

Xpert® 10 color Plus Melt Curve Technologies for Antimicrobial Resistance Gene Detection

1



Add Sample Reagent to sample tube and incubate for 15 minutes at room temperature. Alternatively, leftover specimen treated with sample reagent can be used if kept for less than 2.5 hours at up to 35°C, or less than 4 hours at 2-8°C.

2



Pipette inactivated sample into cartridge

3

Insert cartridge and start test



GeneXpert® I



GeneXpert® II



GeneXpert® IV



GeneXpert® XVI

- *Mycobacterium tuberculosis* assays*
 - Incorporate melt curve technology to differentiate among *rpoB* mutations leading to rifampin resistance to provide better specificity
 - Expand the number of color channels together with melt curve analysis available to enable detection of resistance mutations for isoniazid and second line agents
- Carbapenem resistance gene detection†
 - Use 10 colors to expand the number of targets available in the Xpert® CarbaR assay

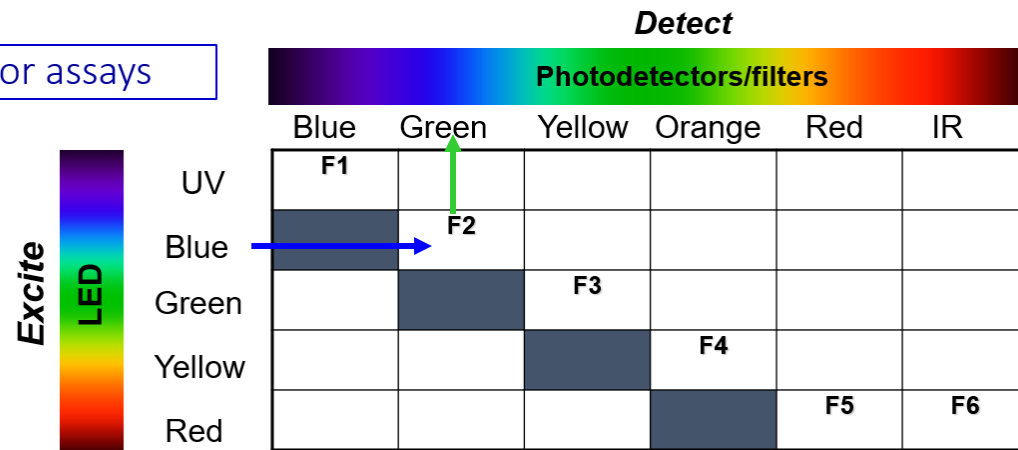
* † CE-IVD. In Vitro Diagnostic Medical Device. Product may not be available in all countries
Xpert MTB/RIF Ultra is not available in US

† US-IVD. For *In Vitro* Diagnostic Use

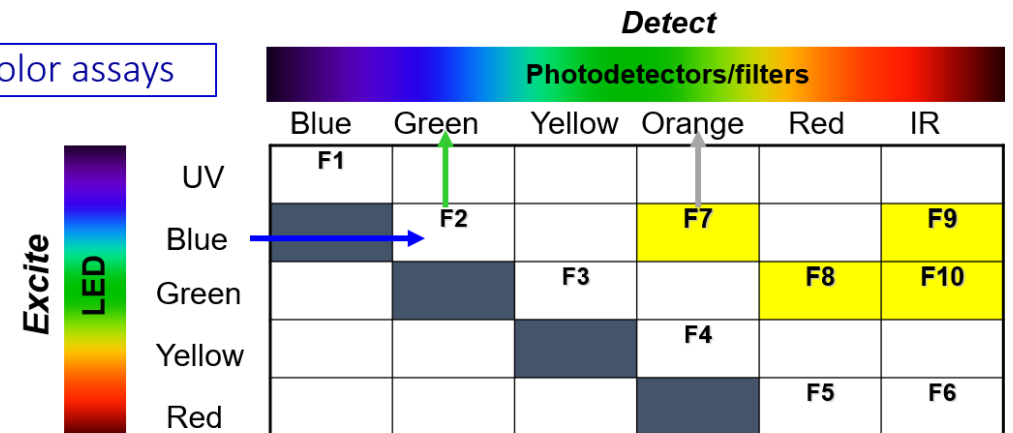
GeneXpert® Optics: Excitation/Detection Matrix

- Each individual reporter to be measured optically in the GeneXpert system can be represented by a characteristic signal vector, which indicates excitation and detection channel pairings
- Expanded matrix of excitation and detection channel pairings for 10-color systems

6 color assays



10 color assays



The public health crisis of Drug Resistant TB and the Xpert® tool

- 10 million people fell ill with TB and 1.4 million died of TB in 2019
- Half a million people were sick with drug resistant TB in 2019
 - Only 38% accessed treatment and of those, only 57% were successfully treated



- Reflex test for samples positive for MTB
- Simultaneous detection of:
 - MTB Complex, mutations associated with INH, ETH, FQ, SLID resistance
- Results in less than 90 minutes¹
- Closed cartridge system minimizes risk of contamination

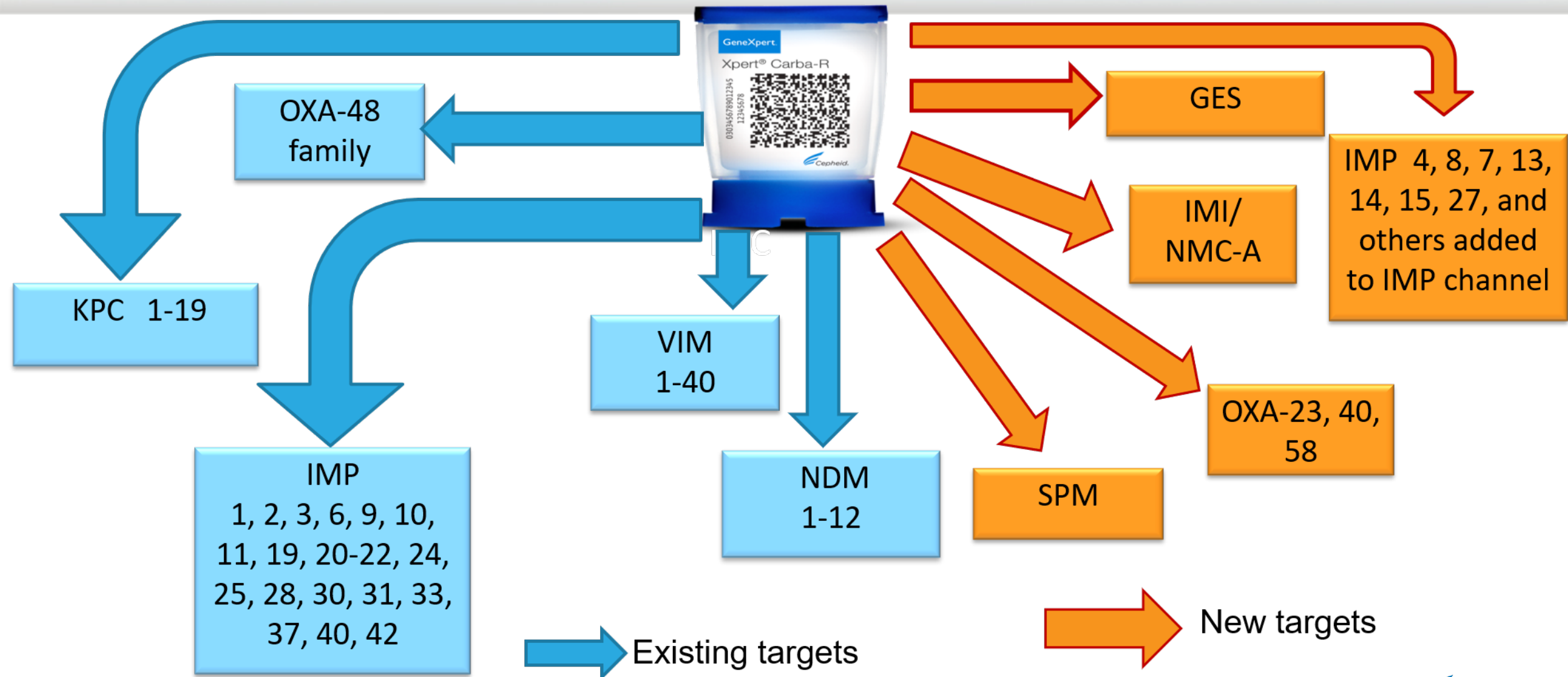
Drug	Gene Target
Isoniazid	<i>inhA</i> promoter <i>katG</i> <i>fabG1</i> <i>oxyR- ahpC</i> intergenic region
Ethionamide	<i>inhA</i> promoter
Fluoroquinolones	<i>gyrA</i> <i>gyrB</i>
Amikacin, Kanamycin, Capreomycin	<i>rrs</i> <i>eis</i> promoter

1. Package Insert Xpert MTB-XDR ENG PI 302-3514 Rev B

• CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

Ref: World Health Organization. Global Tuberculosis Report. 2020.

Xpert® Carba-R Next Gen: 10 Colors, No Melt Curve Analysis Required



"Product in development. Not for use in diagnostic procedures. Not reviewed by any regulatory body."