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Supplementary Materials for

Methodological approach towards a gap assessment of the Serbian microbiology system in the function of surveillance in line with EU standards and *acquis*

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Improving microbiology diagnostic system quality in the function of surveillance on communicable diseases in the Republic of Serbia. 2017 Gap Assessment: indicator framework.

Function 1. System and central functions				
Goal 1 (G1): To map system components of the microbiology system in the function of surveillance				
Outcome		**Indicator**		**Target**
G1.1	Laboratory referral systems and networks at national and international level exist for communicable diseases/AMR issues	**IG.1.1 combined**	**Laboratory referral systems and networks at national and international level exist for communicable diseases/AMR issues**	**Identified targets are met for indicators I1.1.1-I1.1.8**
		I1.1.1	Number of diseases/AMR issues for which Reference laboratories and/or public health bodies are collaborating at national/EU/international level	>10 diseases/AMR issues at national >5 diseases/AMR issues at EU/international level
		I1.1.2	Level of operational implementation of a national sentinel network of virology laboratories for surveillance of acute respiratory viral infections	Fully operational system implemented
		I1.1.3	Average number of blood culture sets tested/1000 hospital inpatient days reported by EARS-Net participating hospitals from your country in 2016	Low (7-16), Medium (17-27), High>27.
		I1.1.4	Number of diagnostic laboratories part of surveillance network/s for communicable diseases in each administrative unit /all responding laboratories per administrative unit	At least one per responding administrative unit (district)

		I1.1.5	Number of diagnostic laboratories part of surveillance networks involved in preparedness and response for communicable diseases in each administrative unit/all responding laboratories part of surveillance networks in each administrative unit	At least one laboratory per administrative unit (district) is part of surveillance networks and reports at least one of the following: • having defined responsibilities in national Public Health preparedness and response (like surveillance, outbreak investigations); • having received specimens from the field during the investigation of public health events or public health surveys; • having given advice on specimen collection and transport practices from the field during the investigation of public health emergencies; or • having received specimens or isolates from clinical laboratories for public health purpose (e.g. routine surveillance, outbreak investigation).
		I1.1.6	Number of diagnostic laboratories that have specific instructions or guidelines for laboratory investigation of public health events in each administrative unit / all participating laboratories per administrative unit	At least one per responding administrative unit (district)
		I1.1.7	Number of diagnostic laboratories referring specimens or isolates to NRL for public health purposes (e.g. routine surveillance, outbreak investigation) / all responding laboratories	At least 70% of all laboratories
		I1.1.8	Number of diagnostic laboratories providing information to epidemiologists on Antibiotic Susceptibility testing patterns when applicable/ all responding laboratories	At least 50%
G1.2	Data is reported and analysed within the microbiology system in the function of surveillance	**IG.1.2 combined**	**Data is reported and analysed within the microbiology system in the function of surveillance**	**Identified targets are met for indicators I1.2.1-I1.2.2**
		I1.2.1	Level of reporting digitalization from laboratory-based national surveillance systems to central level	At least 1 disease reported using machine-machine upload from a laboratory information and management system (LIMS)

		I1.2.2	Timeliness of microbiology system data analysis and reporting in the function of surveillance	Data is centrally analysed and reported to stakeholders for at least 1 communicable disease under EU surveillance at least weekly
G1.3	There is national capacity (locally or through agreements) for diagnostic testing of dangerous/rare/imported pathogens	**IG.1.3 combined**	**There is national capacity (locally or through agreements) for diagnostic testing of dangerous/rare/imported pathogens**	**Identified targets are met for indicator I1.3.1**
		I1.3.1	Number of selected dangerous/rare/imported pathogens for which there is laboratory capacity to confirm/identify and, if appropriate, further characterize in Serbia (locally or through external agreements)	Laboratory capacity to confirm/identify and, if appropriate, further characterize all selected pathogens is in place
G1.4	A national health laboratory system coordination is in place	**IG.1.4 combined**	**A national health laboratory system coordination is in place**	**Identified targets are met for indicators I1.4.1-I1.4.4**
		I1.4.1	Number of diseases/AMR issues coordinated by a dedicated unit in charge of health laboratory coordination within the relevant Ministry	Laboratory coordination for >5 diseases/AMR issues is the responsibility of a dedicated ministerial unit
		I1.4.2	Level of functionality of the dedicated unit in charge of health laboratory coordination within the relevant Ministry	The unit is established by formal decree, with a dedicated budget, coordinating with >5 diseases/AMR specific control programmes and with other ministries and agencies; with an oversight role of reference laboratory designation and operations and of private laboratory regulations and operations

		I1.4.3	Level of implementation of a national policy for health laboratory services defining the goals and objectives of the national laboratory system	A National policy is in place
		I1.4.4	Level of completeness of the policy fully/partially in place	The policy addresses all of the following: coordination and leadership structure and organization, testing capacity, networking mechanisms, role in public health, regulatory framework, quality assurance framework, workforce, equipment and reagent procurement and supplying systems, funding
G1.5	The microbiology system receives dedicated **funding** for primary diagnostic and PH microbiology functions related to communicable diseases under EU notification	**IG.1.5 combined**	**The microbiology system receives dedicated funding for primary diagnostic and PH microbiology functions related to communicable**	**Identified targets are met for indicators I1.5.1-I1.5.4**
		I1.5.1	Level of dedicated funding available to the microbiology system in its function of surveillance/PH of communicable diseases under EU notification	A specific budget line assigned to IPH and/or all NRLs earmarked for notifiable diseases (such as surveillance, core functions of reference laboratories and networks operations)
		I1.5.2	Proportion of NRLs that receive full/partial financial support at least in part by health authorities or other competent bodies for public health microbiology services	Funding is received by all NRLs for all services pertaining PH microbiology (i.e. all core functions)
		I1.5.3	Level of dedicated funding available to the microbiology system in its function of clinical/primary diagnosis of communicable diseases under EU notification	A specific budget is assigned to private and/or public laboratories for the laboratory function of clinical/primary diagnosis of notifiable diseases
		I1.5.4	Proportion of public diagnostic laboratories in which tests are funded/reimbursed in total, or in part, either by a national insurance scheme or by a governmental budget	Tests are fully reimbursed in all public diagnostic laboratories and reimbursement covers sample referral costs

		NA	*Proportion of private diagnostic laboratories in which tests are funded/reimbursed in total, or in part, either by a national insurance scheme or by a governmental budget*	*No target (descriptive var only)*
G1.6	Laboratory technologies and methods to test for communicable diseases under EU notification, are cost-effective and testing prices are regulated and adequate to ensure that costs incurred by laboratories are met	**IG.1.6 combined**	**Laboratory technologies and methods to test for communicable diseases under EU notification, are cost-effective and testing prices are regulated and adequate to ensure that costs incurred by laboratories are met**	**Identified targets are met for indicators I1.6.1-I1.6.2**
		I1.6.1	Level of evidence-base used to select technically and financially appropriate laboratory technologies and methods	A cost-effectiveness analysis has been fully performed to select technically and financially appropriate laboratory technologies and methods to test for communicable diseases under EU notification
		I1.6.2	Level of control on the prices of laboratory testing for communicable diseases under EU notification in the country	Laboratory testing prices for communicable diseases under EU notification are fully regulated by at least one of the following: a national regulation/legislation, a public health insurance system (social security), a private health insurance system
		I1.6.3	Level of laboratory price adequacy to ensure testing costs incurred by public laboratories in staffing and consumables are met	Prices to test for communicable diseases under EU notification are adequate to ensure testing costs are met
G.1.7	The microbiology system respects quality and biosafety standards (central level)	**IG.1.7 combined**	**The microbiology system respects quality and biosafety standards (central level)**	**Identified targets are met for indicators I1.7.1-I1.7.4**
		I1.7.1	Level of establishment of a national laboratory quality office for the oversight of national laboratory quality programmes	A national laboratory quality office for the oversight of national laboratory quality programmes is fully established

		I1.7.2	Level of establishment of comprehensive national general quality norms/sets of standards	National general quality norms/sets of standards are fully established
		I1.7.3	High level performance reached for Tuberculosis Reference Laboratories participating in ECDC ERLTB-Net EQA for culture and susceptibility testing for first- and second-line drugs	Tuberculosis Reference Laboratories that participated in ECDC-funded ERLTB-Net latest external quality assessment scheme achieved 80% performance level for culture and susceptibility testing for first- and second-line drugs
		I1.7.4	Level of establishment (and EU integration) of a Serbian NAC	A National Antimicrobial Susceptibility Committee (NAC) is fully established and its representative is member of EUCAST General Committee

Function 2. Reference laboratory function to produce data/information for added public health value				
Goal 2 (G2): To map core functions and capacities of National Reference Laboratories (NRLs)				
Outcome		Indicator		Target
G2.1	Serbian NRLs are officially nominated by health authorities or other and competent bodies recognized at local level	**IG.2.1 combined**	**Serbian NRLs are officially nominated by health authorities or other competent bodies and recognized at local level**	**Identified targets are met for indicators I2.1.1-I2.1.2**
		I2.1.1	Proportion of NRLs officially nominated by health authorities or other competent bodies	All NRLs are officially nominated by health authorities or other competent bodies
		I2.1.2	Number of diagnostic laboratories non NRL in which staff is aware of the designated reference laboratories for pathogens causing communicable diseases under EU surveillance / all responding laboratories not NRL	80% of non NRL responding laboratories
G2.2	Serbian NRLs have a recognized, role and capacity to perform core function 1: Reference diagnostics	**IG.2.2 combined**	**Serbian NRLs have a recognized, role and capacity to perform core function 1: Reference diagnostics**	**Identified targets are met for indicators I2.2.1-I2.2.8**
		I2.2.1	Proportion of NRLs with a formally recognized responsibility/mandate within Serbia for the performance of core function 1	All NRLs are recognized formally within the country for the performance of core function 1
		I2.2.2	Proportion of NRLs provided with specific funding in 2016 to perform core function 1	80% of NRLs received specific funding in 2016 to perform core function 1
		I2.2.3	Proportion of NRLs with the capacity to perform core function 1 for the pathogen/s included in their NRL mandate	All NRL have the capacity to perform core function 1
		I2.2.4	Proportion of NRLs that performed core function 1 for their mandated pathogen/s in 2016	All NRLs performed core function 1 for their mandated pathogen/s in 2016
		I2.2.5	Level of capacity through the NRL system to diagnose mandated communicable diseases under EU surveillance according to the EU laboratory criteria	All Communicable Diseases under EU surveillance can be diagnosed through the NRL system according to the EU laboratory criteria

		I2.2.6	Proportion of NRLs that received specimens or isolates from other laboratories in 2016	All NRLs received specimens from **most laboratories** in their administrative area of competence (e.g. district) in 2016
		I2.2.7	Number of selected pathogens that Serbian NRLs have the capacity to confirm/identify and, if appropriate, further characterize according to EU standards	Laboratory capacity to confirm/identify and, if appropriate, further characterize all selected pathogens is in place
		I2.2.8	Number of NRL where national guidelines and reference virological diagnostic testing were available in 2016 for the investigation of Severe Acute Respiratory Infection cluster in accordance with WHO guidance	At least in 1 NRL guidelines are available and implemented with monitoring
G2.3	Serbian NRLs have a recognized, role and capacity to perform core function 2: Reference material resource	**IG.2.3 combined**	**Serbian NRLs have a recognized, role and capacity to perform core function 2: Reference material resource**	**Identified targets are met for indicators I2.3.1-I2.3.4**
		I2.3.1	Proportion of NRLs with a formally recognized responsibility/mandate within Serbia for the performance of core function 2	All NRLs are NRLs recognized formally within the country for the performance of core function 2
		I2.3.2	Proportion of NRLs provided with specific funding in 2016 to perform core function 2	At least 80% of NRL received specific funding in 2016 to perform core function 2
		I2.3.3	Proportion of NRLs with the capacity to perform core function 2 for the pathogen/s included in their NRL mandate	All NRL have the capacity to perform core function 2
		I2.3.4	Proportion of NRLs that performed core function 2 for their mandated pathogen/s in 2016	At least 80% of all NRLs performed core function 2 for their mandated pathogen/s in 2016
G2.4	Serbian NRLs have a recognized, role and capacity to perform core function 3: Scientific advice	**IG.2.4 combined**	**Serbian NRLs have a recognized, role and capacity to perform core function 3: Scientific advice**	**Identified targets are met for indicators I2.4.1-I2.4.4**
		I2.4.1	Proportion of NRLs with a formally recognized responsibility/mandate within Serbia for the performance of core function 3	All NRLs are recognized formally within the country for the performance of core function 3
		I2.4.2	Proportion of NRLs provided with specific funding in 2016 to perform core function 3	At least 80% of NRL received specific funding in 2016 to perform core function 3

		I2.4.3	Proportion of NRLs with the capacity to perform core function 3 for the pathogen/s included in their NRL mandate	All NRL have the capacity to perform core function 3
		I2.4.4	Proportion of NRLs that performed core function 3 for their mandated pathogen/s in 2016	At least 80% of all NRLs performed core function 3 for their mandated pathogen/s in 2016
G2.5	Serbian NRLs have a recognized, role and capacity to perform core function 4: Collaboration and research	**IG.2.5 combined**	**Serbian NRLs have a recognized, role and capacity to perform core function 4: Collaboration and research**	**Identified targets are met for indicators I2.5.1-I2.5.4**
		I2.5.1	Proportion of NRLs with a formally recognized responsibility/mandate within Serbia for the performance of core function 4	All NRLs are recognized formally within the country for the performance of core function 4
		I2.5.2	Proportion of NRLs provided with specific funding in 2016 to perform core function 4	80% of NRL received specific funding in 2016 to perform core function 4
		I2.5.3	Proportion of NRLs with the capacity to perform core function 4 for the pathogen/s included in their NRL mandate	All NRL have the capacity to perform core function 4
		I2.5.4	Proportion of NRLs that performed core function 4 for their mandated pathogen/s in 2016	At least 80% of all NRLs performed core function 4 for their mandated pathogen/s in 2016
		NA	*Proportion of NRLs that used in 2016 whole genome sequencing (WGS) -based typing of human pathogens for research purposes*	*No target (descriptive var only)*
G2.6	Serbian NRLs have a recognized, role and capacity to perform core function 5: Monitoring, alert and response	**IG.2.6 combined**	**Serbian NRLs have a recognized, role and capacity to perform core function 5: Monitoring, alert and response**	**Identified targets are met for indicators I2.6.1-I2.6.11**
		I2.6.1	Proportion of NRLs with a formally recognized responsibility/mandate within Serbia for the performance of core function 5	All NRLs are recognized formally within the country for the performance of core function 5
		I2.6.2	Proportion of NRLs provided with specific funding in 2016 to perform core function 5	80% of NRL received specific funding in 2016 to perform core function 5
		I2.6.3	Proportion of NRLs with the capacity to perform core function 5 for the pathogen/s included in their NRL mandate	All NRL have the capacity to perform core function 5

		I2.6.4	Proportion of NRLs that performed core function 5 for their mandated pathogen/s in 2016	At least 80% of all NRLs performed core function 5 for their mandated pathogen/s in 2016
		I2.6.5	Number of diseases/AMR issues for which Reference laboratories and/or public health bodies are collaborating at national level	>10 diseases/AMR issues
		I2.6.6	Proportion of NRLs that received specimens or isolates from other laboratories in 2016	All NRLs received specimens from most laboratories in their administrative area of competence in 2016
		NA	*Proportion of NRLs that used in 2016 whole genome sequencing (WGS) -based typing of human pathogens for routine surveillance*	*No target (descriptive var only)*
		NA	*Proportion of NRLs that used in 2016 whole genome sequencing (WGS) -based typing of human pathogens for outbreak investigation*	*No target (descriptive var only)*
		I2.6.7	Total number of Salmonella isolates genotyped by pulsed-field gel electrophoresis (PFGE) reported to national surveillance divided by the total number of Salmonellosis cases	≥20%
		NA	*Total number of Salmonella isolates genotyped by Multilocus VNTR Analysis (MLVA) or WGS method reported to national surveillance divided by the total number of Salmonellosis cases in 2016*	*No target (descriptive var only)*
		NA	*Total number of multidrug-resistant (MDR)-Mycobacterium tuberculosis isolates genotyped by MIRU-VNTR method reported to national surveillance divided by the total number cases reported*	*No target (descriptive var only)*
		I2.6.8	Total number of invasive Neisseria meningitidis isolates typed by serogroup: MLST: porA:fetA method reported to national surveillance divided by the total number of invasive cases reported	≥20%

		I2.6.9	Total number of HIV isolates genotyped by ARV target sequence analysis reported to national surveillance divided by the total number of new HIV cases reported	Between 20 and 50%
		I2.6.10	Operational contact point for molecular typing (MT-OCP) of Listeria monocytogenes for supporting molecular surveillance development and collaboration through the Epidemic Intelligence System – Food and Waterborne Diseases (EPIS-FWD) platform was nominated.	Nominated operational contact has participated in Urgent Inquiries (UI) AND/OR Molecular Typing Cluster Investigations (MTCI)
		I2.6.11	Number of NRLs reportedly performing annual reporting of integrated cross-sector monitoring of antimicrobial resistance (AMR) in human and animal bacterial isolates of public health relevance, and reporting annually based on antimicrobial susceptibility testing methodology calibrated to ISO and/or EUCAST methods	At least 1 NRL
G2.7	The microbiology system respects quality and biosafety standards (NRL level)	**IG.2.7 combined**	**The microbiology system respects quality and biosafety standards (NRL level)**	**Identified targets are met for indicators I2.7.1-I2.7.3**
		I2.7.1	Number of NRL that accredit at least some of their reference diagnostic tests according to ISO 17025 or ISO 15189	All NRLs are accredited according to ISO 17025 or ISO 15189 for at least some diagnostic tests/methods
		I2.7.2	Number of NRL access biocontainment facilities with biosafety authorisation for performing Biosafety Level 3 operations	At least one NRL
		I2.7.3	All culture-based tuberculosis diagnostic and drug susceptibility tests are restricted to laboratories compliant with performing BSL3 operations	All laboratories performing TB DSTs and culture-based TB diagnostic tests recognize this biosafety restriction

Function 3. Clinical microbiology testing to meet diagnostic needs for the clinical management of patients				
Goal 3 (G3): To map public and private microbiology laboratory capacities				
Outcome		Indicator		Target
G3.1	Public and Private diagnostic laboratories in Serbia are able to diagnose communicable diseases under EU surveillance according to EU laboratory criteria	**IG.3.1 combined**	**Public and Private diagnostic laboratories in Serbia are able to diagnose communicable diseases under EU surveillance according to EU laboratory criteria**	**Identified targets are met for indicators I3.1.1-I3.1.4**
		I3.1.1	Level of capacity through the laboratory diagnostic system (public and private) system to diagnose mandated communicable diseases under EU surveillance according to the EU laboratory criteria	100% Communicable Diseases (except CJD) under EU surveillance can be diagnosed in Serbia
		I3.1.2	Number of diagnostic laboratories receiving specimens or isolates to be tested for communicable diseases under EU surveillance from other laboratories	At least all NRLs
		I3.1.3	Number of diagnostic laboratories referring specimens or isolates to be tested for communicable diseases under EU surveillance to other laboratories in each district	At least one per district
		I3.1.4	Number of diagnostic laboratories providing information to clinicians on Antibiotic Susceptibility testing patterns when applicable/ all responding laboratories *100	At least 80% of all responding laboratories
G3.2	A sufficient number of public and private	**IG.3.2 combined**	**A sufficient number of public and private diagnostic laboratories in Serbia have the capacity to perform comprehensive diagnostic activities in the discipline of bacteriology to meet population needs**	**Identified targets are met for indicators I3.2.1 – I3.2.12**

		I3.2.1	Number of diagnostic laboratories performing microbiology diagnostic activity in bacteriology in 2016 *100	> = 80% of all laboratories
		I3.2.2	Proportion of laboratories performing microbiology diagnostic activity in bacteriology per district in 2016 testing urine samples	At least 80% of all laboratories performing diagnostic activity in bacteriology in 2016
		I3.2.3	Proportion of laboratories performing microbiology diagnostic activity in bacteriology in 2016 testing blood/serum samples	Between 20 and 50% of all laboratories performing diagnostic activity in bacteriology in 2016 100% of all NRL who do bacteriology in their primary diagnostic function
		I3.2.4	Proportion of laboratories performing microbiology diagnostic activity in bacteriology in 2016 testing stool samples	At least 80% of all laboratories performing diagnostic activity in bacteriology in 2016
		I3.2.5	Proportion of laboratories performing microbiology diagnostic activity in bacteriology in 2016 testing cerebrospinal fluid (CSF) samples	Between 20 and 50%of all laboratories performing diagnostic activity in bacteriology in 2016 100% of all NRL who do bacteriology
		I3.2.6	Proportion of laboratories performing microbiology diagnostic activity in bacteriology in 2016 testing respiratory samples (e.g. sputum, bronchoalveolar lavage)	At least 50% of all laboratories performing diagnostic activity in bacteriology in 2016
		I3.2.7	Proportion of laboratories performing microbiology diagnostic activity in bacteriology in 2016 testing swabs	At least 80% of all laboratories performing diagnostic activity in bacteriology in 2016

		NA	*Proportion of laboratories performing microbiology diagnostic activity in bacteriology in 2016 testing exudates*	*No target (descriptive var only)*
		I3.2.8	Proportion of laboratories performing microbiology diagnostic activity in bacteriology in 2016 performing direct microscopy/gram stain	All laboratories performing diagnostic activity in bacteriology in 2016
		I3.2.9	Proportion of laboratories performing microbiology diagnostic activity in bacteriology in 2016 performing cultures	80% laboratories performing diagnostic activity in bacteriology in 2016
		I3.2.10	Proportion of laboratories performing microbiology diagnostic activity in bacteriology in 2016 performing antibiotic susceptibility testing	At least 90% of all laboratories performing diagnostic activity in bacteriology in 2016
		I3.2.11	Number of laboratories performing microbiology diagnostic activity in bacteriology per district in 2016 performing Immunological tests in each district	At least one per district
		I3.2.12	Number of laboratories performing microbiology diagnostic activity in bacteriology in 2016 performing molecular tests	All NRLs
G3.3	A sufficient number of public and private diagnostic laboratories in Serbia have the capacity to perform comprehensive diagnostic activities in the discipline of mycology to meet population needs	**IG.3.3 combined**	**A sufficient number of public and private diagnostic laboratories in Serbia have the capacity to perform comprehensive diagnostic activities in the discipline of mycology to meet population needs**	**Identified targets are met for indicators I3.3.1 – I3.3.8**
		I3.3.1	Number of diagnostic laboratories performing microbiology diagnostic activity in mycology in 2016 in each District	At least one per responding district
		NA	*Proportion of laboratories performing microbiology diagnostic activity in mycology per district in 2016 testing urine samples in each District/ No of laboratories in the District*	*No target (descriptive var only)*
		I3.3.2	Proportion of laboratories performing microbiology diagnostic activity in mycology per district in 2016 testing blood/serum samples in each District/ No of laboratories in the District	At least one per responding district

		I3.3.3	Proportion of laboratories performing microbiology diagnostic activity in mycology per district in 2016 testing stool samples in each District/ No of laboratories in the District	At least one per responding district
		I3.3.4	Proportion of laboratories performing microbiology diagnostic activity in mycology per district in 2016 testing cerebrospinal fluid (CSF) samples in each District/ No of laboratories in the District	At least one per responding district
		I3.3.5	Proportion of laboratories performing microbiology diagnostic activity in mycology per district in 2016 testing respiratory samples (e.g. sputum, bronchoalveolar lavage) in each District/ No of laboratories in the District	At least one per responding district
		I3.3.6	Proportion of laboratories performing microbiology diagnostic activity in mycology per district in 2016 testing swabs	Between 20 and 50% of all laboratories performing diagnostic activity in mycology in 2016
		NA	*Proportion of laboratories performing microbiology diagnostic activity in mycology in 2016 testing skin, nails, hair*	*No target (descriptive var only)*
		NA	*Proportion of laboratories performing microbiology diagnostic activity in mycology in 2016 testing tissue biopsies*	*No target (descriptive var only)*
		NA	*Proportion of laboratories performing microbiology diagnostic activity in mycology in 2016 testing prostatic secretions*	*No target (descriptive var only)*
		NA	*Proportion of laboratories performing microbiology diagnostic activity in mycology per district in 2016 testing exudates*	*No target (descriptive var only)*
		I3.3.7	Proportion of laboratories performing microbiology diagnostic activity in mycology in 2016 performing direct microscopy/ stain	Between 20 and 50% of all laboratories performing diagnostic activity in mycology in 2016
		I3.3.8	Number of laboratories performing microbiology diagnostic activity in mycology per district in 2016 performing cultures in each District	At least one per responding district
		NA	*Proportion of laboratories performing microbiology diagnostic activity in mycology in 2016 performing anti-mycotic susceptibility testing*	*No target (descriptive var only)*

		NA	*Proportion of laboratories performing microbiology diagnostic activity in mycology in 2016 performing Immunological tests*	*No target (descriptive var only)*
		NA	*Proportion of laboratories performing microbiology diagnostic activity in mycology in 2016 performing molecular tests*	*No target (descriptive var only)*
G3.4	A sufficient number of public and private diagnostic laboratories in Serbia have the capacity to perform comprehensive diagnostic activities in the discipline of virology to meet population needs	**IG.3.4 combined**	**A sufficient number of public and private diagnostic laboratories in Serbia have the capacity to perform comprehensive diagnostic activities in the discipline of virology to meet population needs**	**Identified targets are met for indicators I3.4.1 – I3.4.7**
		I3.4.1	Number of diagnostic laboratories performing microbiology diagnostic activity in virology in 2016 per District	At least one per responding district
		NA	*Number of laboratories performing microbiology diagnostic activity in virology per District in 2016 testing urine samples*	*No target (descriptive var only)*
		I3.4.2	Proportion of laboratories performing microbiology diagnostic activity in virology per district in 2016 testing blood/serum samples	At least one per District
		I3.4.3	Proportion of laboratories performing microbiology diagnostic activity in virology per district in 2016 testing stool samples	Between 10 and 20% of all laboratories performing diagnostic activity in virology in 2016
		NA	*Proportion of laboratories performing microbiology diagnostic activity in virology per district in 2016 testing cerebrospinal fluid (CSF) samples*	*No target (descriptive var only)*
		I3.4.4	Number of laboratories performing microbiology diagnostic activity in virology per District in 2016 testing respiratory samples (e.g. sputum, bronchoalveolar lavage)	Between 10-20% all laboratories performing diagnostic activity in virology in 2016
		NA	*Proportion of laboratories performing microbiology diagnostic activity in virology per district in 2016 testing swabs*	*No target (descriptive var only)*
		NA	*Proportion of laboratories performing microbiology diagnostic activity in virology per district in 2016 performing viral cultures*	*No target (descriptive var only)*

		I3.4.5	Proportion of laboratories performing microbiology diagnostic activity in virology per district in 2016 performing Immunological tests	At least 80% of all laboratories performing diagnostic activity in virology in 2016
		NA	*Number of laboratories performing microbiology diagnostic activity in virology per District in 2016 performing molecular tests*	*No target (descriptive var only)*
G3.5	A sufficient number of public and private diagnostic laboratories in Serbia have the capacity to perform comprehensive diagnostic activities in the discipline of parasitology to meet population needs	**IG.3.5 combined**	**A sufficient number of public and private diagnostic laboratories in Serbia have the capacity to perform comprehensive diagnostic activities in the discipline of parasitology to meet population needs**	**Identified targets are met for indicators I3.5.1 – I3.5.12**
		I3.5.1	Number of diagnostic laboratories performing microbiology diagnostic activity in parasitology in 2016 per District	At least one per responding district
		I3.5.2	Number of laboratories performing microbiology diagnostic activity in parasitology per District in 2016 testing urine samples	At least one per responding district
		I3.5.3	Number of laboratories performing microbiology diagnostic activity in parasitology per District in 2016 testing blood/serum samples	At least one per responding district
		I3.5.4	Number of laboratories performing microbiology diagnostic activity in parasitology per District in 2016 testing stool samples	At least one per responding district
		I3.5.5	Number of laboratories performing microbiology diagnostic activity in parasitology in 2016 testing cerebrospinal fluid (CSF) samples	At least one in Serbia
		I3.5.6	Number of laboratories performing microbiology diagnostic activity in parasitology per District in 2016 testing respiratory samples (e.g. sputum, bronchoalveolar lavage)	At least one in Serbia
		I3.5.7	Number of laboratories performing microbiology diagnostic activity in parasitology per District in 2016 testing swabs	At least one per responding district
		I3.5.8	Number of laboratories performing microbiology diagnostic activity in parasitology per District in 2016 testing tissue biopsies	At least one in Serbia
		I3.5.9	Number of laboratories performing microbiology diagnostic activity in parasitology per district in 2016 performing direct microscopy/ stain	At least one per responding district

		I3.5.10	Number of laboratories performing microbiology diagnostic activity in parasitology in 2016 performing cultures	At central level at least one in Serbia
		I3.5.11	Number of laboratories performing microbiology diagnostic activity in parasitology per district in 2016 performing Immunological tests	At least one per responding district
		I3.5.12	Number of laboratories performing microbiology diagnostic activity in parasitology in 2016 performing molecular tests	At least one in Serbia
G3.6	The microbiology diagnostic data management system is a digitalized and adequately protected	**IG.3.6 combined**	**The microbiology diagnostic data management system is a digitalized and adequately protected**	**Identified targets are met for indicators I3.6.1 – I3.6.13**
		I3.6.1	Number of diagnostic laboratories recording original observations/results produced in a worksheet (e.g. excel) or electronic database/ all responding laboratories *100	100% of diagnostic laboratories routinely record data digitally in a standardized format
		I3.6.2	Number of diagnostic laboratories that can provide basic statistical data (e.g., number of tests ordered, aggregated qualitative/quantitative data, etc.)/ number of laboratories digitally recording original observations/results *100	100% of diagnostic laboratories
		I3.6.3	Number of diagnostic laboratories that prepare periodic summary activity reports / number of laboratories digitally recording original observations/results	At least 50% of all diagnostic laboratories
		I3.6.4	Number of diagnostic laboratories protecting access and modification of patient data / all responding laboratories	100% of diagnostic laboratories
		I3.6.5	Number of diagnostic laboratories using any software/applications (eg basic office package, email, internet browsers etc.) / all responding laboratories	At least 80% of all diagnostic laboratories

		I3.6.6	Number of diagnostic laboratories using a Word processor (e.g. Word)/ all responding laboratories using software/applications	At least 80% of all diagnostic laboratories using software/applications
		I3.6.7	Number of diagnostic laboratories using a Spreadsheet processor (e.g. Excel) / all responding laboratories using software/applications	At least 80% of all diagnostic laboratories using software/applications
		I3.6.8	Number of diagnostic laboratories using a Presentation software (e.g. PowerPoint) / all responding laboratories using software/applications	At least 80% of all diagnostic laboratories using software/applications
		I3.6.9	Number of diagnostic laboratories using a Database software (e.g. Access) / all responding laboratories using software/applications	At least 80% of all diagnostic laboratories using software/applications
		I3.6.10	Number of diagnostic laboratories using Internet browsing (e.g. use of web based software, internet browsers) / all responding laboratories using software/applications	At least 80% of all diagnostic laboratories using software/applications
		I3.6.11	Number of diagnostic laboratories using E-mail / all responding laboratories using software/applications	At least 80% of all diagnostic laboratories using software/applications
		I3.6.12	Number of NRL using a full Laboratory Information Management System (LIMS) / all responding NRL using software/applications	At least all NRL using software/applications reporting mandatory communicable diseases *descriptive for all labs*
		I3.6.13	Number of diagnostic NRL a fully functional Laboratory Information Management System (LIMS) / all NRL using a LIMS	At least all NRL *descriptive for all labs*

G3.7	The microbiology system respects quality and biosafety standards (all laboratories in primary diagnostic function)	**IG.3.7a combined**	**The microbiology system respects quality and biosafety standards (all laboratories in primary diagnostic function)**	**Identified targets are met for indicators I3.7.1 – I3.7.8**
		I3.7.1	Number of diagnostic laboratories that had obtained a licencing authorisation/registration by health authorities (or professional organisations) according to legal/regulatory requirements as of 2016/ all responding laboratories	All laboratories have been licenced and hold/have set up: a quality certification (any form), an accreditation (any form), a quality system for management and main technical processes/ testing methods, a list of notifiable diseases, a reporting system, data protection systems, guidelines and other relevant documents, specimen storage systems and in house procedures.
		NA	*Number of laboratories agreeing on biosafety authorisation/permits needed for performing operations at Biosafety Level (BSL)2 and BSL3/ all responding laboratories*	*No target (descriptive var only)*
		I3.7.2	Number of laboratories with available written Biosafety procedures/ all responding laboratories	80% of laboratories have biosafety procedures addressing: PPE, disinfection and sterilization, waste disposal, access restrictions, biosafety equipment, Emergency protocols and have Material Safety Data Sheets available to review in the immediate laboratory area
		I3.7.3	Number of laboratories which have written policy concerning the management of laboratory bio risk (bio safety and bio security) / all responding laboratories, by type of laboratory	100% NRL and 80% diagnostic laboratories have a written policy concerning the management of laboratory bio risk addressing: hazards associated with proposed work and bio risk categorization
		I3.7.4	Number of diagnostic laboratories respecting quality of transport standards/ all diagnostic laboratories referring specimens or isolates to be tested for communicable diseases under EU surveillance	80% of responding laboratories report using appropriate packaging for referring specimens (triple package if air transport, or any package in conformity with local regulations or recommendations) and having a person/s in charge of shipments trained for the transport of infectious substances

		I3.7.5	Number of laboratories never experiencing problems with reagent delivery like delays, temperature not adequate, reference error/all responding laboratories	At least 50% of responding laboratories
		I3.7.6	Number of NRL accredited diagnostic laboratories with standard operating procedure (SOP) for the use of reagents, consumables, supplies/ all responding NRL accredited laboratories	All NRL accredited laboratories
		I3.7.7	Number of accredited NRL diagnostic laboratories with standard operating procedure (SOP) for management and disposal of reagents, consumables, supplies / all responding NRL accredited laboratories	All NRL accredited laboratories
		I3.7.8	Number of diagnostic laboratories maintaining equipment in a safe working condition (including electrical safety)/ all responding laboratories	80% of responding laboratories maintain equipment in safe working conditions and 50% also have a standard operating procedure (SOP) for the management of equipment (identification, maintenance, calibration, etc.)
		IG3.7b combined	**Laboratories have a good general condition of their laboratory building and infrastructure**	**Identified targets are met for indicators I3.7.9 – I3.7.15**
		I3.7.9	Number of diagnostic laboratories reporting that the general condition of the building is good /all responding laboratories	80% of responding laboratories
		I3.7.10	Number of diagnostic laboratories with walls, floors and roofs in good condition /all responding laboratories	80% of responding laboratories
		I3.7.11	Number of diagnostic laboratories with benches in good condition /all responding laboratories	80% of responding laboratories
		I3.7.12	Number of diagnostic laboratories never experiencing electricity interruption /all responding laboratories	80% of responding laboratories
		I3.7.13	Number of diagnostic laboratories with emergency electric generator or other backup power source/all responding laboratories	80% of responding laboratories
		I3.7.14	Number of diagnostic laboratories protecting key equipment by a UPS /all responding laboratories with full/partial emergency electric generator or other backup power source	100% of responding laboratories

		I3.7.15	Number of diagnostic laboratories never facing water shortages /all responding laboratories	80% of responding laboratories
		IG3.7c combined	**Laboratories have a functional laboratory infrastructure to manage specimens or isolates to be tested for communicable diseases under EU surveillance**	**Identified targets are met for indicators I3.7.16 – I3.7.20**
		I3.7.16	Number of diagnostic laboratories with enough space to perform the work without compromising the quality and safety of patients and personnel /all responding laboratories	80% of responding laboratories
		I3.7.17	Number of diagnostic laboratories in which sample collection carried out in room(s) separated from the laboratory examination room(s) /all responding laboratories	80% of responding laboratories
		I3.7.18	Number of diagnostic laboratories in which there is an effective separation between adjacent laboratory sections in which there are incompatible activities (e.g. nucleic acid extraction vs amplification) /all responding laboratories	80% of responding laboratories
		I3.7.19	Number of diagnostic laboratories in which there are designated rooms for specialized testing (TB, brucellosis, etc.) /all responding laboratories	80% of responding laboratories
		NA	*Number of diagnostic laboratories in which there is a negative pressure room /all responding laboratories*	*No target (descriptive var only)*
		I3.7.20	Number of diagnostic laboratories with appropriate storage areas /all responding laboratories	All responding laboratories
		IG3.7d combined	**Laboratories meet staffing requirements (number and management)**	**Identified targets are met for indicators I3.7.21 – I3.7.22**
		13.7.21	Number of diagnostic laboratories with adequate staff to undertake the work according to the law/all responding laboratories	80% of responding laboratories
		13.7.22	Number of diagnostic laboratories with an SOP on the management of personnel /all responding laboratories	80% of responding laboratories

		IG3.7e combined	A sufficient number of laboratories are using standardized clinical breakpoints for interpretative reporting of antibacterial drug susceptibility testing results to clinicians	Identified targets are met are met for indicator I3.7.23
		13.7.23	Percentage of clinical laboratories performing bacteriology that are using standardized clinical breakpoints for interpretative reporting of antibacterial drug susceptibility testing results to clinicians	≥80% of all clinical laboratories reporting performing bacteriology in 2016 are using standardized clinical breakpoints using EUCAST; Among labs not using EUCAST, ≥20% clinical laboratories are using other standardized clinical breakpoints using (CLSI or other)

Mapping of laboratory equipment				
Goal 4 (G4): To map availability of functional equipment in public laboratories				
Outcome		Indicator		Target
G4.1	Equipment is available to allow reference laboratories to perform their function of producing data/information for added public health value	**IG4.1 combined**	**Equipment is available to allow reference laboratories to perform their function of producing data/information for added public health value**	**Identified targets are met for indicators I4.1.1-I4.1.5**
		I4.1.1	Number of NRLs with at least 1 functioning PCR and 1 functioning RT PCR/ total number of responding NRLs	All responding NRLs
		I4.1.2	Number of NRLs with at least 1 functioning -80 Freezer/ total number of responding NRLs	All responding NRLs
		I4.1.3	Number of NRLs with at least 1 functioning thermostat / total number of responding NRLs	All responding NRLs
		I4.1.4	Number of NRLs with at least 1 functioning optic microscope / total number of responding NRLs	All responding NRLs
		I4.1.5	Number of NRLs with a functioning WGS	At least one in Serbia
G4.2	Equipment is available to allow large/very large public laboratories to perform clinical microbiology testing to meet diagnostic needs for the clinical management of patients	**IG4.2 combined**	**Equipment is available to allow large/very large public laboratories to perform clinical microbiology testing to meet diagnostic needs for the clinical management of patients**	**Identified targets are met for indicators I4.2.1 – I4.2.4**
		I4.2.1	Number of large-very large public diagnostic laboratories with at least 1 functioning Biosafety Cabinet class II/ total number of large-very large responding public diagnostic laboratories	All responding large-very large public diagnostic laboratories
		I4.2.2	Number of large-very large public diagnostic laboratories with at least 1 functioning -80 Freezer/ total number of large-very large responding public diagnostic laboratories	All responding large-very large public diagnostic laboratories

		I4.2.3	Number of large-very large public diagnostic laboratories with at least 3 functioning thermostats / total number of large-very large responding public diagnostic laboratories	All responding large-very large public diagnostic laboratories
		I4.2.4	Number of large-very large public diagnostic laboratories with at least 3 functioning optic and 1 functioning fluorescence microscopes / total number of large-very large responding public diagnostic laboratories	All responding large-very large public diagnostic laboratories