

## **GUIDELINES FOR LABORATORY TESTING AT THE NYSDOH WADSWORTH CENTER BIODEFENSE LABORATORY FOR:**

- 1. Vaccine adverse events during the smallpox vaccination program**
- 2. Evaluation of patients with fever and an acute, generalized vesicular or pustular rash.**

The aim of this document is to provide instructions for determining when a sample should be collected for laboratory testing, how the samples should be collected and where the samples should be shipped.

**These guidelines are intended for samples collected throughout New York State, other than New York City. In New York City, the New York City Department of Health and Mental Hygiene should be consulted for guidance on clinical assessment, the need for laboratory testing and collection and transport protocols. See attached list for 24-hour local health department (LHD) and NYC contact information. Samples being submitted to the New York State Department of Health, Wadsworth Center Biodefense Laboratory should follow the protocol guidelines for collection and transport that are described in this document.**

These guidelines were adapted from CDC smallpox collection and transport protocols. The CDC guidelines can be found at the following address:

<http://www.bt.cdc.gov/agent/smallpox/vaccination/vaccinia-specimen-collection.asp>.

### **WHAT NEEDS TO BE DONE FOR A SUSPECTED SMALLPOX VACCINATION ADVERSE EVENT?**

It is anticipated that a low rate of adverse and serious adverse events will occur following smallpox vaccination. A description of the possible adverse events can be found at: <http://www.bt.cdc.gov/agent/smallpox/vaccination>. In NYS, physicians and laboratories are required to report serious adverse events from smallpox vaccination to the local health department (LHD). Examples of serious adverse events include contact vaccinia, eczema vaccinatum, erythema multiforme major or Stevens-Johnson syndrome, fetal vaccinia, generalized vaccinia, inadvertent inoculation, ocular vaccinia, post-vaccinial encephalitis or encephalomyelitis, progressive vaccinia, pyogenic infection of the vaccination site, and any other serious adverse events resulting in hospitalization, permanent disability, life threatening illness or death. In some cases, laboratory testing may be indicated to confirm vaccinia disease. Only the Wadsworth Center laboratory will be conducting this vaccinia testing. The LHD and NYSDOH will assist in determining if laboratory testing is necessary. **Do NOT send samples directly to the Wadsworth laboratory without consultation with the LHD and NYSDOH.** See attached list for 24-hour LHD and NYC contact information. If there are difficulties reaching the LHD, please contact the NYSDOH. During business hours, call 518-473-4436; after hours, call the duty officer at 518-465-9720.

## **WHAT NEEDS TO BE DONE FOR A PATIENT WITH FEVER AND AN ACUTE, GENERALIZED VESICULAR OR PUSTULAR RASH?**

The clinical and laboratory assessment of a patient with a generalized vesicular or pustular rash should make use of the CDC criteria for determining whether the patient is at low, moderate, or high risk for smallpox, as summarized in the CDC poster entitled, "Evaluating Patients for Smallpox" available at: <http://www.bt.cdc.gov/agent/smallpox/diagnosis/evalposter.asp>

Further details on the management of suspect cases of smallpox can be found in the "NYSDOH Guidelines for Management of a Suspect Case of Smallpox in Acute Care Hospitals" on the secure Health Provider Network (HPN) at:

[https://commerce.health.state.ny.us/hpn/hanweb/hospital/Smallpox-NYSDOH\\_Version1a.pdf](https://commerce.health.state.ny.us/hpn/hanweb/hospital/Smallpox-NYSDOH_Version1a.pdf)

**Low risk of smallpox infection.** These cases are illustrated in green on the CDC poster. Low risk cases should have no febrile prodrome OR, if they do have a febrile prodrome, there should be less than four of the minor smallpox criteria. Laboratory testing for Varicella-zoster infection is optional and is dependent on the clinical history and the examination of the patient. If the diagnosis is less certain, laboratory testing in a LRN Level A laboratory should be requested. It is NOT necessary to report the case to the LHD, unless a consultation is needed.

**Moderate risk of smallpox infection.** These cases are illustrated in yellow on the CDC poster. Moderate risk cases should have a febrile prodrome AND one other major smallpox criterion OR a febrile prodrome and at least four minor smallpox criteria. These cases require rapid clinical evaluation and laboratory confirmation by an LRN Level C laboratory either at the Wadsworth Center or the New York City Department of Health and Mental Hygiene. For moderate risk patients, the LHD should be contacted immediately. (See attached contact list for 24-hour LHD and NYC contact information). If there are difficulties reaching the LHD, please contact the NYSDOH. During business hours, call 518-473-4436; after hours, call the duty officer at 518-465-9720. In addition, an infectious disease or dermatology consult should be arranged. The LHD and NYSDOH will assist in determining the likelihood of smallpox and arrange for rapid diagnostic testing, if indicated, at the appropriate LRN Level C Laboratory. At this time, the facility laboratory staff are NOT necessarily expected to be involved with the collection of moderate-risk samples. Ideally, only vaccinated individuals should be allowed to have direct patient contact during moderate-risk specimen collection. All persons who have direct patient contact, regardless of their smallpox vaccination status, must use contact and airborne personal protective equipment (i.e., disposable gloves and gown and an N-95 or higher respirator). The LHD and NYSDOH will send a public health response team to the facility to provide consultation and if needed, to assist with the laboratory diagnosis of these patients, including collection and packaging of clinical specimens. If the decision is made that laboratory testing is necessary, please follow the Sample Collection and Shipping Instructions attached. Please contact the laboratory **PRIOR** to shipping the specimen.

**High-risk of smallpox infection.** These cases are illustrated in red on the CDC poster. High-risk cases should have a febrile prodrome AND classic smallpox lesions AND lesions in the same stage of development on different parts of the body. These cases require rapid clinical evaluation and laboratory confirmation by the CDC. For high-risk patients, the LHD should be contacted immediately. (See attached contact list for 24-hour LHD and NYC contact information). If there are difficulties reaching the LHD, please contact the NYSDOH. During business hours, call 518-473-4436; after hours, call the duty officer at 518-465-9720. At this time, the facility laboratory staff are NOT necessarily expected to be involved with the collection of high-risk samples. Ideally, only vaccinated individuals should be allowed to have direct patient contact during high-risk specimen collection. All persons who have direct patient contact, regardless of their smallpox vaccination status, must use contact and airborne personal protective equipment (i.e., disposable gloves and gown and an N-95 or higher respirator). The LHD and NYSDOH will send a public health response team to the facility to assist with the laboratory diagnosis of these patients, including collection and packaging of clinical specimens, as well as provide consultation on management of the patient and all contacts. Do NOT attempt to collect samples until the case has been reviewed by the public health response team, who will contact CDC if necessary.

## **HOW TO COLLECT SPECIMENS FOR SHIPPING TO NYSDOH WADSWORTH CENTER BIODEFENSE LABORATORY FOR TESTING.**

Persons responsible for specimen collection should follow the steps below for vaccinia virus and moderate-risk smallpox specimen labeling and handling, infection control procedures and specimen collection. For any questions about specimen collection and transport please call the Wadsworth Center Biodefense Laboratory at 518-474-4177 (daytime) or the duty officer 518-465-9720 (after hours).

### **Specimen Labeling and Handling**

A Wadsworth Center Requisition Form **must** accompany all samples. Label all tubes, microscope slides, microscope holders, and swab holders with the patient's name, unique identifier, date of collection, source of specimen (vesicle/pustule) and name of person collecting the specimen.

### **Infection control procedures**

Wear appropriate personal protective equipment (PPE). This includes the following: Disposable latex or vinyl gloves, disposable protective gown, N-95 or higher properly fitted HEPA-filtered respirator (required only when collecting moderate or high risk smallpox samples) and shoe covers.

*CDC recommends that only personnel successfully vaccinated within the last 3 years wearing appropriate PPE (gloves, gown, mask and shoe covers) should be allowed to have direct patient contact during specimen collection for suspected cases of smallpox. Eyewear or face shields should be used if splashing is anticipated.*

*If unvaccinated personnel must be utilized to collect specimens, only those without contraindications to vaccination should be utilized as they would require immediate vaccination if the diagnosis of smallpox is confirmed.*

*NYSDOH recommends that ALL individuals, regardless of vaccination status, who are collecting specimens from and/or caring for suspected smallpox patients, should wear fit-tested N95 or higher masks.*

*Personnel involved with collection of samples should utilize appropriate biosafety practices. For further information, contact appropriate infection control personnel in your facility or the NYS Wadsworth Center Biodefense Laboratory at the above number.*

## Specimen Collection Kits

A limited supply of specimen collection kits is currently available. In the near future, specimen collection kits will be distributed to each local health department and hospital. In the meantime, the local health department and NYSDOH will ensure that the facility receives a kit, if lab testing is appropriate and the facility has not assembled their own kit in-house. However, facilities are encouraged to assemble their own kits ahead of time.

**NOTE:** For your information, the materials used in the NYSDOH Wadsworth Center collection kit are listed below. The NYS Department of Health does not recommend, endorse or support any individual company. Laboratories may know of other vendors not listed here and facilities may use vendors of their choice. However, it is important that only equivalent materials are used in any kit assembled in-house. If there are questions regarding the substitution of materials, please contact the Biodefense lab staff at 518-474-4177.

### NYSDOH Wadsworth Center Collection kit:

- 4 clean glass microscope slides (Electron Microscopy Sciences Cat # 71867-01)
- 1 plastic slide holder (Electron Microscopy Sciences Cat # 71549-01)
- 4 sterile plastic screw-capped tubes (Sarstedt Cat # 71148-01)
- 4 plastic viral Cultorettes (Krackeler Cat # 10-261514-CS)
- Mailing containers and gel packs for transport to the Biodefense Laboratory  
Air Sea Containers (ASC) Industries Inc., 2749 NW 82nd Ave, Miami, FL 33122  
Attn: Alan Bond, (305) 599-9123  
Cat #: ASC-50/1C Dangerous Goods Shipper of 1 Unit (2 Liter) Complete Set

Note: Four collection devices per specimen type are included in the collection kit (three for samples and one as a spare).

Packaging must be certified to meet rigorous performance tests as outlined in the DOT, USPS, PHS and IATA regulations.

**Important Note: Gel packs should be stored at -20°C in a horizontal position so that they will be frozen flat and at the appropriate temperature for shipping.**

### Materials NOT part of NYSDOH Wadsworth Center collection kits but required:

- Biohazard Ziploc<sup>®</sup>-type plastic disposable bags
- 1 disposable scalpel with No. 10 blade **or**
- Several sterile 26-gauge needles **or**
- Sterile microscope slides
- Appropriate Personal Protective Equipment (PPE): Disposable latex or vinyl gloves, disposable protective gowns, protective eyewear, shoe covers, and N-95 or higher properly fitted HEPA-filtered respirators (respirator required only when collecting moderate or high-risk smallpox samples)

## Specimen Collection

NYS is requesting three types of samples: 1) microscope slides of vesicular/pustular fluid obtained by touching the open lesion (a touch prep), 2) a swab used to collect infected cells from the base of the open lesion, and 3) plastic tubes containing the lesion caps.

## Vesicular and Pustular Material

1. Sanitize the patient's skin with an alcohol wipe and allow skin to dry.
2. Using a sterile disposable scalpel, remove the lesion cap and transfer it to a dry, sterile 1.5- to 2-mL sterile screw-capped tube. Label the tube.
3. Clean a microscope slide with an alcohol wipe, allow it to dry, and then label the microscope slide. Collect vesicular/pustular fluid from an opened/uncapped lesion by touching the slide two or three times, with progressive movement, against the lesion. (Fluid may be released from the lesion using a sterile, disposable scalpel or 26-gauge needle.) Allow the slide to air dry for ten minutes. Place slide in the slide holder.
4. Label a swab holder and remove swab from the outer sheath. Collect cells from the lesion base by gently but firmly rolling the swab back and forth across the base of an uncapped lesion (see step 2 above). Return swab to the outer sheath and cap firmly. Activate transport media by pressing firmly on the bottom section of the swab container until liquid is released. Ensure that swab is placed far enough down in the container, and is touching the white plug, to ensure that the transport media moistens it. Replace swab tube in the paper sleeve.
5. Repeat this process twice on different lesions so there is a total of three specimens collected for each sample type: three plastic tubes containing lesion caps, three microscope slides, and three swabs in transport media.
6. After specimen collection is completed all protective materials worn by the specimen collector (gloves, mask, gown, etc.) and all used sample collection materials (alcohol wipes, holders, etc.) must be placed in red biohazard bags and autoclaved or incinerated prior to disposal. Needles, blades and microscope slides used to open vesicles should be disposed of in an appropriate sharps container. **Thorough hand-washing using soap** should be done immediately after specimen collection and following removal of personal protective equipment.

## **HOW TO SHIP SPECIMENS TO NYSDOH WADSWORTH CENTER BIODEFENSE LABORATORY FOR TESTING.**

1. Specimens from one patient only should be packaged together. Specimens contained in the screw capped-tubes should be placed back into the plastic bag provided. Three slides that are being submitted for testing should be contained in the plastic slide holder provided in the collection kit. The tubes containing the culturette swabs should be capped firmly and placed back in the original plastic Culturette wrapper. Place all specimens collected into a Ziploc<sup>®</sup>-type biohazard specimen bag and close tightly. Ensure that the square white packet of absorbent material is in the base of the bottle. Place plastic bag with specimens in bottle. Cap bottle tightly and place into secondary mailer box. Close secondary box and place secondary mailer box and two frozen gel packs into the larger outer mailer with the insulating foam insert. Place Wadsworth Center "Requisition Form" and "Itemized List of Contents" (provided as page 9) on top of insulating foam lid before closing outer box. Secure outer mailer with mailing tape and attach a return address label. If the collection kit and shipping container from the Wadsworth Center Biodefense Laboratory is not being used, the shipping containers must meet the new IATA guidelines for Packaging and Transport of Diagnostic Specimens (Class 6.2; UN 3373). See references below or call the Wadsworth Center Biodefense Laboratory for further instructions if unclear.

**Important note: It is the shippers' responsibility to ensure correct packaging and labeling of shipping containers.**

2. Please contact the Biodefense Laboratory **PRIOR** to shipping at the following numbers: 518-474-4177 (daytime), or the duty officer at 518-465-9720 (after hours). Final instructions will be given at the time of consultation and may involve an escort carrier to ensure sample tracking and integrity.
3. Samples should be shipped to:  
**Dr. Nick Cirino, Room 3020, Biodefense Laboratory, Wadsworth Center, NYS Dept. of Health, 120 New Scotland Avenue, Albany, NY 12208**

If other sample types are deemed necessary, please contact the Biodefense Laboratory for further instruction.

### **Further Information:**

IATA packaging and transport guidelines can be found at <http://www.iata.org> or 1-800-716-6326.  
CDC guidelines can be found at <http://www.bt.cdc.gov/LabIssues/PackagingInfo.pdf>

### **Contact Information:**

For Technical Questions:

NYS Department of Health, Wadsworth Center, Biodefense Laboratory  
Daytime (518) 474-4177      After hours (518) 465-9720

For General Questions:

NYS Department of Health, Wadsworth Center, Laboratory Response Network  
Daytime (518) 457-9795 or via email: [LRNexec@health.state.ny.us](mailto:LRNexec@health.state.ny.us)

***LOCAL HEALTH DEPARTMENT AND NEW YORK CITY PHONE LIST***  
***Business and After Hours Phone Numbers***

***New York City***

**New York City Department of Health and Mental Hygiene**

**Suspected Smallpox Cases:** (212) 788-9830 Business Hours  
(212) 764-7667 or 1-800-222-1222 (After Hours)

**Adverse Events of Vaccination:** 1-866-NYC-DOH1 (Business or After Hours)

<b><i>County</i></b>	<b><i>Business Phone</i></b>	<b><i>After Hours Phone</i></b>
Albany County Health Department	(518) 447-4691	(518) 447-4614
Allegany County Department of Health	(585) 268-9250	(585) 268-9250
Broome County Health Department	(607) 778-2802	(607) 778-1911
Cattaraugus County Health Department	(716) 373-8050	(716) 373-8050
Cayuga County Dept. of Health/Human Serv.	(315) 253-1451	(315) 253-1301
Chautauqua County Health Department	(716) 753-4314	(716) 753-4231
Chemung County Health Department	(607) 737-2028	(607) 737-2028
Chenango County Health Department	(607) 337-1660	(607) 337-1660
Clinton County Health Department	(518) 565-4848	(518) 565-3270
Columbia County Health Department	(518) 828-3358	(518) 828-3344
Cortland County Health Department	(607) 753-5036	(607) 897-3088
Delaware County Public Health Nurs. Serv.	(607) 746-3166	(607) 746-2336
Dutchess County Health Department	(845) 486-3555	(845) 431-6465
Erie County Health Department	(716) 858-7324	(716) 898-4225
Essex County Public Health Department	(518) 873-3515	(888) 270-7249
Franklin County Public Health Services	(518) 481-1707	(800) 533-1555
Fulton County Public Health Department	(518) 736-5720	(518) 736-2100
Genesee County Public Health Department	(585) 344-8506	(585) 343-5000
Greene County Public Health Nursing	(518) 943-6591	(518) 943-2515
Hamilton County Public Health Nursing Serv.	(518) 648-6141	(518) 548-3113
Herkimer County Public Health Nursing Serv.	(315) 867-1430	(315) 867-1430
Jefferson County Pubic Health Service	(315) 786-3710	(315) 786-3770
Lewis County Public Health Agency	(315) 376-5453	(315) 376-5453
Livingston County Health Department	(585) 243-7270	(585) 528-4306
Madison County Health Department	(315) 366-2361	(315) 366-2367
Monroe County Health Department	(585) 274-6068	(585) 760-6500
Montgomery County Public Health	(518) 853-3531	(518) 853-3531

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<i>County</i>	<i>Business Phone</i>	<i>After Hours Phone</i>
Nassau County Health Department	(516) 571-3410	(516) 742-6154
Niagara County Health Department	(716) 439-7430	(716) 439-7430
Oneida County Health Department	(315) 798-6400	(315) 798-5064
Onondaga County Health Department	(315) 435-3252	(315) 426-3860
Ontario County Community Health Serv.	(716) 396-4343	(585) 394-4560
Orange County Health Department	(845) 291-2332	(845) 291-2332
Orleans County Health Department	(585) 589-3278	(585) 589-5527
Oswego County Health Department	(315) 349-3539	(315) 341-0086
Otsego County Health Department	(607) 547-6458	(607) 547-4273
Putnam County Health Department	(845) 278-6558	(845) 225-4300
Rensselaer County Health Department	(518) 270-2626	(518) 270-5252
Rockland County Health Department	(845) 364-2512	(845) 364-8600
St. Lawrence County Public Health Dept	(315) 386-2325	(888) 833-1474
Saratoga County Public Health Nursing Serv.	(518) 584-7460	(518) 584-7460
Schenectady County Public Health Serv.	(518) 386-2810	(518) 437-7878
Schoharie County Health Department	(518) 295-8365	(518) 295-8114
Schuyler County Home Health Agency	(607) 535-8140	(607) 535-8222
Seneca County Health Department	(315) 539-1920	(800) 836-7243 pin #1150
Steuben County Public Health Nursing Serv.	(607) 776-9631	(800) 836-4444
Suffolk County Department of Health Serv.	(631) 853-3005	(631) 852-4820
Sullivan County Public Health Nursing	(845) 292-0100	(845) 292-0100
Tioga County Health Department	(607) 687-8600	(607) 687-1010
Tompkins County Health Department	(607) 274-6674	(607) 274-6600
Ulster County Health Department	(845) 340-3011	(845) 334-2145
Warren County Health Services	(518) 761-6580	(518) 761-6580
Washington County Public Health Service	(518) 746-2400	(518) 746-2400
Wayne County Public Health Service	(315) 946-5749	(315) 946-9711
Westchester County Health Department	(914) 813-5000	(914) 813-5000
Wyoming County Health Department	(585) 786-8890	(585) 786-2233
Yates County Health Department	(315) 536-5160	(315) 536-4438

(Example)

List should be placed on top of insulating foam lid before closing outer box.

Itemized List of Contents:

- 3x Microscope Slides with dried vesicular fluid
- 3x Cryovials each containing less than 1 gram of vesicular material
- 3x Culturette Swabs each containing approx. 0.5ml of Hanks Balanced Salts Solution and vesicular fluid

Note: Samples to be tested for Vaccinia Virus and/or  
Varicella-zoster Virus