Table S2: Essential Qualitative Information for AMR Diagnostic Test Target Product Profiles (TPP).

Characteristic	Qualitative explanation	Examples of External Influencing Factors	Influencing Characteristics (taken from column 1)
Category 'Intended Use'			
Target population	Patients presenting with symptoms indicating an infection. Patients needing monitoring or decision on management and treatment. Screening and surveillance cohorts	Age, gender	Does the patient have an infection? Are microorganisms present (if so, which ones)? Are there Antimicrobial Resistance (AMR) determinants present? Which antimicrobial drug(s) can be used?
Setting	Home, community (e.g. care home, mobile/pop-up ambulatory units), primary care (e.g. general practitioners, doctors' office), pharmacies, emergency department, hospital, intensive care unit	Predominant touch points for target population, location of target population (geography, urban/rural etc.), healthcare system, availability of utilities	Target population, end user
End user (the person performing the test)	Lay person, community health worker, nurse, medical/laboratory technician, general practitioner, medical specialist, clinical scientist, pharmacist	Guidelines defining user qualification	Setting, Does the patient have an infection? Are microorganisms present (if so, which ones)? Are there Antimicrobial Resistance (AMR) determinants present? Which antimicrobial drug(s) can be used? test principle, test system, regulatory
Category 'Diagnostic Question'			
Does the patient have an infection?	Yes (acute, recurrent, relapsing, chronic)/no	Intended or available treatment or management option, scientific knowledge and evidence, disease indication, relative risk of	Setting, Are microorganisms present (if so, which ones)? Are there Antimicrobial Resistance (AMR) determinants present?

		morbidity/mortality, infectivity/transmission	
Are microorganisms present (if so, which ones)?	Yes/no (pathogens/non-pathogens; Gram positive/negative bacteria; spore formers; mycobacteria; spirochaetes; mycoplasmas; viruses; fungi; parasites; phylogenetic classification e.g. species/strain/type)	Intended or available treatment or management option, scientific knowledge and evidence, disease indication, relative risk of morbidity/mortality, infectivity/transmission, WHO prioritisation level	Setting, Does the patient have an infection?
Are there Antimicrobial Resistance (AMR) determinants present (if so, which ones)?	Yes/no (antibacterial-, antifungal-, antiviral-, antiparasitic-resistance; class; name of mechanism/gene; gene sequence)	Intended or available treatment or management option, scientific knowledge and evidence, disease indication, local/regional epidemiology of disease and antimicrobial resistance	Setting, Does the patient have an infection? Are microorganisms present (if so, which ones)?
Which antimicrobial drug(s) can be used?	Sensitivity (Resistant, Sensitive, Sensitive to increased exposure (intermediate); e.g. Minimal Inhibitory Concentration (MIC)) to an individual or panel of antibacterial, antifungal, antiviral, antiparasitic drugs	Intended or available treatment or management option, scientific knowledge and evidence, disease indication, local/regional epidemiology of disease and antimicrobial resistance	Setting, Does the patient have an infection? Are microorganisms present (if so, which ones)?
Category 'Test Description'			
Test principle	Phenotype, genotype, molecular; detection through culture, optical, electrochemical, mass spectrometric, magnetic, mechanical, thermal, acoustic, piezoelectric methods	Health economics	Setting, target analyte(s), time-to-result, analytical sensitivity, analytical specificity
Test system	Instrument (with or without disposable cartridge), instrument-free test/strip/cartridge, sampling device/consumable, additional reagents	Assay complexity, stability of assay components	Setting, test principle, target specimen, sample quantity, operating conditions

Additional third-party consumables	Allowed, not allowed	Intellectual property rights, test tolerance towards non-original consumables, business model	Regulatory
Target analyte(s)	Cells, microorganisms, cell envelope components, vesicles, proteins, nucleic acids, lipids, carbohydrates, small molecules, ions	Scientific knowledge and evidence, intellectual property rights	Diagnostic question (all characteristics), clinical sensitivity, clinical specificity
Throughput[1]	One - multiple test/time	Prevalence/incidence of disease, business model, organisation of working time (shifts vs 24/7), assay complexity	Target population, setting, test principle, test system, instrument size, hands-on steps, time-to-result, retail price, bill of materials
Random access[2]	Yes/No	Prevalence/incidence of disease, assay complexity, business model, organisation of working time (shifts vs 24/7)	Target population, setting, test principle, test system, instrument size, time-to-result, retail price
Disposal	Disposable/reusable/recyclable/biodegradable materials, treatment for biohazard/non-biohazard, toxic/non-toxic waste	Target markets, health economics, public opinion, sustainability of materials	Setting, end user, regulatory, retail price, bill of materials
Instrument size	Instrument free, wearable, handheld, portable, table top, free standing, large, high throughput, automated laboratory systems	Health economics, automation, instrument stacking requirements	Setting, test principle, throughput, instrument weight, sample preparation needs, retail price, bill of materials
Instrument weight	Grams to many kilograms	Target markets, health economics, automation, instrument stacking requirements	Setting, test principle, throughput, instrument size, sample preparation needs, retail price, bill of materials
Power requirements	Mains, battery, solar, self-powered, human-powered, none	Target markets, health economics, automation	Setting, test principle, test system, throughput, instrument

[1] number of tests per unit of time
[2] capacity to add additional samples while others are still being processed

			connectivity, data display, sample preparation needs, operating conditions
Instrument connectivity	No/Yes (connection to hospital information system, electronic health record, epidemiological surveillance, cloud storage, remote access, instrument performance monitoring, data storage and archiving, type of connection (WiFi, Bluetooth, LAN, USB, …))	Target markets, availability of middleware, availability of data protection mechanisms, quality assurance requirements	Setting, end user, power requirements, data display, data input, data export, regulatory, retail price
Result output	Qualitative, quantitative, semi-quantitative	Health economics, assay complexity	Target population, setting, end user, diagnostic question (all characteristics), retail price
Data display	For instrument-free test/strip/cartridge: visual (colour, screen) For instrument-based test: On-/Off-instrument (screen, printout), visual (numeric, textual, colour, graphical), auditory (speech, notification sounds)	Target markets, accessibility (lighting conditions, background noise)	Setting, end user, throughput, power requirements, instrument connectivity, result output, retail price
Data input	Patient ID, Lot/cartridge ID, operator ID, metadata (location, laboratory, date); Manual entry (keypad, touchscreen), automated entry (bar code, RFID, …)	Target markets, data protection and safety regulations	Setting, end user, test system, throughput, instrument size, retail price
Data export	Patient, test, and instrument data; Manual registration, hardware/software interfaces; Secure, encrypted, anonymised; Real time, on demand	Data storage requirements, data protection and safety regulations	Setting, end user, diagnostic question (all characteristics), throughput
Calibration	No (calibration free)/Yes (Location (On site, remote), mode (self-calibrating, user, company technician), frequency (annual to daily, before each measurement), materials (reference standard/materials e.g. provided by QA/QC organisations))	Business model, frequency of use	Setting, test principle, test system, target analyte(s), throughput, regulatory

Maintenance	Yes (frequency of maintenance, operator)/No	Frequency of use, assay complexity, automation	Setting, end user, test system, throughput, sample preparation needs, operating conditions
Shipping/storage conditions (for instrument and disposable or instrument-free test/strip/cartridge/reagents)	Acceptable temperature range (e.g. cold chain requirements); Ability to withstand dusty conditions; Range for relative humidity/non-condensing humidity; Range for altitude	Instrument materials, stability of assay components, robustness of assay	Setting, test principle, test system, shelf life
Shelf life (for instrument and disposable or instrument-free test/strip/cartridge/reagents)	Range in months (at specified temperature/humidity)	Stability of assay components, business model	Setting, test system, shipping/storage conditions, regulatory
Training requirements	Self-training (Instruction manual printed/online, training video), by qualified users, by company expert; duration of training (minutes, hours, days); recommended, mandatory (plus/minus access controlled)	Assay complexity	Setting, end user, test system, result output, data display, data input, data export, calibration, specimen/sample collection, hands on steps, controls, regulatory
Category 'Assay Protocol'			
Target specimen	Hair, cerebrospinal fluid, sweat, tears, saliva, ear wax, tissue, blood (plasma, serum), lymph, interstitial fluid, sputum, pus, bronchoalveolar lavage, nails, faeces, semen, urine, specimen on swabs, nasal washings, exhaled air	Disease indication, target analyte(s) and location/abundance in/on the body, biological risk, requirement for ease of specimen collection, invasiveness, and processing	Setting, diagnostic question (all characteristics)
Specimen/sample collection	Venipuncture, finger prick, salivation, stool collection, gargling, urination, swab/sputum collection, lumbar puncture, intubation, etc.	Disease indication, target analyte(s) and location/abundance in/on the body, biological risk, requirement for ease of specimen collection, invasiveness, and processing	Setting, end user, test system, target analyte(s), target specimen, sample quantity
Sample quantity	µL - mL, mg , g, number of solid pieces/fragments etc.	Disease indication, target analyte(s) and location/abundance in/on the	Test principle, test system, target analyte(s), analytical sensitivity

		body, biological risk, requirement for ease of specimen collection, invasiveness, and processing	
Sample preparation needs	Yes (homogenisation, liquefying, separation, extraction, purification, stabilisation, dilution) / No	Assay complexity	Setting, end user, test principle, test system, throughput, power requirements, target specimen, retail price
Hands-on steps (from the start of sample processing to result)	Refers to the number of steps from the start of sample processing	Competitor performance, assay complexity, invasiveness, and processing	Setting, end user, test principle, test system, throughput, calibration, sample preparation needs, controls, retail price
Hands-on-time (from the start of sample processing to result)	Seconds, minutes, hours	Competitor performance, assay complexity	Setting, end user, test system, throughput, sample preparation needs, retail price
Time-to-result (TTR) (from the start of sample processing to result)	Minutes, hours	Competitor performance, assay complexity, health economics	Target population, setting, diagnostic question (all characteristics), test principle, throughput, hands-on-time
Controls	Yes (internal process, positive, negative controls) / No	Assay complexity, stability of assay components	Test principle, test system, regulatory
Operating conditions	Temperature range; Range for relative humidity, non-condensing humidity; Compatibility with dusty conditions; Resistance to electromagnetic/mechanical/light interference	Stability of assay components, robustness of assay	Setting, test principle, test system
Category 'Performance'			
Analytical sensitivity (Limit of detection (LOD) of the specific target analyte - disease specific)	Given as number/mass of molecules/cells per test/unit volume	Competitor performance, health economics, relative risk of morbidity/mortality, infectivity/transmission	Setting, diagnostic question (all characteristics), target analyte(s), target specimen, clinical sensitivity, regulatory, retail price
Analytical specificity (Detection of the specific target analyte(s)	Given as a percentage or statistical value	Existence and/or presence of similar target analyte(s),	Setting, diagnostic question (all characteristics), target analyte(s),

without cross reacting with non-target analyte(s) of the same type)		competitor performance, health economics	target specimen, clinical specificity, regulatory, retail price
Clinical sensitivity (Correct identification of a specific disease state)	Given as a percentage range or statistical value compared to an accepted (named) reference method	Threat level, competitor performance, health economics, current gold standard, relative risk of morbidity/mortality, infectivity/transmission	Setting, diagnostic question (all characteristics), regulatory
Clinical specificity (Correct identification of those who do not have a specific disease state)	Given as a percentage range or statistical value compared to an accepted (named) reference method	Threat level, competitor performance, health economics, current gold standard, relative risk of morbidity/mortality, infectivity/transmission	Setting, diagnostic question (all characteristics), regulatory
Positive predictive value (PPV) (The proportion of subjects with a positive test result who truly have the specific disease, biomarker, mutation etc., of interest)	Given as a percentage range or statistical value compared to an accepted (named) reference method	Threat level, competitor performance, health economics, current gold standard, relative risk of morbidity/mortality, infectivity/transmission, disease prevalence, pre-test probability	Setting, diagnostic question (all characteristics), regulatory
Negative predictive value (NPV) (The proportion of subjects with a negative test result who truly do not have the specific disease, biomarker, mutation etc., of interest)	Given as a percentage range or statistical value compared to an accepted (named) reference method	Threat level, competitor performance, health economics, current gold standard, relative risk of morbidity/mortality, infectivity/transmission, disease prevalence, pre-test probability	Setting, diagnostic question (all characteristics), regulatory

Reproducibility (The ability of a test to produce the same result after multiple testing under the same conditions)	Quantitative Coefficient of Variation (CV) in inter/intra batch assessment	Threat level, relative risk of morbidity/mortality, competitor performance, health economics	Setting, end user, diagnostic question (all characteristics), regulatory
Category 'Commercial'			
Regulatory	GMP compliant, certified to international standards, e.g. ISO 13485:2016, by regulatory authorities, e.g. CE-IVD, FDA, NMPA, CDSCO	Business model, target market	Setting, end user, diagnostic question (all characteristics), test principle, test system, target analyte(s), target specimen
Retail price	Range of (named) currency per test; 0 (reagent rental model) or range of (named) currency per instrument	Development costs, business model, target market, and other commercial considerations	Target population, setting, end user, test principle, test system, additional third-party consumables, throughput, random access, instrument size, power requirements, instrument connectivity, result output, data display, shelf life (of disposable/instrument-free test/strip/cartridge/reagents), bill of materials
Bill of materials (BOM, sales BOM)	Range of (named) currency per test; range of (named) currency per instrument	Reagents, manufacturing volume	Test principle, test system, additional third-party consumables, throughput, instrument size, power requirements, instrument connectivity, result output, data display, shelf life (of disposable/instrument-free test/strip/cartridge/reagents), analytical sensitivity, analytical specificity