Instructions for Submitting Specimens to CDC Gonorrhea Laboratory for Confirmation Testing and/or Testing of Clinical Treatment Failures

Please note: The CDC will test specimens that have been tested locally and submitted for reference confirmation by the state public health laboratory or those that are submitted as a component of a CDC sponsored project. Private citizens, health practitioners, and hospitals cannot send specimens independently to CDC without prior arrangement with the appropriate state health department. The local (city or county) health department may coordinate this activity with their state health department.

For confirmation of antibiotic resistance, CDC is particularly interested in isolates that demonstrate decreased susceptibility to cephalosporin antibiotics and/or those from cephalosporin treatment failures. CDC will continue to accept other isolates for which a state health department needs confirmation of antimicrobial resistance.

1. *Neisseria gonorrhoeae* isolates (based on a presumptive* or confirmed identification) will be collected.

*A presumptive identification of *N. gonorrhoeae* will be based on the following criteria: (i) growth of typical appearing colonies on a selective medium such as Thayer-Martin at 35°C to 36.5°C in 5% CO_2, (ii) a positive oxidase test, and (iii) the observation of gram-negative, oxidase-positive diplococci in stained smears.

2. Gonococcal specimens should be subcultured from the selective primary medium to a noninhibitory medium, e.g., chocolate agar with 1% IsoVitaleX to obtain a pure culture of the specimen. If the subcultured specimen is not pure, serial subcultures of individual colonies must be performed until a pure culture is obtained. After 18 to 20 hrs. incubation, a heavy suspension of growth from the pure culture should be made in trypticase soy broth containing 20% (v/v) glycerol.

4. Specimens should be frozen to -70°C if possible. If a -70°C freezer is not available, specimens may be frozen to -20°C (freezer/dry ice chest); specimens to be shipped must be placed in the coldest sections of the -20°C freezer (not in the door or at the front of a shelf) and should be stored in containers separate from any other frozen gonococcal cultures (including separate from duplicate frozen specimens). A frost-free freezer should not be used.

5. Specimens must be packed in two leak-proof containers, one inside the other. The package containing the specimens should be packed in insulated styrofoam containers containing dry ice (at least 10 lbs); dry ice should be packed on each side of the package of specimens.

6. Complete CDC Specimen Submission Form (DASH)

http://www.cdc.gov/ncidod/dvbid/misc/CDC50_34.pdf

Information on classification of infectious substances and specific packing instructions came from the IATA - The International Air Transport Association website: http://www.iata.org/whatwedo/cargo/dangerous_goods/infectious_substances.htm.

For additional information on classification of infectious substances, see Appendix A.

For additional information on packing instructions – Class 6 – toxic and infectious substances, see Appendix B.

*Please telephone or e-mail the CDC laboratory **(Kevin Pettus 404- 639- 4338, kbp9@cdc.gov)** **prior** to shipping the specimens to confirm when they will be shipped to ensure that someone in the laboratory will be available to receive the specimens. Ideally, specimens should be *shipped no later than Wednesday in any week* to ensure that they are received at the laboratory before close of business on Friday.

Appendix A
Classification of infectious substances

3.6.2 Division 6.2—Infectious Substances

STATE VARIATIONS: AUG-03 CAG-10 CAG-11 VUG-02
OPERATOR VARIATIONS: AF-04 CO-07 CS-07 FX-09 JJ-06 LA-07 LH-12 OS-03 UU-05

3.6.2.1 Definitions

For the purposes of these Regulations:

3.6.2.1.1 Infectious substances are substances which are known or are reasonably expected to contain
pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi)
and other agents such as prions, which can cause disease in humans or animals.

Note:
Toxins from plant, animal or bacterial sources which do not contain any infectious substances or toxins that are
not contained in substances which are infectious substances should be considered for classification in
Division 6.1 and assigned to UN 3172.

3.6.2.1.2 Biological products are those products derived from living organisms which are manufactured and
distributed in accordance with the requirements of appropriate national authorities, which may have special
licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or
animals, or for development, experimental or investigational purposes related thereto. They include, but are not
limited to, finished or unfinished products such as vaccines.

3.6.2.1.3 Cultures are the result of a process by which pathogens are intentionally propagated. This definition
does not include patient specimens as defined below in 3.6.2.1.4.

3.6.2.1.4 Patient specimens are those collected directly from humans or animals, including, but not limited to,
excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for
purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

3.6.2.1.5 Medical or clinical wastes are wastes derived from the medical treatment of animals or humans or
from bio-research.

3.6.2.2 Classification of Infectious Substances

3.6.2.2.1 Infectious substances must be classified in Division 6.2 and assigned to UN 2814, UN 2900,
UN 3291 or UN 3373, as appropriate.

3.6.2.2.2 Infectious substances are divided into the following categories:

3.6.2.2.2.1 Category A: An infectious substance which is transported in a form that, when exposure to it
occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or
animals. Indicative examples of substances that meet these criteria are given in Table 3.6.D.

Note:
An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in
physical contact with humans or animals.

(a) Infectious substances meeting these criteria which cause disease in humans or both in humans and animals must be assigned to UN 2814. Infectious substances which cause disease only in animals must be assigned to UN 2900.

(b) Assignment to UN 2814 or UN 2900 must be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal.

Notes

*1. The proper shipping name for UN 2814 is **Infectious substance, affecting humans**. The proper shipping name for UN 2900 is **Infectious substance, affecting animals** only.*

2. The following table is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria must be assigned to Category A. In addition, if there is doubt as to whether or not a substance meets the criteria it must be included in Category A.

3. In the following table, the micro-organisms written in italics are bacteria, mycoplasma, rickettsia or fungi.

TABLE 3.6.D
Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicated (3.6.2.2.2.1)

UN Number and ProperShipping Name	Micro-organism
UN 2814 Infectious substance affecting humans	*Bacillus anthracis*(cultures only) *Brucella abortus*(cultures only) *Brucella melitensis*(cultures only) *Brucella suis*(cultures only) *Burkholderia mallei*– *Pseudomonas mallei*– Glanders (cultures only) *Burkholderia pseudomallei*– *Pseudomonas pseudomallei* (cultures only) *Chlamydia psittaci*– avian strains (cultures only) *Clostridium botulinum*(cultures only) *Coccidioides immitis*(cultures only) *Coxiella burnetii*(cultures only)

Crimean-Congo hemorrhagic fever virus

Dengue virus (cultures only)

Eastern equine encephalitis virus (cultures only)

Escherichia coli, verotoxigenic (cultures only)

Ebola virus

Flexal virus

Francisella tularensis(cultures only)

Guanarito virus

Hantaan virus

Hantavirus causing hemorrhagic fever with renal syndrome

Hendra virus

Hepatitis B virus (cultures only)

Herpes B virus (cultures only)

Human immunodeficiency virus (cultures only)

Highly pathogenic avian influenza virus (cultures only)

Japanese Encephalitis virus (cultures only)

Junin virus

Kyasanur Forest disease virus

Lassa virus

Machupo virus

Marburg virus

Monkeypox virus

Mycobacterium tuberculosis(cultures only)

Nipah virus

Omsk hemorrhagic fever virus

Poliovirus(cultures only)

Rabies virus (cultures only)

Rickettsia prowazekii(cultures only)

Rickettsia rickettsii(cultures only)

Rift Valley fever virus (cultures only)

Russian spring-summer encephalitis virus(cultures only)

Sabia virus

	Shigella dysenteriae type 1(cultures only)
	Tick-borne encephalitis virus(cultures only)
	Variola virus
	Venezuelan equine encephalitis virus (cultures only)
	West Nile virus(cultures only)
	Yellow fever virus(cultures only)
	Yersinia pestis(cultures only)
UN 2900	African swine fever virus (cultures only)
Infectious substances	Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus (cultures only)
affecting animals	Classical swine fever virus (cultures only)
	Foot and mouth disease virus (cultures only)
	Lumpy skin disease virus (cultures only)
	Mycoplasma mycoides– Contagious bovine pleuropneumonia (cultures only)
	Peste des petits ruminants virus (cultures only)
	Rinderpest virus (cultures only)
	Sheep-pox virus (cultures only)
	Goatpox virus (cultures only)
	Swine vesicular disease virus (cultures only)
	Vesicular stomatitis virus (cultures only)

3.6.2.2.2.2 Category B: An infectious substance which does not meet the criteria for inclusion in Category A.
Infectious substances in Category B must be assigned to UN 3373.
Note:
The proper shipping name of UN 3373 is ***Diagnostic specimens****,* ***Clinical specimens*** *or* ***Biological substance category B****. From 1 January 2007, it is anticipated that the use of the shipping names Diagnostic specimens and Clinical specimens will no longer be permitted.*

3.6.2.2.3 Exemptions
3.6.2.2.3.1 Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.
3.6.2.2.3.2 Substances containing micro-organisms, which are non-pathogenic to humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.
3.6.2.2.3.3 Substances in a form that any present pathogens have been neutralized or inactivated such that

they no longer pose a health risk are not subject to these Regulations unless they meet the criteria for inclusion in another class.

3.6.2.2.3.4 Environmental samples (including food and water samples), which are not considered to pose a significant risk of infection are not subject to these Regulations, unless they meet the criteria for inclusion in another class.

3.6.2.2.3.5 Dried blood spots, collected by applying a drop of blood onto absorbent material, or faecal occult blood screening tests and blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation are not subject to these Regulations.

3.6.2.2.3.6 Patient specimens for which there is minimal likelihood that pathogens are present are not subject to these Regulations if the specimen is packed in a packaging which will prevent any leakage and which is marked with the words “Exempt human specimen” or “Exempt animal specimen”, as appropriate. The packaging must meet the following conditions:

(a) The packaging must consist of three components:

(b) For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material;

(c) When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

Note:

In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt under this paragraph. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions. Examples of specimens which may be transported under this paragraph include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antigens (PSA); tests required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or therapeutic drug monitoring; tests conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy tests; biopsies to detect cancer; and antibody detection in humans or animals.

3.6.2.3 Biological Products

3.6.2.3.1 For the purposes of these Regulations, biological products are divided into the following groups:

(a) those which are manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals. Substances in this group are not subject to these Regulations.

(b) those which do not fall under paragraph (a) and are known or reasonably believed to contain infectious substances and which meet the criteria for inclusion in Category A or Category B. Substances in this group must be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

Note:

Some licensed biological products may present a biohazard only in certain parts of the world. In that case, competent authorities may require these biological products to be in compliance with local requirements for infectious substances or may impose other restrictions.

3.6.2.4 Genetically Modified Micro-organisms and Organisms

a leak-proof primary receptacle(s);
a leak-proof secondary packaging; and
an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm × 100 mm;

3.2.6.2.4.1 Genetically modified micro-organisms not meeting the definition of an infectious substance must be classified according to Subsection 3.9.

3.6.2.5 Medical or Clinical Wastes

3.6.2.5.1 Medical or clinical wastes containing Category A infectious substances must be assigned to UN 2814 or UN 2900, as appropriate. Medical or clinical wastes containing infectious substances in Category B, must be assigned to UN 3291.

3.6.2.5.2 Medical or clinical wastes which are reasonably believed to have a low probability of containing infectious substances must be assigned to UN 3291.

Note:

The proper shipping name for UN 3291 is ***Clinical waste, unspecified, n.o.s.*** *or* ***(Bio) Medical waste, n.o.s.*** *or* ***Regulated medical waste, n.o.s.****.*

3.6.2.5.3 Decontaminated medical or clinical wastes which previously contained infectious substances are not subject to these Regulations unless they meet the criteria for inclusion in another class.

3.6.2.6 Infected Animals

3.6.2.6.1 A live animal that has been intentionally infected and is known or suspected to contain an infectious substance must not be transported by air unless the infectious substance contained cannot be consigned by any other means. Infected animals may only be transported under terms and conditions approved by the appropriate national authority.

3.6.2.6.2 Unless an infectious substance cannot be consigned by any other means, live animals must not be used to consign such a substance.

3.6.2.6.3 Animal carcasses affected by pathogens of category A or which would be assigned to category A in cultures only, must be assigned to UN 2814 or UN 2900 as appropriate. Other animal carcasses affected by pathogens included in Category B must be transported in accordance with provisions determined by the competent authority.

3.6.2.7 Patient Specimens

Patient specimens must be assigned to UN 2814, UN 2900 or UN 3373 as appropriate except if they comply with 3.6.2.2.3.

Appendix B
Packing instructions – Class 6 – toxic and infectious substances

" Packing Instructions — Class 6 — Toxic and Infectious Substances

PACKING INSTRUCTION 650

STATE VARIATIONS: BHG-02 CAG-05 DQG-03 FRG-06 GBG-05 VCG-04

% OPERATOR VARIATIONS: AF-04 AS-08 BR-14 CI-01 CO-07 CS-07 FX-09 IJ-06 JJ-06 JK-03 KE-06 LA-07 LH-12 MN-03 MS-03 MX-06 MX-11 PX-08 SQ-10 TK-08 UU-05 XK-02

This instruction applies to UN 3373 on passenger and cargo aircraft and CAO.

General Requirements

The packagings must be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including trans-shipment between transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings must be constructed and closed so as to prevent any loss of contents that might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity or pressure.

The packaging must consist of three components:

(a) a primary receptacle(s);

(b) a secondary packaging; and

(c) a rigid outer packaging.

Primary receptacles must be packed in secondary packagings in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings must be secured in outer packagings with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

Packages must be prepared as follows:

(a) For liquid substances:

- The primary receptacle(s) must be leakproof and must not contain more than 1 L;
- The secondary packaging must be leakproof;

- If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them;
- Absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent material, such as cotton wool, must be in sufficient quantity to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;
- # The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure of 95 kPa in the range of -40°C to 55°C (-40°F to 130°F).

  Note:
  $ The capability of a packaging to withstand an internal pressure without leakage that produces the specified pressure differential should be determined by testing samples of primary receptacles or secondary packagings. Pressure differential is the difference between the pressure exerted on the inside of the receptacle or packaging and the pressure on the outside. The appropriate test method should be selected based on receptacle or packaging type. Acceptable test methods include any method that produces the required pressure differential between the inside and outside of a primary receptacle or a secondary packaging. The test may be conducted using internal hydraulic or pneumatic pressure (gauge) or external vaccum test methods. Internal hydraulic or pneumatic pressure can be applied in most cases as the required pressure differential can be achieved under most circumstances. An external vacuum test is not acceptable if the specified pressure differential is not achieved and maintained. The external vacuum test is a generally acceptable method for rigid receptacles and packagings but is not normally acceptable for

  - flexible receptacles and flexible packagings
  - receptacles and packagings filled and closed under a absolute atmospheric pressure lower than 95 kPa

- The outer packaging must not contain more than 4 L. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

(b) For solid substances:

- The primary receptacle(s) must be siftproof and must not exceed the outer packaging weight limit;
- The secondary packaging must be siftproof;

- If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them;
- Except for packages containing body parts, organs or whole bodies, the outer packaging must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold;
- If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, must be used.

An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm (4 in x 4 in).

% The completed package must be capable of successfully passing the drop test described in 6.6.1 except that the height of the drop must not be less than 1.2 m. Following the appropriate drop sequence, there must be no leakage from the primary receptacle(s) which must remain protected by absorbent material, when required, in the secondary packaging.

% For transport, the mark illustrated below must be displayed on the external surface of the outer packaging on a background of a contrasting colour and must be clearly visible and legible. The mark must be in the form of a square set at an angle of 45°(diamond-shaped) with each side having a length of at least 50 mm (2 in), the width of the line must be at least 2 mm and the letters and numbers must be at least 6 mm high. The proper shipping name “Biological Substance, Category B” in letters at least 6 mm high must be marked on the outer package adjacent to the diamond-shaped mark.

Unless all package markings are clearly visible, the following conditions apply when packages are placed in an overpack:

- the overpack must be marked with the word “Overpack”; and
- the package markings must be reproduced on the outside of the overpack.

A Shipper's Declaration for Dangerous Goods is not required.

Specific Requirements

Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen:

- When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations must be met. When used, ice or dry ice must be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack must be leakproof. If dry ice is used, the packaging must be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings.
- The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures, which could result if refrigeration were to be lost.

% Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement of these Regulations except for the following:

(a) the name and address of the shipper and of the consignee must be provided on each package;

(b) the name, and telephone number of a person responsible must be provided on the air waybill or on the package;

(c) the classification must be in accordance to 3.6.2;

(d) the incident reporting requirements in 9.6.1 must be met; and

(e) the inspection for damage or leakage requirements in 9.4.1 and 9.4.2.

Note:
When the shipper or consignee is also the 'person responsible' as referred to in b) above, the name and address need be marked only once in order to satisfy the name and address marking provisions in both a) and b), above.

Passengers and crew members are prohibited from transporting infectious substances as or in carry-on baggage, checked baggage or on their person.

If an Air Waybill is used, the "Nature and Quantity of Goods" box should show "UN 3373" and the text "BIOLOGICAL SUBSTANCE, CATEGORY B".

Clear instructions on filling and closing such packages must be provided by packaging manufacturers and subsequent distributors to the shipper or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for transport.

% Other dangerous goods must not be packed in the same packaging as Division 6.2 Infectious Substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 mL or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances provided these substances meet the requirements of 2.7.1 and 2.7.5. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction, no other requirements in these Regulations need be met.