

UTI: Ideal Test Characteristics



Rapid tests suitable for use in primary care that can 1) identify whether a bacterial infection is present and/ or 2) that identify the most appropriate treatment and, ideally, the underlying pathogen(s). Innovative solutions for use at-home or in the community setting are also encouraged.

Bacterial vs Non-Bacterial Infection Triage Tests

- **Setting: Health Care Level 1 (e.g., Primary Care Physician, Health Centre, Pharmacy) and/ or Urgent Care and Emergency in Health Care Level 2**
- **Diagnostic Type:** Rapid, point-of-care triage tests that determine whether an antibiotic is needed
- **Indication(s):** suspected UTI
- **Impact Measures:** Reduced antibiotic prescribing, reduced return visits, faster infection resolution

	Bacterial vs Non-bacterial Triage Tests
Test Features	<ul style="list-style-type: none"> • Detection of bacterial infection should fit within normal clinical consultation timeframe (e.g., in Level 1/primary care setting < 10 mins) • Low cost • Easy to use (minimal training and infrastructure requirements) • Fully integrated, or semi-integrated with simple sample preparation steps • Diagnostics for use in low resource settings should align with REASSURED • Improved accuracy over UTI dipstick/ host-marker (e.g. CRP) or equivalent • Ideally suitable for elderly/ pregnant/ young patients • Triage test could be linked with AST/ ID test
Example diagnostic technologies/ platforms	<ul style="list-style-type: none"> • Host- or pathogen-based marker detection LFIA • LOC (lab-on-a-chip, e.g., microfluidic test chips with integrated functions) • Closed-cartridge molecular diagnostic systems (compact) • Novel technologies

AST and Pathogen Identification

- **Setting: Health Care Level 1;** Return Visits (unresolved)/ **Level 2/3;** Referral or In-Patient
- **Diagnostic Type:** Rapid AST technologies (ideally incl. pathogen ID) that indicate which antimicrobials should be used
- **Indications:** suspected UTI
- **Impact Measures:** Reduced hospital admissions/ re-admissions, reduced hospital lengths of stay, reduced recurrence/ severe disease, more appropriate antibiotic prescribing, faster infection resolution

	AST + Pathogen ID
Test Features	<ul style="list-style-type: none"> ▪ AST + pathogen ID available for same-day follow-up to fit within primary care or hospital workflows (< 6hrs) ▪ Easy to use (minimal training and infrastructure requirements – should be usable outside of a (reference) lab setting) ▪ AST/ ID could be linked with a triage test
Example diagnostic technologies/ platforms	<ul style="list-style-type: none"> ▪ Automated combined ID + phenotypic AST systems (compact) ▪ Culture-independent molecular methods, e.g., non-phenotypic systems for detecting pathogens and AMR ▪ Novel AST systems including use of metagenomics and AI

NOTE: These are ideal test characteristics, proposals for products that do not meet all the criteria will still be considered

LRTI: Ideal Test Characteristics



Rapid tests to identify presence of a bacterial infection applicable to primary care, community care and hospital triage settings. Rapid, near-patient tests that identify the most appropriate treatment and, ideally, the underlying pathogen for pneumonia applicable to primary care or hospital settings; minimally invasive/ burdensome sample types will be prioritised.

Bacterial vs Non-Bacterial Infection Triage Tests

- **Setting:** Health Care Level 1 (e.g. Primary Care Physician, Health Centre, Pharmacy) and/ or Urgent Care and Emergency in Health Care Level 2
- **Diagnostic Type:** Rapid, point-of-care triage tests that determine whether an antibiotic is needed
- **Indication(s):** suspected CA-LRTI
- **Impact Measures:** Reduced antibiotic prescribing, reduced return visits, faster infection resolution

Bacterial vs Non-bacterial Triage Tests	
Test Features	<ul style="list-style-type: none"> • Detection of bacterial infection should fit within normal clinical consultation timeframe (e.g., in Level 1/primary care setting < 10 mins) • Low cost • Easy to use (minimal training and infrastructure requirements) • Fully integrated, or semi-integrated with simple sample preparation steps • Diagnostics for use in low resource settings should align with REASSURED • Ideally suitable for elderly/ pregnant/ young patients • Triage test could be linked with AST/ ID test
Example diagnostic technologies/ platforms	<ul style="list-style-type: none"> • Host- or pathogen-based marker detection LFIA • LOC (lab-on-a-chip, e.g., microfluidic test chips with integrated functions) • Closed-cartridge molecular diagnostic systems (compact) • Novel technologies

AST and Pathogen Identification

- **Setting:** Health Care Level 1; Return Visits (unresolved)/ Health Care Level 2/3; Referral or In-Patient
- **Diagnostic Type:** Rapid AST technologies (ideally incl. pathogen ID) that indicate which antimicrobials should be used
- **Indications:** suspected LRTI (incl. CA and HAP/VAP)
- **Impact Measures:** Reduced hospital admissions/ re-admissions, reduced hospital lengths of stay, reduced recurrence/ severe disease, more appropriate antibiotic prescribing, faster infection resolution

AST + Pathogen ID	
Test Features	<ul style="list-style-type: none"> ▪ AST + pathogen ID available for same-day follow-up to fit within primary care or hospital workflows (< 6hrs) ▪ Easy to use (minimal training and infrastructure requirements – should be usable outside of a (reference) lab setting) ▪ LRTI: Alternative sample types to sputum and bronchiolar lavage encouraged for LRTI (e.g., whole blood, saliva) ▪ AST/ ID could be linked with a triage test
Example diagnostic technologies/ platforms	<ul style="list-style-type: none"> ▪ Automated combined ID + phenotypic AST systems (compact) ▪ Culture-independent molecular methods, e.g., non-phenotypic systems for detecting pathogens and AMR ▪ Novel AST systems including use of metagenomics and AI

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BSI/Sepsis: Ideal Test Characteristics



Hospital-based tests that can provide faster identification of pathogens and antibiotic susceptibility profile for suspected BSI/ sepsis cases direct from sample. Includes diagnostic innovation for detection and management of the bacterial component of neonatal sepsis.

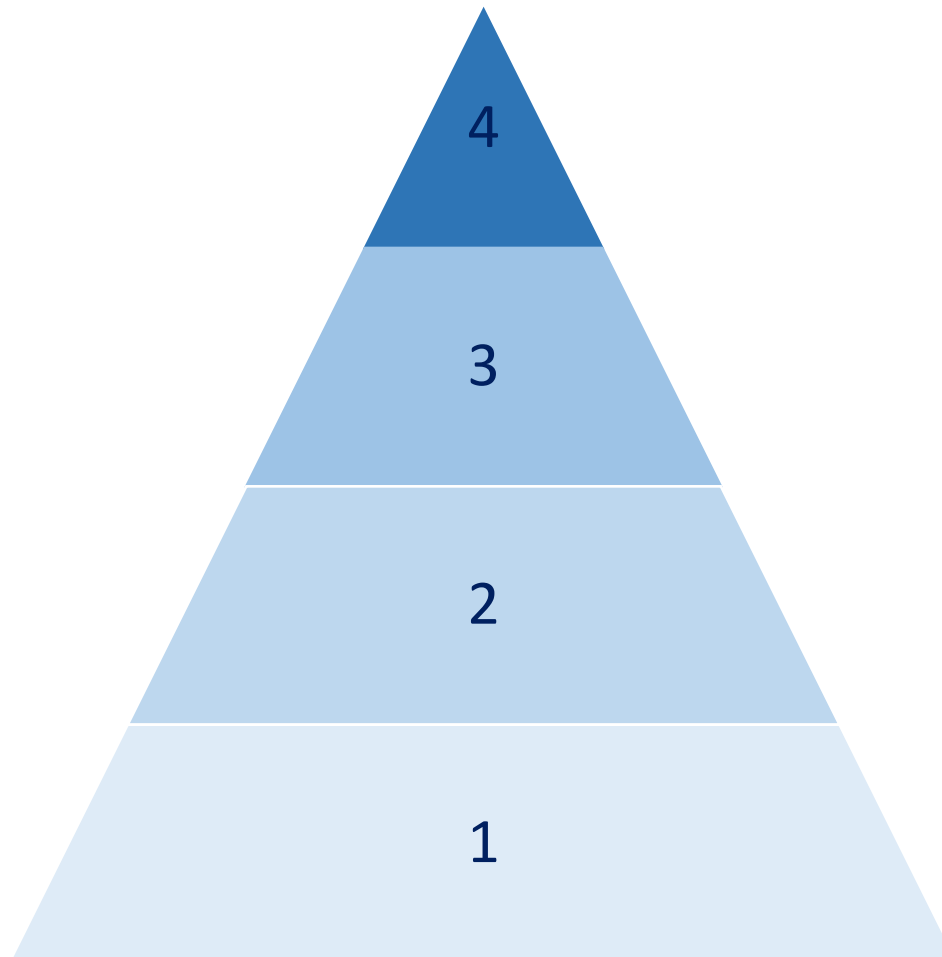
AST + Pathogen ID Alternatives to Blood Culture

- **Setting: Health Care Level 2/3;** referral, emergency department or in-patient
- **Diagnostic Type:** Tests that rapidly detect blood stream infections, and, ideally, the underlying pathogen and susceptibility profile to indicate which antibiotics should be used
- **Indications:** suspected BSI, incl. (neonatal) sepsis
- **Impact Measures:** reduced mortality, faster time to resolution, reduced hospital lengths of stay, faster time to antibiotic de-escalation/ increased ratio of narrow- vs broad-spectrum antibiotics

	Alternatives to blood culture
Test Features	<ul style="list-style-type: none">▪ Provide results that are generated faster than standard blood culture methods (within one hospital shift, < 8hrs)▪ Straight from sample and without separate pre-culture or extensive sample prep▪ Improved, standardised sample collection▪ Reduced risk for contamination▪ Detection element can be de-linked from AST/ ID▪ Needs to be cost-effective given high volume of negative blood cultures
Example diagnostic technologies/ platforms	<ul style="list-style-type: none">▪ Automated combined ID + phenotypic AST systems (ideally compact)▪ Culture-independent molecular methods, e.g., non-phenotypic systems for detecting pathogens and AMR▪ Novel technologies

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Health System Levels



HICs	LMICs
National Reference Laboratory, Academic Medical Centres	National Reference Laboratories <i>Specialised labs and networks, provide assistance with clinical trials, evaluate new technology, conduct surveillance, national reference labs and conduct AST for 1st and 2nd line drugs. Senior health specialists.</i>
Tertiary Care: Hospital Clinics and Public Health Laboratories <i>Specialist treatment</i>	Regional/provincial laboratories <i>Lab capability as for Levels 1 and 2 but also usually cultures samples and conducts pathogen ID and AST for first line drugs. Specialists/senior technicians to operate.</i>
Secondary Care: Emergency and urgent care clinics and walk-in centres <i>Urgent and emergency care and planned or elective care in hospital</i>	District Hospitals <i>Lab capability is as for level 1 but also ability for e.g. gram staining and have some automated kit. Technicians and assistants to operate.</i>
Primary Care <i>Primary care practitioner's clinics, pharmacies and wider community health programmes and initiatives including virtual ward services</i>	Health Centres Health centres, health posts and outreach <i>Centres can perform simple lab POCT inc. simple microscopy. Clinicians & other healthcare workers on site. Health Posts often don't have lab capability but healthcare workers can perform some POCT</i>