TECHNICAL REPORT

EU Laboratory Capability Monitoring System (EULabCap)

Report on 2021 survey of EU/EEA country capabilities and capacities

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This report of the European Centre for Disease Prevention and Control (ECDC) was prepared by Nina Lagerqvist, Jessica Beser and Daniel Palm (ECDC Surveillance Section).

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Abbreviations

AMR	Antimicrobial resistance
AST	Antimicrobial susceptibility testing
BSL	Biosafety level
CPE/CRE	Carbapenemase-producing/carbapenem-resistant Enterobacterales
EARS-Net	European Antimicrobial Resistance Surveillance Network
ECOVID-LabNet	European COVID-19 reference Laboratory Network
ELDSNet	European Legionnaires' disease Surveillance Network
EQA	External quality assessment
ERLTB-Net	European reference laboratory network for tuberculosis
ESBL	Extended spectrum beta-lactamase
EU/EEA	European Union/European Economic Area
EUCAST	European Committee on Antimicrobial Susceptibility Testing
EULabCap	EU Laboratory Capability Monitoring System
EUPert-LabNet	European Pertussis Laboratory Surveillance Network
EVD-LabNet	Emerging Viral Diseases-Expert Laboratory Network
HIV	Human immunodeficiency virus
IQR	Interquartile range
LGV	Lymphogranuloma venereum
MDR TB	Multidrug-resistant tuberculosis
MERS-CoV	Middle East respiratory syndrome coronavirus
MRSA	Methicillin-resistant Staphylococcus aureus
NMFP	National microbiology focal point
NAC	National antimicrobial susceptibility committee
NRL	National reference laboratory
PCR	Polymerase chain reaction
SARI	Severe acute respiratory infection
VTEC/STEC	Verotoxin- or Shiga toxin-producing Escherichia coli
TESSy	The European Surveillance System (ECDC)
DST	Drug susceptibility testing
WGS	Whole genome sequencing
WHO	World Health Organization

Glossary

Laboratory capability	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	Output services completed over a defined time period for each capability [2].
National microbiology focal points	Appointed representatives for public health microbiology in the EU/EEA Member States as part of the Competent Body Structure [3].
National reference laboratories	Public health microbiology laboratories with national responsibility and appropriate tools and skills to be able to support 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's contribution to the detection and diagnosis of infectious microorganisms, and the characterisation and surveillance of microorganisms that have the potential to affect populations [4,5].

Executive summary

Background

ECDC aims to foster and strengthen the public health microbiology system to provide timely and reliable information for infectious threat detection, the assessment of such threats, and their surveillance at the Member State and European Union levels, thereby ensuring the effective prevention and early control of infectious diseases. To ascertain how well this is delivered, ECDC developed, in close collaboration with national microbiology focal points (NMFPs) from all European Union/European Economic Area (EU/EEA) countries and the ECDC Advisory Forum, the EU Laboratory Capability Monitoring System (EULabCap). The biennial EULabCap survey assesses key public health microbiology service capabilities and capacities for EU surveillance and epidemic preparedness. The monitoring results help policy-makers at all levels identify possible areas for action and evaluate the functional impact of capacity-strengthening activities and health system reforms.

This sixth consecutive EULabCap report presents EU/EEA public health laboratory capabilities and capacities from data collected in 2021 and outlines the trend of survey results between 2013 and 2021.

Methods

The EULabCap monitoring tool combines 60 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 European and international technical standards. These indicators are grouped into 12 target areas distributed across three dimensions: primary diagnostic testing, national reference laboratory (NRL) services, and laboratory-based surveillance and epidemic response support. Each indicator can be scored at three levels: low, intermediate, or high capability/capacity. Aggregated target and dimension indices were calculated as the average of component indicator scores, all index values are displayed on a scale of 0–10. EULabCap index scores were graded qualitatively by three performance levels: low (index value range: 0 to 5.9), intermediate (6.0 to 7.9) and high level (8.0 to 10).

The 2021 EULabCap data collection took place from November 2022 to February 2023. A mixed method was used for data collection: ECDC retrieved information for 17 indicators from the European Surveillance System (TESSy) and EU disease network reports and the NMFPs used a questionnaire to collect information from their country for the remaining 43 indicators. Individual country profile reports and EU/EEA benchmarking results were shared with respective NMFP to inform the national stakeholders about key results.

Results

All EU/EEA countries except for one participated in the 2021 survey. Overall, data were reported for 98.4% of EULabCap indicators, with a completeness ratio of between 93 and 100% per country.

Based on changes in the mean EULabCap index score over the surveys conducted from 2013 and onwards, microbiology system performance showed continuous improvement in the participating EU/EEA countries, reaching an overall EULabCap index score of 7.9/10 in 2021. This represents a 14% increase in the EULabCap index score over the past six surveys.

At a country level, the EULabCap index score ranged from 5.6 to 9.3. Although capacity gaps between countries remained apparent in 2021, these disparities have been decreasing over time, with an inter-country index range reduced by one sixth over the 2013–2021 monitoring period.

In 2021, 17 countries reported data resulting in a high-performance level for their public health microbiology system (score 8.0 or above), 11 countries reported an intermediate level (score 6.0 to 7.9), and one country reported a low level (score below 6.0).

The EU/EEA performance level for 10 out of 12 EULabCap target areas was high in 2021, with the following areas of practice showing particular strong performance across EU/EEA:

- Use of standardised antimicrobial susceptibility testing methods;
- Inter-laboratory collaboration within national and EU surveillance networks;
- Active participation in EU disease-specific laboratory network activities.

Progress was noted in several important technical areas in 2021:

- The regulation and support to NRL services gradually strengthened over the survey years, as indicated by an index score of 9.0 in 2021 (compared to 8.5 in 2018 and 8.0 in 2016).

- EU/EEA countries continued to modernise their operations for molecular typing for surveillance with an index score of 9.0 for use of whole genome sequencing (WGS) for routine surveillance and outbreak investigations at national level (compared to 8.7 in 2018 and 5.5 in 2016).
- The collaboration and contribution of reference laboratories to national surveillance networks is progressing across countries with an index score of 9.0 in 2021 (compared to 8.0 in 2018 and 2016).

As in previous surveys, the main target area with opportunity for improvement across the EU/EEA was an inadequate usage or lack of monitoring of diagnostic testing in many countries, with an EU/EEA index score of 6.0 in 2021.

In 2021, 21 of 29 countries showed intermediate to high capacity and capability levels for at least 10 of 12 EULabCap target areas, indicating that a majority of EU/EEA countries have levels of laboratory capability and capacity across targets that should allow for effective public health surveillance and disease threat response.

Conclusions

The continued high response rate to the EULabCap survey highlights the commitment of EU/EEA countries to the assessments of EU/EEA- and country-level public health microbiology system capabilities and capacities. The result of the sixth EULabCap survey confirms that the EU/EEA, with an overall EULabCap index of 7.9/10, increased the capabilities and capacities of the public health microbiology systems to detect, characterise, and respond to infectious disease threats.

While EU/EEA public health microbiology services assessed in the EULabCap 2021 survey met most of the key requirements for communicable disease surveillance and response, results indicated that not all countries had balanced laboratory capabilities and capacities across activity areas. However, the reduced disparities in the EULabCap index between countries compared to earlier surveys indicate technical convergence and progression towards more modern methodologies for detection, surveillance and characterisation of pathogens and antimicrobial resistance and digital interoperability between clinical laboratory and public health information systems for disease surveillance and alert at national levels. Steady increases in country EULabCap indices over the eight-year monitoring period (2013-2021) suggest that identified public health microbiology shortcomings are being addressed and that EU/EEA countries progress towards equitable balance of laboratory capacities and capabilities.

The COVID-19 pandemic put tremendous stress on the EU/EEA public health microbiology system. The updated regulations on serious cross-border threats to health in the EU and amended ECDC mandate put new and increased requirements on Member States and ECDC for effective surveillance and outbreak preparedness. In the light of this, it is likely that the EULabCap survey needs to be modified to accurately capture indicators/requirements relevant for future EU/EEA public health microbiology system.

1 Background

Laboratory detection and the characterisation of infectious agents causing human disease provide essential information for clinical management, public health surveillance, and outbreak alert and response. Sufficient national laboratory capacity for infectious health threat detection and control is required to fulfil the obligations set forth in both EU [6,7] and other international health security legislation [8]. Such capacity relies on the seamless integration of microbiology testing services with public health surveillance systems and on adequate laboratory and information technology infrastructure, skilled professionals, and operational resources.

Public health microbiology systems comprise three intertwined components:

- Clinical laboratories performing primary diagnostic testing, antimicrobial drug susceptibility testing and screening, with a focus on patient management and preventive services.
- Public health laboratories serving as reference functions at a national or subnational level, providing specialist diagnostics and characterisation of biological agents.
- Laboratory networks performing harmonisation of methods, quality assessment, and contributing to public health surveillance and alert systems, nationally and internationally.

ECDC's Founding Regulation (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 characterisation of infectious agents which may threaten public health [9]. In this context, monitoring the laboratory capabilities in the EU/EEA is important to identify best practices and detect potential vulnerabilities. The challenges health systems encountered when facing the COVID-19 pandemic in early 2020 has further underscored the need for robust laboratory systems [10]. Europe has strong assets in this regard and benefits from a legacy of successful cross-border collaboration among public health and infectious disease experts spanning decades. Microbiologists and epidemiologists have for years participated in dedicated European surveillance networks and other professional initiatives to improve laboratory test methods, promote testing quality, and build capacity. Laboratory mapping exercises in the EU, conducted by ECDC [11] and the European Commission [12], have revealed significant differences 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 innovation and harmonisation and the establishment of specialist technical capacity at the supranational level for rare diseases [11,12].

The ECDC public health microbiology strategies aim to strengthen the capability and capacity of the EU public health microbiology system to provide timely and reliable information that underpins infectious threat detection, assessment, and surveillance at the EU level to ensure the effective prevention and control of infectious diseases [4]. ECDC, in close collaboration with its national microbiology focal points (NMFP) and the ECDC Advisory Forum, developed and piloted in 2013 a system (EULabCap) for monitoring key public health microbiology capabilities and capacity for EU surveillance and epidemic preparedness. After piloting the data collection and indicator scoring instrument, the first survey was launched in 2014 (on 2013 system outputs) [13] and repeated, with minor adjustments for subsequent surveys, on an annual then biennial basis until the 2018 survey [13-17]. The COVID-19 pandemic had a far-reaching impact on health systems and service disruptions were reported across all health areas [18]. Because of the evident burden on public health microbiology services during this time, the EULabCap survey was postponed one year to 2022 with collection of data from 2021 system outputs.

During data collection for this survey, a new regulation on serious cross-border threats to health and an amended mandate for ECDC were adopted [6,7]. These legislative acts put emphasis on capacity-building and monitoring across public health functions, including preparedness, laboratories, and surveillance. In order to properly collect relevant indicators, the EULabCap monitoring system will be reviewed before the launch of the next survey.

The NMFPs are the main contributors to the survey data collection and verification. They are also responsible for disseminating the EULabCap country profile report to their national competent bodies, in accordance with their terms of reference [3]. At the national level, detailed benchmarking information provided as EULabCap country profiles identify structural and operational gaps as well as presenting options to strengthen the system where relevant. Stakeholder feedback on EULabCap indicates that the country reports have been useful for advising national authorities on capacity-strengthening actions in many countries [19].

This report presents the results of the sixth EULabCap survey and outline the trend of survey results between 2013 and 2021.

2 Methods

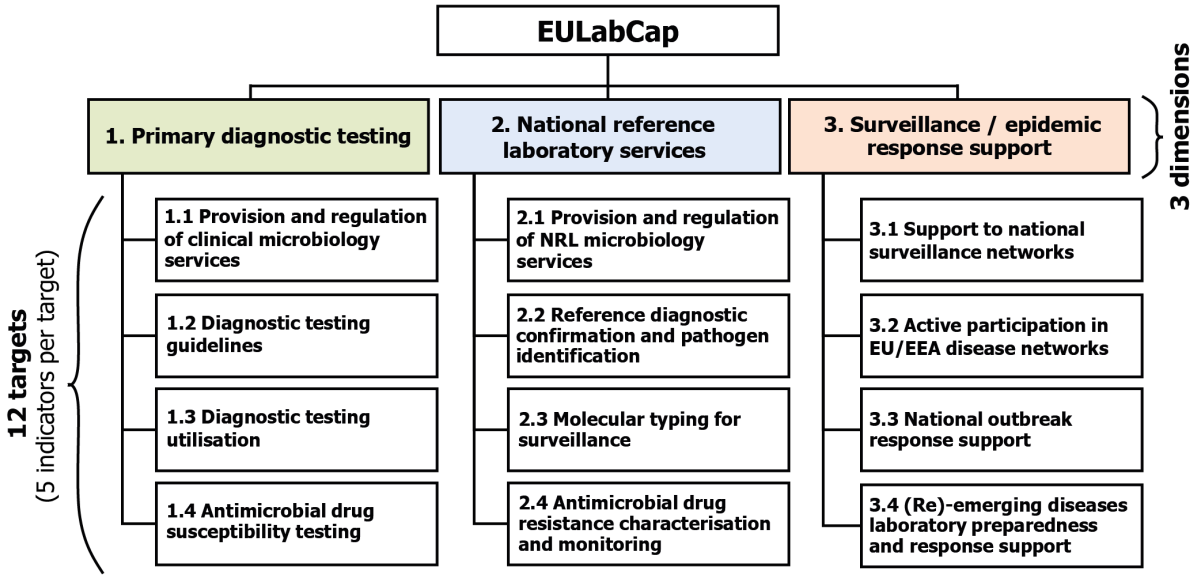
2.1 Survey population

The data call for the 2021 EULabCap survey on the laboratory capabilities and capacities of 27 EU Member States and two EEA countries was launched in November 2022. Liechtenstein was not participating in the survey due to outsourcing arrangements with laboratories in Switzerland, which is not a member of the EU/EEA.

2.2 EULabCap survey tool

The EULabCap monitoring tool is composed of 60 performance indicators (Annex 1), grouped into 12 targets, which are equally distributed across the following three public health microbiology system dimensions: primary diagnostic testing, NRL services, and laboratory-based surveillance and epidemic response support (Figure 1).

Figure 1. Structural overview of the EULabCap monitoring system, by dimensions and targets



The EULabCap indicators are of a composite nature in terms of which system elements are measured (structure or process) and how they measure these elements (functional capability or capacity). The EULabCap survey consists of 28 structure and 32 process indicators, which are divided into 44 indicators on laboratory capability and 16 indicators on capacity (Table 1). The policy rationale for the design of the 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 remaining assess EU surveillance and alert system contributions (Annex 2).

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

Dimension	Number of indicators by element		Number of indicators by function	
Primary diagnostic testing	12	8	11	9
National reference laboratory services	6	14	16	4
Surveillance/epidemic response support	10	10	17	3
Total	28	32	44	16

2.3 Scoring system

Each indicator was scored at three levels: low (0; 'no or limited capability/capacity'), intermediate (1; 'partial capability/capacity', e.g. below the EU target or partial compliance) or high (2; 'complete capability/capacity', e.g. EU target reached or high compliance) (Annex 1). Indicators for which data were not available or that were not applicable (NA) to the country were not scored.

2.4 Indicator modifications

In preparation of the sixth EULabCap survey, performance indicators were reviewed for clarity and applicability by ECDC disease experts and were modified to conform to current EU standard practice, address emerging issues or to improve robustness. The following changes to the EULabCap indicators were implemented in the 2021 survey:

- **Indicator 1.31** – 'Accessible diagnostic testing for HIV infection and/or tuberculosis was available to undocumented migrants in your country' – was replaced with 'Laboratory diagnosis of lymphogranuloma venereum (LGV) infections (i.e., laboratory confirmation of LGV by specific molecular testing)'.
- **Indicators 3.21, 3.23 and 3.25** – 'Active participation in EU disease networks' – were updated to include EU disease-specific networks with annual meeting and/or external quality assessment (EQA) activities in 2021.
- **Indicator 1.42** – 'Percentage of clinical laboratories using EUCAST clinical breakpoints' – the score was adjusted to align with the data range presented by EUCAST [20].
- **Indicator 3.43** – 'Diagnostic and characterisation capability of Ebola virus' – the scoring criteria was changed to include a formal agreement with a laboratory in another country for reference testing.
- **Indicator 2.21** – 'Case confirmation with pathogen identification for EU surveillance' – was updated to conform with the list of 57 communicable diseases and special health issues under EU surveillance [21].

2.5 Data collection and validation

An Excel-based tool, first developed and piloted in close collaboration with the NMFPs, was used for data collection. Data collection and validation were performed between November 2022 and February 2023 using a mixed data collection method. Information was retrieved for the 60 EULabCap indicators as follows: data on 17 indicators were compiled by ECDC from datasets accessible in TESSy and EU disease network reports, and data on 43 indicators were collected by the NMFPs through a questionnaire. The NMFPs were asked to review and verify the data and correct indicator score calculations.

2.6 Data analysis

Data completeness was calculated as a percentage of reported data for each indicator across the EU/EEA per target, dimension and for each individual country. Aggregated performance indices were calculated for each target and dimension as the average of component indicator scores per country; all index values were displayed on a scale of 0–10. To indicate the level of public health microbiology system capability and capacity, EULabCap index scores were graded qualitatively by three performance levels: low level (index value range 0 to 5.9), intermediate level (6.0 to 7.9) and high level (8.0 to 10).

Descriptive data analyses of indices and indicator scores across EU/EEA countries were performed, including measures of central tendency (mean and median) and dispersion (range and interquartile range (IQR)). Means (range) were used for comparing EU/EEA scores by indicator. Medians (IQR) were used for comparing inter-country distribution of EULabCap indices by targets and dimensions over time.

2.7 Data reporting

In addition to the present report, ECDC shared 29 individual EULabCap country profile reports in confidence with the respective NMFPs for their perusal and dissemination to national public health stakeholders. Each country report consisted of a customised one-page executive summary presenting the country index scores, as well as the areas of good national microbiology system capacity/capability and those in need of attention. Country results were visualised with a radar graph displaying the country's index scores and EU/EEA IQR per EULabCap target area, the indicator score distribution, and the country's mean score trend per target between 2013 and 2021.

The EULabCap country capability/capacity levels for 2021 are also published as EU/EEA maps online, illustrating the overall and per system target EULabCap index scores at country level.

3 Results

3.1 Response rate and data completeness

All EU/EEA countries except for Lichtenstein (N=29) participated in the 2021 survey. Data were reported for 98.4% of indicators with a range of complete data reporting of 93–100% by country, 97-99% by dimension, 94–100% by target, and 79-100% by indicator. Three indicators (2.23, 2.24 and 2.35) showed 10% or more missing data in 2021 as compared with four indicators in 2018 and six indicators in 2016 (Annex 3).

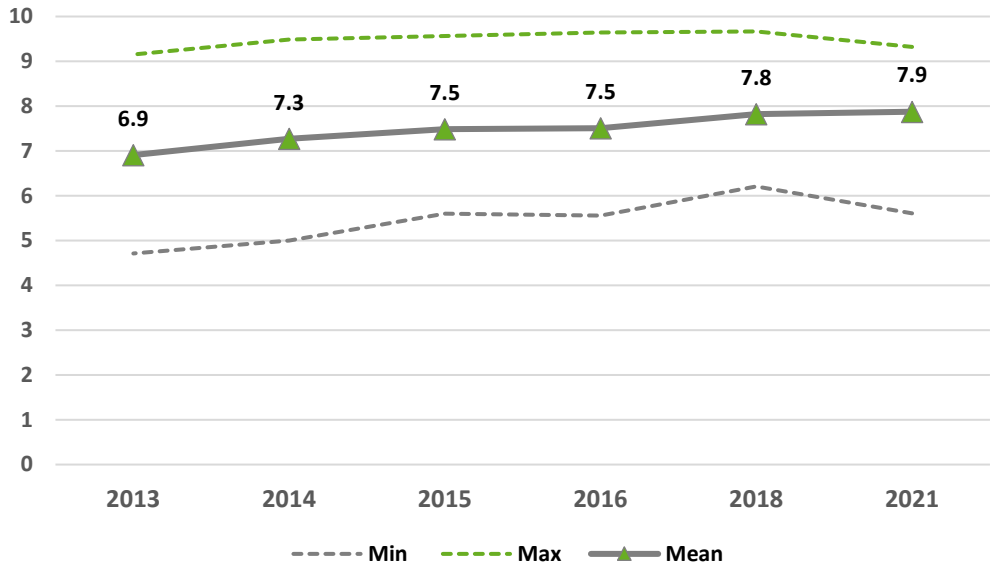
3.2 Laboratory capability and capacity at EU/EEA level

3.2.1 EU/EEA performance level

Based on changes in the mean EULabCap index, the EU/EEA public health microbiology system performance showed continuous improvement over the survey years. The mean EULabCap index reached 7.9/10 for the EU/EEA in 2021, which is a 14% increase since the survey on 2013 system outputs (Figure 2).

Capacity gaps were still apparent in 2021, and national EULabCap index scores ranged from 5.6 to 9.3. However, these disparities have been decreasing over time, with an inter-country index range reduced by one sixth in 2021 as compared to 2013 (Figure 2).

Figure 2. EULabCap index score by survey year, 2013-2021

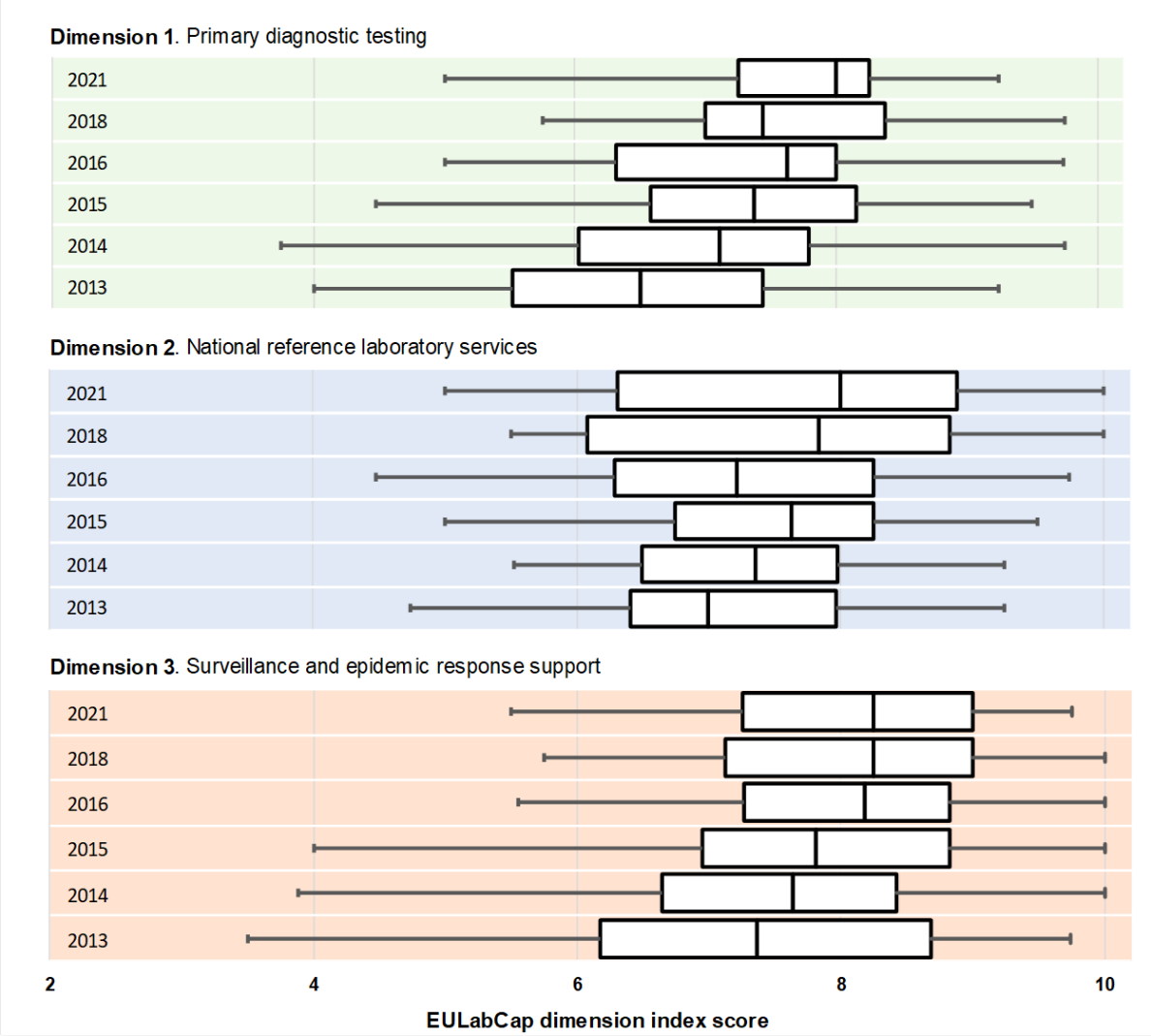


N=29 countries in 2015 and 2021 and N=30 countries in 2013, 2014, 2016 and 2018.

3.2.2 Performance scores by system dimensions

Between 2013 and 2021, the EULabCap indices increased across all three microbiology system dimensions (Figure 3). During the same time period, country disparities within the primary diagnostic testing and surveillance and epidemic response dimensions gradually narrowed. The largest increase over the survey years was noted for the primary diagnostic testing dimension, from 6.5 (IQR 5.5-7.4) in 2013 to 8.0 (IQR 7.3-8.3) in 2021. Since 2018, the median EULabCap index scores for NRL services and laboratory-based surveillance and epidemic response support have stabilized at an intermediate-to-high level. In 2021, these two dimensions showed median index scores of 8.0 (IQR 6.3–8.9) and 8.3 (IQR 7.3–9.0), respectively (Figure 3).

Figure 3. Box plot (median, interquartile range and range) of EULabCap index scores by system dimension and survey year, 2013–2021

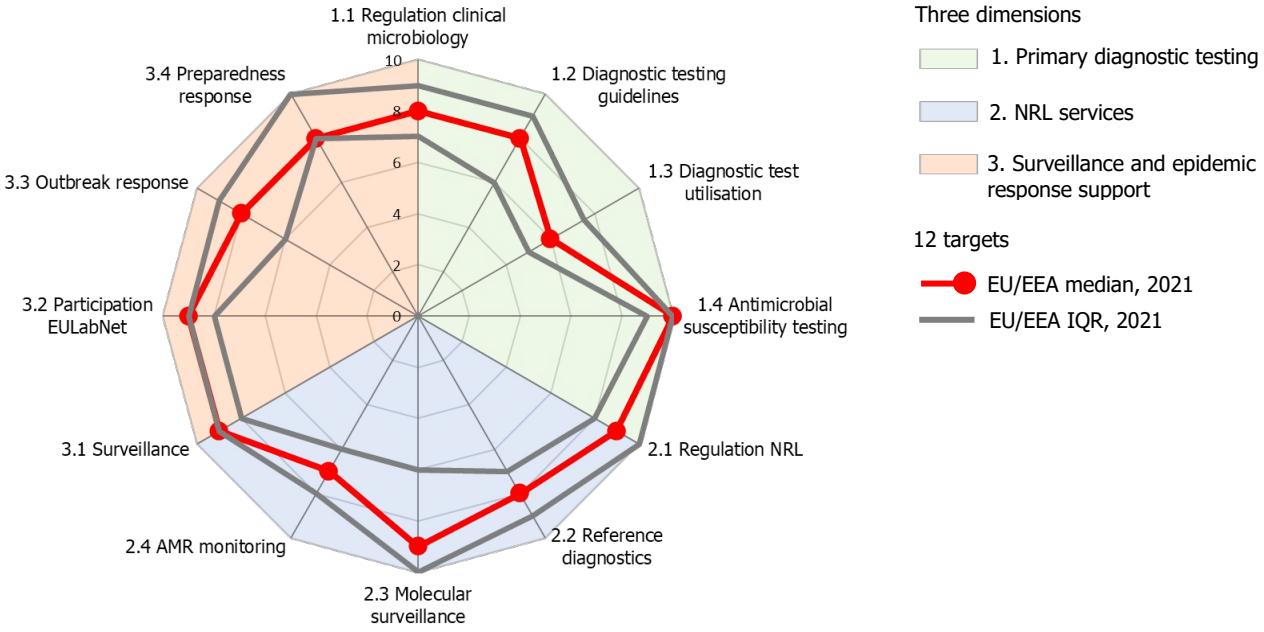


N=29 countries in 2015 and 2021, N=30 countries in 2013, 2014, 2016 and 2018.

3.2.3 Performance scores by system targets

While 10 of 12 EULabCap system targets showed a high level of performance as indicated by a median EU/EEA index score of eight or above, two targets – diagnostic test utilisation and antimicrobial resistance (AMR) monitoring – showed intermediate performance levels (index scores 6 and 7, respectively) (Figure 4).

Figure 4. EULabCap index scores by target in 2021 (N=29 countries)



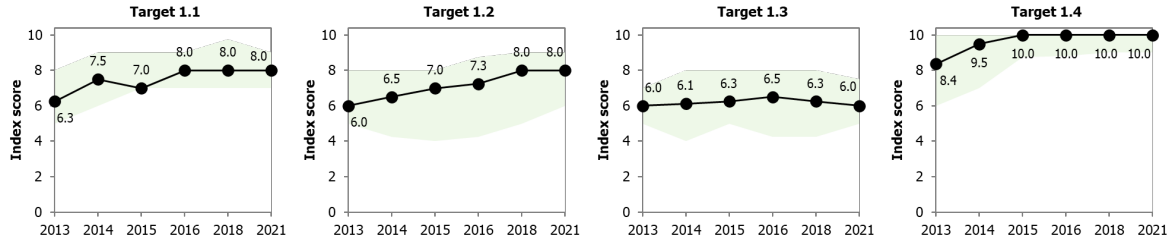
3.2.4 Temporal trends for performance scores by target

To monitor the evolution of the EULabCap system performance level per target and explore the heterogeneity between EU/EEA countries, Figures 5 to 7 present the median EULabCap indices per target and by system dimension from 2013 to 2021. The number of participating countries has varied during the survey years; 29 countries contributed data in 2015 and 2021, and 30 countries in 2013, 2014, 2016 and 2018.

Primary diagnostic testing

Median index scores and IQR for targets in the dimension of primary diagnostic testing are shown in Figure 5. Between 2013 and 2021, the index scores showed either a stable performance level or an upward trend for all primary diagnostic testing targets (Figure 5).

Figure 5. Median and interquartile range of EULabCap target scores in primary diagnostic testing, 2013–2021



EU/EEA median index scores and interquartile range (in green) by survey year for targets within the primary diagnostic testing dimension. N=29 countries in 2015 and 2021, N=30 countries in 2013, 2014, 2016 and 2018.

Target 1.1. Provision and regulation of clinical microbiology services. The score for this target fluctuated during the first EULabCap survey years, however, the results from the past three surveys show a stable overall performance level. In 2021, 19 countries showed a high level of performance (score 8.0 or above) for this target.

Target 1.2. Diagnostic testing guidelines. This target shows a continuous positive trend in performance over time, however, the wide IQR still reflects disparity between countries regarding the availability of national

diagnostic and screening guidelines. In 2021, 15 countries reported a high level of capacity/capability (score 8.0 or above) for this target.

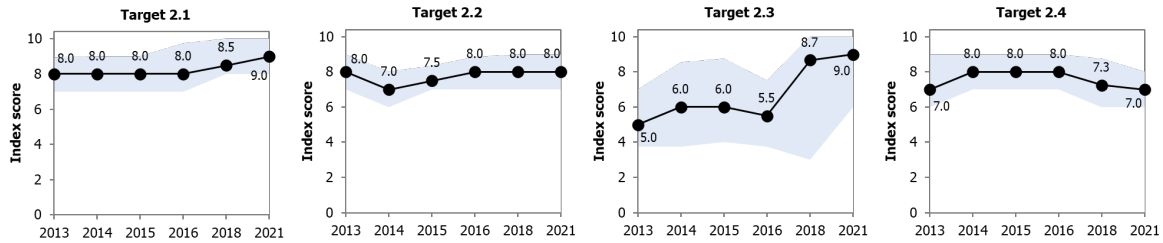
Target 1.3. Diagnostic testing utilisation. This is a weaker target within the primary diagnostic testing dimension, with no improvement over time. Only seven countries had a high level of capacity/capability (score 8.0 or above) for this target in 2021. This target comprises some quantitative indicators on diagnostic and confirmational testing of hospital acquired infections and the overall score of this target can therefore be influenced by changes in disease incidence of indicator pathogens, hospitalisations, or testing due to COVID-19.

Target 1.4. Antimicrobial drug susceptibility testing. EU/EEA countries have shown a rapid and continuous improvement in the use of standard methods and breakpoints over the years, and the score has been consistently high since 2015 for this target. In 2021, 27 countries showed a high level of capacity/capability (score 8.0 or above) for standardized antimicrobial drug susceptibility testing.

National reference laboratory services

Median index scores and IQR for targets in the dimension of NRL services are shown in Figure 6. Between 2013 and 2021, three of four targets in this dimension showed either a stable performance level or an increasing trend. The performance level for one target – characterisation and monitoring of AMR (target 2.4) – has shown a decreasing trend since 2016 and are now at the same level as when the first survey was performed (Figure 6).

Figure 6. Median and interquartile range of EULabCap target scores for national reference laboratory services, 2013–2021



EU/EEA median index scores and interquartile range (in blue) by survey year for targets within the national reference laboratory service dimension. N=29 countries in 2015 and 2021, N=30 countries in 2013, 2014, 2016 and 2018

Target 2.1. Provision and regulation of NRL microbiology services. With regard to organisation, regulation, and funding of NRL infrastructure and delivery of public health functions, high performance levels were found across survey years. In comparison to 2018, there was a further increase in 2021 and 26 countries showed a high level of capacity/capability (score 8.0 or above) for this target.

Target 2.2. Reference diagnostic confirmation and pathogen identification. Good performance results were sustained across countries with an EU/EEA median score of 8.0 and consistently small variations between country EULabCap index scores in recent surveys for this target. In 2021, 17 countries showed a high-performance level, 11 countries an intermediate level and one country reported a low level of capacity/capability for this target area.

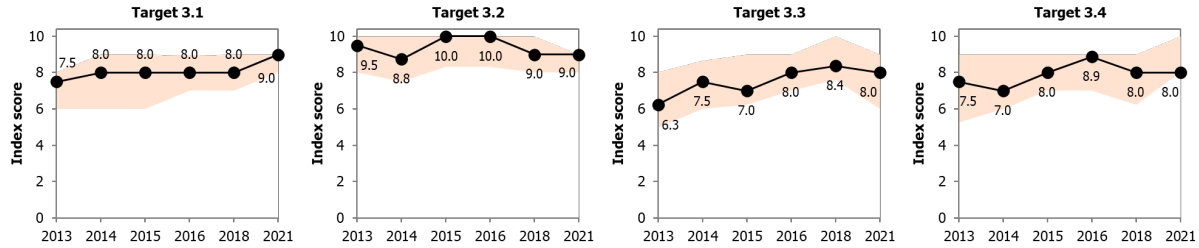
Target 2.3. Molecular typing for surveillance. With a rapidly shifting state of art, indicators for this operational target were adapted several times over the years. The latest adjustments were performed in preparation for the 2018 data collection, when three indicators were updated to score the use of WGS-based typing in line with the ECDC strategic plan for the integration of genomic typing into EU level surveillance [22]. Therefore, numerical scores are not directly comparable between surveys as those indicators have changed from quantitative output capacity in 2013-2016 to qualitative capability criteria in 2018. In 2021, 17 countries showed an overall high level of capability for WGS-based typing. There is however a persistent heterogeneity among EU/EEA countries indicated by a wide dispersion between country index scores.

Target 2.4. Antimicrobial drug resistance characterisation and monitoring. A decrease in performance level have been observed in 2018 and 2021 for this target. In 2021, 11 countries showed a high level of capacity/capability (score 8.0 or above) to accurately characterise and monitor AMR determinants for national/EU-wide surveillance. Decreasing performance in 2021 as compared to 2016 and 2018 was associated with limited monitoring and reporting of drug-resistant influenza for EU surveillance. Similar to target 1.3, this target partly consists of quantitative indicators and can for this reason be affected by changes in disease prevalence and shifting prioritisations and/or relocation of resources as a response to the COVID-19 pandemic.

Laboratory-based surveillance and epidemic response support

Median scores and IQR by target in the dimension of laboratory-based surveillance and epidemic response support are shown in Figure 7. Between 2013 and 2021, targets in this dimension showed either a relatively stable performance level or an increasing trend (Figure 7).

Figure 7. Median and interquartile range of EULabCap target scores for laboratory-based surveillance and epidemic response support, 2013–2021



EU/EEA median index scores and interquartile range (in orange) by survey year for targets within the laboratory-based surveillance and epidemic response support dimension. N=29 countries in 2015 and 2021, N=30 countries in 2013, 2014, 2016 and 2018.

Target 3.1. Support to national surveillance networks. The median index score for this target increased from intermediate in 2013 to high in 2021 while gaps between countries became smaller as represented by a decreasing dispersion. In 2021, 22 countries showed a high-performance level for this target as compared to 19 countries in 2018.

Target 3.2. Active participation in EU/EEA disease networks. High performance levels of NRL participation in EU network activities were seen over survey years. In 2021, laboratories from all 29 countries were actively participating in EU/EEA networks activities, either in the form of EQAs, annual meetings, or both. Over the years, this target suffered from business discontinuity in ECDC-supported laboratory networks, resulting in indicators that could not be scored in 2014-2016 and in 2021. For this survey, the EU network indicators were adopted to include network activities executed during the COVID-19 pandemic.

Target 3.3. National outbreak response support. The contribution of reference laboratories to outbreak detection and investigation has been progressing steadily across countries, with a rise in the median score from 6.3 in 2013 to 8.4 in 2018. In 2021, a slight decrease was observed resulting in a median score of 8.0 for this target with 18 countries showing a high-performance level (score of 8.0 or above), six countries an intermediate level (score 6.0 to 7.9) and five countries showing a low performance level (score below 6) for this public health function.

Target 3.4. (Re-)emerging disease laboratory preparedness and response support. Over the years, the diagnostic capability for rare and (re-)emerging diseases improved in the EU/EEA as indicated by decreasing country disparities. In 2021, a high level of performance (score 8.0 or above) was recorded for 22 countries, resulting in a median index score of 8.0 for this target.

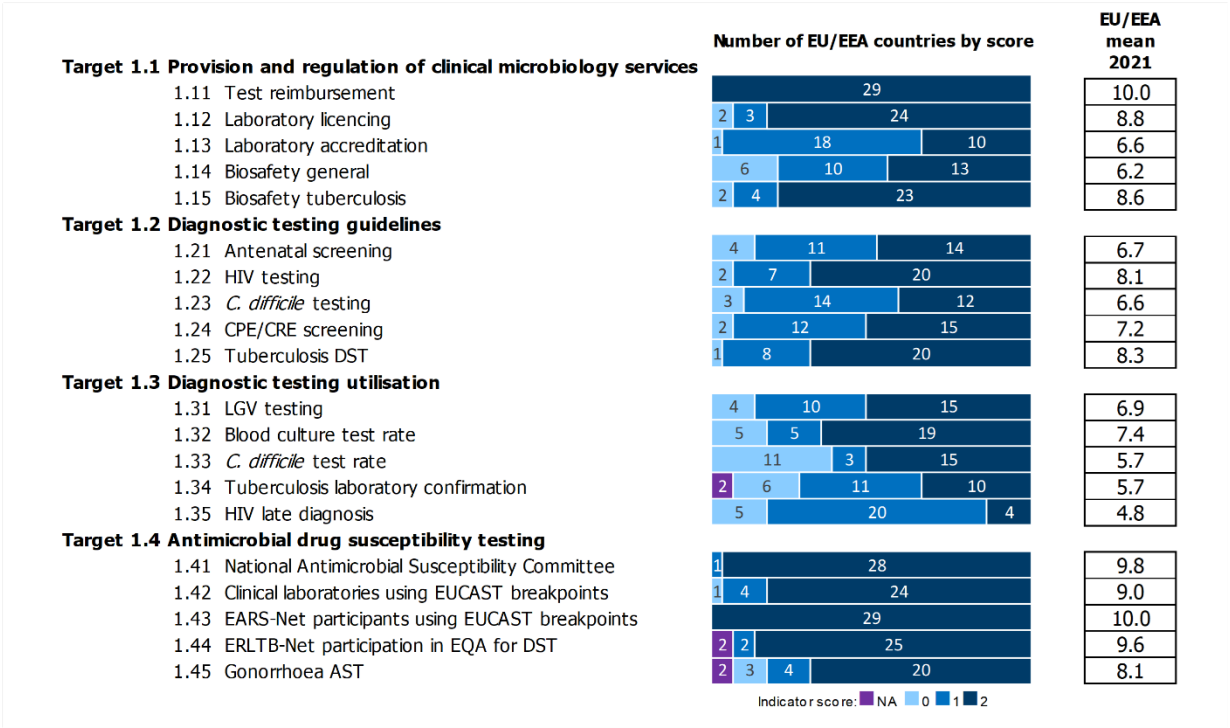
3.2.5 Distribution of indicator scores

Figures 8 to 10 present a detailed analysis of the distribution of country scores and the EU/EEA mean by indicator within each system dimension (primary diagnostic testing, NRL services, and laboratory-based surveillance and epidemic response support) in 2021.

Primary diagnostic testing

Figure 8 shows the distribution of country scores in 2021 for the 20 indicators on primary diagnostic testing and the EU/EEA mean scores per indicator. Several indicators within this EULabCap dimension scored low across the EU/EEA, in particular indicators in the diagnostic testing utilisation target.

Figure 8. Distribution of primary diagnostic testing EULabCap indicator scores by country, 2021



In 2021, all countries publicly funded or reimbursed clinical microbiology tests. Clinical microbiology laboratories were required to obtain a licencing authorisation from health authorities in most countries.

National guidelines that were monitored for compliance in clinical practice were available in many countries, but some still lacked national guidelines for several of the indicator diseases in 2021.

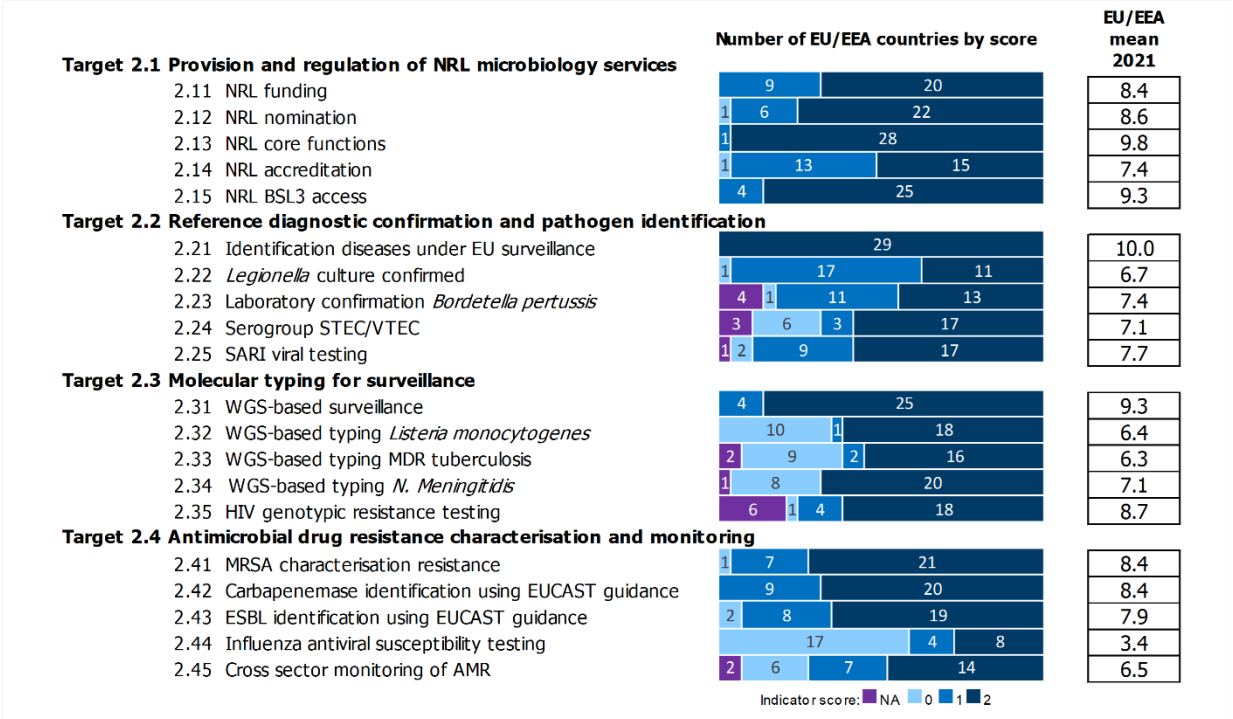
The newly introduced indicator on capability for laboratory diagnostics for LGV infections showed that a majority of EU/EEA countries had specific molecular testing available either at selected/reference laboratories or widely distributed on national level. Gaps remained for access to diagnostic and drug susceptibly testing. For instance, close to one third of the countries did not reach the target of 80% of culture-confirmed pulmonary tuberculosis cases in 2021.

The capacity and capability for antimicrobial susceptibility testing (AST) was maintained at a high level in most EU/EEA countries. Standardisation of AST continued to advance, with European Committee on Antimicrobial Susceptibility Testing (EUCAST) breakpoints being used for interpretive reporting of antibacterial drug susceptibility testing results in more than 90% of clinical laboratories in 24 countries.

National reference laboratory services

Figure 9 shows the distribution of national scores in 2021 for the 20 indicators on NRL services, and the EU/EEA mean scores for these indicators. With few exceptions, indicators on provision and regulation of national reference services and capabilities for reference diagnostic confirmation received an intermediate or high score (1 or 2, respectively). In contrast, several countries reported limited molecular typing capabilities for one or more of the human pathogens surveyed (Figure 9).

Figure 9. Distribution of national reference laboratory services EULabCap indicator scores, 2021



A small increasing trend for the EU/EEA mean was seen for most indicators on the provision and regulation of NRL services in 2021 compared to 2018 [17]. In 2021, NRLs were officially nominated and received either full or partial funding to deliver their public health functions in most EU/EEA countries. A majority of countries reported that the NRLs had full access to biosafety level 3 (BSL3) facilities.

All countries reported reference diagnostic capabilities for case confirmation of at least 36 (range between 43 and 57) of the 57 communicable diseases under EU surveillance as per the EU case definitions updated in 2018 (Annex 4) [21]. Diagnostic capability for 32 of 57 diseases were available in all 29 countries in 2021, compared to 30 diseases in 2018. For some rare diseases (e.g. rabies, Creutzfeldt-Jacob disease, and smallpox) specialised testing facilities, materials, and expertise are required, and bilateral agreements with laboratories in other countries were established for some of the countries with no domestic capability for diagnostic confirmation of such diseases.

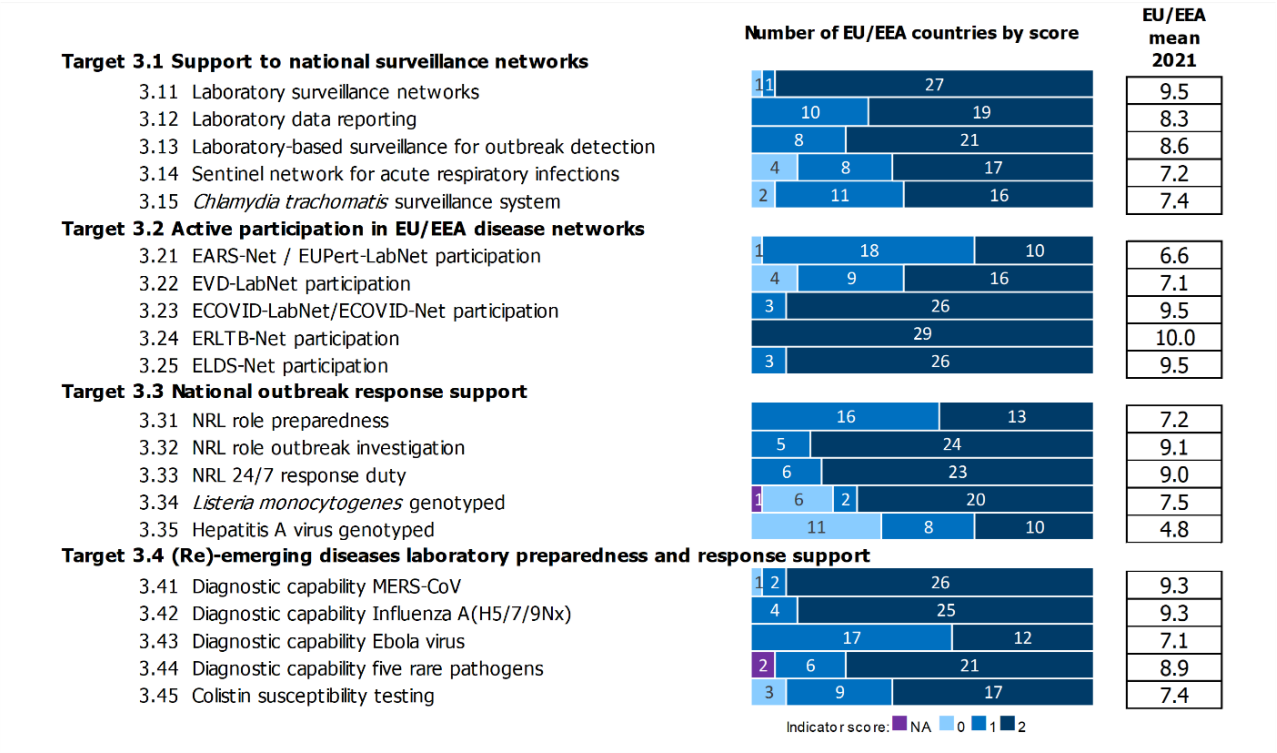
Technical capacity and the use of advanced methods by NRLs progressed further as evident by the major progress seen with practice shift from molecular to genomic surveillance. Between 2016 and 2021 the use of WGS-based typing for routine national surveillance of at least one human pathogen extended from 15 to 25 countries. In 2021, WGS-based typing was used in 14 countries for surveillance and/or outbreak investigation of all three indicator pathogens: *Listeria monocytogenes*, MDR tuberculosis and *N. Meningitidis*.

Regarding AMR characterisation and monitoring, EU/EEA mean indicator scores decreased for all but one indicator (cross sector monitoring of AMR) in 2021 in comparison to indicators scores in 2018. In particular, the capacity indicator for EU AMR surveillance of influenza virus showed uneven performance across countries and decreased from a mean EU/EEA indicator score of 6.3 in 2018 to 3.4 in 2021. However, the decreased performance level for this specific indicator could be explained by lower influenza activity in 2021 compared to previous surveys and is not solely a reflection of reduced capacity of laboratories to perform and report results of influenza AST [23,24]. The quantitative indicator for ECDC-reported susceptibility data on *Salmonella enterica* and *Campylobacter jejuni/C. coli* in accordance with EU cross-sectoral harmonised methodology was fully complied within 14 countries in 2021 as compared to 11 countries in 2018.

Laboratory-based surveillance and epidemic response support

Figure 10 shows the distribution of national scores for the 20 indicators on laboratory-based surveillance and epidemic preparedness and response support with EU/EEA mean score per indicator in 2021. With few exceptions, these indicators showed intermediate or high levels of capability/capacity. For some indicators, the performance continued to progress across countries while the performance level for others decreased as compared with the previous surveys.

Figure 10. Distribution of laboratory-based surveillance and response support EULabCap indicator scores, 2021



In this survey, as in previous years, nearly all countries received top performance scores for the operation of national laboratory surveillance networks for six or more diseases or AMR issues.

An increase in the EU/EEA mean score compared to the survey in 2018 was observed for the indicator on laboratory data reporting, from 7.2 in 2018 to 8.3 in 2021, and close to two thirds of the countries now indicated that they had automated electronic system for reporting clinical microbiology data to national surveillance databases.

Continued high participation in EU disease-specific laboratory network activities were seen in 2021, with EU/EEA mean indicator scores ranging from 6.6 to 10.0 depending on network.

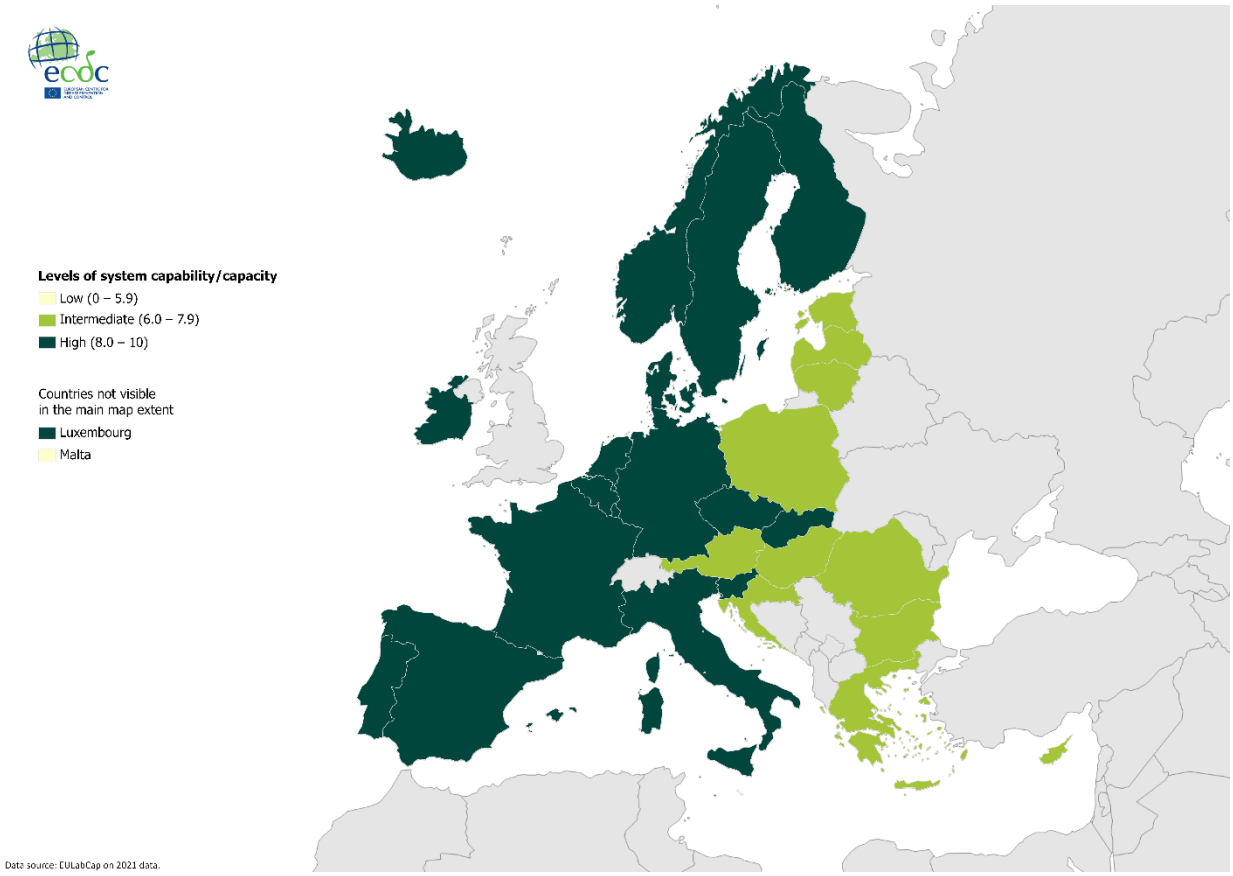
NRL response support duty teams from all countries had defined roles and responsibilities in national preparedness plans for health treats due to epidemic prone or high-consequence pathogens. These were tested by conducting simulation exercises in 13 countries in 2021. All countries involved NRL experts in outbreak investigations at the national level, and in 24 countries they contributed to the investigation of over 25% of the outbreaks, while a majority reported having trained personnel available in 24/7 duty rosters for assistance in outbreak teams at the national level for epidemic-prone/high-consequence pathogens.

Regarding diagnostic capability for (re)-emerging diseases, a vast majority of countries reported that they had the capability for diagnostic testing for indicator pathogens and either perform confirmation/reference testing at national level or via outsourcing arrangements with laboratories in other countries.

3.3 Laboratory capability and capacity at country level

Figure 11 shows the mapping of system capability and capacity performance level (low, intermediate, or high) by country in the EU/EEA in 2021. The country EULabCap index showed a variation between EU/EEA countries yet the gap has been narrowing over the years (Annex 5).

Figure 1. Level of public health microbiology system capability/capacity in 29 EU/EEA countries by EULabCap index, 2021



Overall, 17 countries reported a high level for public health laboratory capacity and capability (index score 8.0 or above), 11 countries reported and intermediate level (6.0 to 7.9) and one country a low EULabCap performance level (score below 6.0) in 2021 (Figure 11).

Over the survey years 2013 to 2021, 16 of 29 countries upgraded their EULabCap index from low (score below 6.0) to intermediate (6.0 to 7.9) in five countries, from low to high level (8.0 or above) in one country and from intermediate to high level in 10 countries (Annex 5). Between 2018 and 2021, five countries progressed to a higher level of national public health microbiology system capability and capacity, one country decreased in level, and the other countries remained at the same level (Annex 5).

As for the country EULabCap performance index scores, target index scores varied between countries. The country performance level for each target is available in a map format (Annex 6). Country-specific radar graphs display the geometric profile of target index scores for each EU/EEA country (2018 and 2021) visualising the structural imbalance in the performance across targets in several countries (Annex 7).

4 Discussion

4.1 Monitoring process

The EULabCap is a collaborative initiative to measure and monitor the capabilities and capacities of EU/EEA microbiology laboratories underpinning effective communicable disease surveillance and epidemic preparedness. The indicator framework jointly developed for this purpose by expert consensus, with its common terminology and taxonomy of public health microbiology services, was essential to its success. The sustained response rate and completeness of data illustrate the continued commitment of national experts to contribute to a robust and transparent European monitoring process.

The EULabCap survey methodology has limitations. Firstly, some indicators vary with respect to country relevance and country-specific system characteristics. For example, some capacity indicators on laboratory-confirmed cases may not apply to smaller countries due to the nature of the disease and low or no case numbers in the country and the assessment of laboratory capability and capacity is likely more accurate for countries with centralised services compared to countries with decentralised services.

Secondly, around two thirds of the indicators are based on self-reporting, and are therefore prone to a degree of subjective interpretation by the national experts who collect the information. External validation of capabilities, for example through EQAs or simulation exercises, can contribute to the mitigation of this limitation [25,26].

Thirdly, indicator data access was not universal, and some NMFPs were unable to collect data for all indicators leaving room for variation in data accuracy and representativeness between countries. This can be related to the lack of an effective data collection tool, a lack of designated NRLs for specific diseases, outsourcing of some of the reference services to other countries, and NMFP time constraints.

Fourthly, quantitative indicators on diagnostic or reference testing capacity should be interpreted with caution, especially in the context of the COVID-19 pandemic. The pandemic had significant impact on the public health laboratory system in many countries, resulting in relocation of resources and shifting priorities [10] combined with low disease incidence in 2021 of surveyed diseases in some EU/EEA countries [27] have an apparent effect on these EULabCap system indicators.

Finally, a few indicators/score criteria have been modified over the survey years. These revisions have ensured that indicators and scoring criteria are in line with new standards of practice and the evolving epidemiological context but also hamper the survey-to-survey comparability of these indicators.

4.2 EU/EEA public health microbiology capabilities and capacities

The result of the sixth EULabCap survey confirms that the collective capability and capacity to detect, characterise and respond to infectious disease threats in EU/EEA steadily increases. The observed increase in the EULabCap index score over the survey years – from 6.9 in 2013 to 7.9 in 2021 – likely reflects genuine improvements of to the public health microbiology systems in the Member States and that identified shortcomings are continuously being addressed.

Over the years, the primary diagnostic testing dimension has consistently scored lower than the other two EULabCap dimensions, reflecting gaps in clinical laboratory service provision and regulations. The performance score for this dimension has however increased and in 2021, reached the same level as that of the NRL services dimension. Several of these improvements were guided by the implementation of harmonised protocols for laboratory-based surveillance and national guidelines for diagnostic testing, technology transfer, and quality assurance activities carried out by EU laboratory networks [28].

All EU/EEA countries declared having access to the laboratory diagnostics required to meet obligations for EU surveillance of specific diseases. There were a handful of rare diseases requiring specialised containment facilities, materials and/or practical expertise for which countries rely on third party arrangements. Most EU/EEA countries also reported extended capabilities for the detection and characterisation of emerging and/or imported pathogens, such as novel types of avian influenza viruses, Middle East respiratory syndrome coronavirus (MERS-CoV), and Ebola virus. This observation is consistent with the results of investigations regarding laboratory preparedness in Europe, including those conducted with the support of ECDC and the EU Health Programme [28,29]. A rapid survey performed in response to the COVID-19 emergency also demonstrated the reactivity across EU/EEA countries to develop, validate and deploy SARS-CoV-2 specific real-time PCR assays for diagnostic confirmation only weeks after discovery of the virus [30]. However, even with rapidly developed assays, many countries later encountered difficulties in scaling up the diagnostic capacity to meet the large-scale diagnostic needs, a shortcoming that was not captured by the EULabCap monitoring tool [31]. Therefore, a lesson learned from this is to consider adding

national capacity indicators for scaling up pandemic diagnostic testing for future EULabCap monitoring surveys or introduce such indicators in the planned assessment tool on preparedness, specifically mentioned in the serious cross-border threats to health regulation [6].

Success in confronting the AMR long-term threat to global health depends on availability to adequate laboratory tests and guidelines. It is reassuring that the capacity for harmonised antimicrobial drug susceptibility testing has been steadily improving in Europe along the lines of the standards set by EUCAST. In 2021, national antimicrobial susceptibility committees (NACs) were established in nearly all Member States to sustain this testing guidance. Clinical laboratories are using EUCAST breakpoints for the interpretation of AST results, enabling robust EU surveillance data reporting on AMR trends to European Antimicrobial Resistance Surveillance Network (EARS-Net), in accordance with the EU case definitions. These achievements are in line with the EU and global-policy focus on combating AMR and a testimony to quality improvement of clinical laboratory practice across Europe [32,33].

A key development identified by the EULabCap results is the integration of WGS in enhanced surveillance of communicable diseases and AMR [34,35]. In 2021, 25 EU/EEA countries reported using WGS in national routine surveillance of at least one human pathogens, as compared to 15 countries in 2016. This dramatic shift in practice is consistent with the ECDC Expert Opinion and will contribute to the possibilities to successfully implement the EU-wide plans for WGS enhanced surveillance [22,36]. The regulation on serious cross-border threats specifies that molecular pathogen data shall be collected if needed for detection or investigation of serious cross-border threats [6]. For the two indicator pathogens, *Neisseria meningitidis* and MDR tuberculosis, a majority of countries (20 and 16 countries, respectively) are using WGS-based typing for both routine national surveillance and outbreak investigations. To further strengthening the capability and capacity for genomic surveillance at regional, national and EU/EEA level, ECDC in collaboration with the European Commission initiated an infrastructure support programme in 2021 [37]. A continuation of this support program has also been launched by DG-HERA and is part of the EU4Health 2022 Annual Work Programme [38].

Regarding laboratory-based surveillance and epidemic response support, the EU/EEA index score increased in 2016 to reach and stabilize on a high level in the two subsequent surveys. The majority of countries scored high on indicators of national laboratory-based surveillance in 2021. Most countries have national networks collaborating to collect data on surveillance for at least six diseases or AMR issues and a majority of countries upload data for surveillance for at least one disease directly from a laboratory information management system. Cluster detection capability is also high even if not all countries perform a weekly analysis to enable early warning. Implementing the automated reporting of laboratory data is a critical step to real-time laboratory-based surveillance.

Participation rate in EU disease-specific laboratory networks has been at a high level since the first EULabCap survey in 2013. This illustrates the continuous and high level of collaboration between laboratory scientists in different countries in the EU/EEA and the success of the networking approach EU has taken for the public health microbiology system as a whole. The COVID-19 pandemic emphasized the immense value of sharing experiences between countries and the importance of support activities to strengthen capacities and ensure the comparability of data. To further support and strengthen the public health microbiology system in the EU/EEA, the European Commission have outlined the plans to fund and integrate European Reference Laboratories (EURLs) into the public health microbiology system [6]. These EURLs will continue and extend the support ECDC has provided to the laboratory networks up to date.

While public health microbiology services in the EU/EEA meet most key requirements for communicable disease surveillance and response, not all Member States showed fully balanced laboratory capabilities and capacities. However, the reduced disparities in the EULabCap index between countries over the survey years indicate technical convergence and progression towards more modern methodologies for detection, surveillance and characterisation of pathogens and antimicrobial resistance and digital interoperability between clinical laboratory and public health information systems for disease surveillance and alert at national levels. Steady increases in country EULabCap indices over the eight-year monitoring period (2013-2021) suggest that identified public health microbiology shortcomings are continuously being addressed and that EU/EEA countries progress towards equitable balance of laboratory capacities and capabilities.

The new regulations that have been adopted for the EU public health area put strong emphasis on capacity-building and monitoring across public health functions, including preparedness, laboratories, and surveillance. This supports the continuation and further development of the EULabCap tool for the assessment of EU/EEA public health laboratory capabilities and capacities.

4.3 Conclusions and potential implications

The results of the sixth EULabCap survey confirmed that the EU/EEA is steadily building stronger capabilities and capacities for laboratory diagnostics and characterisation of infectious agents. Inequalities in laboratory capabilities between countries still exist but these are decreasing.

Strengths of the EU/EEA public health microbiology system were largely consistent across surveys. High performance assets include quality diagnostics, harmonised antimicrobial drug susceptibility testing, quality and responsive NRL services, collaboration between laboratories and surveillance networks, and deployment of advanced WGS methods for pathogen characterisation.

The new regulations adopted for the public health system in the EU/EEA will introduce new requirements, tasks, and expectations. As part of these changes, EU reference laboratories will play a crucial role in supporting the strengthening of the EU/EEA laboratory networks.

In this context, the EULabCap system will remain an important tool for assessing and monitoring laboratory capacity within the EU/EEA. However, considering the evolving public health microbiology landscape, it is likely that the tool will need to be revised in order to collect relevant information accurately.

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Annex 1. EULabCap targets, indicators and scoring options

Dimension 1. Primary diagnostic testing

Targets/indicators	Source	Scoring options
Target 1.1 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 = information not reported by the NMFP 0 = no tests are reimbursed 1 = for hospital in-patient testing 2 = for in- and outpatient testing
Indicator 1.12 Laboratory licencing Clinical microbiology laboratories obtained a licencing authorisation/registration from health authorities (or professional organisations) according to legal/regulatory requirements.	NMFP	NA = information not reported by the NMFP 0 = not required by law/regulation 1 = required for some laboratories 2 = required for all laboratories
Indicator 1.13 Laboratory accreditation Clinical microbiology laboratories accredited their diagnostic tests according to either ISO 17025, ISO 15189, or equivalent national standards.	NMFP	NA = information not reported by the NMFP 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 3.	NMFP	NA = information not reported by the NMFP 0 = not required by law/regulation 1 = for BSL3 facilities 2 = for both BSL2 and BSL3 facilities
Indicator 1.15 Biosafety tuberculosis Culture-based tuberculosis diagnostic and drug susceptibility tests (DST) were restricted to laboratories compliant with performing BSL3 operations in line with the WHO tuberculosis laboratory biosafety manual.	NMFP	NA = information not reported by the NMFP 0 = not required by law/regulation 1 = required for culture-based DSTs 2 = for all TB culture-based tests and DSTs
Target 1.2 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 = information not reported by the NMFP 0 = guidelines are 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 diagnostic testing and implementation is monitored within the country.	NMFP	NA = information not reported by the NMFP 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 *C. difficile* testing National guidelines are available for *Clostridioides difficile* diagnostic testing in healthcare associated diarrhoea and implementation is monitored within the country.	NMFP	NA = information not reported by the NMFP 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/CRE screening National guidelines are available for screening of hospitalised patients for carbapenemase-producing/carbapenem-resistant *Enterobacterales* and implementation is monitored within the country.	NMFP	NA = information not reported by the NMFP 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 Tuberculosis DST National guidelines are available for tuberculosis laboratory diagnostic and drug susceptibility testing and implementation is monitored within the country.	NMFP	NA = information not reported by the NMFP 0 = guidelines not available at the national level 1 = guidelines are available without compliance monitoring 2 = guidelines are implemented with compliance monitoring

Targets/indicators	Source	Scoring options
Target 1.3 Diagnostic testing utilisation		
Indicator 1.31 Diagnostic test LGV Laboratory diagnosis of lymphogranuloma venereum (LGV) infections (i.e. confirmation of LGV by LGV-specific molecular testing).	NMFP	NA = information not reported by the NMFP 0 = testing is not available 1 = limited availability (e.g. only at selected/reference laboratories) 2 = widely available (e.g. with referral from primary care and/or specialised care to clinical laboratories)
Indicator 1.32 Blood culture test rate Number of blood culture sets tested/1 000 hospital bed-days by EARS-Net participating hospitals from your country.	ECDC	0 = information not reported to EARS-Net, or not reported in the country 1 = < 25/1 000 hospital bed-days 2 = 25/1 000 hospital bed-days and more
Indicator 1.33 *C. difficile* test rate Total number of *Clostridioides difficile* diagnostic tests* performed/1000 hospital-bed-days, based on national estimate**. * A test = a stool sample tested by one or more diagnostic *C. difficile* assays including toxin immunoassay, toxin cytotoxic cell-culture assay, PCR, or culture ** Estimate can be determined using a (representative) sample of a survey	NMFP	0 = not measured in the country 1 = < 4/1 000 hospital bed-days 2 = 4 /1 000 hospital bed-days or more
Indicator 1.34 Tuberculosis culture confirmation and DST Percentage of new pulmonary tuberculosis cases confirmed by culture and tested for susceptibility to first-line drugs.	ECDC	0 = <80% culture confirmed 1 = ≥80% culture confirmed BUT <95% DST of cultures 2 = ≥80% culture confirmed AND ≥95% DST of cultures
Indicator 1.35 HIV late diagnosis Percentage of new HIV cases older than 14 years reported with initial CD4 counts (<350 cells/µl - late diagnosis).	ECDC	0 = CD4 cell count not reported to ECDC 1 = > 48 percent 2 = ≤ 48 percent
Target 1.4 Antimicrobial drug susceptibility testing		
Indicator 1.41 National Antimicrobial Susceptibility Committee (NAC) A National Antimicrobial Susceptibility Committee (NAC) is established and its representative attended of EUCAST General Committee meeting.	ECDC	0 = NAC not established or inactive in 2021 1 = NAC formation in process in 2021 2 = NAC established and active in 2021
Indicator 1.42 Clinical laboratories using EUCAST breakpoints Percentage of clinical laboratories in the country that used EUCAST clinical breakpoints for interpretive reporting of antibacterial drug susceptibility testing results to clinicians.	ECDC	0 = <50% of clinical laboratories 1 = 50-90% of clinical laboratories 2 = >90% of clinical laboratories
Indicator 1.43 EARS-Net participants using EUCAST breakpoints Percentage of clinical laboratories participating in EARS-Net that have used EUCAST clinical breakpoints for interpretive reporting of antibacterial drug susceptibility testing results to clinicians	ECDC	NA = information not reported to ECDC 0 = <25% of clinical laboratories 1 = 25-75% of clinical laboratories 2 = >75% of clinical laboratories
Indicator 1.44 ERLTB-Net participation in EQA for DST Tuberculosis Reference Laboratories that participated in ECDC-funded ERLTB-Net external quality assessment scheme in 2021 achieved 80% performance level for culture and susceptibility testing for first- and second-line drugs.	NMFP	NA = information not reported by the NMFP 0 = no participation 1 = participation with performance <80% 2 = participation with performance ≥80%
Indicator 1.45 Gonorrhoea AST National surveillance of gonococcal antimicrobial resistance is providing susceptibility data on 10% or more of reported gonorrhoea cases.	NMFP	NA = information not reported by the NMFP 0 = no surveillance of AMR at national level 1 = susceptibility data were provided for <10% of reported cases 2 = susceptibility data were provided for ≥10% of reported cases

Dimension 2. National reference laboratory services

Targets/indicators	Source	Scoring options
Target 2.1 Provision and regulation of national reference microbiology laboratory 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 = information not reported by the NMFP 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 = information not reported by the NMFP 0 = no NRL was officially nominated 1 = some NRLs were officially nominated 2 = all NRLs were officially nominated
Indicator 2.13 NRL core functions The majority of NRLs delivered the following functions (ECDC will use the answers provided for each function to calculate the indicator score): 2.13(a) Reference diagnostics. 2.13(b) Reference material resources. 2.13(c) Scientific advice and diagnostic guidance. 2.13(d) Collaboration and research development. 2.13(e) Monitoring, alert and response.	NMFP	For 2.13a - 2.13e 0 = no, 1 = yes NA = information not reported by the NMFP 0 = 1-2 functions 1 = 3-4 functions 2 = all 5 functions
Indicator 2.14 NRL accreditation NRLs accredited at least some of their diagnostic tests according to either ISO 17025, ISO 15189, or equivalent national standard.	NMFP	NA = information not reported by the NMFP 0 = no NRL accredited their tests 1 = some NRLs accredited their tests 2 = all NRLs accredited their tests
Indicator 2.15 NRL BSL3 National Public Health Laboratories (NRLs) have access to biosafety level 3 facilities.	NMFP	NA = information not reported by the NMFP 0 = no BSL3 facility available for NRLs 1 = partial access for some BSL3 operations 2 = full access for all BSL3 operations
Target 2.2 Reference diagnostic confirmation and pathogen identification		
Indicator 2.21 Diagnostic identification for diseases under EU surveillance Case confirmation* with pathogen identification for EU surveillance was available within your country by primary and/or reference laboratory for the 57 communicable diseases and related special health issues. *According to the COMMISSION IMPLEMENTING DECISION (EU) 2018/945 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions	NMFP	NA = information not reported by the NMFP 0 = <20 pathogens/issues 1 = 20-35 pathogens/issues 2 = >35 pathogens/issues
Indicator 2.22 *Legionella* culture confirmed Culture confirmation of Legionnaires' disease was performed for EU reported cases in accordance with EU case definition/ELDSNet guidance.	ECDC	0 = not reported to ECDC 1 = <10% of reported cases were culture confirmed 2 = ≥10% of reported cases were culture confirmed
Indicator 2.23 Pertussis laboratory confirmation Laboratory confirmation by culture or PCR of *Bordetella pertussis* infection was performed for EU reported cases in accordance with EU case definition and EUPert-LabNet guidance.	ECDC	NA = not applicable because of zero cases reported, 0 = no case-based reporting to ECDC 1 = <10% of reported cases were culture or PCR confirmed 2 = ≥10% of reported cases were culture or PCR confirmed
Indicator 2.24 Serogroup STEC/VTEC O-serogrouping was performed and reported to ECDC for cases of STEC/VTEC in accordance with EU case definition (percentage of isolates with serogroup reported out of total number of cases reported, excluding non-typeable isolates).	NMFP	NA = information not reported by the NMFP 0 = serogroup was reported for <80% of reported cases 1 = serogroup was reported for 80-95% of reported cases 2 = serogroup was reported for >95% of reported cases
Indicator 2.25 SARI viral testing National guidelines and reference virological diagnostic testing were available for investigation of Severe Acute Respiratory Infection (SARI) cluster in accordance with WHO guidance.	NMFP	NA = information not reported by the NMFP 0 = not available at the national level 1 = implemented without monitoring 2 = implemented with monitoring

Targets/indicators	Source	Scoring options
Target 2.3 Molecular typing for surveillance		
Indicator 2.31 WGS-based surveillance Whole genome sequencing (WGS) -based typing of human pathogens was used in national reference laboratories for routine surveillance of one or more disease/health issue.	NMFP	NA = information not reported by the NMFP 0 = no activity and no national plan in place 1 = no activity but a plan in place/in progress for at least 1 human pathogen 2 = WGS is used routinely for typing in national surveillance of at least 1 human pathogen
Indicator 2.32 WGS-based typing of *Listeria monocytogenes* Use of WGS-based typing of *Listeria monocytogenes* by national public health reference laboratory	NMFP	NA = information not reported by the NMFP 0 = WGS-based typing not available 1 = WGS-based typing used by NRL only for outbreak investigations 2 = WGS-based typing used by NRL for both routine national surveillance and outbreak investigations
Indicator 2.33 WGS-based typing of MDR-TB Use of WGS-based typing of MDR-*M. tuberculosis* isolates by national public health reference laboratory	NMFP	NA = information not reported by the NMFP or not applicable because zero cases reported 0 = WGS-based typing not used by NRL 1 = WGS-based typing used by NRL only for outbreak investigations 2 = WGS-based typing used by NRL for both routine national surveillance and outbreak investigations
Indicator 2.34 WGS-based typing of *N. meningitidis* Use of WGS-based typing of invasive *Neisseria meningitidis* isolates by national public health reference laboratory	NMFP	NA = information not reported by the NMFP or not applicable because zero cases reported 0 = WGS-based typing not used by NRL 1 = WGS-based typing used by NRL only for outbreak investigations, 2 = WGS-based typing used by NRL for both routine national surveillance and outbreak investigations
Indicator 2.35 HIV genotypic resistance testing Total number of HIV isolates genotyped by antiretroviral target sequence analysis divided by the total number of new HIV cases with sufficient HIV viral load reported to national surveillance.	NMFP	NA = information not reported by the NMFP 0 = type reported for <20% of reported cases 1 = type reported for 20-50% of reported cases 2 = type reported for >50% of reported cases
Target 2.4 Antimicrobial drug resistance characterisation and monitoring		
Indicator 2.41 MRSA characterisation resistance 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 = information no reported by the NMFP 0 = not established/in process of establishment 1 = performed upon request from diagnostic laboratory 2 = performed as part of surveillance
Indicator 2.42 Carbapenemase identification using EUCAST guidance Identification of type of carbapenemase was performed for carbapenemase-producing Gram-negative bacilli isolates in accordance with EUCAST guidance.	NMFP	NA = information no reported by the NMFP 0 = not established/in process of establishment 1 = performed upon request from diagnostic laboratory 2 = performed as part of surveillance
Indicator 2.43 ESBL identification using EUCAST guidance Identification of type of extended spectrum beta-lactamase was performed for ESBL-producing Gram-negative bacilli isolates in accordance with EUCAST guidance.	NMFP	NA = information no reported by the NMFP 0 = not established/in process of establishment 1 = performed upon request from diagnostic laboratory 2 = performed as part of surveillance
Indicator 2.44 Influenza antiviral susceptibility testing Human influenza virus susceptibility monitoring to neuraminidase inhibitors by phenotypic/genotypic methods was performed and results were reported by National Influenza Centres/influenza reference laboratories to ECDC.	ECDC	0 = Neuraminidase inhibitors susceptibility not monitored 1 = Neuraminidase inhibitors susceptibility monitoring was performed but results not reported to ECDC 2 = Neuraminidase inhibitors susceptibility monitoring was performed, and results were reported to ECDC

Targets/indicators	Source	Scoring options
Indicator 2.45 Cross sector monitoring of AMR in human bacterial isolates Antimicrobial susceptibility data on *Salmonella* and *Campylobacter* were reported to ECDC in accordance with the EU protocol for harmonized monitoring of antimicrobial resistance in human *Salmonella* and *Campylobacter* isolates.	ECDC	0 = Annual *Salmonella* and *Campylobacter* AST data were not reported to ECDC OR data reported were not compliant with EU harmonised protocol (either not-base-based or not quantitative) 1 = *Salmonella* AST data obtained by a EUCAST recommended method were reported quantitatively to ECDC as per EU protocol at least for (cefotaxime OR ceftazidime) AND (ciprofloxacin OR pefloxacin) AND meropenem 2 = Fulfilling score 1 AND *Campylobacter* AST data obtained by a EUCAST recommended method were reported quantitatively to ECDC as per EU protocol at least for: erythromycin AND ciprofloxacin

Dimension 3. Laboratory-based surveillance and epidemic response support

Targets/indicators	Source	Scoring options
Target 3.1 National surveillance networks		
Indicator 3.11 Laboratory surveillance 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 = information not reported by the NMFP 0 = no national network of laboratories 1 = national networks collaborating for 1-5 diseases/AMR issues 2 = national networks collaborating for more than five diseases/AMR issues
Indicator 3.12 Laboratory data reporting Surveillance networks of clinical laboratories reported microbiological data to a central national public health surveillance database.	NMFP	NA = information not reported by the NMFP 0 = no surveillance 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 laboratory information management system
Indicator 3.13 Laboratory-based surveillance data for early 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 = information not reported by the NMFP 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 network for ARI National Influenza Centres/influenza reference laboratories performed a systematic sentinel sampling of influenza and respiratory syncytial viruses.	ECDC	0 = no systematic sentinel sampling by the National Influenza Centres/influenza reference laboratory 1 = sentinel sampling only for influenza 2 = sentinel sampling for influenza AND respiratory syncytial virus
Indicator 3.15 *Chlamydia trachomatis* surveillance system 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 = information not reported by the NMFP 0 = no reporting at national level 1 = partial system 2 = full system
Target 3.2 Active participation in EU disease networks		
Indicator 3.21 EARS-Net/EUPert-LabNet participation Country was an active participant in the European Antimicrobial Resistance Surveillance Network (EARS-Net) and/or the European Pertussis Laboratory Surveillance Network (EUPert-LabNet) - participated in EARS-Net external quality assessments (EQA) reported to/coordinated by ECDC - participated in EUPert-LabNet external quality assessments (EQA) reported to/coordinated by ECDC	ECDC	NA = information not available/not applicable (e.g. no network membership) 0 = no participation in either EQAs 1 = Participation in EARS-Net EQA or EUPert-LabNet EQA 2 = Participation in EARS-Net EQA and EUPert-LabNet EQA

Targets/indicators	Source	Scoring options
Indicator 3.22 EVD-LabNet participation Country was an active participant in the European expert laboratory network for emerging viral diseases (EVD-LabNet) - participated in external quality assessments (EQA) reported to/coordinated by ECDC - participated in annual meeting	ECDC	NA = information not available/not applicable (e.g. no network membership) 0 = no participation to either EQA or annual meeting 1 = EQA participation OR participation in annual meeting 2 = EQA participation AND participation in annual meeting
Indicator 3.24 ECOVID-LabNet participation Country was an active participant in the European COVID-19 reference laboratory network (ECOVID-LabNet)/European COVID-19 surveillance network (ECOVID-Net) - participated in external quality assessments (EQA) reported to/coordinated by ECDC - participated in annual meeting	ECDC	NA = information not available/not applicable (e.g. no network membership) 0 = no participation to either EQA or annual meeting 1 = EQA participation OR participation in annual meeting 2 = EQA participation AND participation in annual meeting
Indicator 3.24 ERLTB-Net participation Country was an active participant in European reference laboratory Network for TB (ERLTB-Net) - participated in external quality assessments (EQA) reported to/coordinated by ECDC - participated in annual meeting	ECDC	NA = information not available/not applicable (e.g. no network membership) 0 = no participation to either EQA or annual meeting 1 = EQA participation OR participation in annual meeting 2 = EQA participation AND participation in annual meeting
Indicator 3.25 ELDSNet participation Country was an active participant in the European Legionnaires' Disease Surveillance Network (ELDSNet) - participated in external quality assessments (EQA) reported to/coordinated by ECDC - participated in annual meeting	ECDC	NA = information not available/not applicable (e.g. no network membership) 0 = no participation to either EQA or annual meeting 1 = EQA participation OR participation in annual meeting 2 = EQA participation AND participation in annual meeting
Target 3.3 National outbreak response support		
Indicator 3.31 NRL role preparedness NRLs had defined roles and responsibilities described and tested in exercises as part of the national preparedness and response plan for health threats due to epidemic prone/high consequence pathogens.	NMFP	NA = information not reported by the NMFP 0 = no, 1 = yes but without simulation exercises 2 = yes with simulation exercises
Indicator 3.32 NRL role outbreak investigation Percentage of outbreaks investigated at the national level for which NRL personnel participated as a member of the outbreak investigation team.	NMFP	NA = information not reported by the NMFP 0 = no participation in outbreak investigation team 1 = participate in <25% of outbreaks 2 = participate in ≥25% of outbreaks
Indicator 3.33 NRL 24/7 response duty NRLs for epidemic prone/high consequence pathogens have trained personnel available for assistance in outbreak teams at national level.	NMFP	NA = information not reported by the NMFP 0 = no personnel available 1 = personnel available during working hours 2 = personnel available in 24/7 duty roster
Indicator 3.34 *Listeria monocytogenes* genotyped Percentage of the total number of genotyped *Listeria monocytogenes* isolates out of the total number of reported listeriosis cases at national level.	NMFP	NA = information not reported by the NMFP/not applicable (e.g. less than 10 cases per year) 0 = genotyping was not done 1 = type reported for <80% of reported cases 2 = type reported for 80-100% of reported cases
Indicator 3.35 Hepatitis A virus genotyped Percentage of hepatitis A virus clinical samples genotyped out of all hepatitis A cases reported at national level.	NMFP	NA = information not reported by the NMFP 0 = genotyping was not done 1 = type reported for <20% of reported cases 2 = type reported for ≥20% of reported cases
Target 3.4 (Re)-emerging diseases laboratory preparedness and response support		
Indicator 3.41 Diagnostic capability MERS-CoV Diagnostic capability for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) infection available at national level in accordance with WHO surveillance guidance.	NMFP	NA = information not reported by the NMFP 0 = no diagnostic capability 1 = screening test only 2 = screening AND confirmation/identification
Indicator 3.42 Diagnostic capability Influenza A(H5Nx), A(H7Nx) and A(H9Nx) Diagnostic and characterisation capability for avian influenza A(H5Nx), A(H7Nx) and A(H9Nx) viruses available at national level in accordance with ECDC/WHO surveillance guidance.	NMFP	NA = information not reported by the NMFP 0 = no specific diagnostic capability 1 = HA identification available 2 = HA and NA identification available.

Targets/indicators	Source	Scoring options
Indicator 3.43 Diagnostic capability Ebola virus Diagnostic and characterisation capability (within country AND/OR through formal agreement with laboratories in other countries) for Ebola virus infection.	NMFP	NA = information not reported by the NMFP 0 = no national capacity nor formal agreement with other laboratories 1 = molecular detection at BSL3 level or formal agreement with BSL3 laboratory in another country 2 = further characterisation at BSL4 level within the country or formal agreement with BSL4 laboratory in another country
Indicator 3.44 Diagnostic capability for detection of five rare agents One or more reference virology laboratories in your country have detection capability for human infection with the following 5 (re)-emerging pathogens: Chikungunya/Dengue/Hantavirus/Tick borne encephalitis/West Nile (according to the EVD-LabNet directory)	ECDC	0 = for less than 2 pathogens 1 = for at least 2 out of 5 pathogens 2 = for all 5 pathogens
Indicator 3.45 Guidance for colistin susceptibility testing/confirmation and identification of resistance mechanism National guidance was available for colistin susceptibility testing and detection of acquired colistin resistance in carbapenem-resistant *Enterobacterales* and confirmation and identification of colistin resistance mechanisms was provided by NRL to clinical laboratories.	NMFP	NA = information not reported by the NMFP 0 = neither guidance nor reference confirmation were available at national level 1 = technical guidance for colistin susceptibility testing has been issued by the National Antimicrobial Susceptibility Committee (NAC) and/or by the NRL OR confirmation of acquired colistin resistance and identification of resistance mechanism in clinical isolates are provided by the NRL to the clinical laboratories 2 = both of the above criteria described in score 1 were provided to clinical laboratories

Annex 2. Policy rationale for EULabCap targets, 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 Support to 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.
3.2 Active participation in EU disease networks	Active participation and collaboration between experts in EU disease networks promote 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. Missing data by EULabCap indicator, 2013–2021

	Target	Indicator	2013	2014	2015	2016	2018	2021
			% (N=30)	% (N=30)	% (N=29)	% (N=30)	% (N=30)	% (N=29)
Dimension 1	1.1	1.11	6.7	3.3	3.4			
		1.14	3.3					
	1.2	1.22		3.3	3.4			
		1.23	3.3	6.7	6.9	3.3	3.3	
		1.24	3.3	3.3				
	1.3	1.31	10.0		3.4			
		1.32					3.3	
		1.33	20.0	26.7	31.0			
		1.34		10.0	3.4	3.3	10.0	6.9
	1.4	1.41	3.3	3.3	3.4			
		1.42	6.7	3.3	3.4			
		1.44	6.7	6.7	3.4	3.3	6.7	6.9
		1.45		6.7	3.4	3.3		6.9
Dimension 2	2.1	2.11	3.3	3.3	3.4			
		2.12	3.3	3.3				
		2.13	3.3					
		2.14	3.3	10.0	3.4			
		2.15		3.3				
	2.2	2.23		23.3	17.2	3.3	3.3	13.8
		2.24	20.0	20.0	27.6	13.3	10.0	10.3
		2.25	3.3	10.0	10.3	6.7	3.3	3.4
	2.3	2.31	3.3	10.0	6.9	6.7		
		2.32	16.7			10.0		
		2.33	36.7	13.3	13.8	13.3	3.3	6.9
		2.34	13.3	6.7		3.3	3.3	3.4
		2.35	6.7	30.0	31.0	26.7	13.3	20.7
	2.4	2.41	3.3	3.3		3.3	3.3	
		2.42	6.7					
		2.43	6.7	3.3				
		2.44	6.7					
		2.45	3.3	3.3				6.9
Dimension 3	3.1	3.11	3.3	3.3				
		3.12			3.4			
		3.13	13.3	6.7	6.9	3.3		
		3.14	6.7	6.7	3.4			
		3.15	10.0	6.7	6.9	6.7	3.3	
	3.2	3.22	3.3		*			
		3.24	3.3					
		3.25				13.3		
	3.3	3.32					3.3	
		3.33	10.0	6.7	3.4			
		3.34	10.0	13.3	10.3	6.7	3.3	3.4
		3.35	6.7	16.7	13.8	10.0	13.3	
	3.4	3.44	3.3					6.9
		3.45	3.3			3.3		

Only indicators with missing data (scoring option NA) are shown i.e. indicators for which data were not available or data were not applicable to the country.
**Indicators not applicable*

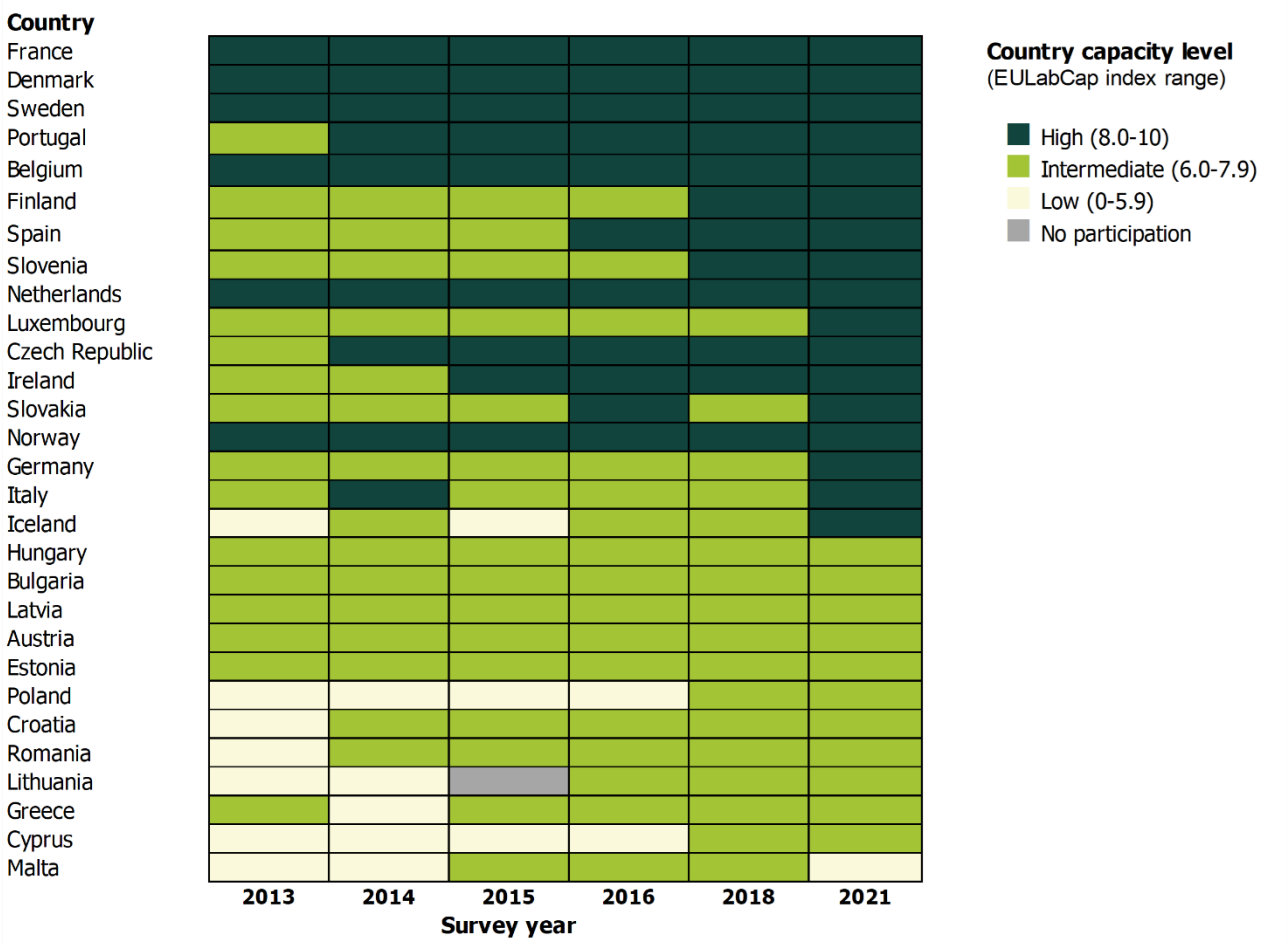
Annex 4. Diagnostic confirmation testing for 57 communicable diseases under EU surveillance, 2021

Diseases are listed in Decision (EU) 2018/945.

Disease/health issue	Number of countries (N=29)
ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) AND HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION	29
AVIAN INFLUENZA A/H5 OR A/H5N1 IN HUMANS	
BRUCELLOSIS (Brucella spp.)	
CAMPYLOBACTERIOSIS (Campylobacter spp.)	
CHOLERA (Vibrio cholerae)	
CRYPTOSPORIDIOSIS (Cryptosporidium spp.)	
DIPHTHERIA (Corynebacterium diphtheriae, Corynebacterium ulcerans and Corynebacterium pseudotuberculosis)	
ECHINOCOCCOSIS (Echinococcus spp.)	
GIARDIASIS (Giardia lamblia)	
GONORRHOEA (Neisseria gonorrhoeae)	
HAEMOPHILUS INFLUENZAE, INVASIVE DISEASE (Haemophilus influenzae)	
HEPATITIS A (Hepatitis A virus)	
HEPATITIS B (Hepatitis B virus)	
HEPATITIS C (Hepatitis C virus)	
INFLUENZA (Influenza virus)	
LEGIONNAIRES' DISEASE (Legionella spp.)	
LISTERIOSIS (Listeria monocytogenes)	
MALARIA (Plasmodium spp.)	
MEASLES (Measles virus)	
MENINGOCCOCAL DISEASE, INVASIVE (Neisseria meningitidis)	
PERTUSSIS (Bordetella pertussis)	
PNEUMOCOCCAL INVASIVE DISEASE(S) (Streptococcus pneumoniae)	
RUBELLA (Rubella virus)	
RUBELLA, CONGENITAL (including Congenital Rubella Syndrome)	
SALMONELLOSIS (Salmonella spp. other than Salmonella Typhi and Salmonella Paratyphi)	
SHIGA TOXIN/VEROCYTO-TOXIN PRODUCING ESCHERICHIA COLI INFECTION (STEC/VTEC)	
SHIGELLOSIS (Shigella spp.)	
SYPHILIS (Treponema pallidum)	
SYPHILIS, CONGENITAL AND NEONATAL (Treponema pallidum)	
TOXOPLASMOSIS, CONGENITAL (Toxoplasma gondii)	
TUBERCULOSIS (Mycobacterium tuberculosis complex)	
TYPHOID/PARATYPHOID FEVER (Salmonella Typhi/Paratyphi)	
CHIKUNGUNYA VIRUS DISEASE (Chikungunya virus)	28
DENGUE (Dengue virus)	
LEPTOSPIROSIS (Leptospira spp.)	
MUMPS (Mumps virus)	
PLAGUE (Yersinia pestis)	
SEVERE ACUTE RESPIRATORY SYNDROME — SARS (SARS-coronavirus, SARS-CoV)	
TRICHINELLOSIS (Trichinella spp.)	

Disease/health issue	Number of countries (N=29)
TULARAEMIA (Francisella tularensis)	
VIRAL HAEMORRHAGIC FEVERS (VHF)	
WEST NILE FEVER (West Nile virus infection, WNV)	
YERSINIOSIS (Yersinia enterocolitica, Yersinia pseudotuberculosis)	
ZIKA VIRUS DISEASE (Zika virus)	
ANTHRAX (Bacillus anthracis)	27
CHLAMYDIAL INFECTION (Chlamydia trachomatis), INCLUDING LYMPHOGRANULOMA VENEREUM (LGV)	
LYME NEUROBORRELIOSIS (Borrelia burgdorferi)	
POLIOMYELITIS (Polio virus)	
TETANUS (Clostridium tetani)	
YELLOW FEVER (Yellow fever virus)	
ZIKA VIRUS DISEASE, CONGENITAL (Zika virus)	
Q FEVER (Coxiella burnetii)	26
BOTULISM (Clostridium botulinum)	25
TICK-BORNE ENCEPHALITIS (TBE virus)	
RABIES (Lyssavirus)	23
SMALLPOX (Variola virus)	21
CREUTZFELDT-JAKOB DISEASE, VARIANT (vCJD)	19

Annex 5. EU/EEA country EULabCap performance level by year, 2013–2021

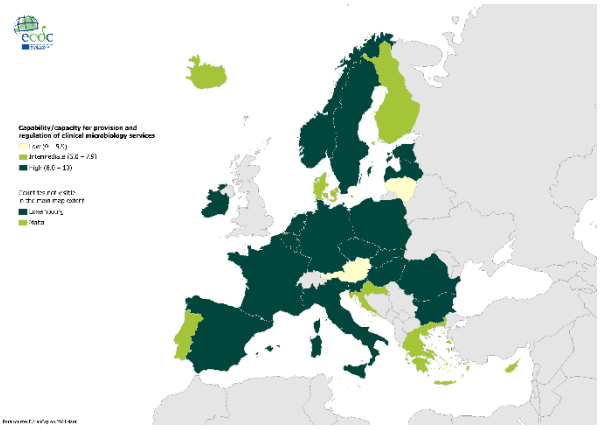


** N=29 countries, United Kingdom participated in the EULabCap surveys 2013-2018 but are not shown; countries sorted by decreasing score in 2021.*

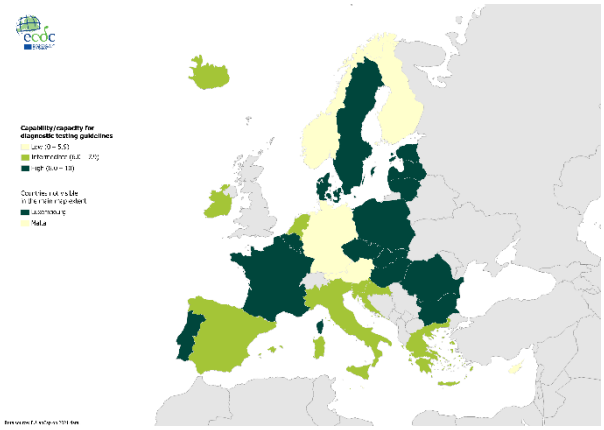
Annex 6. EULabCap target performance by country, 2021

Dimension 1: Primary diagnostic testing, 2021

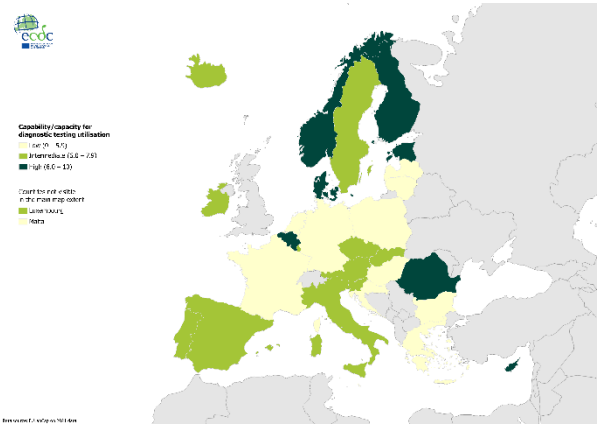
Target 1.1 Provision and regulation of clinical microbiology services



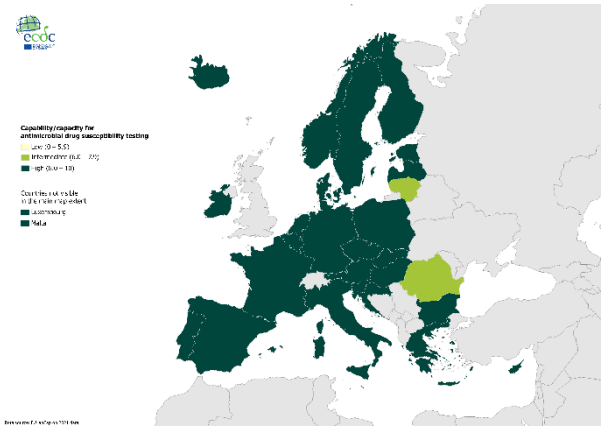
Target 1.2 Diagnostic testing guidelines



Target 1.3 Diagnostic testing utilisation

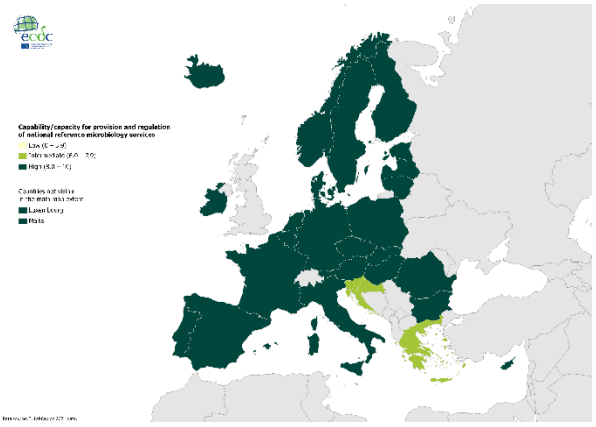


Target 1.4 Antimicrobial drug susceptibility testing

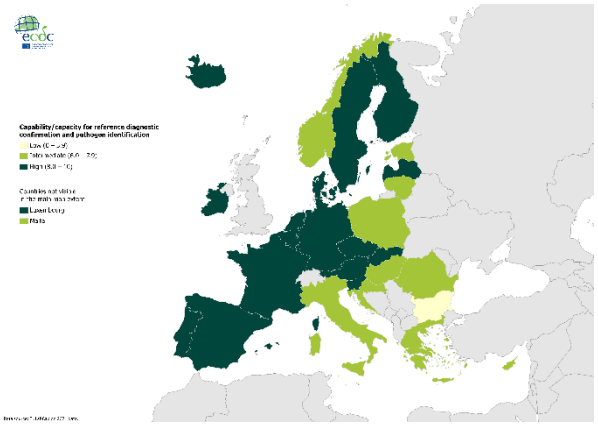


Dimension 2: National reference laboratory services, 2021

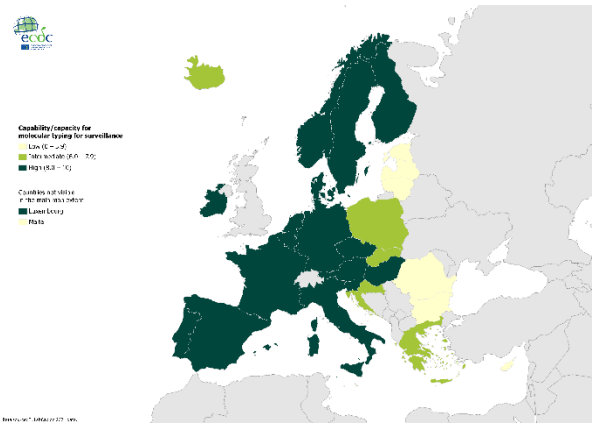
Target 2.1 Provision and regulation of national reference microbiology services



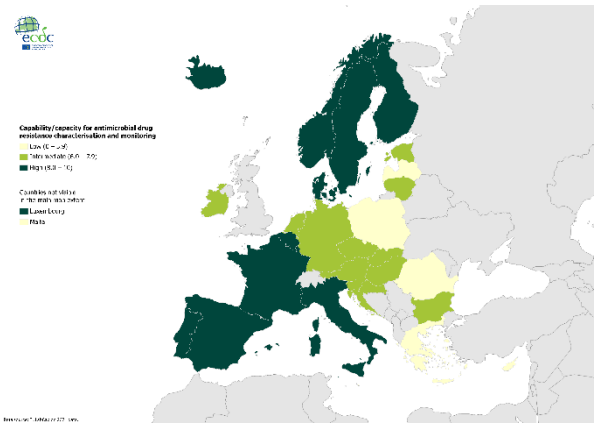
Target 2.2 Reference diagnostic confirmation and pathogen identification



Target 2.3 Molecular typing for surveillance

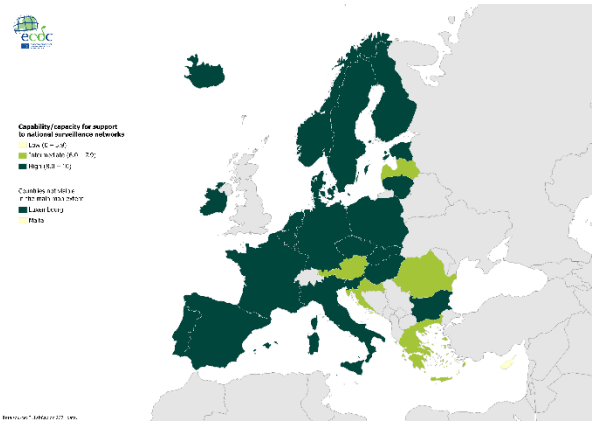


Target 2.4 Antimicrobial drug resistance characterisation and monitoring

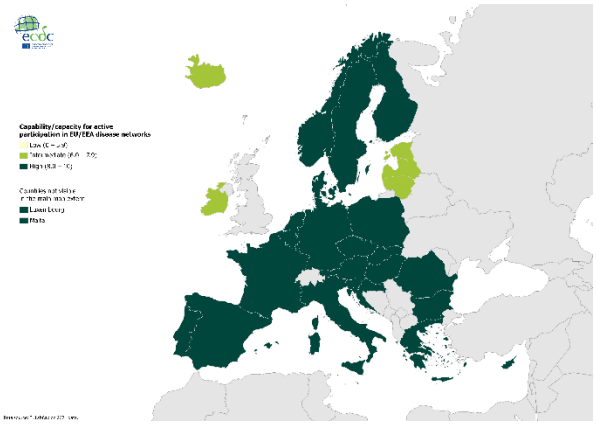


Dimension 3: Laboratory-based surveillance and epidemic response support, 2021

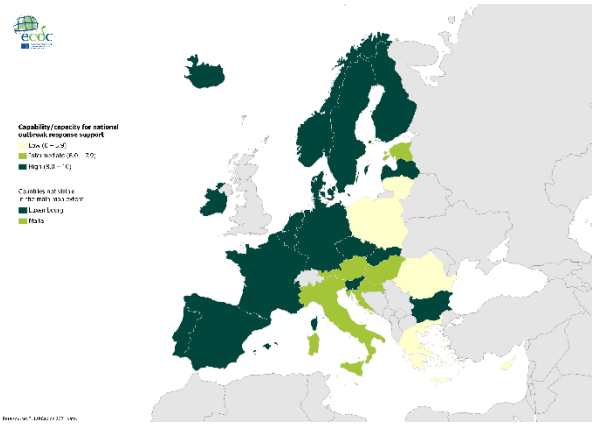
Target 3.1 Support to national surveillance networks



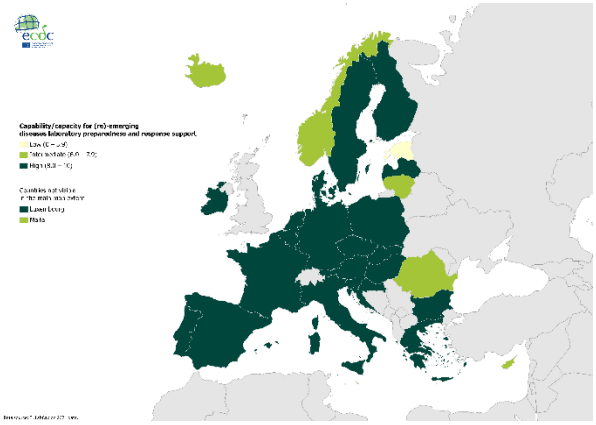
Target 3.2 Active participation in EU/EEA disease networks



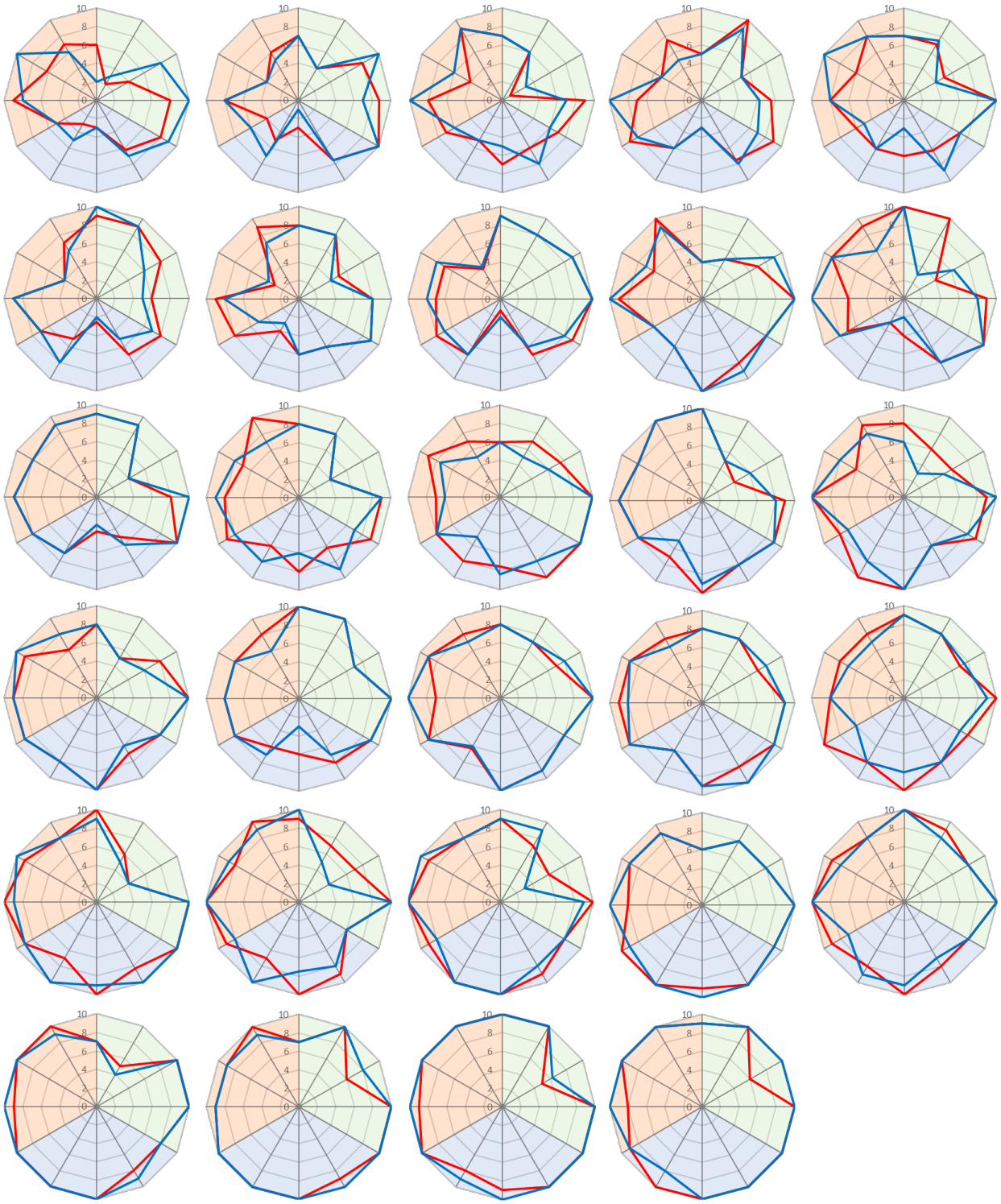
Target 3.3 National outbreak response support



Target 3.4 (Re)-emerging diseases laboratory preparedness and response support



Annex 7. Radar graphs of EULabCap target index scores for each country, 2018 and 2021



The radar charts compare the EULabCap target index scores of 29 EU/EEA countries and two survey years: 2021 (red line) and 2018 (blue line). The charts are displayed in ascending order of total index country score (2021) and arranged from top left to bottom right (lowest to highest score).

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