TECHNICAL REPORT

EU Laboratory Capability Monitoring System (EULabCap)

Report on 2013 survey of EU/EEA country capabilities and capacities

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ERRATUM: At the request of the countries, data reporting errors in 2013 indicator scores were corrected retrospectively in 2016. This resulted in small changes of the EU mean of nine indicator scores and an increase in the average EULabCap index score from 6.8 to 6.9. The corrections neither changed the levels of system capability/capacity by country, nor the overall results and conclusions of the report by target/dimension of the public health microbiology system.

Changes in the text:
Page 1, 2, 6, 16, 17**:** average index score corrected from 6.8 to 6.9.
Page 6: index score distribution was updated for the three dimensions from 6.4 (IQR 5.4-7.4) to 6.5 (IQR 5.5–7.3) for primary diagnostic testing; from 7.0 (IQR 6.1-7.8) to 7.0 (IQR, 6.4–8.0) for NRL services, and from 7.3 (IQR 5.9-8.7) to 7.4 (IQR, 6.2–8.7) for laboratory-based surveillance and epidemic response support.
Page 8 and 10: the range of the overall EULabCap index was changed from 4.1-9.2 to 4.7-9.2
Page 10, 12, 13, 15: Figures 7, 9, 10 and 11 were replaced with adjusted ones, respectively, as the EU means were updated.
Page 9, 30, 31, 32: the performance level "medium" was replaced by "intermediate" in all the figures present in the referred pages.

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Abbreviations

AF	Advisory Forum
AMR	antimicrobial resistance
ARV	antiretroviral
CPE	Carbapenemase-producing *Enterobacteriaceae*
EARS-Net	European Antimicrobial Resistance Surveillance Network
EQA	External Quality Assessment
EU/EEA	European Union/European Economic Area
EULabCap	EU Laboratory Capability Monitoring System
ERLTB-Net	European Reference Laboratories Network for Tuberculosis
ESBL	extended spectrum beta-lactamase-producing *Enterobacteriaceae*
EUCAST	European Committee on Antimicrobial Susceptibility Testing
FWD	food and waterborne diseases
HIV	human immunodeficiency virus
IQR	inter-quartile range
MDR TB	multidrug-resistant tuberculosis
MERS-CoV	Middle East respiratory syndrome coronavirus
MLST	Multi-Locus Sequence Typing
NMFP	National Microbiology Focal Points
NRL	National Reference Laboratories
OECD	The Organisation for Economic Cooperation and Development
PCR	polymerase chain reaction
Q1	first quartile
Q3	third quartile
SMAP	Strategic Multi-Annual Plan
VTEC/STEC	verotoxin/Shiga toxin-producing *E. coli*
TESSy	The European Surveillance System
TB	tuberculosis
TB-DST	tuberculosis drug susceptibility testing
VHF	viral haemorrhagic fever
WGS	Whole Genome Sequencing
WHO	World Health Organization

Glossary of terms

Laboratory capability	Consists of the ability to perform the following functions: manage laboratory activities; perform sample management; conduct testing and analysis for routine and surge capacity; support public health investigations and report results [1].
Laboratory capacity	Consists of output services completed over a defined time period for each capability [2].
National Microbiology Focal Points	Nominated representatives for public health microbiology in the EU/EEA Member States as part of the Competent Body Structure [3].
National Reference Laboratories	Laboratories with national responsibility and appropriate tools and skills to be able to collaborate in national surveillance and capacity to deal with emergency situations [4,5].
Public health microbiology	A cross-cutting area of microbiology that spans the fields of human, animal, food, water, and environmental microbiology, with a focus on human health and disease. It covers the laboratory contribution to detection and diagnosis of infectious microorganisms, and the characterisation and surveillance of microorganisms with the potential to affect populations [4,5].

Executive summary

Background

The ECDC public health microbiology strategy (2012–2016) and laboratory support within ECDC strategic multi-annual programme (2014–2020) aim to strengthen the capability and capacity of the EU public health microbiology system to provide the timely and reliable information that underpins infectious threat detection, assessment and surveillance at Member State and EU level for effective prevention and control of infectious diseases [4,6]. To ascertain how well this is delivered, ECDC, in close collaboration with the National Microbiology Focal Points (NMFP) and the Advisory Forum (AF), has developed and piloted a system (EULabCap) for monitoring key public health microbiology capabilities and capacity for EU surveillance and epidemic preparedness on an annual basis. This assessment aims to help policymakers identify possible areas for action and to evaluate the impact of capacity strengthening activities and health system reforms. This report presents the indicator results in 2013 for 30 EU and EEA (European Economic Area) countries.

Methods

The EULabCap monitoring tool combines 60 technical indicators to assess the capability and capacity of microbiology laboratories to provide essential public health functions, as defined in EU policies and action plans, international health regulations and technical standards. The indicators are grouped into 12 targets which are distributed across the following three public health microbiology system dimensions: primary diagnostic testing, national microbiology reference laboratory (NRL) services and laboratory-based surveillance and epidemic response support. Each indicator can be scored at three levels: low, intermediate and high capability or capacity. Aggregated indices have been calculated for each target and dimension as the average of component indicator scores, adjusting all index values on a scale of 0–10.

The EULabCap indicators are of a composite nature in terms of which element (structure or process) of the public health microbiology system they measure and how they measure it (functional capability or capacity). They comprise 24 structure and 36 process indicators. They are divided into 38 indicators of laboratory capability and 22 of service capacity. About 3/4 of the indicators are based on EU policy targets or international technical standards, while the remainder assess EU surveillance and alert system contributions.

A mixed method was used for data collection and scoring. To minimise the data reporting burden for the Member States, information for 20 indicators was retrieved by ECDC from data sets accessible in The European Surveillance System (TESSy) and EU disease network reports. The NMFPs used a questionnaire to collect information from their country for the remaining 40 indicators.

The first data call on 2013 outputs was launched in September 2014. Two rounds of validation were performed with the NMFPs to ensure data accuracy and preliminary reports were reviewed in joint consultation with the NMFPs and the AF in May 2015. The draft reports were critically reviewed and the findings broadly supported in terms of validity and public health relevance. The AF/NMFPs advised ECDC on the main conclusions to be drawn from the first survey, as well as the optimal reporting and publication format to enable benchmarking.

Results

The country response to the survey was 100% (30/30 EU/EEA countries). Data from 2013 were provided for 96% of the indicators (range per country, 70–100%). The average EULabCap aggregated index score was 6.9 on a scale of 1–10, suggesting that the EU as a whole has a strong public health microbiology system capability and substantial capacity to fulfil its surveillance and response requirements.

Substantial inter-country variation was found across all system targets, with overall performance indices per country ranging from 4 to 9. There was also diversity of scores among targets, with common challenging areas for which many countries lacked critical capabilities and/or showed low capacity. The areas of best practice with consistently high scores, largely meeting policy targets and standards, included antimicrobial drug susceptibility testing and antimicrobial drug resistance characterisation and monitoring, capabilities of national reference laboratory services, and laboratory collaboration within national and EU surveillance networks. The main challenges were in the target areas for provision and regulation of clinical microbiology services; diagnostic testing utilisation; diagnostic testing guidelines and national reference laboratory services relating to molecular typing for surveillance and national outbreak response support.

Conclusion

The high response rate of the EU/EEA countries in the first EULabCap survey highlights the EU/EEA countries' commitment to participating in this new health system monitoring and benchmarking process, thanks to the engagement of the NMFPs.

The first results showed that in 2013 the EU had a strong overall public health microbiology system capability, as indicated by the average index score of 6.9 out of 10. However, there was substantial inter-country variation in the scores, especially in primary diagnostic services and in some of the functions and technical capabilities of reference laboratories.

The results were perceived by the AF and NMFPs as offering significant added value for the comparison of best practices, as well as for considering specific areas of improvement. In addition, they encouraged the use of this information for benchmarking public health microbiology systems by country. The annual reporting of EULabCap information can be used to monitor strengths and vulnerabilities in the national and EU network systems. It is anticipated that it will be useful to inform public health policies and evaluate their impact.

Introduction

The detection and characterisation of infectious agents causing human disease by diagnostic and reference microbiology laboratories provides pivotal information for clinical management, public health surveillance and outbreak alert and response. As the epidemic of Ebola virus disease in West Africa has dramatically shown, any gap in laboratory capacity at local and national levels may prove disastrous due to delayed outbreak recognition and response. Provision of sufficient national laboratory capacity for infectious health threat detection and control is required to fulfil the obligations set forth in EU [7] and international legislation [8]. This capacity hinges on close collaboration with the national surveillance institutes and adequate funding, infrastructure, and human resources within the national healthcare system.

Public health microbiology systems comprise three intertwined components. First, clinical laboratories performing primary diagnostics, antimicrobial drug susceptibility testing and screening focused on patient management and preventive services. Second, public health laboratories serving reference functions on a national or subnational level such as specialist diagnostics and biological agent characterisation. Third, laboratory networks performing harmonisation of methods, quality assessment and contribution to public health surveillance and alert systems, nationally and internationally.

National health systems in Europe are undergoing continuous administrative and organisational reforms to face up to the challenge of maintaining universal access to essential and high-quality care with reduced resources [3]. Following the financial crisis in 2008, health expenditure has either stopped growing or even decreased in various degrees across the EU Member States [3]. Public health budget cuts have affected resources available to and investment in laboratory operations. The Founding Regulation of ECDC (EC No. 851/2004) states that 'by encouraging cooperation between expert and reference laboratories, the Centre shall foster the development of sufficient capacity within the Community for the diagnosis, detection, identification and characterization of infectious agents which may threaten public health' [9]. In this dynamic context, monitoring the collective laboratory capabilities in the EU/EEA is important to identify best practices and address potential vulnerabilities.

Europe benefits from a decade-long legacy of collaboration between infectious disease experts, microbiologists and epidemiologists in dedicated surveillance networks and other professional initiatives to harmonise laboratory methods, promote quality, and build capacity. Results from previous laboratory mapping exercises in the EU conducted by ECDC [9] and the European Commission [10], have revealed a wide diversity in services, infrastructure, technical capacity, public health activities and human resources. Specific areas identified as being of potential EU added-value included the training of laboratory staff, method harmonisation and the devolution of specialist technical capacity at supranational level [9,10].

The ECDC public health microbiology strategy (2012–2016) and laboratory support within its strategic multi-annual programme (2014–2020) aim to strengthen the capability and capacity of the EU public health microbiology system to provide the timely and reliable information that underpins infectious threat detection, assessment and surveillance at Member State and EU level, as needed for effective prevention and control of infectious diseases [4,6]. To ascertain how well this is delivered, ECDC, in close collaboration with the National Microbiology Focal Points (NMFP) and the Advisory Forum (AF), developed and piloted a system (EULabCap) for monitoring key public health microbiology capabilities and capacity for EU surveillance and epidemic preparedness on an annual basis. After piloting the data collection and indicator scoring instrument in 2012–14, the first data call was launched in 2014 to collect the information on 2013 system outputs for 30 EU/EEA countries.

The NMFP are the main contributors to the data collection and verification. They are responsible for disseminating the annual EULabCap country profile report within their Competent Bodies, in accordance with their terms of reference [6]. At the national level information can be used for informing decision makers on options to strengthen the system where relevant (e.g. by adopting good practice or initiating bilateral laboratory cooperation). ECDC will also use the annual results on EULabCap to plan its laboratory support work in the coming years.

This report presents the EULabCap survey results as achieved in 2013 for 30 EU/EEA countries.

Materials and methods

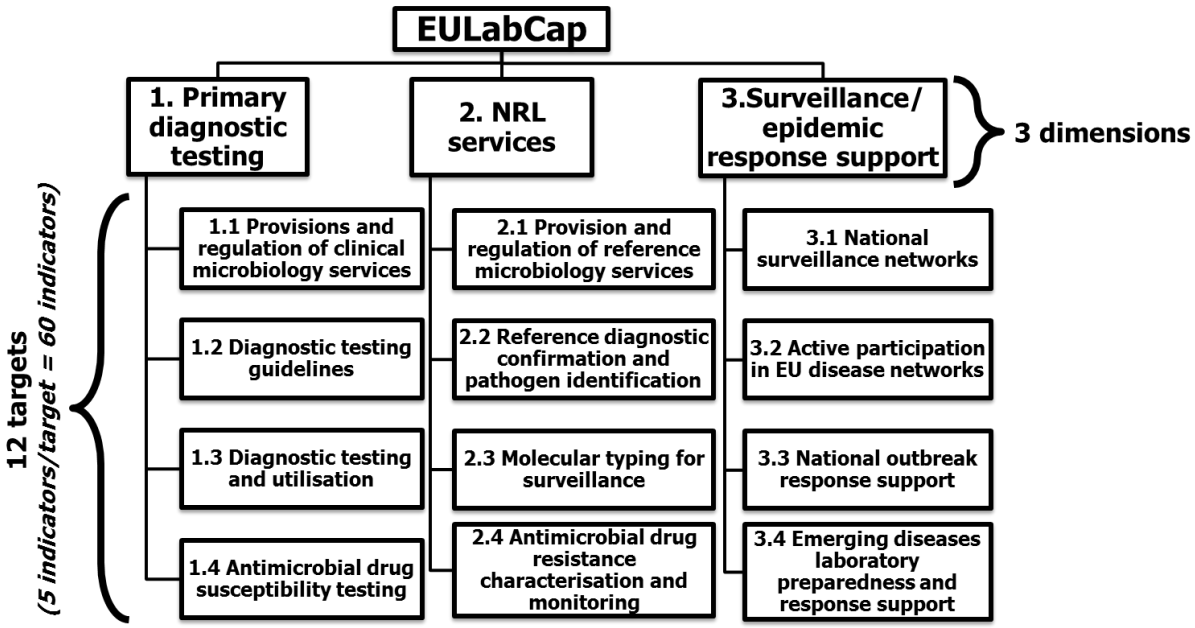
Survey population

The first data call was launched in September 2014 to collect the information on the 2013 capabilities and capacities of the 28 EU Member States and two EEA countries. Liechtenstein declined the offer to be included in the survey due to the outsourcing arrangements they have in place with laboratories in Switzerland to meet their public health microbiology needs.

Survey tool

An Excel-based data collection tool was developed and pilot tested for feasibility and clarity in close collaboration with the NMFPs. The EULabCap monitoring tool is composed of 60 performance indicators grouped into 12 targets (Annex 1) which are equally distributed across the following three public health microbiology system dimensions: primary diagnostic testing, national microbiology reference laboratory (NRL) services and laboratory-based surveillance and epidemic response support (Figure 1).

Figure 1. Structural overview of the EULabCap indicators as grouped by dimension and target



The EULabCap indicators (Annex 1) are of a composite nature in terms of what element of the system they measure (structure or process) and how they measure it (functional capability or capacity). They comprise 24 structure and 36 process indicators. They are divided into 38 indicators for laboratory capability and 22 for capacity (Table 1). The policy rationale for the design of indicators/targets and score levels was based on previously agreed EU policy targets or international technical standards for three-quarters of the indicators, while the remainder assess EU surveillance and alert system contributions (Annexes 2 and 3).

Table 1. Distribution of EULabCap indicators by dimension, element and function measured

Dimension	Number of indicators by element		Number of indicators by function	
	Structure	Process	Capability	Capacity
Primary diagnostic testing	11	9	11	9
National microbiology reference laboratory services	5	15	14	6
Laboratory-based surveillance and epidemic response support	8	12	13	7
Total	24	36	38	22

Scoring system

Each indicator has three possible scores (0, 1, 2) and a 'not available' or 'not applicable' option. Each score was assigned to either a low, intermediate or high level of laboratory capability/capacity, based on the WHO laboratory assessment tool (Table 2) [11].

Table 2. Interpretation of score levels for laboratory capability and capacity

Source	Interpretation	Level
0	No or limited capability/capacity	Low
1	Partial capability/capacity (e.g. below the EU target, or partial compliance)	Intermediate
2	Complete capability/capacity (e.g. EU target reached, or high compliance)	High
NA*	Capability/capacity not known	

* NA (not available or not applicable) was not included in the calculation of the specific target.

Data collection and validation process

A mixed method was used for data collection. To minimise the burden for the Member States, information for 20 indicators was retrieved by ECDC from data sets accessible in The European Surveillance System (TESSy) and EU disease network reports. The NMFP collected information for the remaining 40 indicators by means of a questionnaire (Annex 3). Two rounds of validation were performed with the NMFP to ensure data accuracy and correct score calculation.

Data analysis and interpretation

Data completeness was calculated as a percentage for each indicator across the EU/EEA and overall for each country. Aggregated performance indices were calculated for each target and dimension as the average of component indicator scores per country, adjusting values on a scale of 0–10. Descriptive data analysis including measures of central tendency (mean and median) and dispersion (standard deviation and inter-quartile range) of indicator scores and aggregated indices across the EU/EEA were calculated using Excel 2010. Overall EULabCap index scores per country were graded qualitatively at three performance levels: low (0 to 5.9), intermediate (6.0 to 7.9) and high (8.0 to 10). Statistical analysis of the correlation between EULabCap country score and national health expenditure per capita in 2012, as reported to OECD (The Organisation for Economic Cooperation and Development) [3], was performed using STATA 13.

The draft preliminary EULabCap 2013 reports (individual country reports and EU/EEA report) were shared with NMFPs for review in April 2015. The EU report was critically reviewed and discussed at the joint NMFP-Advisory Forum meeting in May 2015. The draft reports were broadly supported in terms of validity and public health relevance of the findings, subject to minor modifications of the tool. One indicator was found not to be feasible and was replaced in the majority of countries. A further 10 indicators were edited to enhance clarity or precision in June 2015. A final round of 2013 data reporting/verification for these indicators was undertaken with all NMFPs between June and September 2015.

Data reporting

Aggregated report for the EU/EEA

This technical report displays aggregated data on the EULabCap scores for all 30 participating EU/EEA countries, using histograms, radar and bar graphs, and maps to visualise the distribution of performance scores for the system overall, by target and dimension. A scatterplot diagram and linear regression analysis are presented to explore the relation between EULabCap index and national health expenditure in the previous year.

Individual country reports

For all the 30 participating EU/EEA countries an individual EULabCap country report was prepared, including detailed information on the country's profile. This report was shared with the respective NMFP, intended for dissemination within and use by the Coordinating Competent Bodies of the country.

Each country report displayed the country's scores for all indicators compared with the mean EU/EEA scores for each target and indicator. In addition, a radar graph comparing the country score with the EU inter-quartile range (IQR) for the 12 targets enabled the identification of targets with deviations below or above the EU middle range. For individual country reports, the country EULabCap indices were grouped into four relative levels of public health microbiology system capabilities and capacities: imbalanced (first quartile score), fair (second quartile score), strong (third quartile score) and very strong (fourth quartile score).

A customised executive summary addressing the question 'How well was your country performing in 2013?' highlighted country-specific areas of high performance and drew attention to areas of under-performance based on the reported indicators.

Results

Response rate and data completeness

The country response to the survey was 100% (30/30 countries). The 2013 data for all 30 countries were provided for 95% of the indicators (1 717 out of 1 800 data points), ranging from 70–100% by country and from 64–100% by indicator (Figure 2).

Six indicators had missing data from more than three countries (Figure 2). Those indicators were, in order of increasing completeness, 2.34, 3.13, 2.32, 1.33, 2.24 and 2.33.

Figure 2. Indicator completeness and distribution of missing data by country (sorted by descending order of completeness

COUNTRY	INDICATOR REFERENCE NUMBER																																																											TOTAL
	1.11	1.12	1.13	1.14	1.15	1.21	1.22	1.23	1.24	1.25	1.31	1.32	1.33	1.34	1.35	1.41	1.42	1.43	1.44	1.45	2.11	2.12	2.13	2.14	2.15	2.21	2.22	2.23	2.24	2.25	2.31	2.32	2.33	2.34	2.35	2.41	2.42	2.43	2.44	2.45	3.11	3.12	3.13	3.14	3.15	3.21	3.22	3.23	3.24	3.25	3.31	3.32	3.33	3.34	3.35	3.41	3.42	3.43	3.44	3.45	
Belgium																																																													0
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Portugal											■		■																■			■	■		■																										6
Poland											■		■								■	■	■						■					■					■																						8
Iceland																			■														■	■									■	■			■		■						■				■		9
Malta																■	■							■					■	■	■	■			■		■	■		■	■		■	■	■								■	■	■						18
TOTAL	2	0	0	1	0	0	0	1	1	0	3	0	6	0	0	1	2	0	2	0	1	1	1	1	0	0	0	0	6	1	1	5	11	4	2	1	2	2	2	1	1	0	4	2	3	0	1	0	1	0	0	0	3	3	2	0	0	0	1	1	83

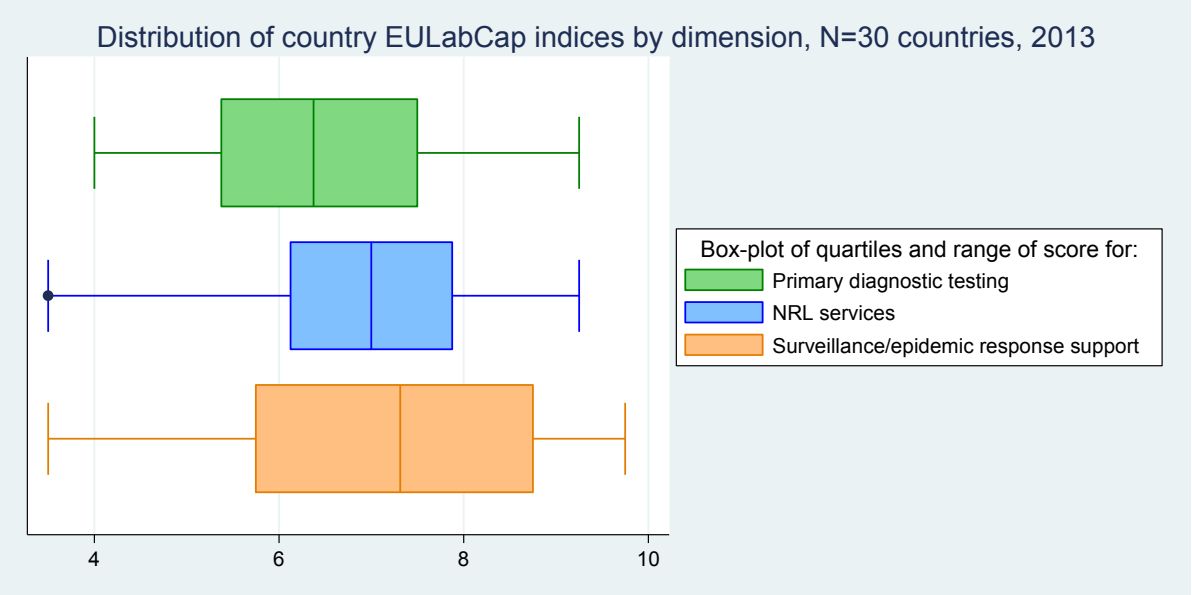
NA (not applicable) answers correspond to blue cells

Laboratory capabilities and capacities at EU/EEA level

The average EULabCap aggregated index score was 6.9 on a scale of 1–10.

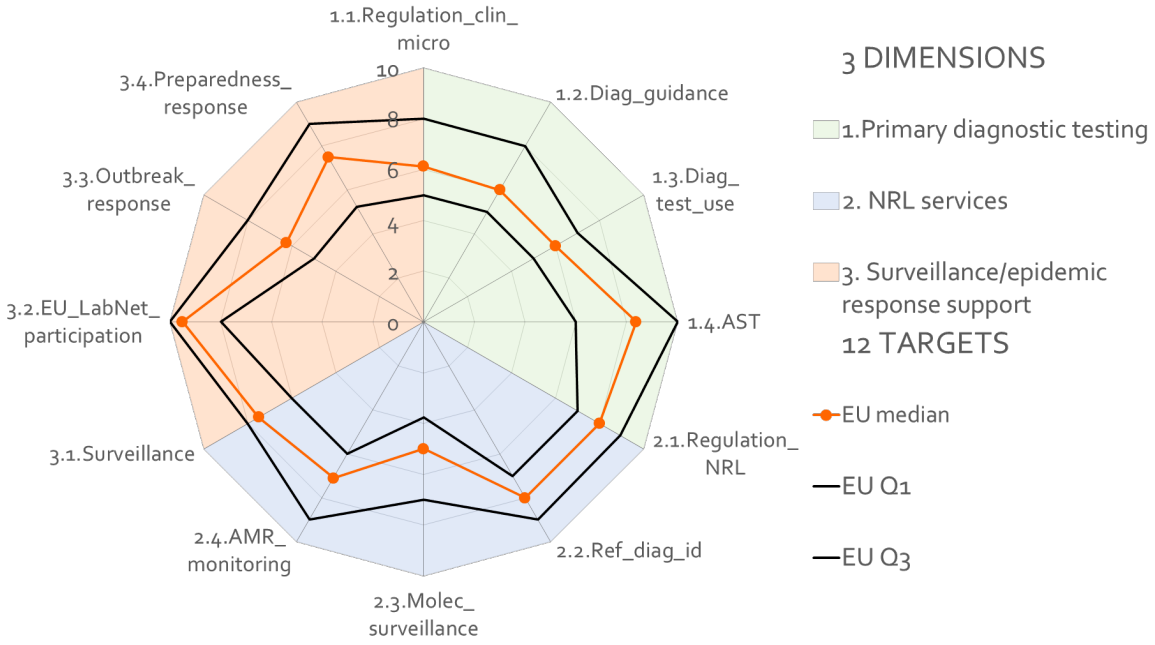
The index scores showed different distributions across dimensions, with a median index of 6.5 (IQR 5.5–7.3) for primary diagnostic testing, 7.0 (IQR, 6.4–8.0) for NRL services and 7.4 (IQR, 6.2–8.7) for laboratory-based surveillance and epidemic response support (Figure 3).

Figure 3. Boxplot of the EULabCap index scores by dimension (N=30 countries)



The distribution of the EU median and interquartile range for EULabCap index scores by target and dimension of the public health microbiology system is shown in Figure 4.

Figure 4. Distribution (median and inter-quartile range) of country EULabCap 2013 index scores by target (N=30 EU/EEA countries)



Grouping these results according to the EU/EEA median score per target made it possible to identify three levels of target capability/capacity (high, intermediate and low comparative performance) (Table 3).

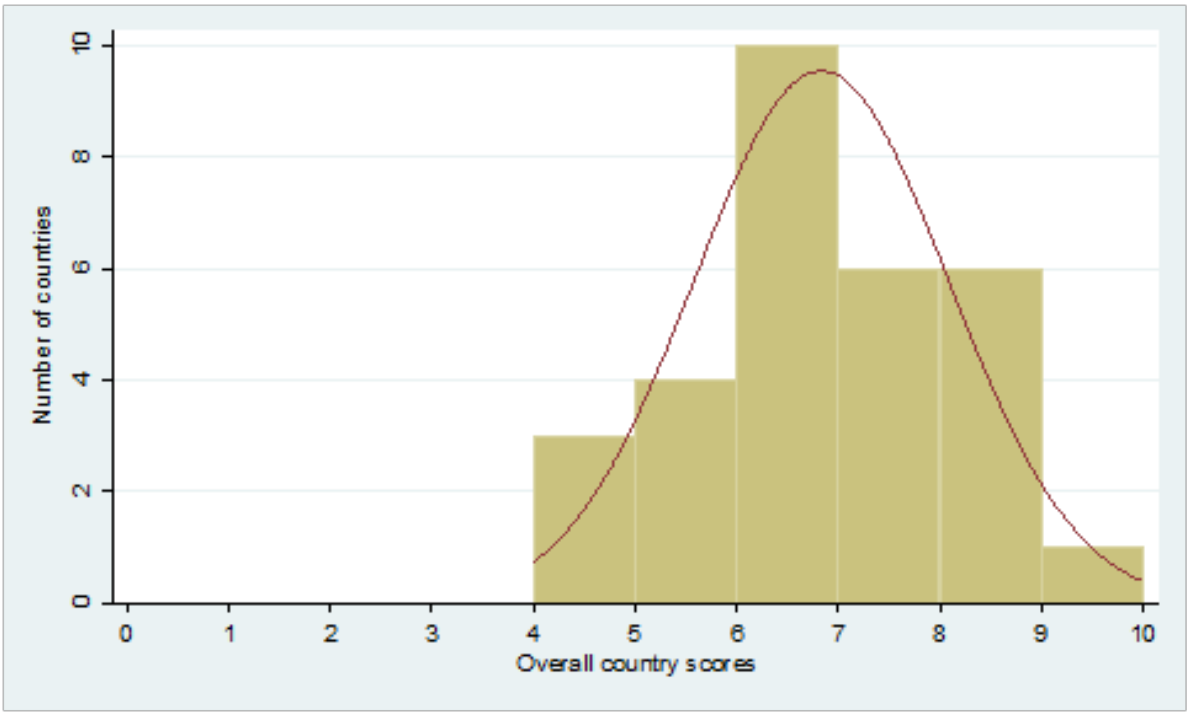
Table 3. Distribution of EU capability/capacity based on EU median index scores by target

High performance targets (median ≥ 7.4)	Intermediate performance targets (median 6.4-7.3)	Low performance targets (median ≤ 6.3)
1.4 Antimicrobial drug susceptibility testing	2.4 Antimicrobial drug resistance characterisation and monitoring	1.1 Provision and regulation of clinical microbiology services
2.1 Provision/regulation of national reference microbiology services	3.1 National surveillance networks	1.2 Diagnostic testing guidelines
2.2 Reference diagnostic confirmation and pathogen identification	3.3 National outbreak response support	1.3 Primary diagnostic testing utilisation
3.2 Active participation in EU disease networks	3.4 (Re-)emerging diseases laboratory preparedness and response support	2.3 Molecular typing for surveillance

Laboratory capabilities and capacities at country level

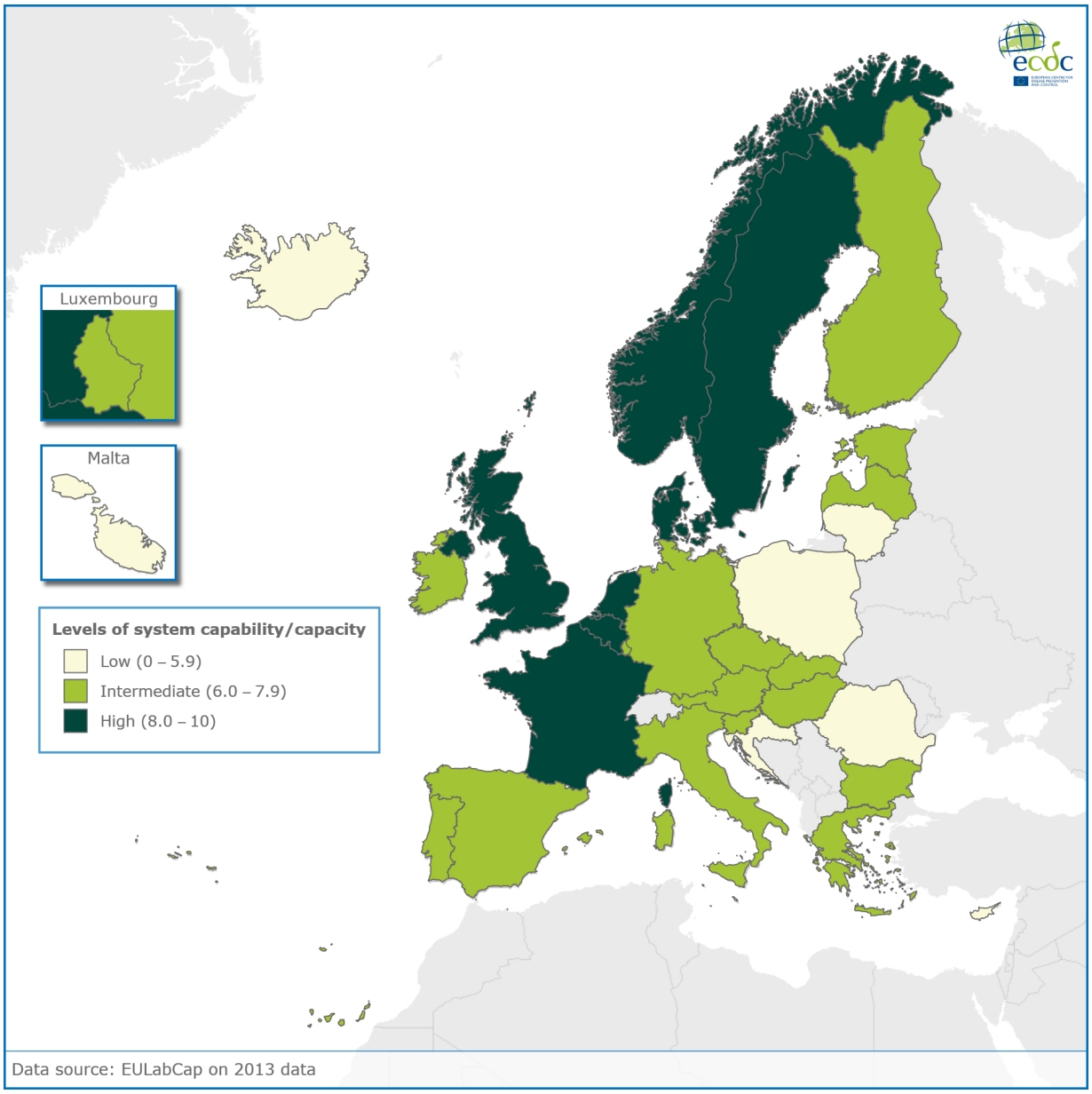
The EULabCap index showed substantial inter-country variation with unimodal distribution of country scores ranging from 4.7 to 9.2 (Figure 5).

Figure 5. Distribution of overall EULabCap index country scores 2013 (N=30 EU/EEA countries)



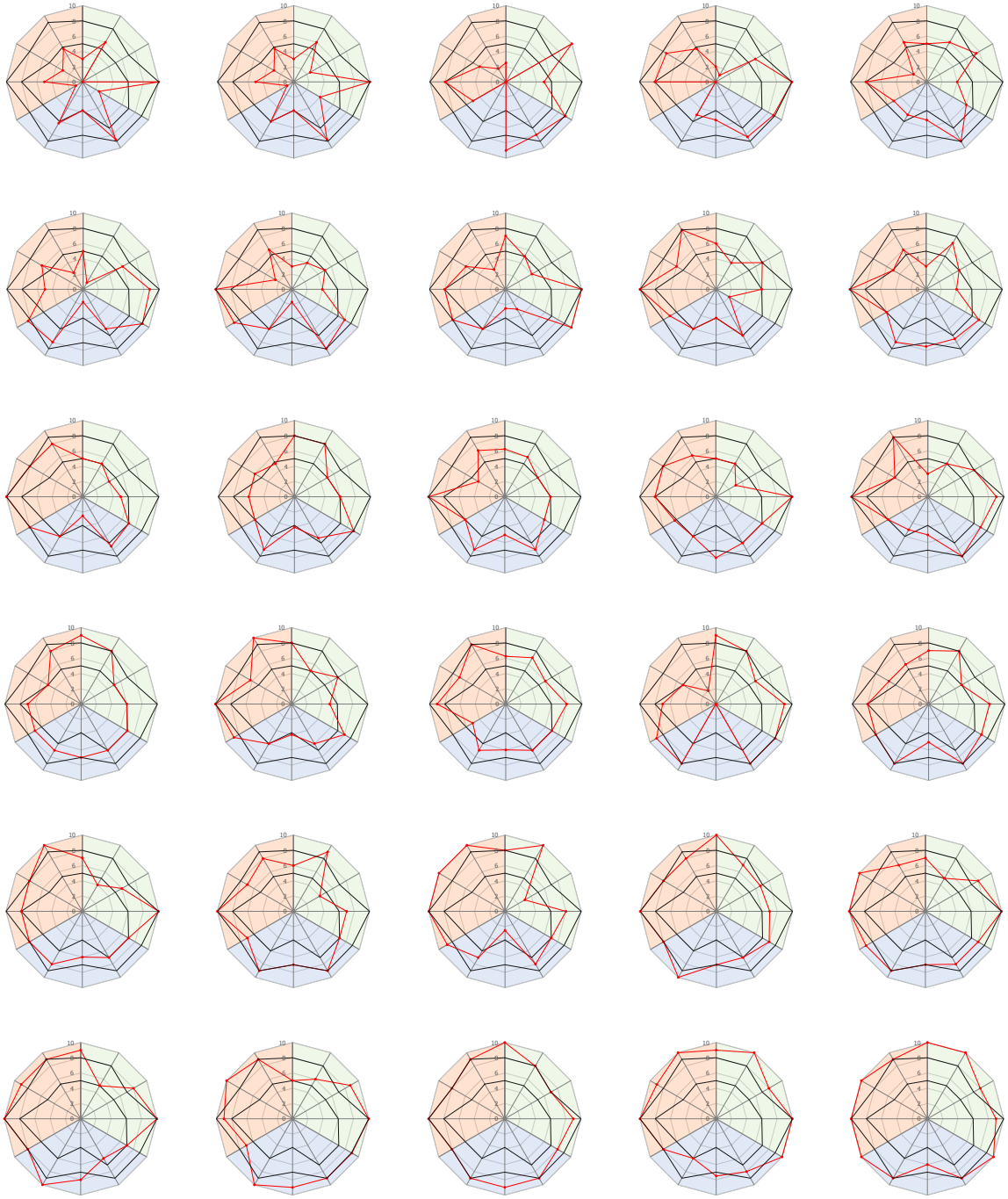
The map in Figure 6 shows the geographical distribution of performance by country based on three levels (low, medium and high). In addition, Annex 4 includes maps showing the geographical distribution of each target performance level by country based on the same three categories as Figure 6.

Figure 6. Levels of public health microbiology system capabilities and capacities (N=30 EU/EEA countries)



In addition to variation in the EULabCap overall country score, there was substantial variation within each country in the target index scores distribution. This is shown in the radar graphs (Figure 7), displaying the shape linking target index scores for each EU/EEA country. There is a noticeable imbalance in the performance scores achieved across targets in a number of countries.

Figure 7. Radar graphs of EULabCap target index scores for each country (red line), from top left to bottom right, in ascending order of total index country score, compared with the EU inter-quartile range (grey line), N=30 EU/EEA countries, 2013

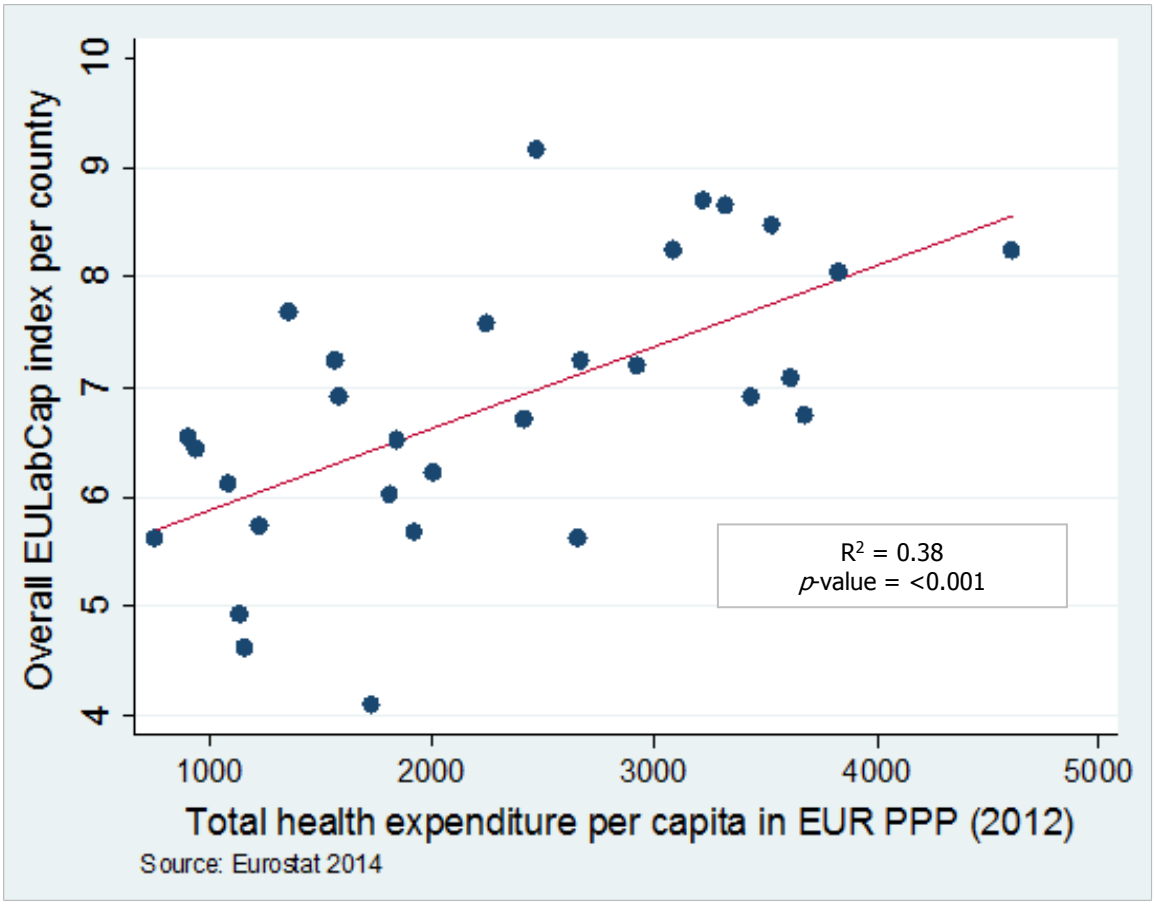


The graphs display the same variables and axis scales as shown in Figure 4.

Relation between capability index and health expenditure

The overall EULabCap capability index ranged from 4.7 to 9.2/10 by country. As data on direct monetary or other resource inputs into the national microbiology system are not available, an exploratory analysis was performed to examine the relation between country capability index and national health expenditure [3,12], used as crude proxy of financial input (Figure 8). A direct linear relationship was found between the country level of expenditure and the EULabCap index. However, only about 38 percent of the variance in the EULabCap index across countries was predicted by the level of health expenditure, indicating that other factors enabled low resource spending countries to achieve strong performance with their microbiology system.

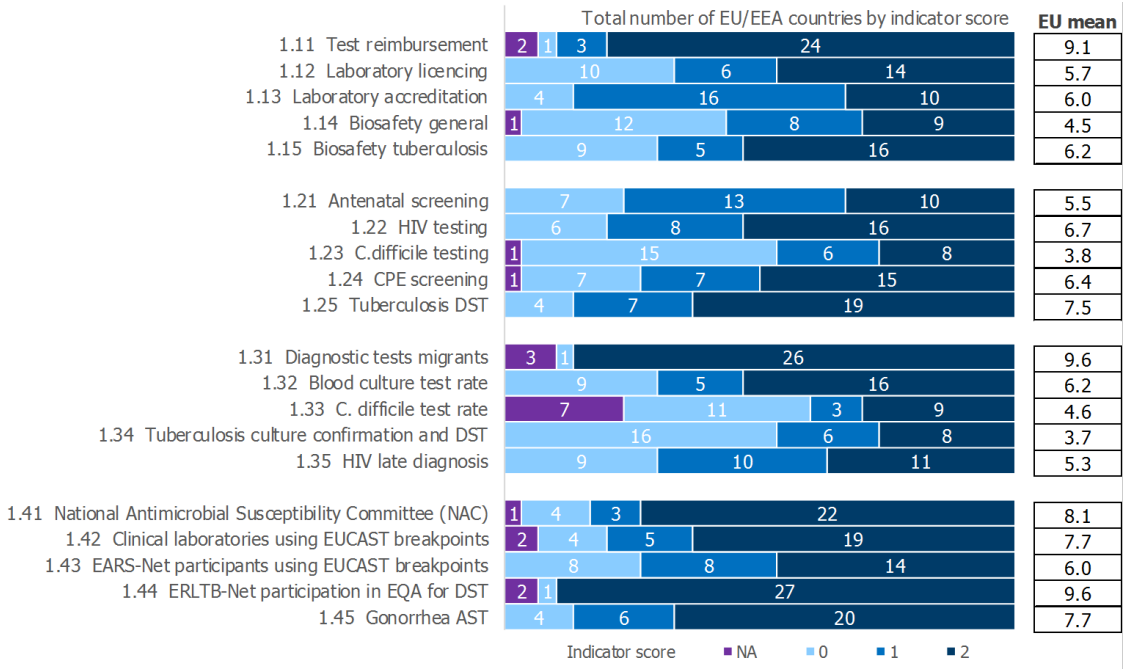
Figure 8. Scatter plot and correlation coefficient based on linear regression between the EULabCap country index 2013 and total national health expenditure per capita in 2012 (N=30 EU/EEA countries) [3]



Primary diagnostic testing

A more detailed analysis of country scores per indicator in each system dimension revealed EU strengths and weaknesses in specific technical areas. Figure 9 displays the distribution of countries' scores and the EU/EEA mean for the 20 primary diagnostic testing indicators.

Figure 9. EU distribution of scoring results by country for the 20 EULabCap indicators within the dimension of primary diagnostic testing



Lower levels of capability/capacity were noted for a number of indicators within targets on the provision and regulation of clinical microbiology services, diagnostic testing guidance and primary diagnostic testing utilisation. In particular, substantial gaps were noted for medical laboratory licensing, accreditation and biosafety regulation and oversight (Target 1.1). Guidance on diagnostic testing was frequently lacking or not evaluated for antenatal infection and for *Clostridium difficile* infection (Target 1.2). With regard to capacity indicators for test service utilisation (Target 1.3), a majority of EU/EEA countries missed the TB and HIV testing targets from EU action plans for disease control and a majority did not measure *Clostridium difficile* testing rates in hospital care for 2013.

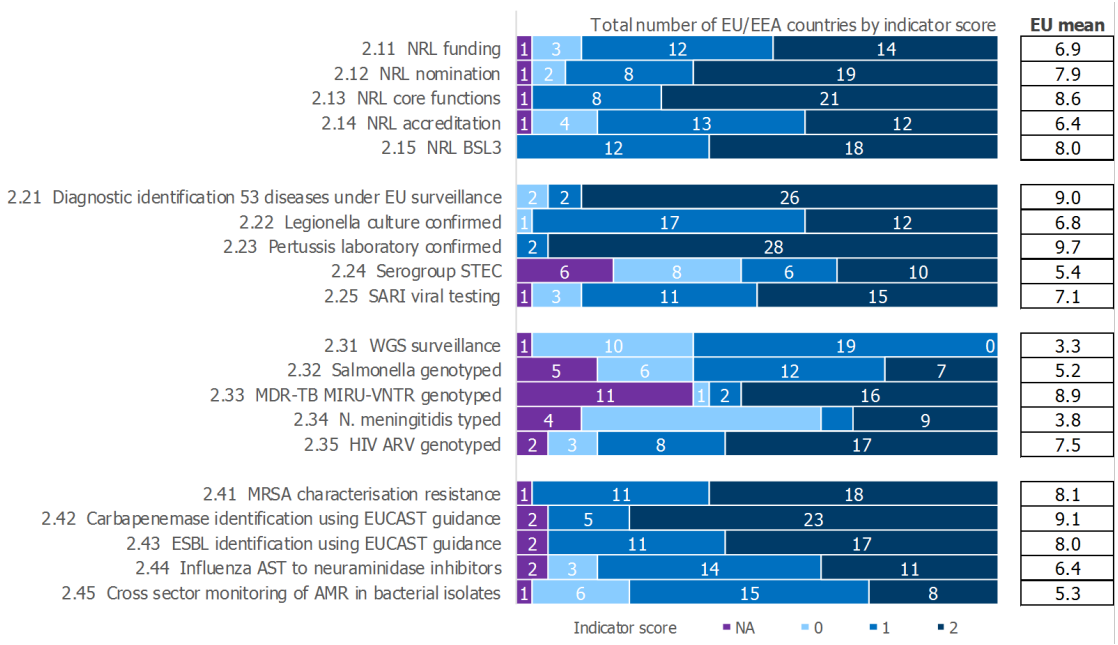
In contrast, primary antimicrobial drug susceptibility testing (Target 1.4) showed high levels of capability/capacity, highlighted by wide implementation of EUCAST standards and high quality results in external quality assessment schemes in the majority of EU/EEA countries.

From the perspective of accessibility of care, it is noticeable that clinical microbiology laboratory tests were publicly funded or reimbursed at least in part for in- and out-patient testing in 77% of EU/EEA countries and that testing for HIV infection and tuberculosis was available to undocumented migrants in 87% of countries.

National reference laboratory service

Figure 10 displays the distribution of countries' scores and the EU/EEA mean for the 20 National Reference Laboratory services indicators.

Figure 10. EU distribution of scoring results by country for the 20 EULabCap indicators within the dimension of National Reference Laboratory services



Notes on Fig. 10:

Indicator 2.24. STEC serogrouping coverage. Non-typeable and non-typed isolates were included in the percentage calculation of those with serogrouping. This calculation might have underestimated the countries' real capabilities as non-typeable isolates may occur due to biological variation.

Indicator 2.33. MDR-TB genotyping coverage. One third of the countries had a 'non-applicable' value because data were retrieved from TESSy and they did not participate in the ECDC molecular typing for surveillance pilot project activities for MDR-TB. The performance measured by this indicator depends on countries volunteering to participate in these EU activities.

Indicator 2.34. *N. meningitidis* genotyping coverage. Performing MLST, *fetA* and *porA* sequencing for a full application of the EU-recommended *Neisseria meningitidis* fine typing scheme is resource-demanding. Partial application (i.e. reporting *fetA* and *porA* sequences) is not taken into account with the indicator as scored in 2013.

Overall, the provision/regulation of national reference microbiology services including diagnostic confirmation, pathogen identification and antimicrobial drug resistance monitoring by NRL (Targets 2.1, 2.2 and 2.4) showed high score levels for most capability/capacity indicators.

In particular, 90% of EU/EEA countries reported in-country capability for case confirmation and pathogen identification for more than 35 of the 53 EU-notifiable communicable diseases (Indicator 2.21) according to the laboratory criteria described in the EU case definitions [13]. Confirmation capability was reported by all EU/EEA countries for 10 listed diseases (Table 4). These include high-priority and/or epidemic-prone diseases (e.g. influenza, tuberculosis and listeriosis). For 47 listed diseases there was also widespread capability for detection and diagnosis in 25–30 countries. Fewer (15 to 24) countries could domestically confirm the remaining rare diseases or agents which require specialised testing facilities, materials, and know-how (e.g. viral haemorrhagic fever, smallpox or rabies). For all countries that do not have national capabilities, the NMFP mentioned that they have technical cooperation with other countries.

Table 4. Number of EU/EEA countries reporting diagnostic confirmation and pathogen identification testing available within the country for the 53 diseases/health issues listed in Decision 2119, in accordance with the EU surveillance case definitions of the Community Network [13]

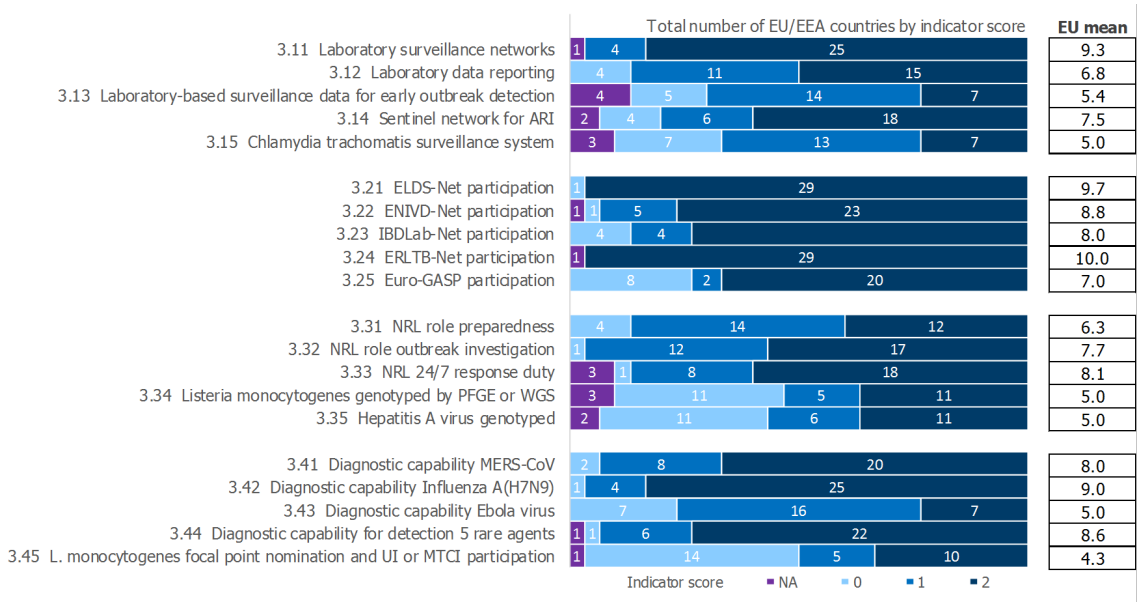
Disease/health issue	No. of countries (N=30)	Disease/health issue	No. of countries (N=30)
Influenza	30	Gonorrhoea	27
Influenza A		Legionnaires' disease	
Listeriosis		Poliomyelitis	
Measles		Q Fever	
Meningoccocal disease, invasive		West Nile Fever	
Pneumococcal disease, invasive		Echinococcosis	26
Rubella		SARS	
Salmonellosis (not *S.* Typhi, *S.* Paratyphi)		Tick-borne encephalitis	
Tuberculosis		Trichinellosis	
Avian influenza	29	Chlamydial infection, including LGV	25
Cholera		Leptospirosis	
Diphtheria		Plague	
Haemophilus influenzae, invasive		Tularaemia	
Hepatitis B		Viral haemorrhagic fevers	
Hepatitis C		Tetanus	24
Malaria		Botulism	23
Mumps		Yellow fever	22
Rubella, congenital		Creutzfeldt-Jakob disease, variant	21
STEC/VTEC		Rabies	
Toxoplasmosis		Smallpox	15
Typhoid/paratyphoid fever			
AIDS and HIV	28		
Anthrax			
Brucellosis			
Campylobacteriosis			
Cryptosporidiosis			
Giardiasis			
Hepatitis A			
Pertussis			
Shigellosis			
Syphilis			
Syphilis, congenital and neonatal			
Yersiniosis			

In contrast, the use of molecular typing characterisation of pathogens for surveillance (Target 2.3) indicated a low level of capability/capacity in many EU/EEA countries, as measured by the indicators. However, many of these indicators were scored based on TESSy reported data and therefore did not measure the national typing capacity but the capacity shared at EU surveillance level, a process which in 2013 was at the early stage of development (based on volunteer country participation). As expected, in 2013 no country was routinely using whole genome sequencing-based typing of human pathogens for national surveillance, as no such protocol had yet been standardised.

Laboratory-based surveillance and epidemic response support

Figure 11 indicates the distribution of countries' scores and the EU/EEA mean score for the 20 laboratory-based surveillance and epidemic response support indicators.

Figure 11. EU distribution of scoring results by country for the 20 EULabCap indicators within the dimension of surveillance and response support



Overall, indicators of laboratory contribution to national surveillance networks, national outbreak response support, and preparedness and response for (re-)emerging diseases showed an intermediate level of capability/capacity performance. The target 'Active participation in EU disease networks' had the best performance overall with an EU/EEA mean score of 8.6, reaching near complete country participation for the tuberculosis and *Legionella* networks.

Strong performance scores were also reported by a majority of countries for the operation of national sentinel surveillance networks. Remarkably, 83% of EU/EEA countries had collaboration in place between reference laboratories and national networks of clinical laboratories for more than five diseases under surveillance.

However, many countries reported low or medium scores for automation of microbiology data reporting and capability of cluster detection especially based on molecular typing (e.g. for *Listeria* or hepatitis A). Laboratory expert participation in outbreak response also showed limited performance for many countries. Although 60% of EU/EEA countries had a 24/7 NRL response support duty in place in 2013, only 40% of the countries reported strong NRL contribution to outbreak investigations and testing of preparedness plans.

Discussion

The EULabCap is the first initiative to measure the whole spectrum of microbiology laboratory capabilities and capacities required to underpin effective communicable disease surveillance and epidemic preparedness at the EU and country levels. The use of a new indicator framework applying a common terminology and taxonomy of services was pivotal to the success of this process. With an average EULabCap index score of 6.9 on a scale of 0–10 in 2013, the EU as a whole showed evidence of a strong public health microbiology system, with substantial capacity to collectively fulfil its communicable disease surveillance and response requirements.

The data collection method proved feasible in this first call for 2013 data. The remarkable 100% country response and 96% completeness of indicators showed the commitment of the NMFP to this project. However, the dataset had some limitations. For various reasons some countries were not able to provide data for all indicators. Explanations for the missing information included: a lack of formally designated NRL or outsourcing of reference services to other countries; low disease incidence or limited referral of samples to NRL from primary diagnostic laboratories; countries having a small population with centralised care and primary/specialist laboratory testing and time constraints for collecting the information from other stakeholders or databases. Indicators that measure information sharing within a national reference laboratory system are only applicable to countries with more than one clinical and reference laboratory. As 'not available/not applicable' values were not included in the performance score calculation by target, this ascertainment bias may have led to an under- or over-estimation of performance. The missing data or not applicable indicators were low frequency and therefore unlikely to affect the overall robustness of the indicators, except for a few countries. In addition, the four indicators on microbial typing performance, which were considered less robust due to difficulties in data collection and/or scoring criteria, will be improved in the next survey.

Significantly, two-fold variation in EULabCap country indices was noted across the EU/EEA. A moderate linear correlation was observed between the country index and the total health expenditure. However, only about a third of the inter-country variance in the EULabCap index was predicted by the level of health expenditure. This observation suggests that there are more factors determining system strength than the overall health spending per capita. High capability indices were noted in some low spending countries and vice versa, suggesting either a different allocation of these expenditures to the laboratory services between countries, and/or differences in the cost-efficiency of services.

The comparison of score distribution by dimension indicated the lowest EU median scores in the primary testing dimension, reflecting gaps in clinical laboratory service provision and regulation within national healthcare systems. The median score of EULabCap index for the NRL services dimension was high and showed limited inter-country variance. This observation may reflect convergence across the EU of national public health practices after several decades of sharing experience and collaboration. Nevertheless, five years after publication of the NMFP consensus guidance, NRLs were not officially nominated by health authorities in one third of the EU/EEA countries and only a minority of countries have reached agreement on accreditation and public funding of these services. Regarding NRL contribution to surveillance and response, strong overall EU indices were accompanied by wider inter-country variance. The high level of participation in ECDC disease-specific laboratory networks is a key finding that builds on a legacy of longstanding collaboration between laboratory scientists and public health specialists in Europe.

The high level of capability/capacity noted in antimicrobial drug susceptibility testing highlights the successful implementation of the harmonised susceptibility breakpoints established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST). This positive finding can be related to the number of EU initiatives and the fact that global policy is now focusing on the health threat of antimicrobial resistance. It is also a credit to professional leadership across Europe to see how antimicrobial testing practice has been harmonised to improve the quality of care and surveillance [14,15].

Regarding molecular typing, low scores were expected in 2013 for indicators on typing capacity as reported to TESSy since the integration of molecular typing into EU surveillance was only piloted by voluntary reporting on foodborne disease and MDR-TB. Moreover, as indicated in the footnote to Figure 13, based on feedback from participants a number of minor corrections will be introduced in the next survey to the classification criteria for measuring typing coverage. It will be interesting to follow the trends in future TESSy reporting of molecular typing information and to see how quickly the 19 countries planning to use whole genome sequencing for surveillance move to practical application.

Strong scores were reported by a majority of countries for the operation of national sentinel surveillance networks. However, most countries reported low or medium scores for indicators of rapid microbiology data reporting and cluster detection capability. This finding indicates that there are opportunities for enhanced application of IT solutions to facilitate laboratory-based surveillance and alert systems within and across EU/EEA countries.

Almost all countries declared having access to the range of specific agent diagnostic capabilities required to meet EU surveillance reporting obligations. There were only a handful of rare diseases or high-consequence pathogens requiring specialised containment facilities for which countries relied on third party arrangements. It would be useful to know in terms of preparedness whether these external service agreements were ad hoc or through pre-

arranged contracts. The data reported here on diagnostic capability may overstate the true capability and not assess capacity in terms of volume or frequency of testing. It would be informative to cross-check these self-reported domestic or cross-border technical capabilities with the results of recent External Quality Assessment (EQA) exercises for the detection of specific agents [16-19]. This is illustrated by the discrepancies recorded in the EQA exercise for diphtheria diagnostics held in 2013: only 9/30 participating EU/EEA countries correctly detected toxin production in *Corynebacterium diphtheriae* strains [17], whereas 29/30 countries reported diphtheria diagnostic confirmation capability in accordance with the EU case definition in EULabCap.

A majority of EU/EEA countries had a strong capacity for diagnosis and further characterisation of emerging disease agents, such as avian influenza H7N9, MERS-CoV, Ebola virus and rare and/or imported viruses. This observation is consistent with the results of dedicated activities in the field of preparedness and response for these agents in Europe [19]. Since information on capability/capacity for diagnostics of other (re-)emerging infectious diseases (e.g. Lyme disease, new strains of multidrug-resistant bacteria) is not captured by the EULabCap, should an event occur caused by these or other unusual agents, ad hoc surveys within EU disease networks should be undertaken to rapidly appraise the detection capacity in Europe.

Conclusions

With an average EULabCap aggregated index score of 6.9 out of 10, the EU as a whole shows evidence of a strong overall public health microbiology system capability and substantial capacity to fulfil its surveillance and response requirements.

However, substantial inter-country variation was found across all system targets, and the average EU/EEA scores were also divergent across targets, indicating that there were common challenge areas for which many countries showed more limited provision of critical capabilities and/or low capacity.

The main challenges were found in:

- primary diagnostic service regulation, guidance and utilisation
- laboratory support to national outbreak response.

The areas of best practice with consistently high levels of performance, largely meeting policy targets and standards, included:

- primary antimicrobial drug susceptibility testing and antimicrobial resistance monitoring,
- capability scope of the national reference laboratory services
- active laboratory collaboration within national and EU surveillance networks.

The EULabCap annual monitoring aims to inform national competent bodies as well as policy makers at the national and EU level. This first survey on 2013 capacities sets out the baseline for monitoring country and EU public health microbiology performance. ECDC will prioritise its support activities to focus on challenging areas within its mandate, in collaboration with the EU/EEA countries, the European Commission and other European agencies and partners. Future surveys should provide information for evaluating the impact of national policies and EU support activities on system performance.

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Annex 1. EULabCap survey list of targets, indicators and scoring options (with shorthand annotation for results presentation in red)

Dimension 1. Primary Diagnostic Testing - Primary_diag

Targets/Indicators	Source (NMFP/ECDC) and scoring options
Target 1.1. Regulation_clin_micro Provision and regulation of clinical microbiology services.	
Indicator 1.11. Test_reimbursement Clinical microbiology laboratory tests were funded/reimbursed in total, or in part, either by a national insurance scheme or by a governmental budget.	NMFP NA = not available, 0 = no tests are reimbursed, 1 = for hospital in-patient testing, 2 = for in- and outpatient testing.
Indicator 1.12. Lab_licencing Clinical microbiology laboratories obtained a licencing authorisation/registration from health authorities (or professional organisations) according to legal/regulatory requirements.	NMFP NA = not available, 0 = not required by law/regulation, 1 = required for some laboratories, 2 = required for all laboratories.
Indicator 1.13. Lab_accreditation Clinical microbiology laboratories accredited (one or more) of their diagnostic tests according to ISO 17025, ISO 15189, or equivalent national standards. Please specify which standard(s) in the column 'Additional information'.	NMFP NA = not available, 0 = no laboratories, 1 = some laboratories, 2 = all laboratories.
Indicator 1.14. Biosafety_general Clinical microbiology laboratories must receive a biosafety authorisation/permit for performing operations at Biosafety Level (BSL)2 and BSL3.	NMFP NA = not available, 0 = not required by law/regulation, 1 = for BSL3 facilities, 2 = for both BSL2 and BSL3 facilities.
Indicator 1.15. Biosafety_TB Culture-based tuberculosis diagnostic and drug susceptibility tests were restricted to laboratories compliant with performing BSL3 operations in line with the WHO Tuberculosis laboratory biosafety manual.	NMFP NA = not available, 0 = not required by law/regulation, 1 = for DSTs, 2 = for all TB culture tests and TB DSTs.
Target 1.2 Diag_guidance Diagnostic testing guidelines	
Indicator 1.21. Antenatal_screening National guidelines are available for antenatal screening of congenital infection and implementation is monitored within the country.	NMFP NA = not available, 0 = guidelines not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Indicator 1.22. HIV_testing National guidelines are available for HIV testing.	NMFP NA = not available, 0 = guidelines not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Indicator 1.23. Cdif_testing National guidelines are available for *Clostridium difficile* diagnostic testing in healthcare-associated diarrhoea.	NMFP NA = not available, 0 = guidelines not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Indicator 1.24. CPE_screening National guidelines are available to screen hospitalised patients for carbapenem-non-susceptible/carbapenemase-producing *Enterobacteriaceae* .	NMFP NA = not available, 0 = guidelines not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Indicator 1.25. TB_diag_DST National guidelines are available for tuberculosis laboratory diagnostics and drug susceptibility testing.	NMFP NA = not available, 0 = guidelines not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Target 1.3 Diag_test_use Diagnostic testing utilisation	
Indicator 1.31. Diag_test_migrants Accessible diagnostic testing for HIV infection and/or tuberculosis was available to undocumented migrants in your country.	NMFP NA = not applicable, 0 = testing is not available, 1 = testing available for HIV infection, 2 = testing available for HIV infection and tuberculosis.
Indicator 1.32. Blood_culture_test_rate Average number of blood culture sets tested/1000 hospital inpatient days reported by EARS-Net participating hospitals from your country. *The current report is based on 2012 data.	ECDC NA = not available/not applicable, 0 = information not reported to EARS-Net, 1 = low blood culture test utilisation rate/1000 patient days (first quartile), 2 = fair to high blood culture utilisation rate/1 000 patient days (upper three quartiles).

Targets/Indicators	Source (NMFP/ECDC) and scoring options
Indicator 1.33. Cdif_test_rate Total number of *Clostridium difficile* diagnostic tests** performed/1 000 hospital-in-patient days, based on national estimate*. *Estimate can be determined by a (representative) sample via survey **A test = a stool sample tested for 1 or more diagnostic *C. difficile* assays including toxin immunoassay, toxin cytotoxic cell-culture assay, PCR, or culture.	NMFP **NOTE: ECDC will use the numbers provided to calculate quartiles.** NA = not available, 0 = not measured in the country, 1 = low diagnostic test utilisation rate/1000 patient days (first quartile); 2 = fair to high diagnostic test utilisation rate/1 000 patient days (upper three quartiles).
Indicator 1.34. TB_culture_DST Proportion of new pulmonary tuberculosis cases confirmed by culture and tested for susceptibility to first-line drugs.	ECDC NA = not available, 0 = <80% culture confirmed AND no DST, 1 = ≥80% culture confirmed BUT not 100% DST, 2 = ≥80% culture confirmed AND 100% DST.
Indicator 1.35. HIV_late_diag Proportion of new HIV cases older than 14 years with initial CD4 counts (CD4<350 cells/µl - late diagnosis) reported.	ECDC **NOTE: ECDC will use the numbers provided to calculate the country specific score according to the EU median (value).** NA = not available/not applicable, 0 = CD4 cell count not reported to TESSy, 1 = >EU Median, 2 = ≤EU Median.
Target 1.4 AST Antimicrobial drug susceptibility testing	
Indicator 1.41. NAC A National Antimicrobial Susceptibility Committee (NAC) is established and its representative is a member of EUCAST General Committee.	ECDC NA = not available/not applicable, 0 = not established, 1 = NAC formation in process, 2 = NAC established.
Indicator 1.42. EUCAST_bkpt_use Percentage of clinical laboratories that have used EUCAST 2013 clinical breakpoints for interpretive reporting of antibacterial drug susceptibility testing results to clinicians.	ECDC NA = not available/not applicable, 0 = <10% clinical laboratories, 1 = 10-50% clinical laboratories, 2 = >50% clinical laboratories.
Indicator 1.43. EUCAST_bkpt_use_EARSNet Percentage of clinical laboratories participating in EARS-Net that have used EUCAST 2013 clinical breakpoints for interpretive reporting of antibacterial drug susceptibility testing results to clinicians.	ECDC NA = not available/not applicable, 0 = <25% clinical laboratories, 1 = 25-75% clinical laboratories, 2 = >75% clinical laboratories.
Indicator 1.44. ERLTB_0.8_DST Tuberculosis Reference Laboratories that participated in ECDC-funded ERLTB-Net external quality assessment scheme in 2013 achieved 80% performance level for culture and susceptibility testing for first- and second-line drugs.	NMFP NA = not available/not applicable, 0 = no participation, 1 = participation with performance <80%, 2 = participation with performance ≥80%.
Indicator 1.45. Gono_0.1_AST National surveillance of gonococcal antimicrobial resistance is providing susceptibility data on 10% or more of notified gonorrhoea cases.	NMFP NA = not available/not applicable, 0 = no surveillance of AMR at national level, 1 = <10% of notified cases, 2 = ≥10% of notified cases.

Dimension 2. National reference laboratory services – NRL

Targets/Indicators	Source (NMFP/ECDC) and scoring options
Target 2.1 Regulation_NRL Provision and regulation of national reference microbiology services	
Indicator 2.11. NRL_funding National Reference Laboratory (NRL) for public health microbiology services were financially supported at least in part by health authorities or other competent bodies.	NMFP NA = not available, 0 = no funding, 1 = funding to some NRLs, 2 = funding to all NRLs.
Indicator 2.12. NRL_nomination NRLs were officially nominated by health authorities or other competent bodies.	NMFP NA = not available/not applicable, 0 = no, 1 = some NRLs, 2 = all NRLs.
Indicator 2.13. NRL_core_functions 2.13(a). The majority of NRLs delivered reference diagnostics. 2.13(b). The majority of NRLs delivered reference material resources. 2.13(c). The majority of NRLs delivered scientific advice and diagnostic guidance. 2.13(d). The majority of NRLs delivered collaboration and research development. 2.13(e). The majority of NRLs delivered monitoring, alert and response.	NMFP NA = not available/not applicable, 0 = no, 1 = yes. **NOTE: ECDC will use the scores provided for each function to calculate the overall score.** NA = not available/not applicable, 0 = 1-2 functions, 1 = 3-4 functions, 2 = all 5 functions.
Indicator 2.14. NRL_accreditation NRLs accredit at least some of their diagnostic tests according to ISO 17025, ISO 15189 or equivalent national standard.	NMFP NA = not available/not applicable, 0 = no NRL accredited their tests, 1 = some NRLs, 2 = all NRLS.
Indicator 2.15. NRL_BSL3 NRLs have access to biocontainment facilities with biosafety authorisation for performing BSL 3 operations.	NMFP NA = not available/not applicable, 0 = no BSL3 facility available for NRLs, 1 = partial access for some BSL3 operations, 2 = full access for all BSL3 operations.
Target 2.2 Ref_diag_id Reference diagnostic confirmation and pathogen identification	
Indicator 2.21. Diag_ident_53diseases Case confirmation* with pathogen identification for EU surveillance was available within your country by primary and/or reference laboratory for the 53 communicable diseases and health issues. * according to the laboratory criteria described in the case definitions of the Community Network (Decision 2119/98/EC).	NMFP NA = not available/not applicable, 0 = <20 pathogens/issues, 1 = 20-35 pathogens/issues, 2 = >35 pathogens/issues.
Indicator 2.22. Legionella_0.1_cult Culture confirmation of Legionnaires' disease was performed for notified cases in accordance with EU case definition/ELDS-Net guidance.	ECDC NA = not available/not applicable, 0 = not reported, 1 = <10%, 2 = ≥10%.
Indicator 2.23. Pert_conf_0.1 Laboratory confirmation of pertussis (by culture or PCR) was performed for notified cases in accordance with EU case definition/EUPertLabNet guidance.	ECDC NA = not available/not applicable, 0 = no cases reported, 1 = <10%, 2 = ≥10%.
Indicator 2.24. Serogroup_STEC Serogrouping of Shiga toxin-producing/verotoxin-producing *Escherichia coli* (STEC/VTEC) isolates was performed in 2013 in accordance with EU case definition/ECDC FWD network guidance.	ECDC NA = not available/not applicable, 0 = <80%, 1 = 80-99%, 2 = 100%.
Indicator 2.25. Test_SARI_viral National guidelines and reference virological diagnostic testing were available for investigation of Severe Acute Respiratory Infection clusters in accordance with WHO guidance.	NMFP NA = not available/not applicable, 0 = not available at the national level, 1 = implemented without monitoring, 2 = implemented with monitoring.
Target 2.3 Molec_surveillance Molecular typing for surveillance	
Indicator 2.31. WGS_surveillance Whole genome sequencing (WGS) -based typing of human pathogens was used in national reference laboratories for routine surveillance.	NMFP NA = not available, 0 = no national plan in place, 1 = a plan in place/in progress for at least 1 human pathogen, 2 = WGS-based typing is used routinely for national surveillance - of at least 1 human pathogen.
Indicator 2.32. Salm_0.2_typing Total number of Salmonella isolates genotyped by pulsed-field gel electrophoresis (PFGE) or Multilocus VNTR Analysis (MLVA) or WGS method reported to TESSy divided by the total number of Salmonellosis cases reported to TESSy.	ECDC NA = not available, 0 = not reported to TESSy, 1 = <20%, 2 = ≥20%.
Indicator 2.33. MDR-TB_0.5_MIRU-VNTR Total number of multidrug-resistant (MDR)-*Mycobacterium tuberculosis* isolates genotyped by MIRU-VNTR method reported to TESSy divided by the total number cases reported to TESSy. Please comment if done at national level but not reported to TESSy.	ECDC NA = not available/not applicable, 0 = <20%, 1 = 20-50%, 2= > 50%.
Indicator 2.34. N_meningitidis_0.2_mol.typing Total number of invasive *Neisseria meningitidis* isolates typed by serogroup: MLST:porA:fetA method reported to TESSy divided by the total number of invasive cases reported to TESSy. Please comment if done at national level but not reported to TESSy.	ECDC NA = not available/not applicable, 0 = not reported to TESSy, 1 = <20%, 2 = ≥20%.
Indicator 2.35. HIV_0.5_ARVseq Total number of HIV isolates genotyped by ARV target sequence analysis reported to TESSy divided by the total number of new HIV cases reported to TESSy. Please comment if done at national level but not reported to TESSy.	NMFP NA = not available/not applicable, 0 = <20%, 1 = 20-50%, 2 = >50%.

Targets/Indicators	Source (NMFP/ECDC) and scoring options
Target 2.4 AMR_monitoring Antimicrobial drug resistance characterisation and monitoring	
Indicator 2.41. MRSA_charact_surv Identification of antimicrobial resistance mechanisms and/or genotyping was performed for methicillin-resistant *Staphylococcus aureus* (MRSA) isolates in accordance with EUCAST/*Staphylococcus aureus* reference laboratory network guidance.	NMFP NA = not available/not applicable, 0 = not established/in process of establishment, 1 = performed upon request from diagnostic laboratory, 2 = performed as part of structured surveys for monitoring purposes.
Indicator 2.42. Carbapenemase_id_surv Identification of type of carbapenemase was performed for carbapenemase producing Gram-negative bacilli isolates in accordance with EUCAST 2013 guidance.	NMFP NA = not available/not applicable, 0 = not established/in process of establishment, 1 = performed upon request from diagnostic laboratory, 2 = performed as part of structured surveys for monitoring purposes.
Indicator 2.43. ESBL_id_surv Identification of type of extended spectrum beta-lactamase was performed for ESBL-producing Gram negative bacilli isolates in accordance with EUCAST 2013 guidance.	NMFP NA = not available/not applicable, 0 = not established/in process of establishment, 1 = performed upon request from diagnostic laboratory, 2 = performed as part of structured surveys for monitoring purposes.
Indicator 2.44. Influenza_NA-inhibitors_AST Human influenza virus susceptibility monitoring to neuraminidase inhibitors by phenotypic/genotypic methods was performed (by national services or a service agreement with another country) for human viral samples in accordance with ERLI-Net guidance.	ECDC NA = not available/not applicable, 0 = method established but not used for weekly reporting, 1 = samples send for central testing to WHO CC, 2 = method established and weekly reporting to TESSy.
Indicator 2.45. AMR_animal_human_surv Cross-sector monitoring of antimicrobial resistance (AMR) in human and animal bacterial isolates of public health relevance was performed and reported annually based on antimicrobial susceptibility testing methodology calibrated to ISO and/or EUCAST methods.	NMFP NA = not available/not applicable, 0 = not established, 1 = occasional joint surveys, 2 = integrated annual reporting.

Dimension 3. Laboratory-based surveillance and epidemic response support - Surv_response_support

Targets/Indicators	Source (NMFP/ECDC) and scoring options
Target 3.1 Surveillance National surveillance networks	
Indicator 3.11. Lab_surv_networks Reference laboratories and/or public health bodies were collaborating with national networks of clinical laboratories contributing data on surveillance of communicable diseases.	NMFP NA = not available/not applicable, 0 = no national networks, 1 = networks for 1-5 diseases/AMR issues, 2 = networks for more than five diseases/AMR issues.
Indicator 3.12. Lab_date_reporting Surveillance networks of clinical laboratories reported microbiological data to a central national public health surveillance database. *LIMS = laboratory information and management system.	NMFP NA = not available/not applicable, 0 = no report OR only paper-based reporting, 1 = for at least one disease by online forms/email files, 2 = for at least one disease by machine to machine upload from a LIMS.
Indicator 3.13. Outbreak_detection Microbiology data from laboratory-based national surveillance systems were centrally analysed and reported to stakeholders for incidence trends and early warning of excess rates/clusters of epidemic prone disease above baseline rates for diseases under EU surveillance.	NMFP NA = not available/not applicable, 0 = not performed at national level, 1 = for at least one disease performed at least monthly, 2 = for at least one disease performed at least weekly.
Indicator 3.14. Sentinel_net_ARI National sentinel network of virology laboratories was operating for surveillance of acute respiratory viral infections.	NMFP NA = not available/not applicable, 0 = no ARI OR ILI sentinel laboratory network operational, 1 = only influenza, 2 = influenza AND other respiratory viruses.
Indicator 3.15. Chlamydia_surv National system for collecting and reporting surveillance data on *Chlamydia trachomatis* infection was in place AND reported laboratory-based information in accordance with the guidance for *Chlamydia* control in Europe.	NMFP NA = not available/not applicable, 0 = no reporting at national level, 1 = partial system, 2 = full system.
Target 3.2 EU_LabNet_participation Active participation in EU disease networks	
Indicator 3.21. ELDSNet_participation Country was an active participant in the European Legionnaires' Disease Surveillance Network (ELDS-Net) - participated in external quality assessments (EQA) reported to/coordinated by ECDC - participated in annual meeting.	ECDC NA = not available/not applicable, 0 = no, 1 = EQA OR annual meeting, 2 = EQA AND annual meeting
Indicator 3.22. ENIVDNet_participation Country was an active participant in the European Network for diagnostics of imported viral diseases (ENIVD-Net) - participated in annual meeting - updating laboratory capacity information.	ECDC NA = not available/not applicable, 0 = no, 1 = annual meeting OR updated capabilities, 2 = annual meeting AND updated capabilities.
Indicator 3.23. IBDLabNet_participation Country was actively participating in the European Invasive bacterial diseases Laboratory Network (IBD-LabNet) - participated in annual meeting - participated in workshops.	ECDC NA = not available/not applicable, 0 = no, 1 = annual meeting OR workshops, 2 = annual meetings AND workshops.
Indicator 3.24. ERLTBNet_participation Country was an active participant in European Reference Laboratory Network for TB (ERLTB-Net) - participated in annual meeting - completed list of capabilities in reference service table.	ECDC NA = not available/not applicable, 0 = no, 1 = annual meeting OR updated capabilities, 2 = annual meeting AND updated capabilities.
Indicator 3.25. EuroGASP_participation Country was an active participant in the European Gonococcal Antimicrobial Surveillance Programme (Euro-GASP) - participated in EQA and/or laboratory training - participated in data collection for *Neisseria gonorrhoea* antimicrobial susceptibility testing.	ECDC NA = not available/not applicable, 0 = no, 1 = EQA OR laboratory training, 2 = susceptibility testing.
Target 3.3 Outbreak_response National outbreak response support	
Indicator 3.31. NRL_roles_preparedness NRLs had defined roles and responsibilities described in the national preparedness plan for response to epidemic prone/high consequence pathogens.	NMFP NA = not available/not applicable, 0 = no, 1 = yes but without simulation exercises, 2 = yes with simulation exercises.

Indicator 3.32. NRL_role_outbreak Proportion of outbreaks investigated at the national level for which NRL personnel participated as a member of outbreak investigation team.	NMFP NA = not available/not applicable, 0 = no, 1 = <25% of outbreaks, 2 = ≥25% of outbreaks.
Indicator 3.33. NRL_24/7_response NRLs for epidemic prone/high consequence pathogens have a mandate and trained personnel available for assistance in outbreak teams at national level.	NMFP NA = not available/not applicable, 0 = no, 1 = working hours, 2 = 24/7 duty roster.
Indicator 3.34. Listeria_0.8_PFGEtyping Total number of *Listeria* isolates genotyped by pulsed-field gel electrophoresis (PFGE) out of total number of notified cases.	NMFP NA = not available/not applicable, 0 = not done, 1 =<80%, 2 = 80-100%.
Indicator 3.35. HAV_0.2_genotyping Total number of hepatitis A virus clinical samples genotyped by sequence analysis out of all hepatitis A cases.	NMFP NA = not available/not applicable, 0 = not done, 1 = <20%, 2 = ≥20%.
Target 3.4 Preparedness_response (Re)-emerging diseases laboratory preparedness and response support	
Indicator 3.41. Diag_cap_MERS-CoV Diagnostic capability for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) infection in accordance with WHO surveillance guidance.	NMFP NA = not available/not applicable, 0 = no, 1 = screening test only, 2 = screening AND confirmation/identification.
Indicator 3.42. Diag_cap_H7N9 Diagnostic capability for avian influenza A(H7N9) virus in accordance with ECDC/WHO surveillance guidance.	NMFP NA = not available/not applicable, 0 = no, 1 = screening test only, 2 = screening AND confirmation/identification (H AND N antigens).
Indicator 3.43. Diag_cap_Ebola Diagnostic capability (within country AND/OR through formal international agreement with other laboratories) for Ebola virus infection.	NMFP NA = not available/not applicable, 0 = no national capacity but agreement, 1 = molecular detection at BSL3 level, 2 = further characterisation at BSL4 level.
Indicator 3.44. Diag_cap_5rare One or more reference virology laboratories in your country have detection capability for the following five rare and/or imported viruses: Chikungunya/Dengue/Hantavirus/Tick borne encephalitis/West Nile fever.	ECDC NA = not available/not applicable, 0 = none, 1 = for at least 2 out of 5, 2 = for all five.
Indicator 3.45. Listeria_MT-OCP An operational contact point for molecular typing (MT-OCP) of *Listeria monocytogenes* is nominated for supporting molecular surveillance development and collaboration through the Epidemic Intelligence System – Food and Waterborne Diseases (EPIS-FWD) platform and has participated in Urgent Inquiries (UI) and/or Molecular Typing Cluster Investigations (MTCI).	ECDC NA = not available/not applicable, 0 = no MT-OCP for *Listeria monocytogenes* nominated, 1 = MT-OCP for *Listeria monocytogenes* nominated, 2 = MT-OCP for *Listeria monocytogenes* participates in UIs and/or MTCIs.

Annex 2. Policy rationale for the EULabCap targets of key capabilities/capacities

Target	Rationale for key capability/capacity
1.1. Provision and regulation of clinical microbiology services.	Provision of reliable, quality-assured, safe and fully accessible clinical diagnostic microbiology services is a prerequisite for adequate case ascertainment and surveillance/threat notification systems.
1.2 Diagnostic testing guidelines	Availability of national primary diagnostic and screening testing guidelines (e.g. who to test, how to test, and when to test) is a prerequisite to guarantee sufficient sensitivity for case ascertainment and surveillance/threat notification systems.
1.3 Diagnostic testing utilisation	Awareness of national testing practices provides a basis for monitoring sensitivity of case ascertainment and surveillance/notification systems.
1.4 Antimicrobial drug susceptibility testing	Implementation and monitoring of compliance with EU standards for antimicrobial drug susceptibility testing is a prerequisite for accurate and comparable EU surveillance of antimicrobial resistance, in accordance with EU strategy on AMR.
2.1 Provision and regulation of national reference microbiology services	Organisation, regulation, and funding of national reference laboratory infrastructure and core public health functions are key elements for informing surveillance and epidemic preparedness at national and EU levels, in accordance with NMFP consensus.
2.2 Reference diagnostic confirmation and pathogen identification	Availability of national reference laboratory testing capability and capacity and a robust sample referral and reporting system to the national authorities is a prerequisite for effective surveillance and epidemic preparedness at national and EU levels in accordance with NMFP consensus.
2.3 Molecular typing for surveillance	Development and implementation of harmonised methodologies to integrate molecular typing data into surveillance for priority diseases form a prerequisite for informing public health action based on EU-wide risk assessment of disease transmission.
2.4 Antimicrobial drug resistance characterisation and monitoring	Accurate characterisation and monitoring of antimicrobial resistance determinants across human and animal populations for national/EU-wide surveillance informs public health action to contain cross-border and cross-species transmission of multidrug-resistant pathogens.
3.1 National surveillance networks	National surveillance networks connecting clinical/public health laboratories for reporting diagnostic information to surveillance databases and linking microbiological and epidemiological information are essential for efficient communicable disease and drug resistance surveillance and early infectious threat detection.

Target	Rationale for key capability/capacity
3.2 Active participation in EU disease networks	Active participation and collaboration between experts in EU disease networks promotes exchange of best practice and capacity building which foster sufficient collective capacity in the EU for threat detection, investigation, disease surveillance and epidemic preparedness.
3.3 National outbreak response support	Preparation and involvement of the national reference laboratory capacities and staff in outbreak monitoring and response activities in collaboration with clinicians, epidemiologists, and microbiologists ensure the effective contribution of laboratory testing to support epidemic detection and control.
3.4 (Re)-emerging diseases laboratory preparedness and response support	Up-to-date diagnostic capability for rare and (re)-emerging diseases and effective channels for collaboration are critical for laboratory preparedness and the deployment of timely and reliable emergency response to national and cross-border events.

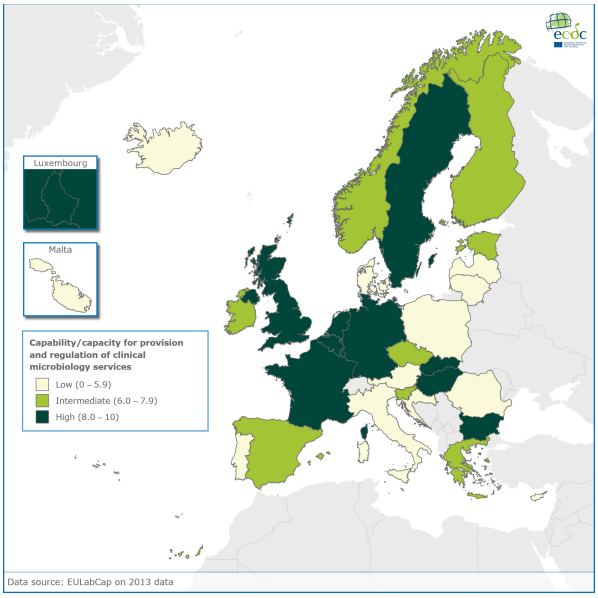
Annex 3. References to EU/WHO policy documents or international standards applied for the design and performance scoring of EULabCap indicators

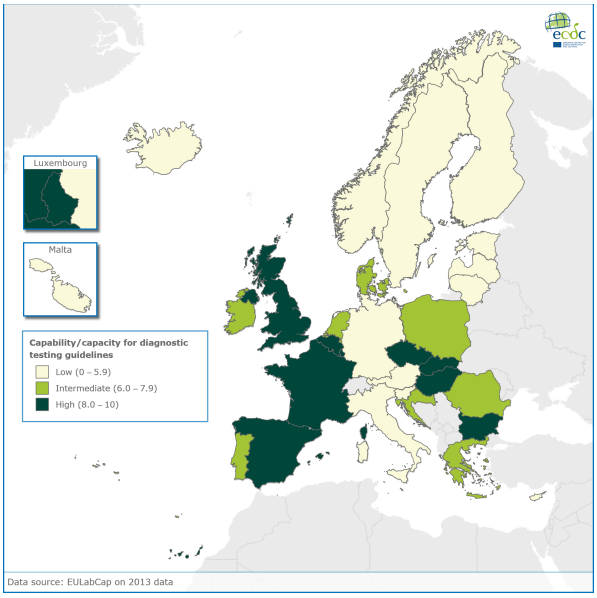
Indicator reference number	Reference document(s)	Hyperlink
1.15	WHO Tuberculosis laboratory biosafety manual	http://www.who.int/tb/publications/2012/tb_biosafety/en/
	European Union Standards for Tuberculosis Care	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3393116/pdf/erj-39-04-807.pdf
	Framework Action Plan to fight tuberculosis in the European Union	http://ecdc.europa.eu/en/publications/publications/0803_spr_tb_action_plan.pdf
1.22	United Nations General Assembly Special Sessions on HIV/AIDS - Guidelines on construction of core indicators	http://www.unaids.org/en/media/unaids/contentassets/dataimport/pub/manual/2009/jc1676_core_indicators_2009_en.pdf
	HIV testing: increasing uptake and effectiveness in the European Union	http://ecdc.europa.eu/en/publications/Publications/101129_GUI_HIV_testing.pdf
	Dublin declaration on Partnership to fight HIV/AIDS in Europe and Central Asia	http://www.unicef.org/ceecis/The_Dublin_Declaration.pdf
1.24	Risk assessment on the spread of carbapenemase-producing *Enterobacteriaceae* (CPE)	http://staging.ecdcdmz.europa.eu/en/publications/Publications/110913_Risk_assessment_resistant_CPE.pdf
1.25	Framework Action Plan to fight tuberculosis in the European Union	http://ecdc.europa.eu/en/publications/publications/0803_spr_tb_action_plan.pdf
1.31	Migrant health: Access to HIV prevention, treatment and care for migrant populations in EU/EEA countries	http://ecdc.europa.eu/en/publications/publications/0907_ter_migrant_health_hiv_access_to_treatment.pdf
1.32	Antimicrobial resistance surveillance in Europe	http://ecdc.europa.eu/en/publications/Publications/antimicrobial-resistance-surveillance-europe-2012.pdf
1.33	Underdiagnosis of *Clostridium difficile* across Europe: the European, multicentre, prospective, biannual, point-prevalence study of *Clostridium difficile* infection in hospitalised patients with diarrhoea (EUCLID)	http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(14)70991-0/abstract
	Clostridium difficile: Guidance on infection prevention and control	http://ecdc.europa.eu/en/healthtopics/Healthcare-associated_infections/guidance-infection-prevention-control/Pages/guidance-prevention-control-infections-CDI.aspx
1.34	Framework Action Plan to fight tuberculosis in the European Union	http://ecdc.europa.eu/en/publications/publications/0803_spr_tb_action_plan.pdf
1.35	Global update on HIV treatment 2013: Results, impact and opportunities; WHO in partnership with UNICEF and UNAIDS	http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/20130630_treatment_report_en.pdf
	Dublin declaration on Partnership to fight HIV/AIDS in Europe and Central Asia	http://www.unicef.org/ceecis/The_Dublin_Declaration.pdf
1.41	EUCAST - Interaction of EUCAST Steering Committee with the network of national antimicrobial susceptibility testing committees	http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/EUCAST_SOPs/EUCAST_SOP_5_0_Interaction_with_NACs_20130104.pdf
1.42	EUCAST - Breakpoint tables for interpretation of MICs and zone diameters	http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/Breakpoint_tables/Breakpoint_table_v_3.1.pdf
1.43	EUCAST - Breakpoint tables for interpretation of MICs and zone diameters	http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/Breakpoint_tables/Breakpoint_table_v_3.1.pdf
1.44	Framework Action Plan to fight tuberculosis in the European Union	http://ecdc.europa.eu/en/publications/publications/0803_spr_tb_action_plan.pdf
1.45	Strengthening antimicrobial surveillance - Expanding Euro-GASP	http://www.ecdc.europa.eu/en/healthtopics/gonorrhoea/response-plan/Pages/strengthening-antimicrobial-surveillance.aspx

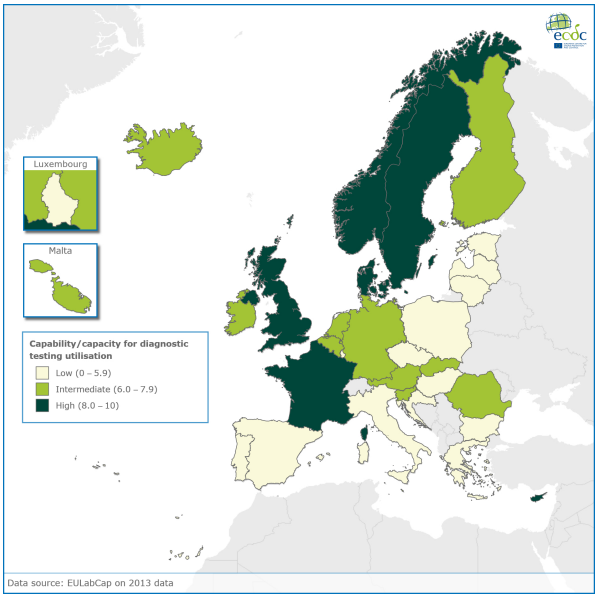
Indicator reference number	Reference document(s)	Hyperlink
	Response plan to control and manage the threat of multidrug-resistant gonorrhoea in Europe	http://www.ecdc.europa.eu/en/publications/Publications/1206-ECDC-MDR-gonorrhoea-response-plan.pdf
	Gonococcal antimicrobial susceptibility surveillance in Europe, 2011	http://www.ecdc.europa.eu/en/publications/publications/gonococcal-antimicrobial-susceptibility-surveillance-27-mar-2013.pdf
2.11	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
2.12	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
2.13	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
2.14	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
2.15	WHO laboratory biosafety manual	http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf?ua=1
2.21	Case definitions for reporting communicable disease to the Community Network	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:262:0001:0057:EN:PDF
2.22	European Legionnaires' Disease Surveillance Network (ELDSNet)	http://ecdc.europa.eu/en/publications/publications/1202-ted-eldsnet-operating-procedures.pdf
2.23	External quality assurance scheme on PCR for *Bordetella pertussis*, 2012	http://www.ecdc.europa.eu/en/publications/Publications/20120906-TER-EQA-pertusis.pdf
2.24	Diagnostic work-up of suspected STEC enteritis and HUS cases related to the ongoing outbreak of STEC O104:H4	http://ecdc.europa.eu/en/healthtopics/escherichia_coli/outbreaks/laboratory_resources/Pages/diagnostic_guidance.aspx
2.25	WHO SARS International Reference and Verification Laboratory Network: Policy and Procedures in the Inter-Epidemic Period	http://www.who.int/csr/resources/publications/en/SARSReferenceLab.pdf?ua=1
2.32	Molecular surveillance pilot - Evaluation report, 2014, Meeting minutes 38th Advisory Forum	http://www.ecdc.europa.eu/en/aboutus/organisation/af/Pages/Meeting_minutes.aspx
2.34	Resolution of a Meningococcal Disease Outbreak from Whole-Genome Sequence Data with Rapid Web-Based Analysis Methods	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3421817/pdf/zjm3046.pdf
2.35	WHO HIV Drug Resistance Surveillance Network	http://www.who.int/drugresistance/hivaids/en/HIVdrugnetwork.pdf
2.41	EUCAST guidelines for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance	http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/Resistance_mechanisms/EUCAST_detection_of_resistance_mechanisms_v1.0_20131211.pdf
2.42	EUCAST guidelines for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance	http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/Resistance_mechanisms/EUCAST_detection_of_resistance_mechanisms_v1.0_20131211.pdf
2.43	EUCAST guidelines for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance	http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/Resistance_mechanisms/EUCAST_detection_of_resistance_mechanisms_v1.0_20131211.pdf
2.44	ERLI-Net: Key tasks of the network	http://ecdc.europa.eu/en/activities/surveillance/eisn/laboratory_network/pages/key_tasks.aspx
2.45	EUCAST - Breakpoint tables for interpretation of MICs and zone diameters	http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/Breakpoint_tables/Breakpoint_table_v_3.1.pdf
3.11	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
3.13	Case definitions for reporting communicable disease to the Community Network	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:262:0001:0057:EN:PDF
3.15	*Chlamydia* control in Europe	http://www.ecdc.europa.eu/en/publications/publications/0906_gui_chlamydia_control_in_europe.pdf
3.21	ELDSNet	http://ecdc.europa.eu/en/activities/surveillance/eldsnet/pages/index.aspx
3.22	ENIVD-CLRN	http://www.ecdc.europa.eu/en/activities/diseaseprogrammes/emerging_and_vector_borne_diseases/pages/enivd.aspx
3.23	IBDLab-Net	http://www.ecdc.europa.eu/en/activities/surveillance/EU_IBD/Pages/index.aspx

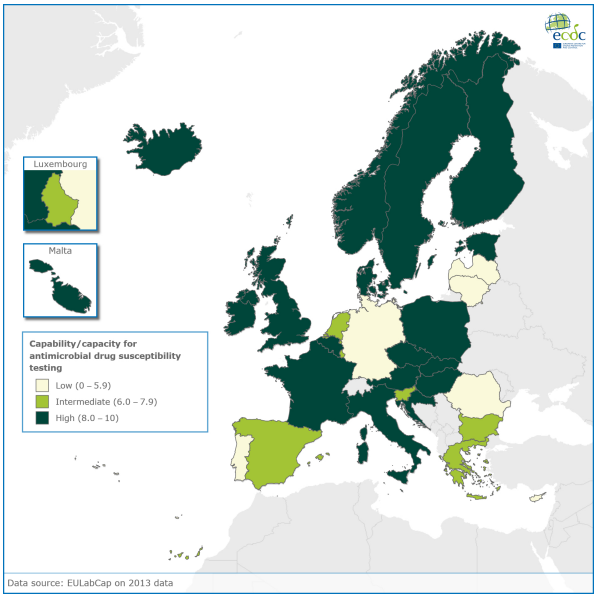
Indicator reference number	Reference document(s)	Hyperlink
3.24	ERLTB-Net	http://www.ecdc.europa.eu/en/press/news/Documents/100125_ERLN_TB_information_flyer.pdf
3.25	Euro-GASP	http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19995
3.31	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
3.32	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
3.33	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
3.41	WHO guidelines for investigation of cases of human infection with Middle East Respiratory Syndrome Coronavirus (MERS-CoV), July 2013	http://www.who.int/csr/disease/coronavirus_infections/MERS_CoV_investigation_guideline_Jul13.pdf?ua=1
	Severe respiratory disease associated with Middle East respiratory syndrome coronavirus (MERS-CoV)	http://www.ecdc.europa.eu/en/publications/Publications/Middle-East-respiratory-syndrome-coronavirus-Saudi%20Arabia-Qatar-Jordan-Germany-United-Kingdom.pdf
3.42	Laboratory preparedness in EU/EEA countries for detection of novel avian Influenza A (H7N9) virus, May 2013	http://www.eurosurveillance.org/images/dynamic/EE/V19N04/art20682.pdf
3.43	Algorithm for laboratory diagnosis of Ebola virus disease	http://ecdc.europa.eu/en/healthtopics/ebola_marburg_fevers/algorithm-evd-diagnosis/Pages/default.aspx
3.45	EPIS	http://www.ecdc.europa.eu/en/activities/epidemicintelligence/pages/epidemicintelligence_tools.aspx

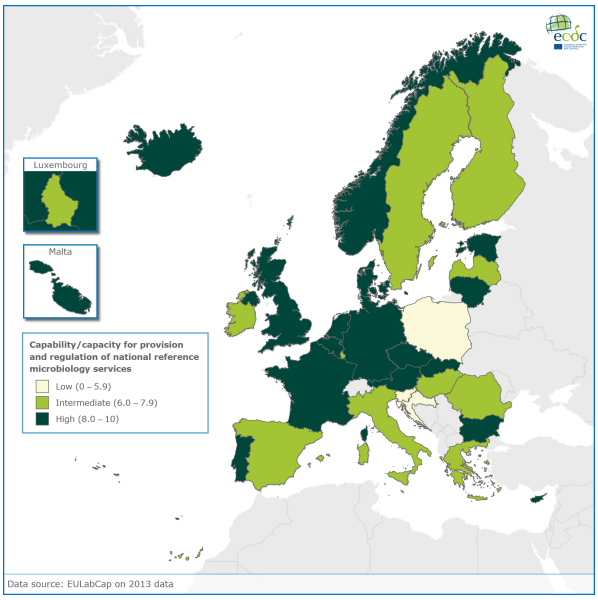
Annex 4. Maps showing geographical distribution of each target performance level by country based on three levels (low, intermediate and high)

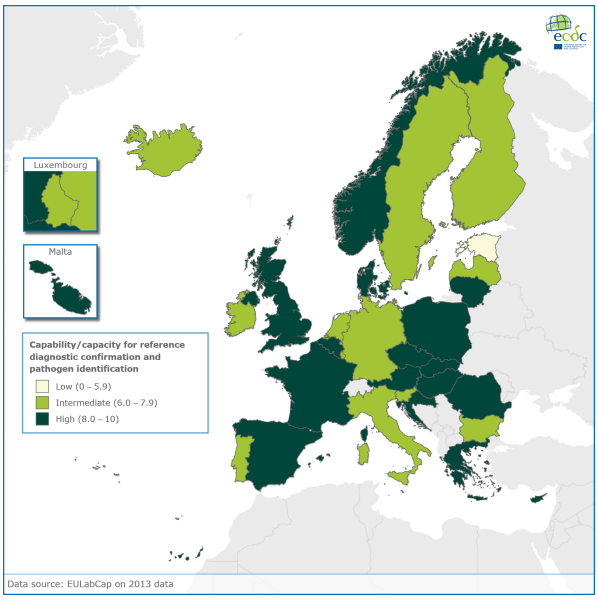


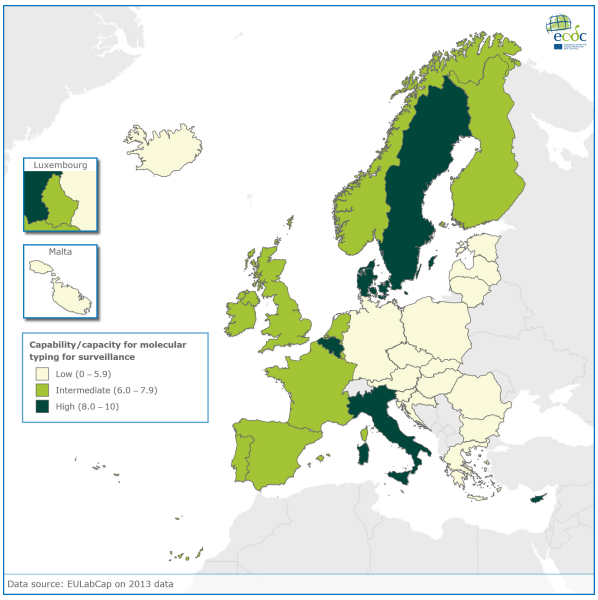


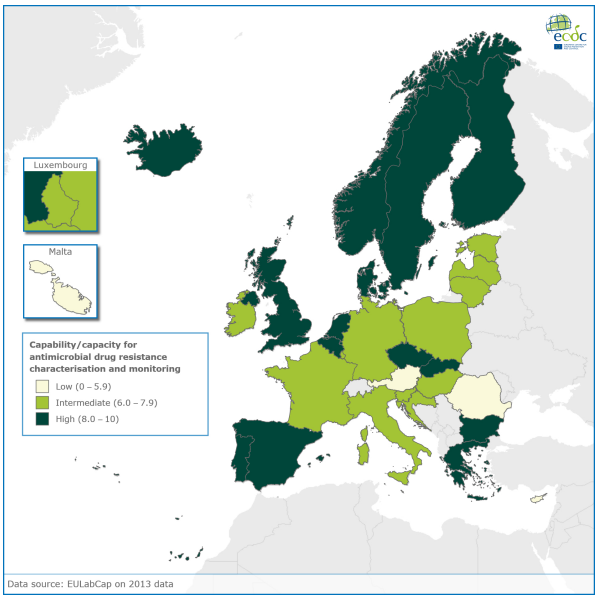


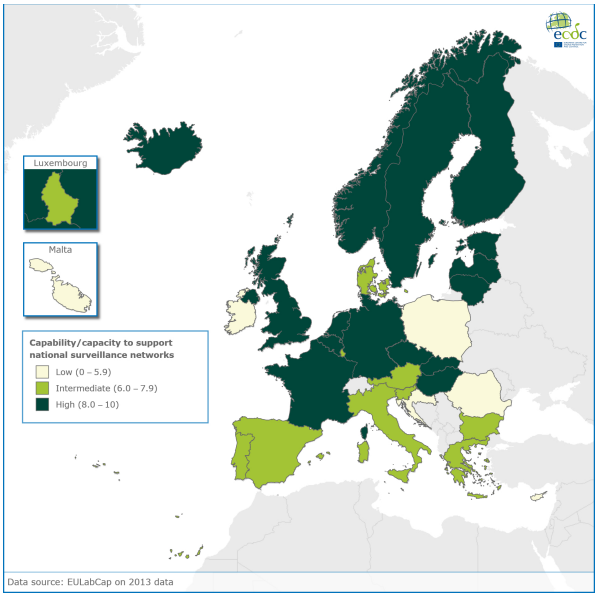


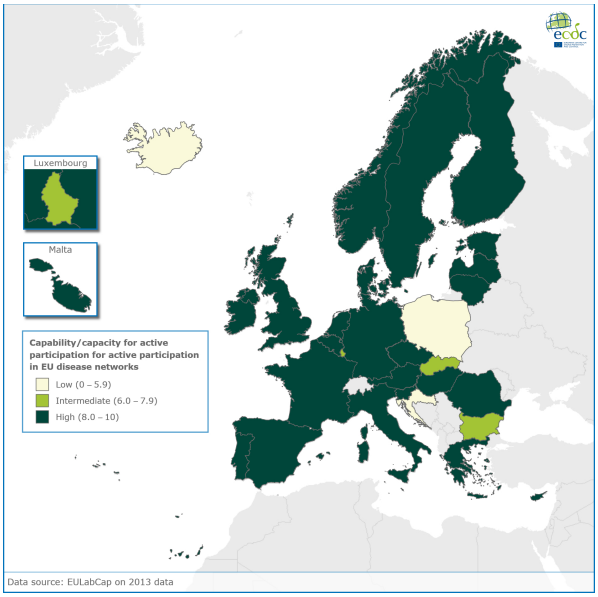

Luxembourg
Malta
Capability/capacity for provision and regulation of national reference microbiology services
Low (0 – 5.9)
Intermediate (6.0 – 7.9)
High (8.0 – 10)
Data source: EULabCap on 2013 data

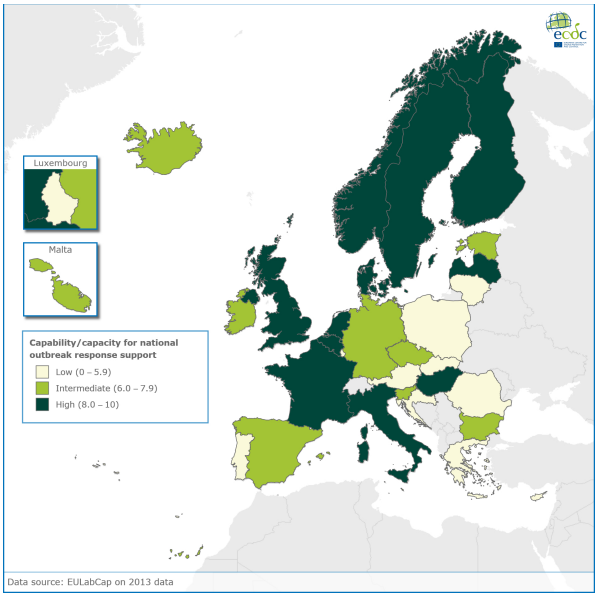

Luxembourg
Malta
Capability/capacity for reference diagnostic confirmation and pathogen identification
Low (0 – 5.9)
Intermediate (6.0 – 7.9)
High (8.0 – 10)
Data source: EULabCap on 2013 data

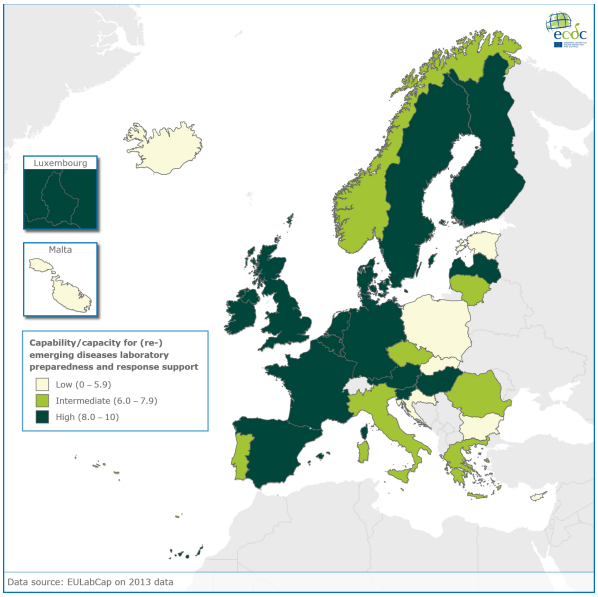

Luxembourg
Malta
Capability/capacity for molecular typing for surveillance
Low (0 – 5.9)
Intermediate (6.0 – 7.9)
High (8.0 – 10)
Data source: EULabCap on 2013 data


Luxembourg
Malta
Capability/capacity for antimicrobial drug resistance characterisation and monitoring
Low (0 – 5.9)
Intermediate (6.0 – 7.9)
High (8.0 – 10)
Data source: EULabCap on 2013 data


Luxembourg
Malta
Capability/capacity to support national surveillance networks
Low (0 – 5.9)
Intermediate (6.0 – 7.9)
High (8.0 – 10)
Data source: EULabCap on 2013 data


Luxembourg
Malta
Capability/capacity for active participation for active participation in EU disease networks
Low (0 – 5.9)
Intermediate (6.0 – 7.9)
High (8.0 – 10)
Data source: EULabCap on 2013 data


Luxembourg
Malta
Capability/capacity for national outbreak response support
Low (0 – 5.9)
Intermediate (6.0 – 7.9)
High (8.0 – 10)
Data source: EULabCap on 2013 data


Luxembourg
Malta
Capability/capacity for (re-) emerging diseases laboratory preparedness and response support
Low (0 – 5.9)
Intermediate (6.0 – 7.9)
High (8.0 – 10)
Data source: EULabCap on 2013 data

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