CARB-X
Combating Antibiotic Resistant Bacteria

CARB-X Diagnostics Target Product Profile		
Variable	Minimal Requirement	Ideal Requirement
1. Product Use Summary/Differentiation Strategy		
Intended Use(s)		
Proposed target populations		
Lowest complexity level (e.g. moderate, CLIA-waived, etc.)		
Lowest level user		
2. Design		
Format		
Target analyte		
Sample type/collection		
Sample volume		
Detection		
Supplies needed		
Results Reported		
3. Performance		
Species differentiation		
Polymicrobial infections		
Analytic sensitivity/LOD		
Diagnostic/Clinical sensitivity		
Diagnostic/Clinical specificity		
Time to result (if culture required, also time from a positive culture)		
Throughput		
Target shelf life/stability		
Ease of use		
Results Interpretation and Output		
Operating Conditions		
4. Manufacturing / Commercial Details		

Target Cost of Goods Sold (consumables, instr., etc.)		
Target Average Sales Price (consumables, instr., etc.)		
Target launch countries / SRAs		

Competitive Differentiation Matrix			
	Competitor 1	Competitor 2	Competitor 3
Overview: Brief description of how the competitor is used clinically, whether it is considered standard-of-care.			
Differentiation Areas: What liabilities do the competitor products possess and which attributes will your product have/need to enable penetration into the marketplace? Add rows for each general category (e.g. affordability, throughput, TTR, sample type, existing install-base, etc.)			
Clinical Comparator: Will this product likely be a comparator used during development of your product?			

The competitor products should also include products that are currently in clinical development and may represent the standard-of-care in the future. Please include both systems currently commercially available as well as those in development.

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CARB-X Diagnostics Guidance Note

Please find some noted below aspects you may wish to cover within the Target Product Profile, this is not a comprehensive list and should be added to as appropriate to best describe the positioning of the technology.

1. Product Use Summary/Differentiation Strategy
    a. Intended use –sample ID and/or AST; pathogens to be covered
    b. Proposed target populations – including primary clinical indications
    c. Lowest complexity level (e.g. moderate, CLIA-waived, etc.) – for example a point-of-care device may require no infrastructure, a highly specialized diagnostic might be in a centralized lab facility
    d. Lowest level user – for example from community healthcare worker up to highly specialized highly trained user
2. Design
    a. Format – for example microfluidics, multiplexed, immunoassays such as lateral flow
    b. Target analyte – DNA, RNA, enzymes, antigens
    c. Sample type/collection – blood, urine, sputum, CSF etc.; if appropriate also include sample collection method such as finger stick or blood draw
    d. Sample volume – from l to ml as appropriate
    e. Detection – naked eye; battery or main powered reader; fluorescence etc.
    f. Supplies needed – all reagents and supplies needed, for some point of care devices it may be contained within the kit.
    g. Results reported – how are results reported to clinician?
3. Performance
    a. Species differentiation – as stated
    b. Analytic sensitivity/ LOD – smallest quantity of the analyte that can be determined and distinguished from a control or blank sample with a reasonable level of certainty
    c. Diagnostic/ clinical sensitivity – shown as a percentage (true positive rate)
    d. Diagnostic/ clinical specificity – shown as a percentage (true negative rate)
    e. Time to a result – time from getting the sample to making a clinical decision. If the diagnosis is based on a positive culture, then the time from a positive culture should also be included to clarify any assumptions about time from sample to positive culture result. If the format will also require sample stacking which may therefore delay overall time to a result this should be noted.
    f. Throughput – number of tests to be carried out within a stated time; also note whether samples will be stacked or it's a multiplexed format
    g. Target shelf life stability – this can cover the whole diagnostic and/or specific reagents, include both time and temperature range
    h. Ease of use – from easy to complex (consider overall requirements including lowest user level, level of operator input, whether it may require calibration etc.); may include number of steps, level of detail needed for instructions (also include level of complexity and if CLIA-waived)
    i. Ease of results interpretation – for example consider whether automated, will require operator interpretation, whether simple yes/no or requires some level of quantification. If more complex interpretation, consider how it impacts therapeutic decisions, whether it allows for data transfer for results to be reviewed by qualified personnel; whether requires language specific instructions

4. Product cost
    a. Target COGS – items having a one-off use; cost-of-goods (consumables, instrument, etc)
    b. Target ASP – suggested average sales price based on a given volume of sales (consumables, instrument, etc)
    c. Target launch countries / SRAs – this should consider incidence rates based on intended use and proposed target populations, as well as affordability and access provisions; include which Stringent Regulatory Authorities pathways will be pursued