Rapid Diagnostics

from a Developer Perspective

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Disclaimer

The views expressed here are my personal opinions and do not represent my employer.

Rapid Diagnostic Development

Clinical Value: *What is the need?*

Rapid Antimicrobial Testing (Susceptibility vs. Resistance)

Design Requirements: *How will the device fulfill the need?*

- Time To Results (<8hrs)
- Target(s)
- Specimen(s)
- Clinical Workflow
- IVDR/IVDD
- Cost

Technological Approach: Phenotypic, Genetic or Genomic?

Technology Pugh Matrix

Comprehensive
Limited / Potential
X / $$$

Requirements	AST				AMR		
	Trad. Manual*	Trad. Automated	Rapid Trad.	Genomic Predictive	Genetic PCR/Iso	Genomic Targeted	Genomic Metagenomic
Time to Results (≤8 hrs.)	X	X	√	Library Prep	√	Library Prep	Library Prep
Target(s)	√	√	Limited		Limited		
Specimen(s)	√	√	Limited	Limited	√	Limited	Limited
Clinical Workflow	√	√	Adjunct	SA	Adjunct	SA	SA
IVDD/IVDR	Gold Std	√	√	AI	√		AI
Cost	$	$	$$	$$$	$$	$$$	$$$

*Baseline
√ = Available
SA= Stand Alone

Technology Gaps

- Traditional (Man/Auto): TTR 1-3 days!
- Rapid Traditional: Limited panel leads to adjunct testing
- Genetic: Limited panel leads to adjunct testing, Resistance-only
- Genomic: TTR 1-2 days, $$$, No AI guidance

Technology Barriers

Needle in a Haystack; Pure Colony; Bronze standards; Target Prevalence; No AI Guidance