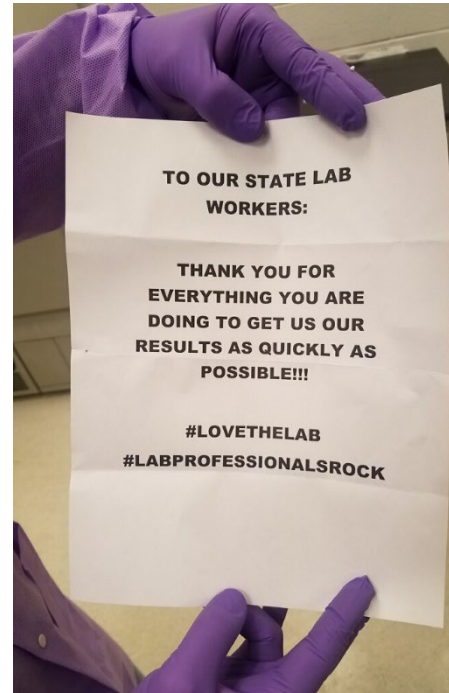




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Public Health Laboratory Emergency Response: Experiences from the Wadsworth Center, NYSDOH



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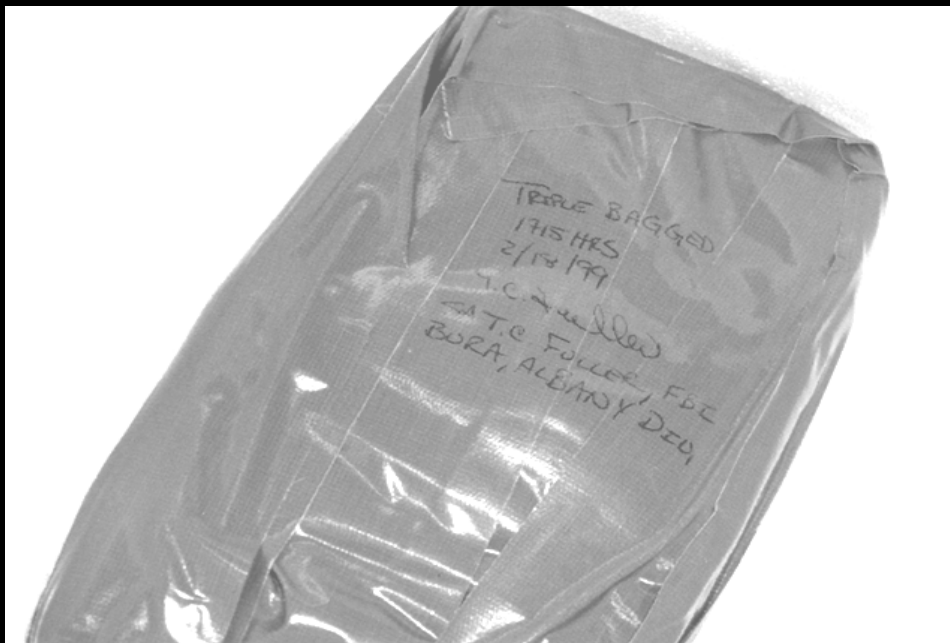
Case Study- Wadsworth Center, NYSDOH Intentional Release of *B. anthracis* through US Postal System- 2001 and mpox Response-2022



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First Environmental Biothreat Sample Received at the Wadsworth Center- February 18, 1999



Environmental Biothreat Samples Received at the Wadsworth Center- October 2001



Lessons Learned from 2001 Deliberate Release of *B. anthracis* in the U.S Postal System

- Dedicated team of public health laboratorians needed for emergency response to biotreatments
 - 20 laboratorians hired for biotreat/emerging infectious diseases threats in 2002 in NY
- Additional instruments and supplies must be available for lab response efforts
 - US DHHS/CDC Public Health Emergency Preparedness funding used for purchase of equipment and supplies
- Assay development needed to improve lab response time
 - Newly hired personnel created tests using latest technology (2002-present)
- Additional laboratory capacity needed for biotreat response
 - Established NYS Laboratory Response Network (LRN) in 2002
 - Established permitting process for environmental labs through regulation to test for biotreat and chemical threat agents in 2002



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Mpox Response at the Wadsworth Center- May 2023




Photo: Mike Wren, NYSDOH

What Went Well During Mpox Response?

- Availability of FDA cleared assay
- Trained personnel
- Close communication with CDC/LRN
- Distribution of guidance and information through the NYS Clinical Laboratory Evaluation Program (CLEP)
- LDT guidance available in June 2023 for labs to validate test for additional capacity



Wadsworth Center Developed Streamlined Mpox Laboratory Developed Test Guidance



Department of Health

KATHY HOCHUL
Governor

MARY T. BASSETT, M.D., M.P.H.
Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

Streamlined Guidelines and Submission Template for the Rapid Validation and Approval of Molecular Assays for Orthopox and/or Monkeypox Virus, June 2022

Please submit all information as outlined below to: cleval@health.ny.gov.

Note that all submissions will be categorized as High Risk and testing may not commence until explicit approval is granted. A Risk Attestation Form is not required with this submission.

All materials are maintained under strict confidentiality. As relates to New York State's Freedom of Information Law (commonly called FOIL); the Department's Records Access Officer has advised Wadsworth Center that if documents are marked "proprietary" or "confidential" or with any labeling indicative of the submitter's desire for an increased level of protection based on the submission content, such protection from immediate release based on a FOIL request is justified. Laboratories will be given an opportunity to block information release if a request for the material is filed under the FOIL by presenting evidence that the materials contain trade secrets. Marking should minimally appear on the cover page of each unit of material. Documents not marked with such terms will not block release of the submission through a FOIL request.

Section 1: GENERAL INFORMATION

Laboratory Name:	NYS PFI #:	
Contact Person:		
Phone:	Fax:	Contact E-mail:
Assay (Ortho or Monkeypox):		
Target Population:		
Methodology (chemistry/platform):		
Target genes (including internal controls):		
Validated Specimen Type(s):		
Clinical Purpose (detection, quantification):		



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What Did Not Work Well During Mpox Response?

- No fully automated mpox assay
- Testing at start of response needed to be performed in BSL3 laboratory
- No national repository available for assay validation materials
- Only 2 labs permitted in NY to perform mpox testing in May 2023
- Lack of capacity or lack of access to testing in some areas of US



Existing Gaps in Laboratory Response to Biothreats/Emerging Threats

- Lack of environmental laboratory capacity for biothreat testing
- Lack of fully automated tests for response to biothreats/emerging threats
- Lack of specimen repository needed to increase lab capacity rapidly
- Availability of tests for emerging infectious diseases such as Ebola, Marburg, and other hemorrhagic fever viruses
- Lack of consistent funding for emerging threats



Photo courtesy of the Wadsworth Center, NYSDOH