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Republic of Latvia
Cabinet
Regulation No. 7
Adopted 5 January 1999

Procedures for Registration of Infectious Diseases

Issued pursuant to Section 10 and Section 14, Paragraph one, Clause 4 of the Epidemiological Safety Law

1. This Regulation prescribes the procedures by which:

1.1. the cases where human infectious diseases and infection therewith (hereinafter - infectious diseases) have been determined and cases where infectious disease-causing agents have been determined shall be registered; and

1.2. the Food and Veterinary Service and the Centre for Disease Prevention and Control shall exchange information regarding cases where infectious diseases referred to in Annex 1 to this Regulation have been detected in humans or animals, as well as regarding cases where the disease causing agents have been detected in food products or in the environment of food undertakings.

[25 June 2002; 8 September 2009; 15 May 2012]

2. Registration of infectious diseases and their causal agents in the case of their determination shall be an epidemiological surveillance measure that includes reporting on infectious diseases and recording thereof.

3. The recording of agents of infectious diseases and of infectious diseases detected in the laboratory in accordance with Annexes 2 and 3 to this Regulation shall be insured by the Centre for Disease Prevention and Control and an epidemiologist of the relevant regional department thereof.

[15 May 2012]

4. Information regarding the spread of infectious diseases and epidemiological situation (retaining the

confidentiality of personal statistical data) shall be available to all natural and legal persons.

5. [4 April 2006]

6. If a health care practitioner has established that a patient has an infectious disease referred to in Annex 2 to this Regulation or if he or she has professionally grounded suspicions that a patient has become infected with the disease referred to in Annex 2 to this Regulation, the health care practitioner, in accordance with Paragraph 7 of this Regulation, shall notify regarding:

6.1. diagnosis of the infectious disease;

6.2. change or cancelling of the diagnosis of the infectious disease;

6.3. the final diagnosis of the infectious disease, laboratory confirmation thereof and the outcome of the disease;

6.4. [4 April 2006];

6.5. [8 September 2009].

[4 April 2006; 8 September 2009]

7. If an infectious disease is determined or professionally grounded suspicions arise regarding infection of a patient with an infectious disease, a health care practitioner shall:

7.1. regarding the diseases referred to in group 1 of Annex 2 to this Regulation, report without delay to the Centre for Disease Prevention and Control at any time of day or night by telephone and in writing by sending a completed urgent report form by fax, by post, by courier or electronically, and register the fact of notification in the medical documentation of the patient;

7.2. regarding the diseases referred to in group 2 of Annex 2 to this Regulation, report to the epidemiologist of the relevant regional department of the Centre for Disease Prevention and Control within one working day by telephone and in writing if it is the first notification on the infectious disease, or within three working days in writing if it is a notification on changing or revoking the diagnosis of an infectious disease or the final diagnosis of an infectious disease, its confirmation by the laboratory and the outcome of the disease. Written notification is sending a completed urgent report form by fax, by post, by courier or electronically, and registering the fact of notification in the medical documentation of the patient;

7.3. regarding the diseases referred to in group 3 of Annex 2 to this Regulation (except human immunodeficiency virus infection (HIV), AIDS and tuberculosis), report to the epidemiologist of the relevant regional department of the Centre for Disease Prevention and Control in writing within three working days by sending a completed urgent report form by fax, by post, by courier or electronically, and register the fact of notification in the medical documentation of the patient;

7.4. regarding human immunodeficiency virus infection (HIV), AIDS and tuberculosis report to the Centre for Disease Prevention and Control within three working days in writing or electronically by completing the medical documentation in accordance with the laws and regulations regarding the procedures for the record-keeping of medical and registration documentation of medical treatment institutions.

[8 September 2009; 15 May 2012; 30 July 2013]

7.^{1} If the possible infectious disease has been first determined by a health care practitioner of the emergency medical assistance team, it shall provide the urgent report only regarding non-hospitalised persons. If the person is hospitalised and the diagnosis of a possible infectious disease is not rescinded, the urgent report shall be provided by the health care practitioner of the hospital's admission department.

[4 April 2006]

7.^{2} Prior to notifying the authorities referred to in Paragraph 3 of this Regulation, the health care practitioners shall inform the person regarding which the notification is being made by indicating the aim of the notification and attesting that the information provided in the urgent report form shall be used for the epidemiological surveillance only. If the reported-on person is a minor or the court has recognised him or her as legally incompetent, the legal representative of such person shall be informed.

[4 April 2006]

7.^{3} The head of an educational institution, social care institution or another institution shall ensure the provision of information by telephone to the epidemiologist of the relevant regional department of the Centre for Disease Prevention and Control, if he or she suspects a group illness (there are two (or more) persons in the institution with the following signs of infectious disease - diarrhoea, vomiting, jaundice of skin, mucous membrane or the eyeballs, elevated body temperature, skin eruption or other skin blemish).

[4 April 2006; 8 September 2009; 15 May 2012]

7.[4] If a patient suffering from gonorrhoea has not had sexual contact while undergoing medical treatment with ceftriaxone or cefixime and clinical symptoms of gonorrhoea have not disappeared, the health care practitioner shall notify the epidemiologist of the relevant department of the Centre for Disease Prevention and Control thereof in writing within three days, by sending a completed form of urgent notification by fax, by post, by courier or electronically, and register the fact of notification in the medical documentation of the patient.

[22 January 2013]

7.[5] If a newborn infant is diagnosed with an infectious disease referred to in Annex 2 to this Regulation or there are professionally grounded suspicions regarding infection with such infectious disease, the health care practitioner shall in addition complete the form of urgent notification regarding the mother of the newborn infant within the time period referred to in Paragraph 7 of this Regulation, send the abovementioned form to the epidemiologist of the relevant department of the Centre for Disease Prevention and Control by fax, by post, by courier or electronically, and register the fact of notification in the medical documentation of the patient (mother of the newborn infant).

[22 January 2013]

8. The territorial unit of the Food and Veterinary Service and the epidemiologist of the relevant regional department of the Centre for Disease Prevention and Control shall, within not more than two days, exchange information regarding the cases when infectious diseases or the relevant disease-causing agents have been detected if:

8.1. substantiated suspicions regarding infection of a human while using certain food products in nutrition or being in contact with animals have arisen, as well as if the disease-causing agents have been detected in food products or in the environment of food undertakings; or

8.2. any of the diseases referred to in Annex 1 to this Regulation has been detected in an animal and there is a possibility of human infection.

[25 June 2002; 3 July 2007; 8 September 2009; 15 May 2012]

9. [8 September 2009]

9.[1] After isolation of the culture of micro-organism from the human material, as well as when isolating a micro-organism from any sample that has been taken within the framework of epidemiological examination or implementing the programmes of epidemiological surveillance, the head of a laboratory or his or her authorised person shall send the sample to the laboratory accredited by the limited liability company "Standardisation, Metrology and Accreditation Centre" in conformity with the standard LVS EN ISO 15189:2008 L "Medical laboratories - Particular requirements for quality and competence" for detailed examination and regarding the accreditation of which the Ministry of Economics has notified in the newspaper *Latvijas Vēstnesis* [the official Gazette of the Government of Latvia], and which executes the functions of the national reference centre in the field of microbiology and virology (hereinafter - reference laboratory). The reference laboratory shall carry out the following:

9.[1] 1. identification and typology with detection of toxigenicity, if the isolated culture of micro-organism is *Corynebacterium diphtheria* and *Corynebacterium ulcerans*;

9.[1] 2. identification and typology, if the isolated culture of micro-organism is *Neisseria meningitidis*;

9.[1] 3. [8 September 2009];

9.[1] 4. [8 September 2009];

9.[1] 5. affirmative testing of carbapenem-producing micro-organisms of genus *Enterobacteriaceae*.

[30 June 2008; 8 September 2009; 22 January 2013]

9.[2] The health care practitioner shall ensure the delivery of the human material sample to the reference laboratory in order to carry out the investigations referred to in Annex 3 to this Regulation, if there is substantiated suspicion regarding patient's falling ill with:

9.[2] 1. [30 June 2008];

9.[2] 2. [30 June 2008];

9.[2] 3. [30 June 2008];

9.[2] 4. hantavirus infection;

9.[2] 5. [30 June 2008];

9.[2] 6. [30 June 2008];

9.[2] 7. poliomyelitis and other enterovirus infection with meningitis serosa and encephalitis;

9.[2] 8. avian influenza virus or another influenza virus, which is considered by the World Health Organisation as a potential agent of pandemic;

9.[2] 9. West Nile fever;

9.[2] 10. [30 June 2008];

9.[2] 11. measles, rubella and epidemic parotitis (in order to perform isolation of viruses, detection of nucleic acids and genotyping);

9.[2] 12. Dengue virus;

9.[2] 13. Q fever (*Coxiella burnetii*);

9.[2] 14. any dangerous infectious disease referred to in Annex 2 to this Regulation.

[3 July 2007; 30 June 2008; 8 September 2009; 22 January 2013]

9.[3] The head of a microbiology laboratory or his or her authorised person shall ensure the supply of primary positive blood sample to the reference laboratory for the confirmation of diagnosis, if the following has been determined:

9.[3]1. HIV antibodies;

9.[3]2. antibodies of IgM class of the virus of mumps, measles or rubella virus. In case of the outbreak of the abovementioned diseases (10 and more cases of contracting the disease) the head of the microbiology laboratory or his or her authorised person shall co-ordinate the number of samples to be supplied with the Centre for Disease Prevention and Control for approval in the reference laboratory;

9.[3] 3. antibodies of Hepatitis C virus, if it is not possible to perform the affirmative testing of detection of Hepatitis C nucleic acids and Hepatitis C virus core or affirmative test of detection of antibodies.

[30 June 2008; 8 September 2009; 15 May 2012; 30 July 2013]

9.[4] If a health care practitioner has professionally grounded suspicions regarding a patient being infected with any of the infectious diseases referred to in Annex 3 to this Regulation, the health care practitioner shall ensure laboratory investigation of the patient using any of the methods for determining the presence of an agent indicated in Annex 3 to this Regulation. In case of exacerbation (10 and more cases of contracting the disease) the health care practitioner shall co-ordinate the number of patients to be undergoing laboratory investigation with the epidemiologist of the relevant regional department of the Centre for Disease Prevention and Control.

[8 September 2009; 15 May 2012]

9.[5] After isolation of *Salmonella, Shigella, Yersinia, Campylobacter, Listeria, Escherichia coli*, producing Shiga toxin/verotoxin (hereinafter - *STEC/VTEC*), and *Streptococcus pneumoniae* micro-organism culture from human material sample (in case of *Streptococcus pneumoniae* - if it has been isolated from cerebrospinal fluid or other usually sterile clinical material), as well as isolating the abovementioned agents from any sample taken within the scope of epidemiological investigation or epidemiological monitoring, the microbiology laboratory shall ensure type-determination of the isolated agent, determining the serotype for *Salmonella, Shigella, Yersinia, Listeria, STEC/VTEC* and *Streptococcus pneumoniae* cultures and cultures of *Campylobacter* species. If there are no technical possibilities of determining the serotype or species of the agent at the microbiology laboratory, the head of the laboratory or his or her authorised person shall send the culture of the isolated agent for detailed investigation to the laboratory referred to in Paragraph 9.[1] of this Regulation. In case of an outbreak (10 and more cases of contracting or infection) the head of the laboratory or his or her authorised person shall co-ordinate the quantity of isolated cultures of agents subject to type-determination with the epidemiologist of the relevant regional department of the Centre for Disease Prevention and Control.

[22 January 2013]

9.[6] The epidemiologist of the relevant regional department of the Centre for Disease Prevention and Control is entitled to request the head of the microbiology laboratory and to receive the isolated agent for further detailed investigation at the laboratory referred to in Paragraph 9.[1] of this Regulation or at a foreign competent laboratory, if it is necessary for epidemiological investigation.

[22 January 2013]

10. The head of a microbiology laboratory or his or her authorised person shall notify the epidemiologist of the relevant regional department of the Centre for Disease Prevention and Control regarding direct or indirect detection of the presence of infectious disease-causing agents indicated in Annex 3 to this Regulation in the examined human material sample or its approval in another laboratory:

10.1. regarding agents referred to in group 1 without delay by telephone, and register the fact of notification;

10.2. regarding agents referred to in group 2 within 72 hours, by sending completed form of urgent notification by fax, by post, by courier or electronically, and register the fact of notification.

[8 September 2009; 15 May 2012]

10.[1] The head of a microbiology laboratory or his or her authorised person shall submit to the Centre for Disease Prevention and Control a report on the carried out HIV tests by the fifth date of each month in conformity with the laws and regulations regarding the procedures for record-keeping of medical and registration documentation of medical treatment institutions.

[30 June 2008; 8 September 2009; 15 May 2012]

10.[2] If the head of a microbiology laboratory or his or her authorised person, in accordance with Paragraph 10 of this Regulation, reports regarding isolation of the agent *Neisseria gonorrhoeae* referred to in Paragraph 17 of Annex 3 to this Regulation, the method and results of testing the sensitivity to antimicrobials shall be indicated in the urgent report form, if such testing has been performed. If there are no technical possibilities of determining the sensitivity of the agent *Neisseria gonorrhoeae* to ceftriaxone or cefixime, or any other requested antimicrobial, in the microbiology laboratory, the head of the laboratory or his or her authorised person shall send the micro-organism culture to the laboratory referred to in Paragraph 9.[1] of this Regulation for determination of sensitivity to ceftriaxone, cefixime, ciprofloxacin, azitromycin, spectinomycin, gentamycin and tetracycline.

[22 January 2013]

10.[3] If the microbiology laboratory has performed diagnostics confirming HIV infection, the head of the laboratory or his or her authorised person shall, within three days, send the positive result of the affirmative test to the Centre for Disease Control and Prevention.

[22 January 2013]

10.[4] The head of the microbiology laboratory or his or her authorised person shall, within three days, send the testing report to the Centre for Disease Control and Prevention on the result of determining the sensitivity of the isolated *Micobacterium tuberculosis* against first-line and second-line medicinal products.

[22 January 2013]

10.[5] The head of the microbiology laboratory or his or her authorised person shall, each quarter until the fifth date of the first month of the quarter, submit a report to the Centre for Disease Control and Prevention on the case of the isolated *S.aureus, S.pneumoniae, E.coli, K.pneumoniae, P.aeruginosa, E.faecium/faecalis*, completing the form indicated in Annex 4 to this Regulation regarding the respective agent.

[22 January 2013 / The procedures referred to in the Paragraph are applicable from 1 April 2013. See Paragraph 15]

11. [8 September 2009]

12. [4 April 2006]

12.[1] The authorities referred to in Paragraph 3 of this Regulation shall ensure the exchange of the epidemiological information referred to in Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community, Commission Decision No 2000/57/EC of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council (notified under document number C(1999) 4016), Commission Decision No 2000/96/EC of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under

Decision No 2119/98/EC of the European Parliament and of the Council (notified under document number C(1999) 4015), Commission Decision No 2002/253/EC of 19 March 2002 laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (notified under document number C(2002) 1043) (2002/253/EC), Commission Decision No 2003/534/EC of 17 July 2003 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions and amending Decision 2002/253/EC as regards the case definitions for communicable diseases (notified under document number C(2003) 2301) (Text with EEA relevance), Commission Decision No 2003/542/EC of 17 April 2003 amending Decision 2000/96/EC as regards the operation of dedicated surveillance networks (notified under document number C(2003) 2522) (Text with EEA relevance) (2003/542/EC), Commission Decision No 2007/875/EC of 18 December 2007 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions (notified under document number K(2007) 6355), Commission Decision No 2008/351/EC of 28 April 2008 amending Decision 2000/57/EC as regards events to be reported within the early warning and response system for the prevention and control of communicable diseases (notified under document number K(2008) 1574), Commission Decision No 2008/426/EC of 28 April 2008 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (notified under document number C(2008) 1589), Commission Decision No 2009/312/EC of 2 April 2009 amending Decision 2000/96/EC as regards dedicated surveillance networks for communicable diseases (notified under document number C(2009) 2351) and Commission Decision No 2009/363/EC of 30 April 2009 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (notified under document number C(2009) 3517), as well as Commission Implementing Decision 2012/506/EC of 8 August 2012 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council, with epidemiological surveillance authorities of the European Union Member States.

[8 September 2009; 22 January 2013]

13. The compliance with this Regulation shall be controlled by the Health Inspectorate.

[30 June 2008]

14. [25 June 2002]

14.[1] By 1 October 2009 in the case referred to in Sub-paragraph 7.4 of this Regulation the health care practitioner shall complete the medical documentation regarding patients diagnosed with tuberculosis in accordance with the laws and regulations regarding the procedures for the record-keeping of medical and registration documentation of medical treatment institutions and send it to the State Agency of Tuberculosis and Lung Diseases within three days.

[8 September 2009]

15. The procedures referred to in Paragraph 10.[5] of this Regulation shall apply from 1 April 2013.

[22 January 2013]

Prime Minister V. Krištopans

Minister for Welfare V. Makarovs

Annex 1
Cabinet Regulation No. 7
5 January 1999

[26 June 2002; 4 April 2006; 3 July 2007; 8 September 2009; 15 May 2012; 22 January 2013]

Infectious Diseases from which Both Humans and Animals Suffer

The territorial unit of the Food and Veterinary Service and the epidemiologist of the relevant regional department of the Centre for Disease Prevention and Control shall exchange information regarding cases where the following infectious diseases have been determined in humans or animals:

1. Brucellosis

2. [4 April 2006]

3. *Diphyllobothriasis*

4. E.coli O157:H7 infection

5. Echinococcosis

6. [4 April 2006]

7. Tick-borne viral encephalitis

8. Yersiniosis

9. Campylobacteriosis

10. [4 April 2006]

11. Leptospirosis

12. Anthrax (Syberian plague)

13. Listeriosis

14. Equine glanders and melioidosis

15. Foot-and-mouth disease

16. Ornithosis (psittacosis)

17. Q-fever and other rickettsioses

18. [4 April 2006]

19. Salmonellosis

20. Toxoplasmosis

21. Rabies

22. Trichinellosis

23. [4 April 2006]

24. Tularaemia

25. Plague

26. Vibriosis

27. Avian influenza or other reemerged zoonosis.

28. Toxocariosis

Minister for Welfare V. Makarovs

Annex 2
Cabinet Regulation No. 7
5 January 1999

[3 July 2007; 8 September 2009; 22 January 2013; 30 July 2013]

Infectious Diseases Subject to Registration

No.	Infectious disease subject to registration	Group	Institution for the Epidemiological Surveillance of Infectious Diseases
			[8 September 2009]
1.	Acute flaccid paralysis for children up to 15 years of age	2.	
2.	Acute intestinal diseases, except for non-infectious etiology diseases	2.	
3.	Anisakiasis	3.	

4.	Anogenital herpes viral infection	3.
5.	Ascariasis	3.
6.	Invasive *Haemophilus influenzae* disease	2.
7.	Small pox*	1.
8.	Brucellosis	2.
9.	Human immunodeficiency virus (HIV) disease and AIDS	3.
10.	Cysticercosis	3.
11.	Another dangerous infectious disease, having reappeared*	1.
12.	Dermatophytosis (microsporosis, trichophitosis)	3.
13.	Diphyllobothriasis	3.
14.	Diphtheria and carrying of diphtheria bacteria	2.
15.	Yellow fever	1.
16.	[8 September 2009]	2.
17.	E. coli infection caused by entero-haemorrhagic *Escherichia coli*, Haemolytic uraemic syndrome or thrombocyte purpura haemorragica	2.
18.	Echinococcosis	3.
19.	Mumps	2.
20.	Epidemic louse-borne typhus fever* and Brill's disease*	1.
21.	Tick-borne encephalitis	2.
22.	Ehrlichiosis	3.
23.	Pertussis	2.
24.	Gonococcal infection	3.
25.	Hantavirus infection	2.
26.	Sexually transmitted diseases caused by chlamydias, including chlamydial lymphogranuloma (*lymphogranuloma venereum*)	3.
27.	Cholera and carrying of cholera bacteria*	1.
28.	Equine glanders and melioidosis	2.
29.	Yersiniosis	2.
30.	Campylobacteriosis	2.
31.	Scabies	3.
32.	Creutzfeldt-Jakob disease	3.
33.	Cryptosporidosis	2.
34.	Lyme disease	3.
35.	Legionnaires disease	2.
36.	Leprosy	3.
37.	Leptospirosis	2.
38.	Anthrax*	1.
39.	Listeriosis	2.
40.	Malaria and the carrying of the aģents of malaria	2.
41.	Measles	2.
42.	Rubella, including congenital rubella syndrome	2.
43.	Meningitis, encephalitis	2.
44.	Meningococcal infection	2.
45.	Plague*	1.
46.	Foot-and-mouth disease	2.
47.	Ornithosis (psittacosis)	2.
48.	Poliomyelitis*	1.
49.	Avian influenza* or another influenza caused by virus, which is considered by the World Health Organisation as a potential agent of pandemics (until the time when stable spread of influenza is detected in Latvia)	1.

50.	West Nile Virus	2.	
51.	Q-fever and other rickettsioses	2.	
52.	Salmonellosis and the carrying of the agents thereof	2.	
53.	Syphilis, including congenital syphilis	3.	
54.	[8 September 2009]	2.	
55.	Severe acute respiratory syndrome (SARS)*	1.	
56.	Tetanus	2.	
57.	Shigellosis and the carrying of the agents thereof	2.	
58.	Taeniasis	3.	
59.	Toxoplasmosis	3.	
60.	Rabies	1.	
61.	Trichinellosis	2.	
62.	Trichuriasis (trichocephaliasis)	3.	
63.	Tuberculosis	3.	
64.	Tularaemia	2.	
65.	Louse-borne relapsing fever*	1.	
66.	Bacterial food-borne intoxications, including botulism	2.	
67.	Typhoid fever and paratyphoid, including the carrying of the agents of typhoid fever and paratyphoid	2.	
68.	Varicella	2.	
69.	Chronic viral hepatitis and confirmed carrying of viral hepatitis	3.	
70.	Viral haemorrhagic fevers*, including Ebola virus disease, Lassa fever, Marburg virus disease, Crimean Congo haemorrhagic fever	1.	
71.	Giardiasis	3.	
72.	Invasive pneumoccocal disease	3.	
73.	Dengue fever	3.	
74.	Acute viral hepatitis	2.	

Note: *Dangerous infectious diseases.

Minister for Welfare V. Makarovs

Annex 3
Cabinet Regulation No. 7
5 January 1999

[8 September 2009; 22 January 2013; 30 July 2013]

Infectious Disease-causing Agents Detected in the Laboratory and Subject to Registration, Methods for the Determination thereof and Samples to be Investigated

No.	Infectious-disease causing agent(infectious disease)	Method	Clinical material	Group
I. Bacterial infectious diseases				
1.	*Bacillus anthracis* (anthrax)	isolation	not defined**	1.
		detection of nucleic acids	not defined**	1.
2.	*Bordetella pertussis* (pertussis)	isolation	not defined**	2.
		detection of nucleic acids	not defined**	2.
		specific antibodies response*	serum	no need to be reported
3.	*Brucella spp.* (brucellosis)	isolation	not defined**	2.
		specific antibodies response*	serum	2.
4.	*Campylobacter spp.*	isolation	stool, blood	2.

	(campylobacteriosis)			
5.	*Chlamydia trachomatis* (sexually transmitted disease induced by chlamydia, including *lymphogranuloma venereum, LGV*)	isolation	from anogenital tract or conjunctiva	2.
		direct immune fluorescent reaction	not defined**	2.
		detection of nucleic acids	not defined**	2.
		in case of LGV: isolation or detection of nucleic acids with additional identification of L1, L2 or L3 serovariant (genovariant)	not defined**	2.
6.	*Clostridium botulinum* (botulism)	isolation	stool (infant botulism), material from wound (wound botulism)	2.
		detection of botulinum toxin	not defined**	2.
7.	*Clostridium tetani* (tetanus)	isolation	from infected part	2.
		detection of tetanus toxin	serum	2.
8.	*Corynebacterium diphtheriae, Corynebacterium ulcerans* (diphtheria and the carrying of the agents of diphtheria)	isolation of *C. diphtheriae* or *C. ulcerans* producing toxins	not defined**	2.
9.	*Coxiella burnetii* (*Q* fever)	isolation	not defined**	2.
		detection of nucleic acids	not defined**	2.
		specific antibodies response* (IgG of IgM II phase)	serum	no need to be reported
10.	*Escherichia coli* producing Shiga toxin/verotoxin (STEC/VTEC) (entero-haemorrhagic *Escherichia coli* induced escherihiosis (STEC/VTEC))	isolation	not defined**	2.
		detection of gene(s) stx1 or stx2 nucleic acids	not defined**	2.
		detection of free Shiga toxins	not defined**	2.
		specific antibodies response*	serum	2.
11.	*Francisella tularensis* (tularemia)	isolation	not defined**	2.
		detection of nucleic acids	not defined**	2.
		specific antibodies response*	serum	2.
12.	*Haemophilus influenzae* (invasive *Haemophilus influenzae* infection)	isolation	normally sterile material	2.
		detection of nucleic acids	normally sterile material	2.
13.	*Legionella pneumophila* (Legionnaires' disease)	isolation (*Legionella spp.*)	respiratory secretion, any normally sterile material	2.
		detection of nucleic acids (*Legionella spp.*)	not defined**	2.
		detection of antigen (*Legionella pneumophila*)	urine, respiratory secretion, lung tissues	2.
		specific antibodies response* to *Legionella spp*.	serum	2.
14.	*Leptospira interrogans* (leptospirosis)	isolation	not defined**	2.
		detection of nucleic acids	not defined**	2.
		detection with immunofluorescence reaction method	not defined**	2.
		specific antibodies response*	serum	2.
15.	*Listeria monocytogenes* (listeriosis)	isolation	normally sterile material	2.
		isolation	normally non-sterile material taken from foetus,	2.

			stillborn, newborn or the mother at or within 24 hours of birth	
16.	[22 January 2013]			
17.	*Neisseria gonorrhoeae* (gonococcal infection)	isolation	not defined**	2.
		detection of nucleic acids	not defined**	2.
		detection by a non-amplified nucleic acid probe	not defined**	2.
		detection of intracellular gram negative diploccocci (gonococci)	swab from male urethra	2.
18.	*Neisseria meningitidis* (invasive meningococcal disease)	isolation	normally sterile material	2.
		detection of nucleic acids	normally sterile material, purpuric skin lesions	2.
		detection of antigen	cerebrospinal fluid	2.
		detection of gram-negative diplococci under microscope	cerebrospinal fluid	2.
19.	*Salmonella species* (salmonellosis and the carrying of the agents thereof)	isolation	not defined**	2.
20.	*Salmonella typhi* and *Salmonella paratyphi* (typhoid fever and paratyphoid fever, including the carrying of the agents of typhoid fever and paratyphoid fever)	isolation	not defined**	2.
21.	*Shigella species* (shigellosis and the carrying of the agents thereof)	isolation	not defined**	2.
22.	[22 January 2013]			
23.	*Treponema pallidum* (syphilis)	dark field microscopy	lesion exudates, tissues, in case of congenital and neonatal syphilis - also umbilical cord, placenta, nasal discharge	2.
		direct immune fluorescent reaction	exudates of damages, tissues, in case of hereditary syphilis and syphilis in newborn infants - also umbilical cord, placenta, nasal discharge	2.
		detection of nucleic acids (PCR)	lesion exudates or tissues	2.
		Screening tests***: non-treponemal tests (SED, VDRL, RPR)	blood, serum	no need to be reported****
		Screening tests***: non-treponemal tests (VDRL)	cerebrospinal fluid of a newborn infant	2.
		Screening tests***: *Treponema pallidum* hemagglutination test (TPHA)	blood, serum	no need to be reported****
		Screening tests***: *Treponema pallidum* particle agglutination test (TPPA)	blood, serum	no need to be reported****
		Detection of IgM and/or IgG specific antibodies (affirmative	blood, serum	2.

		test)		
24.	*Vibrio cholerae* (cholera)	isolation	not defined**	1.
25.	*Yersinia enterocolitica* and *Yersinia pseudotuberculosis* (yersiniosis)	isolation	not defined**	2.
26.	*Yersinia pestis* (plague)	isolation	not defined**	1.
		detection of nucleic acids (F1 antigen)	not defined**	1.
		specific antibodies response* (to *Yersinia pestis* F1 antigen)	serum	1.
27.	Carbapenem-resistant micro-organisms of genus *Enterobacteriaceae*	isolation	not defined**	2.
		detection of nucleic acids	not defined**	2.
II. Infectious diseases of viruses				
1.	Hepatitis A virus (Hepatitis A)	detection of nucleic acids	serum, stool	2.
		specific antibodies response*	serum	2.
		detection of antigen	stool	2.
2.	Hepatitis B virus (Hepatitis B)	response of specific IgM antibodies to Hepatitis B virus core antigen	serum	no need to be reported
3.	Hepatitis C virus (Hepatitis C)	detection of nucleic acids	serum	2.
		detection of virus core antigen	serum	2.
		specific antibodies response*, confirmed with affirmative test for detection of antibodies (for example, immunoblot) in persons older than 18 month	serum	2.
4.	Yellow fever virus (yellow fever)	isolation	not defined**	2.
		detection of nucleic acids	not defined**	2.
		detection of antigen	not defined**	2.
		specific antibodies response*	serum	2.
5.	Enterovirus (meningitis, encephalitis)	isolation	not defined**	2.
		specific antibodies response*	serum	no need to be reported
		detection of nucleic acids	cerebrospinal fluid	2.
6.	Epidemic parotitis virus (epidemic parotitis)	isolation	not defined**	2.
		detection of nucleic acids	not defined**	2.
		specific antibodies response*, characteristic to acute infection	serum, saliva	2.
7.	Type I and II *Herpes Simplex* viruses (anogenital herpes virus infection)	isolation	not defined**	2.
		direct immune fluorescent reaction	not defined**	2.
		detection of nucleic acids	not defined**	2.
8.	*Lyssa virus* (rabies)	isolation	not defined**	2.
		detection of nucleic acids	not defined**	2.
		direct immune fluorescent reaction	not defined**	2.
		specific antibodies response* with virus neutralisation test	serum, cerebrospinal fluid	2.
9.	Rubella virus (rubella)	isolation	not defined**	2.
		detection of nucleic acids	not defined**	2.
		specific antibodies response* (IgG)	serum saliva	2.
		specific antibodies response* (IgM)	serum	2.
10.	Measles virus (measles)	isolation	not defined**	2.
		detection of nucleic acids	not defined**	2.

		specific antibodies response*, characteristic to acute infection	serum, saliva	2.
		direct immune fluorescent reaction with specific monoclonal antibodies	not defined**	2.
11.	*Poliovirus* (poliomyelitis)	isolation	not defined**	1.
12.	Avian influenza virus or another influenza virus, which is considered by the World Health Organisation as a potential agent of pandemics	isolation	not defined**	1.
		detection of nucleic acids	not defined**	1.
		specific antibodies response*	serum	1.
13.	West Nile fever virus (West Nile fever)	isolation	blood, cerebrospinal fluid	2.
		detection of nucleic acids	blood, cerebrospinal fluid	2.
		specific antibodies response*	serum, cerebrospinal fluid	2.
14.	*SARS-coronavirus* (*SARS*)	isolation and identification (RT-PCR)	not defined**	1.
		detection of nucleic acids	not defined**	1.
		specific antibodies response*	serum	1.
15.	*Variola virus* (small pox)	isolation	not defined**	1.
		detection of nucleic acids	not defined**	1.
		Identification of *Orthopox* virus particles with electron microscopy	not defined**	1.
16.	Viruses that cause acute intestinal infections (for example, rotavirus, norovirus, astrovirus, adenoviruses)	detection of antigen	stool	2.
		detection of nucleic acids	stool	2.
17.	Viruses inducing viral hemorrhagic fever (viral hemorrhagic fever)	isolation	not defined**	1.
		detection of nucleic acids	not defined**	1.
18.	Dengue fever virus (Dengue fever)	isolation of the virus	not defined**	2.
		detection of nucleic acids	not defined**	2.
		detection of antigen	not defined**	2.
		specific antibodies response*	serum	2.
III. Parasitic infectious diseases				
1.	*Cryptosporidum* (cryptosporidosis)	detection of oocists	stool	2.
		detection of parasites	intestinal fluid, small-bowel biopsy specimens	2.
		detection of nucleic acids	stool	2.
		detection of antigen	stool	2.
2.	*Echinococcus spp.* (echinococcosis)	specific antibodies response*	serum	2.
		detection of nucleic acids	not defined**	2.
3.	*Giardia lamblia* (giardiasis)	detection of cysts or trophozoites	stool, duodenal fluid, sample of small-bowel biopsy	2.
		detection of antigen	stool	2.
4.	*Plasmodium spp.* (malaria)	detection of parasites, using light microscopy	blood, swab	2.
		detection of nucleic acids	blood	2.
		detection of antigen	not defined**	2.
5.	*Toxoplasma gondii* (toxoplasmosis)	detection of *T. gondii*	not defined**	2.
		detection of nucleic acids	not defined**	2.
		specific antibodies response*	serum	2.
6.	*Trichinella spp.*	detection of *Trichinella* larvae	tissues obtained in	2.

	(trichinellosis)		muscle biopsy	
		specific antibodies response*	serum	2.
7.	*Toxocara canis* (visceral migrating larva *larva migrans,* toxocariasis)	specific antibodies response, confirmed by different antibody test	serum	2.

Notes.

1. Specific antibodies response* - if not indicated otherwise - presence of IgM class antibodies, if the patient has not been recently vaccinated or had a diagnostically significant increase in the titre of specific antibodies.

2. Not defined** - the type of clinical material shall be determined by a health care practitioner according to the course of the disease and laboratory requirements.

3. Screening test*** - if syphilis has been diagnosed, the screening test shall be confirmed by a test for detection of specific IgM and/or IgG class antibodies - immune-ferment test, immunoblot test, immunofluorescence test (FTA-abs).

4. No need to be reported**** - except the case, if positive result of laboratory investigation is detected to a mother of a newborn infant or a child until reaching two years of age.

Annex 4
Cabinet Regulation No. 7
5 January 1999

[22 January 2013]

Name of the medical treatment institution _____

Code ☐☐☐☐☐☐☐☐☐

Report on the Isolated Case of *S.aureus, S.pneumoniae, E.coli, K.pneumoniae, P.aeruginosa, E.faecium/faecalis*

(underline as appropriate)

I. GENERAL INFORMATION

(to be completed regarding each isolate)

1.	Name of the laboratory
2.	Name of the isolated agent (for *S.pneumoniae* indicate the serotype)
3.	Testing method
4.	Sample number
5.	Clinical material (mark as appropriate): ☐ blood ☐ cerebrospinal fluid ☐ other usually sterile clinical material (indicate) _____
6.	Sampling date (dd/mm/yyyy)
7.	Sampling time (hh/mm)
8.	Sender of the sample (health care practitioner/laboratory)
9.	Given name, surname or initials of the patient
10.	Sex (underline as appropriate): male, female, unknown
11.	Date of birth (dd/mm/yyyy)
12.	Diagnosis/clinical symptoms
13.	Examined (underline as appropriate): in an inpatient institution, as an outpatient, not known, other
14.	Name of the inpatient/outpatient institution
15.	Date of hospitalisation (dd/mm/yyyy) Profile of the unit (underline as appropriate): therapy, paediatrics/neonatal ICU, surgery, haematology/oncology, obstetrics/gynaecology, ICU, emergency medical care, urology, infectology, other (indicate) _____ , not known

16.	Detection of sensitivity to antibacterial preparations (underline as appropriate): performed, not performed, not known

Part I of testing report was completed by _____

(given name, surname)

Telephone _____

II. RESULTS OF SENSITIVITY TESTING

(only the table for the particular micro-organism isolate must be completed)

1. *S.aureus,* isolated from blood or other usually sterile clinical material

No.	Antibacterial preparation	Final interpretation (S, I, R or NI)	Disk method (mm)	Interpretation of the disk method (S, I, R or NI)	MIC (mg/l)	MIC interpretation (S, I, R or NI)	E-test (mg/l)	E-test interpretation (S, I, R or NI)
1.	**Cefoxitin**							
	disk concentration							
2.	**Oxacillin** and/or							
	methicillin and/or							
	flucloxacillin and/or							
	cloxacillin and/or							
	dicloxacillin							
3.	**Ciprofloxacin** and/or							
	norfloxacin and/or							
	ofloxacin and/or							
	levofloxacin							
4.	**Rifampin**							
5.	**Linezolid**							

Other testing methods:

1) *mec A* gene determination with the PCR method (mark as appropriate) ☐ positive ☐ negative ☐ unknown

2) detection of penicillin binding protein 2a (mark as appropriate) ☐ positive ☐ negative ☐ unknown

2. *S.pneumoniae,* isolated from blood, cerebrospinal or other usually sterile clinical material

No.	Antibacterial preparation	Final interpretation (S, I, R or NI)	Disk method (mm)	Interpretation of the disk method (S, I, R or NI)	MIC (mg/l)	MIC interpretation (S, I, R or NI)	E-test (mg/l)	E-test interpretation (S, I, R or NI)
1.	**Oxacillin**							
	disk concentration							
2.	**Penicillin**							
3.	**Erythromycin** and/or							
	clarithromycin and/or							
	azithromycin							
4.	**Cefotaxime**							

	and/or							
	ceftriaxone							
5.	**Norfloxacin**							
	disk concentration							
6.	**Ciprofloxacin** and/or							
	ofloxacin and/or							
	levofloxacin							
7.	**Moxifloxacin**							

3. *E.coli,* isolated from blood, cerebrospinal or other usually sterile clinical material

No.	Antibacterial preparation	Final interpretation (S, I, R or NI)	Disk method (mm)	Interpretation of the disk method (S, I, R or NI)	MIC (mg/l)	MIC interpretation (S, I, R or NI)	E-test (mg/l)	E-test interpretation (S, I, R or NI)
1.	**Amoxicillin** and/or							
	ampicillin							
2.	**Gentamicin** and/or							
	tobramycin and/or							
	amikacin							
3.	**Ciprofloxacin** and/or							
	ofloxacin and/or							
	levofloxacin							
4.	**Cefotaxime** and/or							
	ceftriaxone and/or							
	ceftazidime							
5.	**Imipenem** and/or							
	meropenem							

Other testing methods:

1) detection of extended-spectrum beta-lactamasis (mark as appropriate) ☐ positive ☐ negative ☐ unknown

2) detection of carbapenemasis (mark as appropriate) ☐ positive ☐ negative ☐ unknown

4. *K.pneumoniae*, isolated from blood, cerebrospinal or other usually sterile clinical material

No.	Antibacterial preparation	Final interpretation (S, I, R or NI)	Disk method (mm)	Interpretation of the disk method (S, I, R or NI)	MIC (mg/l)	MIC interpretation (S, I, R or NI)	E-test (mg/l)	E-test interpretation (S, I, R or NI)
1.	**Gentamicin** and/or							
	tobramycin and/or							
	amikacin							
2.	**Ciprofloxacin** and/or							
	ofloxacin and/or							
	levofloxacin							
3.	**Cefotaxime** and/or							

	ceftriaxone and/or							
	ceftazidime							
4.	**Imipenem** and/or							
	meropenem							

Other testing methods:

1) detection of extended-spectrum beta-lactamasis (mark as appropriate) ☐ positive ☐ negative ☐ unknown

2) detection of carbapenemasis (mark as appropriate) ☐ positive ☐ negative ☐ unknown

5. *P.aeruginosa*, isolated from blood, cerebrospinal or other usually sterile clinical material

No.	Antibacterial preparation	Final interpretation (S, I, R or NI)	Disk method (mm)	Interpretation of the disk method (S, I, R or NI)	MIC (mg/l)	MIC interpretation (S, I, R or NI)	E-test (mg/l)	E-test interpretation (S, I, R or NI)
1.	**Piperacillin** and/or							
	piperacillin/ tazobactam							
2.	**Gentamicin** and/or							
	tobramycin							
3.	**Amikacin**							
4.	**Ciprofloxacin** and/or							
	levofloxacin							
5.	**Ceftazidime**							
6.	**Imipenem** and/or							
	meropenem							

Other testing methods:

detection of extended-spectrum beta-lactamasis (mark as appropriate) ☐ positive ☐ negative ☐ unknown

6. *E.faecium/faecalis*, isolated from blood, cerebrospinal or other usually sterile clinical material

No.	Antibacterial preparation	Final interpretation (S, I, R or NI)	Disk method (mm)	Interpretation of the disk method (S, I, R or NI)	MIC (mg/l)	MIC interpretation (S, I, R or NI)	E-test (mg/l)	E-test interpretation (S, I, R or NI)
1.	**Amoxicillin** and/or							
	ampicillin							
2.	**Gentamicin (high level)**							
	disk concentration							
3.	**Vancomycin**							
4.	**Teicoplanin**							
5.	**Linezolid**							

Notes.

1. R - resistant.

2. I - moderately sensitive.

3. S - sensitive.

4. NI - no interpretation.

Part II of testing report was completed by _____

(given name, surname)

Telephone _____