MINISTRY OF HEALTH

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No: 40/2018/TT-BYT

Hanoi , December 7 , 2018

CIRCULARS

REGULATIONS ON MANAGEMENT OF INFECTIOUS DISEASE SPECIMEN

Pursuant to the Law on Prevention and Control of Infectious Diseases ;

Pursuant to Decree No. 75/2017/ND-CP dated June 20, 2017 of the Government regulating the functions, tasks, powers and organizational structure of the Ministry of Health;

At the request of the Director of the Department of Preventive Medicine;

The Minister of Health promulgates a Circular regulating the management of infectious disease specimens.

Chapter I

GENERAL RULES

Article 1. Scope of regulation and subjects of application

1. This Circular regulates the management of infectious disease specimens for the purposes of prevention, research, diagnosis and treatment of human diseases, including: collection, preservation, packaging, storage and use . Use, exchange, destroy, and transport infectious disease specimens out of the testing facility.

2. This Circular does not regulate samples that do not contain infectious substances or samples that contain infectious substances in neutral or inactivated form that are not capable of causing disease in humans, or blood samples and blood products used in blood transfusion activity.

3. This Circular applies to agencies, organizations and individuals that have functions and carry out activities of collecting, preserving, packaging, storing, using, exchanging, destroying and transporting samples. infectious disease specimens leave the testing facility.

Article 2. Explanation of terms

In this Circular, the following terms are understood as follows:

1. Specimens include samples of blood, serum, plasma, urine, stool, human body secretions , other samples from humans containing infectious substances, strains of microorganisms, samples containing microorganisms. organisms capable of causing disease in humans.

2. Infectious substances are substances that contain or have the potential to contain microorganisms (including viruses, bacteria, parasites, fungi) and prions that cause infectious diseases in humans, including type A and type B. .

3. Class A infectious substances are substances that, when exposed during transportation, can cause life-threatening diseases, death or permanent disability in humans according to the provisions in Appendix I issued together with according to this Circular.

4. Type B infectious substances are infectious substances that are not on the list of type A infectious substances specified in Clause 3 of this Article.

5. UN 2814 is the abbreviation for the phrase United Nations 2814, the United Nations symbol applied to the transportation of type A infectious substances.

6. UN 3373 is the abbreviation of the phrase United Nations 3373, a symbol of the United Nations applied to the transportation of class B infectious substances.

7. Class 6.2 (Class 6.2) is a separate classification class for potentially infectious substances according to United Nations guidelines.

8. A culture sample is a sample obtained as a result of the intentional multiplication of a pathogen.

chapter II

REGULATIONS ON COLLECTION, PRESERVATION, PACKAGING, TRANSPORTATION, STORAGE, USE, RESEARCH, EXCHANGE AND DESTROY OF PATHOGIC SAMPLES

Article 3. Collecting patient samples

1. Collecting clinical samples must comply with professional and technical procedures and avoid infection to the person taking the sample, the person being sampled, other relevant people, the community and the environment.

2. When collecting patient samples, the collector must fill out all information in the Information Sheet enclosed with the patient specimen according to the provisions in Appendix II issued with this Circular and send the form along with the patient sample.

Article 4. Preserving and packaging medical samples

1. After being taken and collected, the specimen must be preserved according to the regulations in Appendix III issued with this Circular before being transported to the testing facility.

2. Packaging of medical specimens containing or suspected of containing type A or type B infectious substances is as prescribed in Appendix IV issued with this Circular.

Article 5. Labeling of medical samples

1. The label on each test tube or specimen container includes the following information:

a) Full name of the person being sampled or code number;

b) Specimen type (e.g. whole blood, serum, plasma, urine, stool, cerebrospinal fluid, or other specimen type);

c) Sample collection time (including hour, day, month, year).

In case of using encryption method, it must ensure all information content specified in this Clause.

2. The label in the outermost layer includes the following information:

a) Sender's name, phone number and address;

b) Phone number of the responsible person (in case of sending through an intermediary);

c) Name, phone number and address of the receiving facility (unit);

d) Appropriate code according to United Nations regulations for international and domestic transportation;

d) Required storage temperature;

e) When using dry ice or liquid nitrogen, it is necessary to state the name of the refrigerant, the code according to United Nations regulations and the net weight;

g) Transport sample classification label suitable for each infectious substance as prescribed in Appendix V issued with this Circular.

Article 6. Transport of medical samples

1. The unit collecting the specimen must notify the laboratory that receives the specimen type; sent date ; Means of transportation and expected time the sample will arrive at the receiving unit.

2. Patient samples must be preserved according to the regulations in Appendix III issued with this Circular throughout the process of transportation to the testing facility.

3. Dimensions, weight, and packaging volume of medical samples when transported by air:

a) For specimens containing type A infectious substances: Each package of liquid specimens must not exceed 50 ml for passenger aircraft or no more than 04 liters for cargo aircraft . Each solid specimen package must not exceed 50 g for passenger aircraft or no more than 04 kg for cargo aircraft;

b) For medical specimens containing type B infectious substances: Each package of liquid specimens must not exceed 01 liter, the total of medical specimen packages after packaging must not exceed 04 liters. Each package of solid specimens must not exceed 04 kg/bale.

4. Transporting specimens by sea, road, and rail: Each outer packaging has a minimum size of 100 mm x 100 mm on each side, with no maximum size limit.

5. Persons transporting clinical specimens must use available equipment and tools to prevent the spread of infectious agents to humans and the environment.

Article 7. Troubleshooting when patient samples are spilled during transportation

1. Spill handling must be carried out according to the spill handling procedure in Appendix VI issued with this Circular.

2. The person transporting the specimen should contact the unit receiving or sending the sample or the nearest medical facility for instructions on handling measures.

3. In case of direct exposure to infectious material, the exposed area must be washed with soap and water or with a disinfectant and the exposed person must be taken immediately to the nearest medical facility. for advice and treatment.

4. After implementing the handling measures in Clauses 2 and 3 of this Article, the implementer must report the incident to the sample sending unit. For type A infectious substances, it must be immediately reported to the Department of Health in the area where the incident occurred.

Article 8. Receiving, using and storing medical specimens

1. After receiving notice from the unit sending the sample, the laboratory must arrange reception staff. When receiving a patient sample, the person receiving the sample must comply with the testing facility's regulations on opening the sample box, recording the time of receipt, the name of the recipient, the condition of the sample upon receipt, and comparing the accepted or rejected standards. refuse to accept samples from the receiving facility.

2. The receiving facility conducts testing according to professional and technical procedures for each type of specimen and the purpose of using the specimen.

3. Stored specimens must be preserved to prevent infection to humans and the environment.

4. Receiving, using, and storing patient samples must ensure biosafety according to the provisions of Circular No. 37/2017/TT-BYT dated September 25, 2017 of the Minister of Health regulating Practice biosafety in the laboratory.

Article 9. Destruction of medical samples

Destruction of clinical samples must be carried out in accordance with regulations on hazardous medical waste treatment in Circular No. 37/2017/TT-BYT dated September 25, 2017 of the Minister of Health regulating practice. ensuring biological safety in the laboratory and Joint Circular No. 58/2015/TTLT-BYT-BTNMT dated December 31, 2015 of the Ministry of Health and the Ministry of Natural Resources and Environment regulating medical waste management international.

Chapter III

TERMS ENFORCEMENT

Article 10. Implementation effect

1. This Circular takes effect from January 25, 2019.

2. In case the legal documents referenced in this Circular are amended, supplemented or replaced, the legal documents that have been amended , supplemented or replaced shall apply. position.

Article 11. Responsibility for implementation

1. The Department of Preventive Medicine acts as the focal point to organize and inspect the implementation of this Circular.

2. Department of Medical Examination and Treatment Management; The Department of Science, Technology and Training coordinates with the Department of Preventive Medicine to guide and inspect the implementation of research, use and storage of medical samples by organizations and individuals.

3. The Ministry of Health Inspectorate coordinates with functional departments and agencies under the Ministry of Health to conduct inspections nationwide on transportation, preservation, storage, use, research, exchange and destroy clinical samples related to infectious disease agents.

4. The Department of Health of provinces and centrally run cities shall conduct local inspections of collection, transportation , preservation , storage , use , and research activities . Storing , exchanging, and destroying medical samples related to infectious disease agents.

5. Institutes of Hygiene and Epidemiology, Pasteur Institute under the Ministry of Health, Preventive Medicine Centers/Disease Control Centers of provinces and centrally run cities, hospitals, agencies, organizations, and individuals Relevant individuals are responsible for implementing this Circular.

During the implementation process, if there are any difficulties or problems, agencies, organizations and individuals should report them to the Ministry of Health (Department of Preventive Medicine) for consideration and resolution./.

KT. MINISTER
DEPUTY MINISTER Nguyen Truong Son

Recipient:
- Committee on Social Affairs of the National Assembly;
- Government Office (Department of KGVX, Official Gazette, InformationDepartment);
-Minister (to report);
Local Deputy Ministers(to coordinate and direct);
- Ministry of Justice (Department of KTVBQPPL);
- Ministries, ministerial-level agencies, and agencies under the Government;
- People's Committees of provincesandcentrally run cities;
- Departments, Bureaus, VPB, Ministry Inspectorate, General Department under the Ministry of Health;
- Units under the Ministry of Health;
- Health ministries and branches;
- Department of Health of provincesandcentrallyrun cities; - TTKSBT/TTYTDP, TTPCSR, TTKDYTQT of provinces andcentrallyrun cities; - Electronic information portal, Ministry of Health; - Save: VT, DP (03b), PC (02b).

APPENDIX I

LIST OF INFECTIOUS SUBSTANCES CLASS A *(Issued together with Circular No. 40/20 1 8/TT-BYT dated December 7, 2018 of the Minister of Health)*

TT	TRANSPORTATION CODE ACCORDING TO UN	NAME OF MICROBIOLOGY T
	UN 2814 **Infectious substances affect humans**	*Bacillus anthracis* (culture sample) *Brucella abortus* (culture sample) *Brucella melitens is (* cultured sample) *Brucella suis* (culture sample) *Burkho l deria mallei - Pseudomonas mallei* (culture specimen)

			Burkholder i a pseudomallei - Pseudomonas pseudomallei (culture specimen)
			Chlamydia ps i ttaci - avian strains (culture samples)
			Clostridium botulinum (culture sample)
			Cocc i dioides imm i tis (cultured sample)
			Cox i ella burnetii (culture sample)
			Crimean-Congo hemorrhagic fever virus
			Dengue virus (culture sample)
			Eastern equine encephalitis virus (culture sample)
			Escherichia coli , verotoxigenic (cultured sample)
			Ebola virus
			Flexal Virus
			Francisella tularensis (cultured specimen)
			Guanarito virus
			Hantaan Virus
			Hantavirus causes hemorrhagic fever with pulmonary syndrome
			Hendra virus
			Hepatitis B virus (culture sample)
			Herpes B virus (culture sample)
			Human immunodeficiency virus (culture sample)
			Highly pathogenic avian influenza virus (culture sample)
			Japanese Encephalitis Virus (culture sample)
			Junin virus
			Kyasanur Forest disease virus
			Lassa virus
			Machupo virus
			Marburg virus
			Monkeypox virus
			Mycobacterium tuberculosis (culture sample) [1]
			Nipah virus
			Omsk hemorrhagic fever virus
			Polio virus (culture sample)
			Rabies Virus (culture sample)
			Rickettsia prowazekii (cultured specimen)
			Rickettsia rickettsii (culture sample)
			Rift Valley fever virus (culture sample)
			Russian spring-summer encephalitis virus (culture sample)
			Sabia virus
			Shigella dysenter i ae type 1 (culture sample)
			Virus causing tick-borne encephalitis (culture sample)

		Smallpox Virus Venezuelan equine encephalitis virus (culture sample) West Nile virus (culture sample) Yellow Fever Virus (culture sample) *Yersinia pestis* (culture sample)

[1] For road transport, cultures used for diagnostic or clinical purposes may be classified as Class B infectious substances.

APPENDIX II

INFORMATION FORM SUBMITTED WITH PATIENT SPECIMEN *(Issued together with Circular No. 40 /2018/TT-B Y T dated December 7 , 2018 of the Minister of Health)*

1. Patient's full name: …….. Age ....

2. Gender : ....

3. Date, month, year of birth: ……. / …….. / ....

4. Address: …….. Phone: ....

5. Date of illness onset: …….. / ……. / ....

6. Preliminary diagnosis: ....

7. Place of treatment : ....

8. Type of specimen : ....

9. Date and time of specimen collection: ....

10. Specimen code: ....

11. Testing requirements ....

12. Full name of person collecting patient samples: ....

13. Unit sending patient samples: ....

14. Address: ……. Phone: ....

Person writing the ballot *(sign, write full name)*

Note :

The coupon sample is kept in a sealed, waterproof bag placed in the specimen container.

APPENDIX III

REQUIREMENTS FOR PRESERVATION OF PATIENTS BEFORE AND DURING TRANSPORTATION *(Issued together with Circular No. 40/2018/TT-B Y T dated December 7 , 2018 of the Minister of Health)*

After being collected, the sample is transferred to the appropriate testing facility in the fastest time, preferably within 2 hours from the time the sample is taken, for processing depending on the intended use. If the sample is not sent within 2 hours, the storage conditions after sample collection must be followed according to the table below:

Sample type	Uses	Storage conditions	Storage time	Storage tools	Note
Serum/plasma samples	Molecular biology testing	4 - 8°C	≤ 48 hours	Appropriate sample test tube	
		-20°C or -70°C	> 48 hours		
	Detect antibodies and antigens	4 - 8 °C	≤ 10 days		
		-20°C	> 10 days		
Whole blood*	Molecular biology testing	4 - 8°C	≤ 48 hours	Test tube for sampling	
		-20°C or -70°C	> 48 hours		
	Detect antibodies and antigens	4 - 8°C	≤ 48 hours		
		- 20°C	> 48 hours		

	Isolation of microorganisms	18- 30°C	<24 hours		*Except for Meningococcus* and Pneumococcus bacteria **
		4 - 8°C	≥ 24 hours and < 48 hours		
Throat swab/pharyngeal swab/pharyngeal swab/	Molecular biology testing	4 - 8°C	≤ 48 hours	Test tube for sampling	
		-20°C or -70°C	> 48 hours		Store in a specialized transportation environment
	Detect antibodies and antigens	4 - 8°C	≤ 48 hours		
		- 20°C	> 48 hours		
	Isolation of microorganisms	18 - 30°C	<24 hours		- Store in a specialized transportation environment - *Except for Meningococcus* and *Pneumococcus* bacteria **
		4 - 8°C	≥ 24 hours and < 48 hours		
Endotracheal fluid/sputum samples/burns/skin fragments	Molecular biology testing	4 - 8°C	≤ 48 hours		
		-20°C or -70°C	> 48 hours		
	Detect antibodies and antigens	4- 8°C	≤ 48 hours		
		- 20°C	> 48 hours		
	Isolation of microorganisms	18 - 30°C	<24 hours		*Except for Meningococcus* and Pneumococcus bacteria **
CSF	Molecular biology testing	4 - 8°C	≤ 48 hours	Test tube for sampling	
		-20°C or -70°C	> 48 hours		
	Detect antibodies and antigens	4 - 8°C	≤ 48 hours		
		-20°C	> 48 hours		
	Detect parasites	4- 8°C	≤ 48 hours		
		-20°C or -70°C	> 48 hours		
	Isolation of microorganisms	18- 30°C	< 24 hours		
		4 - 8°C	≥ 24 hours and <48 hours		*Except for Meningococcus* and Pneumococcus bacteria **
Feces	Isolation of microorganisms	4 - 8°C	≤ 48 hours	The bottle is a sample	
		-70°C	> 48 hours		
	Detect parasites	4 - 8°C		Sampling vial	Sample mixed with 10% formaline or PVA in a 3:1 ratio
	Antigen /molecular biology detection test	-15°C		Sampling vial	
Rectal swab sample	For all diagnostic tests	4 - 8°C	< 24 hours	Rectal swab in a specialized transport medium tube	
		-20°C or -70°C	≥ 24 hours		For molecular biology testing only
Urine	Used for all diagnostic tests	4 - 8°C	< 24 hours	Sampling vial	Storage below 0°C is not allowed .

**For whole blood samples, before storing the sample at negative temperatures, it is necessary to separate serum and plasma.*

*** For samples used to culture and isolate Meningococcus and Pneumococcus bacteria: specimens need to be preserved in a specialized transport environment; If transported within 24 hours, specimens must be kept at room temperature (20-25°C); If the specimen is not delivered to the laboratory within 24 hours, it must be stored in a 35-37°C incubator with a 5 % C O $_2$ atmosphere , within a maximum of 4 days . Laboratory. During transportation, specimens must be kept at temperatures between 20-35°C.*

APPENDIX IV

PACKAGING OF INFECTIOUS DISEASE SPECIMEN *(Issued together with Circular No. 40 / 2018/ T T-B Health dated December 7 , 2018 of the Minister of Health)*

For infectious disease specimens, 3-layer packaging must be ensured as follows:

1. The first layer (specimen tube) must be sealed, the bottle / tube lid must be tightly attached with adhesive tape, paraffin paper or clamps to prevent leakage, if the tube is Specimens made of glass must have additional packaging measures to avoid breakage;

2. Second layer (box, bag containing specimen tubes):

a) Must ensure no leakage or waterproofing; Make sure the first layer is not tilted .

b) Between the first and second layers there must be a soft, impact-resistant material. If the specimen is a solution, sufficient absorbent material must be added to absorb the specimen solution in case of spillage. at ;

c) The first or second layer must be able to withstand temperatures from -40°C to + 55 °C and be able to withstand pressure of 95 kPa or more;

3. The third layer (outermost layer): made of hard material, minimum outer dimension of each side is 10 cm;

a) Containers or boxes used for transportation must be made from hard materials that are sturdy , impact-resistant, and leak-proof (for cold storage with wet ice) ;

b) Containers or boxes used for transportation must have ventilation holes (for cold storage with dry ice);

c) Containers or boxes used for transportation must be able to withstand low temperatures and retain their shape when stored and transported (for cold storage with liquid nitrogen).

d) Between the second layer and the outermost layer, there must be a waterproof sealed bag containing a list of samples, an information sheet attached to the samples in Appendix II issued with this Circular and procedures for handling spills. comply with the provisions in Appendix VI issued with this Circular.

4. Medical samples must be packaged separately, not with other goods. When packaging multiple samples, each sample, after being packaged in the first layer, must be placed separately to prevent contact between them in the second layer.

5. When samples need to be stored in frozen conditions, refrigerants (such as dry ice, liquid nitrogen or other refrigerants) must be used and these refrigerants must be located nearby. beyond the second layer.

6. For samples refrigerated by liquid nitrogen : The 1st and 2nd layers must be made of materials that can withstand the deep subzero temperatures of liquid nitrogen . The third layer must be a specialized tank/tank to transport liquid nitrogen .

7. If suspected of containing type A infectious substances, the sample list must clearly state "Suspected type A infectious substances" in parentheses.

8. Class A infectious substances should be transported in packaging that meets United Nations Class 6.2 specifications.

APPENDIX V

TYPES OF LABELS USED WHEN TRANSPORTING INFECTIOUS SUBSTANCES *(Issued together with Circular No. 40/2018/TT-BYT dated December 7 , 2018 of the Minister of Health)*

1. Label 1: Used for clinical samples containing type A infectious substances or suspected of containing type A infectious substances

Label name: Infectious substance

Minimum size: 1 00 x 1 00 mm (small package: 50 x 50 mm)

Number of labels per package: 1

Color: Black and white

2. Label 2: Use for specimens containing type B infectious substances

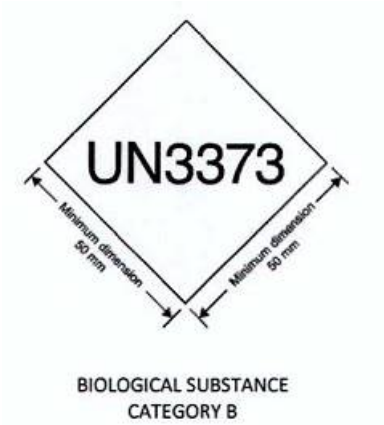
Label name: Group B infectious substance

Minimum dimensions (shipped by air): 50 x 50 mm

Minimum height of letters and numbers: 6 m m

Color: Not specified, must contrast with the color of the outer packaging layer

The lettering " BIOLOGICAL SUBSTANCE, CATEGORY B " is at least 6 m high



3. Label 3: Used for liquid nitrogen, substances packaged with liquid nitrogen. Label 4 is used in conjunction with label 1 or label 2

Label name: Non-toxic, non-flammable gas

Minimum size: 100 x 100 mm (small package: 50 x 50 mm)

Number of labels per package: 1

Color: Blue and white or blue and black

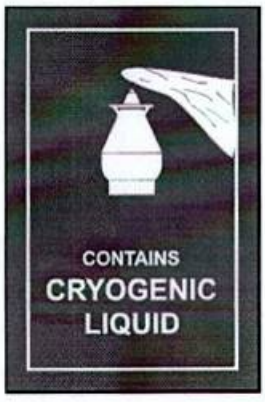
4. Label 4: Used for cryogenic liquids, used for transportation by air, deep-cooled liquefied gases. Label 5 is used in conjunction with labels 1 , 2, and 4 as appropriate.

Brand name: Cryogenic liquid

Minimum size: 74 x 105 mm

Number of labels per package : 1

Color: Blue and white



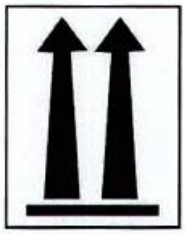
5. Label 5: Used to indicate the direction of the first packaging layer. Used when the volume of sample containing Class A infectious substances in each container in the first layer of packaging exceeds 50 ml when transported by air .

Label name: Orientation label

Minimum size: 74 x 105 mm

Number of labels per package : 2 (on opposite sides)

Color: Black and white or red and white



APPENDIX VI

SPILL INCIDENT HANDLING PROCEDURES *(Issued together with Circular No. 40 /2018/TT-BYT dated December 7 , 2018 of the Minister of Health)*

Spill handling procedures:

Step 1: Block off the area where the incident occurred;

Step 2: Use gloves, protective clothing, masks or glasses appropriate for each type of pathogen;

Step 3: Cover the entire spill area with a cloth or absorbent paper;

Step 4: Pour appropriate disinfectant onto spilled area from outside to inside, leave for 30 minutes;

Step 5: Collect contaminated materials into leak-proof waste containers (glass or sharp objects, if any, put into sharp materials containers for disposal).

Step 6: Report the spill to the person responsible.

- Note :

- If necessary, repeat steps 3-5 to clean up the spill area.

- Spill handling procedures are kept in a sealed, waterproof bag placed in the specimen container.