

5.3.5 If shipping to international destinations, import permits may be required. The shipper shall notify the intended recipient that their government agencies

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should be contacted regarding needed permits. *E. coli* O157:H7 has been placed on the Department of Commerce's Commerce Control List, requiring a CDC permit for international shipments but not domestic shipments.

5.4 Shipping Requirements

- 5.4.1 All shipments shall be handled by a traceable overnight delivery service.
- 5.4.2 Attachment 04, MDP Shipment Form, shall be completed and accompany each shipment.
- 5.4.3 Dry ice shall be used when shipping glycerol or Microbank™ vials.

5.5 Documentation Requirements

- 5.5.1 RDE documentation requirements reside in MDP-DATA-01
- 5.5.2 **A record logbook** shall document the transport for each vial by containing the following information:
 - Identity of bacterium shipped
 - Quantity shipped in each package, i.e., total volume (mL) or total mass size (g) of material in all test tubes or vials and number of such primary containers
 - Laboratory reference number for the individual culture and sample identifier (RDE unique number)
 - Date shipped and commercial shipping company used
 - Identity of produce from which each bacterium was isolated, and the State of origin in the United States, if available
 - Shipping conditions used shall be described as ambient temperature, ice packs, or Dry Ice (specify net weight)
 - Initials of person performing the packaging
 - Initials of person shipping cultures
 - The identity of the facility to which each package is shipped and the date the receiving laboratory was notified of shipment
 - Confirmation of sample receipt

5.6 Requirements of the Culture Repository

- 5.6.1 The laboratory acting as the culture repository shall not perform any analytical examination or verification analyses on the materials sent for archival.

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- 5.6.2 All isolates shall be held at -70°C or lower, for an indeterminate period of time
- 5.6.3 The culture repository shall only ship cultures to other facilities as requested in writing by the Monitoring Programs Office.
- 5.6.4 The inventory control system implemented by the laboratory may be manual, electronic or a combination of both. At a minimum, the control system must document:
- Sample identifier (RDE unique number)
 - Receipt/Inclusion Date & Recipient Identifier
 - Description of organism
 - Storage location
 - Subculture identifier
- 5.6.5 Sub-culturing Repository Organisms

The laboratory responsible for maintaining the repository shall develop and implement internal procedure(s) for the recovery and sub-culturing of organisms.

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Revision 01

October 2004

MPO

- Updated references
- Removed revision numbers from attachments
- Corrected Attachment 01

MDP-SHIP-03 Attachment 01: Shipment Destinations, Contacts and Schedules

SOP Section	Shipment by	Culture	Number of Vials	Purpose of Shipment	Frequency of Shipments	Address	Contact Person
5.1.1	MDP Participating Laboratories	Positive mixed cultures from MDP-MTH-01	1 - ship 1 – save in lab	mPCR for pathogenic <i>E. coli</i>	Quarterly (beginning of Jan, Apr, Jul & Nov)	FDACS Bureau of Food Laboratories, Bldg. 9 93125 Conner Blvd. Tallahassee, FL 32399-1650	Grace Hall Tel: (850) 488-4407 Fax: (850) 487-6573 hallg@doacs.state.fl.us
5.1.2.1 5.1.2.2	MDP Participating Laboratories	Microbank™ vials of target organisms	<i>E. coli</i> – 3 Others - 2	Archival & subsequent shipment to Reference Laboratory	Upon confirmation of isolate	NSL 801 Summit Crossing Place, Suite B, Gastonia, NC 28054	Charles Lay Tel: (704) 867-3873 Fax: (704) 853-2800 Charles.Lay@usda.gov
5.2.1	Culture Repository at NSL	Microbank vials of all isolates received from participating labs	1 per organism	Additional testing	Upon receipt	FDA/CVM Div of Animal & Food Microbiology 8401 Muirkirk Rd. Laurel, MD 20708	David White Tel: (301) 827-8037 dwhite@cvm.fda.gov
5.2.2		Microbank vials of pathogenic <i>E. coli</i> received from participating labs	1 per organism	Serotyping	Quarterly (beginning of Feb, May, Aug & Dec)	Penn St Gastroenteric Disease Center Wiley Laboratory Orchard Road University Park, PA 16802	Dr. Chobi DebRoy Tel: (814) 863-2167 Fax : (814)863-2167 rcd3@psu.edu or Mike Davis mads@psu.edu

MDP SHIP-03 Attachment 02:**MDP Participating Laboratories Addresses and Contact Staff for Shipment of Cultures**

MDP Laboratory	Contact Person
California Dept. of Food & Agriculture, Division of Inspection Services CDFA Agricultural Microbiology Laboratory McClellan Park (McClellan AFB), Bldg. 929, 5431 Arnold Ave. McClellan, CA 95652	Debora Vail 916-643-8818; cell: 916-275-1954 fax: 916-643-8806 dvail@cdfa.ca.gov
Colorado Dept. of Agriculture, Inspection & Consumer Services Div. Laboratory Section, 2331 West 31st Avenue Denver, CO 80211-3859	Kristi McCallum 303-477-0014 fax: 303-480-9236 Kristina.mccallum@ag.state.co.us
Florida Dept of Agriculture & Consumer Services Bureau of Food Laboratories Bldg. 9, 3125 Conner Boulevard Tallahassee, FL 32399-1650	Grace Hall 850-488-4407 fax: 850-487-6573 hallg@doacs.state.fl.us
Michigan Dept of Agriculture Laboratory Division 1615 South Harrison Road East Lansing, MI 48823-5224	Fran Mohnke 517-203-1396 fax: 517-337-5094 Mohnkef@michigan.gov
Minnesota Department of Agriculture Laboratory Services Division 90 West Plato Blvd. Room 241 St. Paul, MN 55107-2004	Kevin Vought 651-215-0391 fax: (651) 297-8787 kevin.vought@state.mn.us
New York Dept of Agriculture Food Laboratory 1220 Washington Avenue, State Office Campus Bldg. 7, 3rd Floor Albany, NY 12235	Kurt Mangione 518-457-2453 fax: 518-485-8097 Kurt.Mangione@agmkt.state.ny.us
Ohio Dept of Agriculture, Consumer Analytical Laboratory Bldg 3 8995 East Main St. Reynoldsburg, OH 43068	Maureta Ott 614-728-2790 fax: 614-728-6322 ott@odant.agri.state.oh.us
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Wisconsin Dept of Agriculture, Trade, and Consumer Protection Bureau of Lab Services 4702 University Avenue Madison, WI 53705	Cindy Koschmann 608-267-3509 fax: 608-266-1560 Cindy.koschmann@datcp.state.wi.us
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Isolates of Target Organisms



