



DETECT Target Product Profile (TTP) for severe infections (bloodstream/HAP/VAP)

	Characteristic	Minimum requirement (Must-have)	Optimal requirement (Good-to-have)
1	Intended use	<p>1) Ability to detect one or more priority pathogens as listed (<i>Escherichia coli</i>, <i>Klebsiella pneumonia</i>, <i>Enterobacter spp.</i>, or <i>Pseudomonas aeruginosa</i> or <i>Acinetobacter baumannii</i>)</p> <p>AND</p> <p>2) Ability to detect <u>genetic determinants</u> of antimicrobial resistance</p> <p>Clinical indication: for purposes of patient management and antibiotic stewardship of severe infections.</p>	<p>1) Able to do multiple pathogen identification (<u>Enterobacterales</u> such as <i>Escherichia coli</i>, <i>Klebsiella pneumonia</i>, <i>Enterobacter spp.</i>, and/or <i>Pseudomonas aeruginosa</i> and/or <i>Acinetobacter baumannii</i> or <i>Candida spp.</i>, or <i>Staphylococcus aureus</i>)</p> <p>AND</p> <p>2) <u>Phenotypic</u> antimicrobial susceptibility for <u>all</u> antibiotics OR <u>genetic determinants</u> of antimicrobial resistance</p> <p>Clinical indication: for purposes of patient management and antibiotic stewardship of severe infections</p>
2	Genetic determinants (for bacteria and for genotyping)	<p>1) <u>Carbapenem resistance</u> (e.g. <i>blaKPC</i>, <i>blaNDM</i>, <i>blaOXA</i>, <i>blaIMP</i>, <i>blaVIM</i>)</p> <p>OR</p> <p>2) <u>Extended-spectrum beta-lactamases</u> (<i>blaCTXM</i>, <i>blaTEM</i>, <i>blaSHV</i>)</p>	<p>1) <u>Carbapenem resistance</u> (e.g. <i>blaKPC</i>, <i>blaNDM</i>, <i>blaOXA</i>, <i>blaIMP</i>, <i>blaVIM</i>)</p> <p>AND</p> <p>2) <u>Extended-spectrum beta-lactamases</u> (<i>blaCTXM</i>, <i>blaTEM</i>, <i>blaSHV</i>)</p> <p>AND</p> <p>3) <i>mecA/mecC</i> (<i>S. aureus</i>)</p>
3	Clinical specimen	Blood (e.g. whole blood, plasma, or serum) or	-



		upper respiratory specimen (e.g. sputum, bronchoalveolar lavage, tracheal/endotracheal aspirate)	
4	Culture-dependence	-	Culture-independence (from clinical specimen directly) Note: More applicable to respiratory specimen for now; Blood will likely require some form of culturing to increase bacterial load
5	Sample capacity / throughput	Able to perform single runs of ~5 samples per run	Able to perform single runs of >10 samples per run
6	Point-of-care (POC)	<u>Near POC</u> defined as requiring processing in laboratory	<u>True POC</u> defined as result readout available at bedside
7	Automation	Automated (<u>excluding</u> sample preparation)	<u>Fully</u> automated (<u>including</u> sample preparation)
8	Training requirements	Trained laboratory technician with basic microbiology skills	Minimal training required and non-laboratory staff may also operate
9	Ease of use	-Few manual steps for sample preparation or addition of reagents with clear instructions provided	No need for additional consumables outside of kit ; sample to result cartridge/closed system
10	Power requirements	-Able to operate with standard and stable AC supply	No need for electricity to operate or battery-operable
11	Price per test (at 100,000 tests per year)	≤ <u>US\$ 20</u> at volume production.	≤ <u>US\$ 15</u> at volume production.
12	Time to result - ID and phenotyping/genotypic results	≤ 90 minutes	≤ 60 minutes



References

1. World Health Organization. WHO bacterial priority pathogens list, 2024: Bacterial pathogens of public health importance to guide research, development and strategies to prevent and control antimicrobial resistance [Internet]. www.who.int. 2024. Available from: <https://www.who.int/publications/i/item/9789240093461>
2. Antimicrobial Resistance Division (AMR). Target product profiles for antibacterial resistance diagnostics [Internet]. Who.int. World Health Organization; 2019 [cited 2025 Sep 9]. Available from: <https://www.who.int/publications/i/item/10665331054>