

**Regulations Regarding the Procedures for Granting and Cancellation of the Status of the National Reference Laboratory in the Field of Epidemiological Safety or Suspension of the Operation Thereof, and also Regarding the Rights and Obligations of the National Reference Laboratory**

*Issued pursuant to  
Section 5, Paragraph four of the Epidemiological Safety Law*

**I. General Provision**

1. This Regulation prescribes:
  - 1.1. the procedures for granting the status of the national reference laboratory in the field of epidemiological safety (hereinafter – the reference laboratory);
  - 1.2. the procedures for cancelling the status of the reference laboratory and suspending the operation thereof;
  - 1.3. the rights and obligations of the reference laboratory.

**II. Procedures for Granting, Cancellation of the Status of the Reference Laboratory, and Suspension of the Operation Thereof**

2. The status of the reference laboratory shall be granted to the laboratory if it conforms to the following requirements:
  - 2.1. the laboratory has been accredited for clinical and environmental specimen testing with the national accreditation body in accordance with laws and regulations regarding the assessment, accreditation and supervision of the conformity assessment bodies;
  - 2.2. the laboratory is suitable for work with Group 2 and Group 3 biological agents and conforms to the requirements for the laboratory of the 2nd and 3rd insulation level;
  - 2.3. the laboratory has practical work experience of at least five years in the reference fields referred to in Annex to this Regulation;
  - 2.4. the laboratory investigation spectrum, equipment and qualification of specialists enable to ensure the performance of the obligations referred to in Paragraph 10 of this Regulation;
  - 2.5. the laboratory has been included in the register of medical treatment institutions.
3. The Ministry of Health (hereinafter – the Ministry) shall assess the conformity of the medical treatment institution with the requirements referred to in Paragraph 2 of this Regulation and grant the status of the reference laboratory thereto.
4. The Ministry shall publish the information regarding granting the status of the reference laboratory on its website.
5. The Ministry may suspend the operation of the reference laboratory if it fails to conform to any of the requirements referred to in Paragraph 2 of this Regulation or fails to conform to the

obligations referred to in Paragraph 10 of this Regulation which cause risks for ensuring epidemiological supervision functions of infectious diseases.

6. By suspending the operation of the reference laboratory the Ministry shall determine a certain period of time for the prevention of the detected non-conformities, and also determine how the performance of the reference laboratory functions will be ensured.

7. The Ministry shall evaluate the submitted documents which attest that the deficiencies referred to in Paragraph 5 of this Regulation have been rectified, assess the conformity of the laboratory with the requirements referred to in Paragraph 2 of this Regulation, and renew the operation of the suspended reference laboratory, if the deficiencies due to which the activity was suspended have been rectified.

8. The Ministry may cancel the status of the reference laboratory, if there is at least one of the following reasons and the relevant medical treatment institution:

8.1. has requested to cancel the status of the reference laboratory;

8.2. has not eliminated the deficiencies within the time period referred to in Paragraph 6 of this Regulation due to which the operation of the reference laboratory was suspended;

8.3. has been excluded from the register of medical treatment institutions;

8.4. fails to conform to the mandatory requirements laid down in the laws and regulations for medical treatment institutions and their structural units.

9. The Ministry shall publish the information regarding cancelling the status of the reference laboratory on its website.

### **III. Rights and Obligations of the Reference Laboratory**

10. The reference laboratory has the following obligations:

10.1. the performance of reference investigations in accordance with Annex to this Regulation, including:

10.1.1. confirmatory diagnosis;

10.1.2. clarification of unclear investigation results of other laboratories (if the result is doubtful or in contradiction with clinical or epidemiological information) by using the method and testing system most appropriate for the particular situation;

10.1.3. examination of a repeat specimen or separated agent culture, using different methods appropriate for the situation (also the method already used) and testing systems;

10.1.4. investigation of unusual (non-typical) specimens for the purpose of diagnosis;

10.1.5. confirmatory detection of antimicrobial susceptibility;

10.1.6. diagnosis of infectious diseases to be registered in the European Union and Latvia and epidemiologically significant infectious diseases that guarantees accessibility of investigations in the country in accordance with the laws and regulations regarding the procedures for registering infectious diseases, and also identification of the agents of imported, rare, new and re-emerging infectious diseases by ensuring the diagnosis thereof or co-operation with the competent laboratories for the performance of such investigations;

10.1.7. sending specimens to other laboratories for identification of Group 4 biological agents, and also if it is not possible to carry out investigation in the reference laboratory in accordance with Annex to this Regulation or according to the co-ordinated activity programme of the reference laboratory for the current year;

10.1.8. performance of investigations in the case of public health risk (also biologic terrorism), including investigation of the specimens of unknown origin in the Biosafety Level 3 Laboratory;

10.1.9. ensuring permanent readiness (24 hours each day) for work in emergency situations of a dangerous infectious disease, outbreak, epidemic, biological terrorism, and other emergency situations of the public health, and also quick and operative action in order to receive and examine specimens;

10.2. participation in ensuring supervision, monitoring, warning and response measures in the field of epidemiological safety in co-operation with the Disease Prevention and Control Centre (hereinafter – the Centre), including:

10.2.1. participation in investigation of the outbreak of infectious diseases, also by carrying out or organising finding out the relationship of agents or typing (also molecular typing with sequencing), and also performance of other investigations according to epidemiological indications and taking into account the proposal of the Centre;

10.2.2. participation in specific epidemiological supervision researches according to the activity programme of the reference laboratory for the current year;

10.2.3. provision of reports to the commissioning party and the Centre regarding the reference testing results;

10.2.4. provision of information to the Centre regarding non-typical and unusual cases;

10.3. co-operation with international institutions and participation in researches, including:

10.3.1. with the European Centre for Disease Prevention and Control and other international organisations regarding the issues within the competence of the laboratory;

10.3.2. with the World Health Organisation in issues which are related to supervision of the the actual infections (for example, influenza, poliomyelitis, measles and rubella, tuberculosis), including regular and extraordinary informing regarding laboratory monitoring results of these infections and maintaining the accreditation granted by the World Health Organisation which is based on the qualification test results, and also the results of laboratory testing and evaluation of technical possibilities;

10.3.3. participation in local and international projects, including scientific researches in the field of epidemiological supervision in order to improve the quality of the performance of the main functions of the laboratory and extend the reference possibilities;

10.4. co-operation with other national and foreign laboratories in order:

10.4.1. to exchange with the information regarding the methods to be used in laboratory diagnosis;

10.4.2. to exchange with the information regarding the types of infectious disease agents;

10.4.3. to exchange with reference materials and samples related to diagnosis of infectious diseases;

10.4.4. to exchange with information regarding those infectious disease agents with which both the humans and animals fell ill, including mutual informing regarding new, rare or re-emerging zoonoses in Latvia;

10.4.5. to participate in international laboratory comparative tests in the reference fields on regular basis;

10.5. methodological work and consulting, including:

10.5.1. organising and co-ordinating inter-laboratory comparative testing programmes, and also provision of technical consultations in the reference fields to other laboratories;

10.5.2. development of recommendations, algorithms of laboratory testing work, and informative materials for the laboratories, medical practitioners, and laboratory specialists, co-ordinating it with experts of the sector;

10.5.3. validation of new laboratory diagnostic methods and technologies of infectious diseases and introduction thereof in practice, and also informing and consulting of other laboratories in relation to introduction of these new methods and development of the relevant recommendations;

10.5.4. training and consulting the personnel involved in the laboratory work in order to co-ordinate diagnostic methods in the country;

10.5.5. provision of consultations to the Ministry, the Centre, and other public health authorities and laboratories in issues which are related to policy planning, development of guidelines, and improvement of the system for investigation and supervision of infection outbreaks;

10.6. ensuring of reference resources and materials:

10.6.1. ensuring the purchase and distribution of reagents necessary for bacteriological diagnosis of tuberculosis and diagnosis of human immunodeficiency virus (HIV) infection according to the annual reference laboratory activity programme for the laboratories involved in the epidemiological supervision by supervising the use of reagents;

10.6.2. establishment, maintenance and issuance of agent strains, antigens, nucleic acids, antibodies, and also reserves of clinical specimens containing the agents within the framework of the reference activity;

10.7. to prepare each year and submit to the Ministry by 15 September the programme for the reference laboratory investigations for the next year, co-ordinated with the National Health Service (hereinafter – the Service) and the Centre, which is the basis for the Service to enter into an agreement with the reference laboratory regarding the performance of the reference laboratory obligations, taking into account the available State budget funding. The following shall be laid down in the programme:

10.7.1. the planned amount of the investigations of the reference laboratory in accordance with Annex to this Regulation and the funding necessary for it;

10.7.2. the planned amount of the investigations of infectious diseases to be registered in the European Union and Latvia and epidemiologically significant infectious diseases and the funding necessary for it, and also the funding for unexpected epidemiologically significant cases;

10.7.3. the reference fields (investigations) the performance of which will be ensured in other laboratories, including outside Latvia, and the funding necessary for it;

10.7.4. the planned participation in international comparative tests and the funding necessary for it;

10.7.5. the planned inter-laboratory tests in the reference fields and the funding necessary for it;

10.7.6. the planned number of molecular-epidemiological typing investigations in the field of epidemiological safety and the funding necessary for it;

10.7.7. the funding necessary for the maintenance of reference resources and materials and introduction of new investigations;

10.7.8. the planned seminars for the representatives of the laboratory who are carrying out diagnosis of infectious diseases, and the funding necessary for it;

10.7.9. the planned participation of the experts of the reference laboratory in seminars and training programmes, and the funding necessary for it;

- 10.7.10. the planned method validations and the funding necessary for them;
- 10.7.11. the expected number of scientific publications of the employees of the laboratory in the reference fields;
- 10.7.12. other measures for the current year.

11. The reference laboratory shall prepare a report each year co-ordinated with the Service and the Centre and submit it for the evaluation to the Ministry until 1 March of the following year regarding the performance of the obligations specified in Paragraph 10 of this Regulation in the previous year. The reference laboratory shall publish the co-ordinated report on its website. The following information shall be indicated in the report:

- 11.1. the results of performance of the reference functions in each reference field;
- 11.2. distribution and use of the budget granted for the reference function;
- 11.3. information regarding the organised inter-laboratory comparative tests;
- 11.4. the performance of the obligations of the reference laboratory, including the results of methodological work.

12. The reference laboratory has the following rights according to the granted field of reference:

- 12.1. to receive from medical treatment institutions the agent strain of the reference field, nucleic acids, antigen, antibody specimens, and also clinical specimens which contain agents for additional investigations and establishment of reserves;
- 12.2. to publish informative materials and provide information regarding the issues within the competence of the reference laboratory;
- 12.3. to organise and manage seminars and trainings;
- 12.4. to invite experts in order to carry out the tasks related to the activity of the reference laboratory;
- 12.5. to enter into agreements with other laboratories and medical treatment institutions which conform to the requirements referred to in Paragraph 2 of this Regulation, including the requirement to work with the agents of the relevant biological group, or with the reference laboratories recognised in the European Union Member States or European Economic Area states, or with the laboratories accredited by the World Health Organisation in order to ensure performance of certain tasks of the reference laboratories and cost effectiveness;
- 12.6. to carry out other laboratory investigations paid from the State budget resources or paid laboratory investigations which are not included in the obligations of the reference laboratory if the performance of such investigations, accounting and funding thereof are separated from the investigations to be carried out in the field of activity of the reference laboratory;
- 12.7. to participate in scientific projects and attract the funding necessary for them.

#### **IV. Closing Provision**

13. Until the day of entering into the agreement referred to in Sub-paragraph 10.7 of this Regulation with a medical treatment institution to which the status of the reference laboratory has been granted in accordance with the procedures laid down in Paragraph 3 of this Regulation, but not later than until 1 January 2018, the functions of the reference laboratory shall be ensured by the medical treatment institution with which the agreement regarding provision of the obligations of a reference laboratory has been entered into in accordance with laws and regulations regarding procedures for organising and financing the health care.

Prime Minister

Māris Kučinskis

Minister for Health

Anda Čakša

## Investigations Ensured by the National Reference Laboratory in the Field of Epidemiological Safety

No.	Diseases	Infectious agent	Reference investigations
<b>1. Bacterial infections</b>			
1.1.	Botulism	<i>Clostridium botulinum</i>	<ul style="list-style-type: none"> <li>• Determination of toxin (botuline)<sup>1</sup></li> <li>• Investigation of specimens of unknown origin</li> </ul>
1.2.	Brucellosis	<i>Brucella spp.</i>	<ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Investigation of specimens of unknown origin</li> </ul>
1.3.	Diphtheria and carrying diphtheria agents	<i>Corynebacterium diphtheriae</i> , <i>Corynebacterium ulcerans</i> , <i>Corynebacterium pseudotuberculosis</i>	<ul style="list-style-type: none"> <li>• Confirmatory identification of agent culture with detection of toxigenicity (including toxigenicity gene)<sup>2</sup></li> <li>• Typing<sup>2</sup></li> </ul>
1.4.	Epidemic louse-borne typhus* and Brill's disease*	<i>Riketsia provaceki</i>	<ul style="list-style-type: none"> <li>• Diagnosis or specimen sending to other laboratory (outside Latvia)</li> </ul>
1.5.	Ehrlichiosis (including human granulocytic anaplasmosis)	<i>Ehrlichia spp.</i> <i>Anaplasma phagocytophilum</i>	<ul style="list-style-type: none"> <li>• Confirmatory diagnosis<sup>3</sup></li> <li>• Monitoring of agent circulation in vectors<sup>4</sup></li> </ul>
1.6.	Pertussis	<i>Bordetella pertussis</i> , <i>Bordetella parapertussis</i>	<ul style="list-style-type: none"> <li>• Confirmatory identification of agent culture<sup>3; 4</sup></li> <li>• Other confirmatory diagnosis<sup>3</sup></li> </ul>
1.7.	Gonococcal infection	<i>Neisseria gonorrhoeae</i>	<ul style="list-style-type: none"> <li>• Confirmatory identification of agent culture<sup>1</sup></li> <li>• Detection of susceptibility to antimicrobials<sup>1</sup></li> </ul>
1.8.	Sexually transmitted chlamydial diseases, including chlamydial lymphogranuloma (LGV – <i>lymphogranulomavenereum</i> )	<i>Chlamydia trachomatis</i>	<ul style="list-style-type: none"> <li>• Confirmatory diagnosis<sup>3</sup></li> <li>• LGV diagnosis (typing)</li> </ul>
1.9.	Cholera and carrying cholera agents*	<i>Vibrio cholerae</i>	<ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Typing</li> <li>• <i>Vibrio cholerae</i> circulation monitoring in the</li> </ul>

			environment <sup>4</sup>
1.10.	Invasive <i>Haemophilus influenzae</i> disease	<i>Haemophilus influenzae</i>	<ul style="list-style-type: none"> <li>• Confirmatory identification of <i>H. influenzae</i> cultures<sup>1</sup></li> <li>• Typing<sup>1</sup></li> </ul>
1.11.	Meningococcal disease, invasive	<i>Neisseria meningitidis</i>	<ul style="list-style-type: none"> <li>• Confirmatory identification of agent culture<sup>2</sup></li> <li>• Typing<sup>2</sup></li> </ul>
1.12.	Invasive pneumococcal disease	<i>Streptococcus pneumoniae</i>	<ul style="list-style-type: none"> <li>• Typing of invasive <i>S. pneumoniae</i><sup>1</sup></li> </ul>
1.13.	Yersiniosis	<i>Yersinia enterocolitica</i> , <i>Yersinia pseudotuberculosis</i>	<ul style="list-style-type: none"> <li>• Confirmatory identification of agent culture<sup>1</sup></li> <li>• Typing<sup>1</sup></li> </ul>
1.14.	Campylobacteriosis	<i>Campylobacter spp.</i>	<ul style="list-style-type: none"> <li>• Confirmatory identification of the cultures of micro-organisms of <i>Campylobacter genus</i><sup>1; 3</sup></li> </ul>
1.15.	Lyme disease (lyme boreliosis)	<i>Borrelia burgdorferi</i>	<ul style="list-style-type: none"> <li>• Confirmatory diagnosis<sup>1; 3</sup></li> <li>• Monitoring of agent circulation in vectors<sup>4</sup></li> </ul>
1.16.	Legionnaires' disease (legionellosis)	<i>Legionella spp.</i>	<ul style="list-style-type: none"> <li>• Confirmatory diagnosis<sup>3; 4</sup></li> <li>• Typing<sup>4</sup></li> </ul>
1.17.	Lepae	<i>Micobacterium leprae</i>	<ul style="list-style-type: none"> <li>• Diagnosis or specimen sending to other laboratory (outside Latvia)</li> </ul>
1.18.	Leptospirosis	<i>Leptospira spp.</i>	<ul style="list-style-type: none"> <li>• Confirmatory diagnosis<sup>3</sup></li> <li>• Microbiological identification of leptospira to sero-group<sup>1</sup></li> </ul>
1.19.	Splenic fever(Anthrax)*	<i>Bacillus anthracis</i>	<ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Investigation of specimens of unknown origin</li> </ul>
1.20.	Listeriosis	<i>Listeria monocytogenes</i>	<ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Detection of antimicrobial susceptibility</li> <li>• Confirmatory identification of agent culture<sup>1</sup></li> <li>• Typing<sup>1</sup></li> </ul>
1.21.	Plague*	<i>Yersinia pestis</i>	<ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Investigation of specimens of unknown origin</li> </ul>
1.22.	Ornithosis (psittacosis)	<i>Chlamydia psittaci</i>	<ul style="list-style-type: none"> <li>• Diagnosis</li> </ul>
1.23.	Q fever	<i>Coxiella burnetii</i>	<ul style="list-style-type: none"> <li>• Investigation of specimens of unknown origin</li> <li>• Differential diagnosis with other rickettsioses</li> </ul>

			<ul style="list-style-type: none"> <li>• Diagnosis or specimen forwarding to other laboratory (outside Latvia)</li> </ul>
1.24.	Salmonellosis, typhoid and paratyphi and carrying agents thereof	<i>Salmonella spp.</i> , including <i>Salmonella typhi</i> and <i>Salmonella paratyphi</i>	<ul style="list-style-type: none"> <li>• Confirmatory identification of the cultures of micro-organisms of <i>Salmonella</i> genus up to serotype<sup>1</sup></li> <li>• Typing<sup>4</sup></li> </ul>
1.25.	Syphilis, including congenital and neonatal	<i>Treponema pallidum</i>	<ul style="list-style-type: none"> <li>• Confirmatory diagnosis of primary positive serological results<sup>1;5</sup></li> <li>• Diagnosis of congenital syphilis<sup>3;5</sup></li> </ul>
1.26.	Tetanus	<i>Clostridium tetani</i>	<ul style="list-style-type: none"> <li>• Diagnosis or specimen forwarding to other laboratory (outside Latvia)</li> </ul>
1.27.	Shiga toxin/verocytotoxin producing <i>Escherichiacoli</i> , haemolytic uraemic syndrome or thrombocytopenic purpura hemorrhagica	<i>E. coli</i> which produces shiga toxin/verocytotoxin (STEC/VTEC)	<ul style="list-style-type: none"> <li>• Identification of cultures of confirmatory <i>E. coli</i> which produces shiga toxine/verocytotoxine<sup>1</sup></li> <li>• Typing<sup>1</sup></li> </ul>
1.28.	Shigellosis, carrying agents thereof	<i>Shigella spp.</i>	<ul style="list-style-type: none"> <li>• Confirmatory identification of the cultures of micro-organisms of <i>Shigella</i> genus<sup>1</sup></li> <li>• Typing<sup>1</sup></li> </ul>
1.29.	Tuberculosis	<i>Mycobacterium tuberculosis complex</i>	<ul style="list-style-type: none"> <li>• Confirmatory diagnosis<sup>2</sup></li> <li>• Sensitivity detection<sup>2</sup></li> <li>• Typing<sup>2</sup></li> <li>• Genotype detection<sup>4</sup></li> </ul>
1.30.	Tularaemia	<i>Francisella tularensis</i>	<ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Investigation of specimens of unknown origin</li> </ul>
1.31.	Louse borne relapsing fever*	<i>Borellia recurrentis</i>	<ul style="list-style-type: none"> <li>• Diagnosis or specimen sending to other laboratory (outside Latvia)</li> </ul>
<b>2. Virus infections</b>			
2.1.	Acute and/or chronic viral hepatitis and carrying hepatitis virus	Hepatitis A virus	<ul style="list-style-type: none"> <li>• Confirmatory diagnosis<sup>3</sup></li> <li>• Typing<sup>4</sup></li> </ul>
		Hepatitis B virus	<ul style="list-style-type: none"> <li>• Confirmatory diagnosis<sup>1;3</sup></li> <li>• Typing<sup>4</sup></li> <li>• Resistance monitoring</li> <li>• Treatment efficiency monitoring</li> </ul>
		Hepatitis C virus	<ul style="list-style-type: none"> <li>• Confirmatory diagnosis<sup>1;3</sup></li> <li>• Typing<sup>1;4</sup></li> <li>• Treatment efficiency monitoring</li> </ul>

		Hepatitis D virus	• Confirmatory diagnosis <sup>1;3</sup>
		Hepatitis E virus	• Diagnosis
2.2.	Smallpox*	Variola virus	• Investigation of specimens of unknown origin • Sample sending to BSL4 laboratory (outside Latvia)
2.3.	Human Immunodeficiency Virus (HIV) infection and AIDS	Human Immunodeficiency Virus (HIV)	• Diagnosis confirming HIV infection <sup>2</sup> • Typing • Detection of HIV resistance • AIDS diagnosis • Treatment efficiency monitoring • Diagnosis of HIV opportunistic infections
2.4.	Dengue fever	Dengue fever virus	• Diagnosis or specimen sending to other laboratory (outside Latvia)
2.5.	Yellow fever	Yellow fever virus	• Diagnosis or specimen sending to other laboratory (outside Latvia)
2.6.	Mumps	Mumps virus	• Approval of primary positive serological results <sup>2</sup> • Molecular biological diagnosis <sup>2</sup> • Virological diagnosis <sup>2</sup> • Sending virus isolates to the international reference laboratory • Typing <sup>4</sup>
2.7.	Tick-borne encephalitis	Tick-borne encephalitis virus	• Confirmatory diagnosis <sup>3</sup> • Monitoring of virus circulation in vectors <sup>4</sup>
2.8.	Hantavirus infection	Hantaviruses	• Diagnosis
2.9.	Influenza and other respiratory viruses	Influenza viruses	• Diagnosis <sup>3</sup> • Detection of resistance within the framework of monitoring <sup>4</sup> • Identification of virus strains <sup>4</sup> • Typing <sup>4</sup> • Monitoring of influenza viruses <sup>4</sup> • Sending virus isolates to the international reference laboratory
		Other respiratory viruses	• Diagnosis <sup>4</sup> • Monitoring of the circulation of respiratory

			viruses <sup>4</sup>
	Avian influenza in humans* or other influenza which is caused by the virus which the World Health Organisation considers to be a cause for a possible pandemic	Avian influenza virus or other influenza virus which the World Health Organisation has recognised to be a cause for a possible pandemic	<ul style="list-style-type: none"> <li>• Diagnosis<sup>2</sup></li> <li>• Identification of virus strains</li> <li>• Typing<sup>2</sup></li> <li>• Sending virus isolates to the international reference laboratory</li> </ul>
2.10.	Measles	Measles virus	<ul style="list-style-type: none"> <li>• Approval of primary positive serological results<sup>2</sup></li> <li>• Molecular biological diagnosis<sup>2</sup></li> <li>• Virological diagnosis<sup>2</sup></li> <li>Differential diagnosis with parvovirus infection B19 and other viruses</li> <li>• Typing<sup>4</sup></li> <li>• Sending virus isolates to the international reference laboratory</li> </ul>
2.11.	Rubella, congenital rubella (including congenital rubella syndrome)	Rubella virus	<ul style="list-style-type: none"> <li>• Approval of primary positive serological results<sup>2</sup></li> <li>• Molecular biological diagnosis<sup>2</sup></li> <li>• Virological diagnosis<sup>2</sup></li> <li>Differential diagnosis with parvovirus infection B19 and other viruses</li> <li>• Typing<sup>4</sup></li> <li>• Forwarding virus isolates to the international reference laboratory</li> </ul>
2.12.	Meningitis, encephalitis (etiologies of enteroviruses)	Enteroviruses (except polioviruses)	<ul style="list-style-type: none"> <li>• Diagnosis</li> <li>Differential diagnosis with viruses of herpes simplex group and other viruses</li> <li>• Typing</li> <li>• Monitoring of enterovirus circulation in the environment</li> </ul>
	Poliomyelitis* and acute flaccid paralysis for children up to 15 years of age	Polioviruses	<ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Monitoring of virus circulation in the environment</li> <li>• Typing</li> <li>• Sending a specimen and/or virus isolates to the international reference laboratory</li> </ul>
2.13.	West Nile fever	West Nile virus	<ul style="list-style-type: none"> <li>• Diagnosis or specimen sending to other laboratory</li> </ul>

			(outside Latvia)
2.14.	Severe acute respiratory syndrome (SARS)*	SARS coronavirus**	• Diagnosis or specimen sending to other laboratory (outside Latvia)
	Middle East Respiratory Syndrome (MERS)*	MERS coronavirus**	• Diagnosis or specimen sending to other laboratory (outside Latvia)
2.15.	Rabies	Rabies virus ( <i>Lyssavirus</i> )	• Diagnosis or specimen sending to other laboratory (outside Latvia)
2.16.	Varicella	<i>Varicella zoster</i> virus	• Confirmatory diagnosis <sup>3</sup>
2.17.	Acute intestinal infections of virus etiology, carrying viruses	Rotavirus Norovirus Adenovirus Astrovirus Other caliciviruses (including Sapovirus)	• Confirmatory diagnosis <sup>3</sup> • Typing <sup>4</sup> • Detection of disease etiology for children vaccinated against rotavirus infection
2.18.	Haemorrhagic fevers of viruses*	Ebola virus** Marburg virus** Lassa virus** Crimean-Congo haemorrhagic fever virus** and other haemorrhagic fever viruses**	• Diagnosis or specimen sending to BSL4 laboratory (outside Latvia)
<b>3. Parasitary infections</b>			
3.1.	Echinococcosis	<i>Echinococcus spp.</i>	• Confirmatory diagnosis <sup>3</sup>
3.2.	Cryptosporidiosis	<i>Cryptosporidium spp.</i>	• Confirmatory diagnosis <sup>3</sup>
3.3.	Malaria and other blood parasites and carrying malaria agents	<i>Plasmodium spp.</i>	• Confirmatory diagnosis <sup>3</sup>
3.4.	Toxoplasmosis (incl. congenital toxoplasmosis)	<i>Toxoplasma gondii</i>	• Confirmatory diagnosis <sup>3</sup>
3.5.	Trichinellosis	<i>Trichinella spp.</i>	• Confirmatory diagnosis <sup>3</sup>
3.6.	Giardiasis	<i>Giardia lamblia</i>	• Confirmatory diagnosis <sup>3</sup>
<b>4. Other, rare and new infections</b>			
4.1.	Babesiosis	<i>Babesia</i>	• Monitoring of agent circulation in vectors <sup>4</sup>
4.2.	Creutzfeldt-Jakob disease	Protein of pathological form, prion	• Diagnosis or specimen sending to other laboratory (outside Latvia)
4.3.	Other infectious disease emerged anew or re-emerged, including dangerous	Other micro-organisms emerged anew** or re-emerging	• Diagnosis or specimen sending to other laboratory (outside Latvia)
4.4.	Other rare or imported infection	Chikungunya virus, Japanese encephalitis virus, Zika virus and other	• Diagnosis or specimen sending to other laboratory (outside Latvia)

4.5.	Other bacterial infections	<i>Clostridium perfringens</i> and others	• Molecular biological diagnosis <sup>1; 4</sup>
<b>5. Infections related to health care and antimicrobial resistance of micro-organisms</b>			
5.1.	Infection initiated by <i>C. difficile</i>	<i>Clostridium difficile</i>	• Confirmatory diagnosis <sup>3</sup> • Detection of antimicrobial susceptibility and toxins <sup>1; 3</sup> • Typing of bacteria and toxins <sup>4</sup>
5.2.	Invasive infections initiated by micro-organisms of <i>Staphylococcus aureus</i> , <i>Streptococcus pneumoniae</i> , <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> , <i>Pseudomonas aeruginosa</i> , <i>Enterococcus faecium/faecalis</i> , <i>Acinetobacter</i> genus	The micro-organisms of <i>Saphylococcus aureus</i> , <i>Streptococcus pneumoniae</i> , <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> , <i>Pseudomonas aeruginosa</i> , <i>Enterococcus faecium/faecalis</i> , <i>Acinetobacter</i> genus to be notified in the national anti-microbial resistance supervision network	• Confirmatory diagnosis, including detection of antimicrobial susceptibility <sup>4</sup> • Typing <sup>4</sup>
5.3.	Infections initiated by MRSA micro-organisms and carrying agent thereof	<i>Staphylococcus aureus</i> (MRSA)	• Confirmatory diagnosis <sup>3; 4</sup> • Typing <sup>4</sup>
5.4.	Infections initiated by VRSA micro-organisms and carrying agent thereof	<i>Staphylococcus aureus</i> (VRSA, VISA)	• Confirmatory diagnosis <sup>2</sup>
5.5.	Infections initiated by <i>Enterococcus</i> (VRE) resistant to vancomycine	<i>Enterococcus</i> (VRE)	• Confirmatory diagnosis <sup>3; 4</sup>
5.6.	Infections initiated by bacteria of <i>Enterobacteriaceae</i> genus	<i>Enterobacteriaceae</i> genus	• Confirmatory diagnosis <sup>1; 4</sup>
5.7.	Infections of micro-organisms of <i>Enterobacteriaceae</i> genus with reduced susceptibility to carbapenems	<i>Enterobacteriaceae</i> genus	• Confirmatory diagnosis <sup>2</sup> • Typing <sup>2</sup> • Detection of resistance mechanisms <sup>2</sup>
5.8.	Other infections related to health care	Micro-organisms with non-typical, new or especially dangerous resistance	• Confirmatory diagnosis <sup>2</sup>
		Investigation of outbreaks of infections caused by other micro-organisms related to health care	• Confirmatory diagnosis <sup>3; 4</sup> • Typing <sup>4</sup>

Notes.

1. \*Dangerous infectious disease.

2. \*\* Group 4 biological agents.
3. <sup>1</sup> If primary investigation laboratory has no capacity to carry out confirmatory diagnosis.
4. <sup>2</sup> Always after separation of micro-organism culture or obtaining primary positive result.
5. <sup>3</sup> If testing result is in contradiction with clinical and/or epidemiological information.
6. <sup>4</sup> Investigation according to epidemiological indications, including within the framework of outbreak, or specific supervision researches.
7. <sup>5</sup> If the primary investigation laboratory has no sufficient capacity to carry out confirmatory diagnosis for certain groups of inhabitants (for example, donors, pregnant female).

Minister for Health

Anda Čakša