

# Gene Xpert (Cepheid)



- Single use cartridges

- Extraction and amplification: in the cartridge



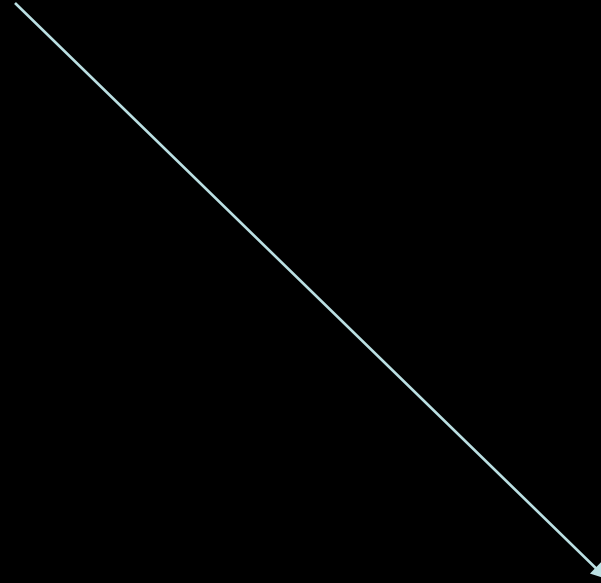
- Fully Automated

## Using the Cepheid Gene Xpert:

Clinical  
Specimen



Treat specimen with NALC-  
NaOH and make concentrate



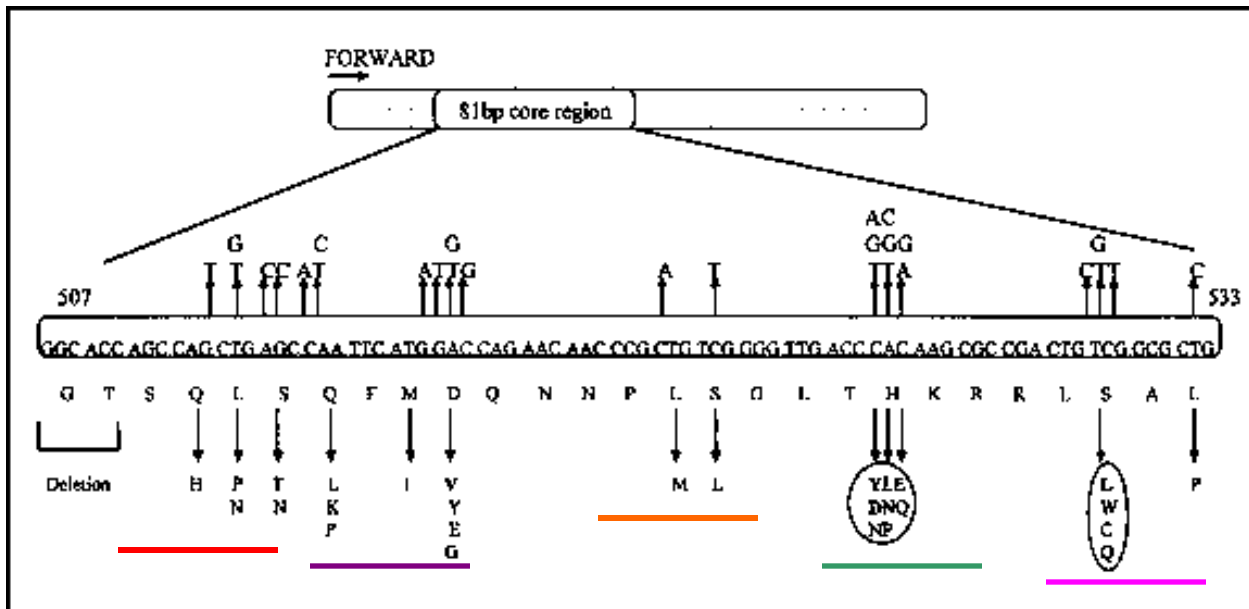
**Results**



GeneXpert

# GeneXpert: *nested* PCR on *rpoB*

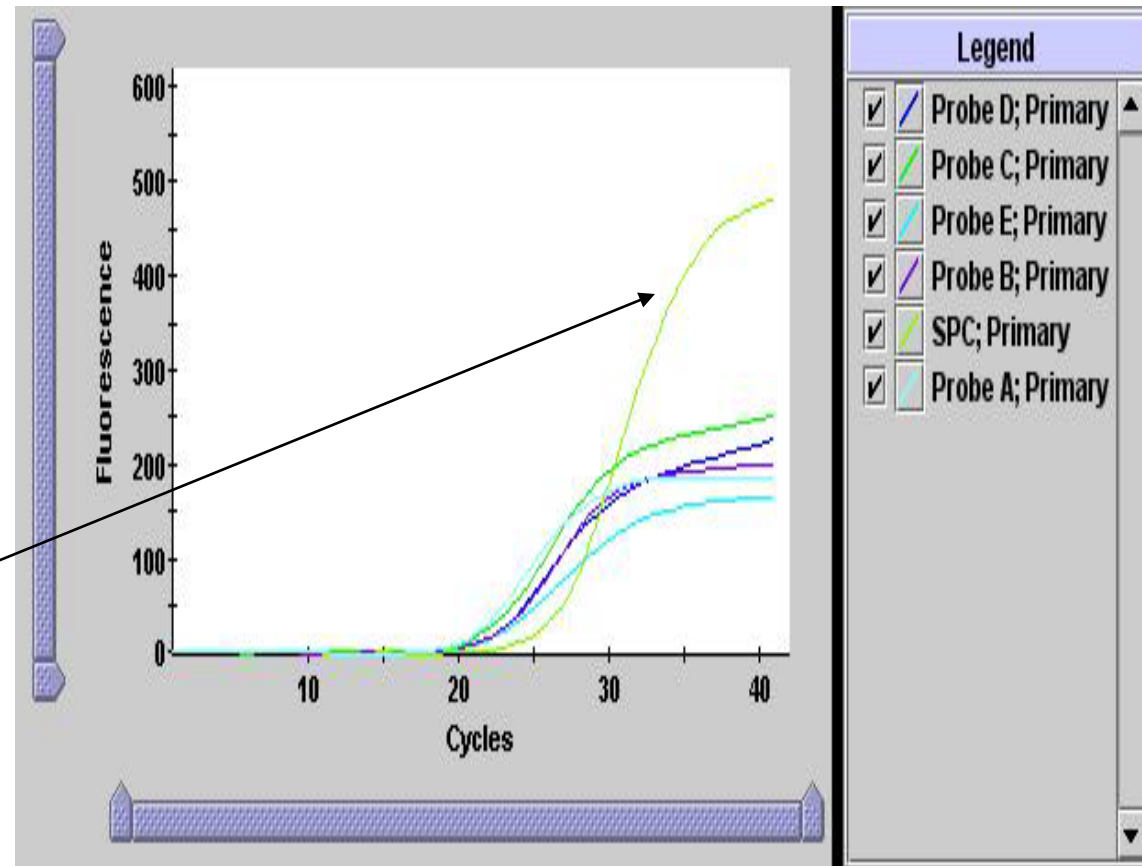
- The target of rifampin: RNA polymerase subunit B
- PCR amplifies a small region relevant for rifampin resistance; uses **5 probes** to assess for mutations



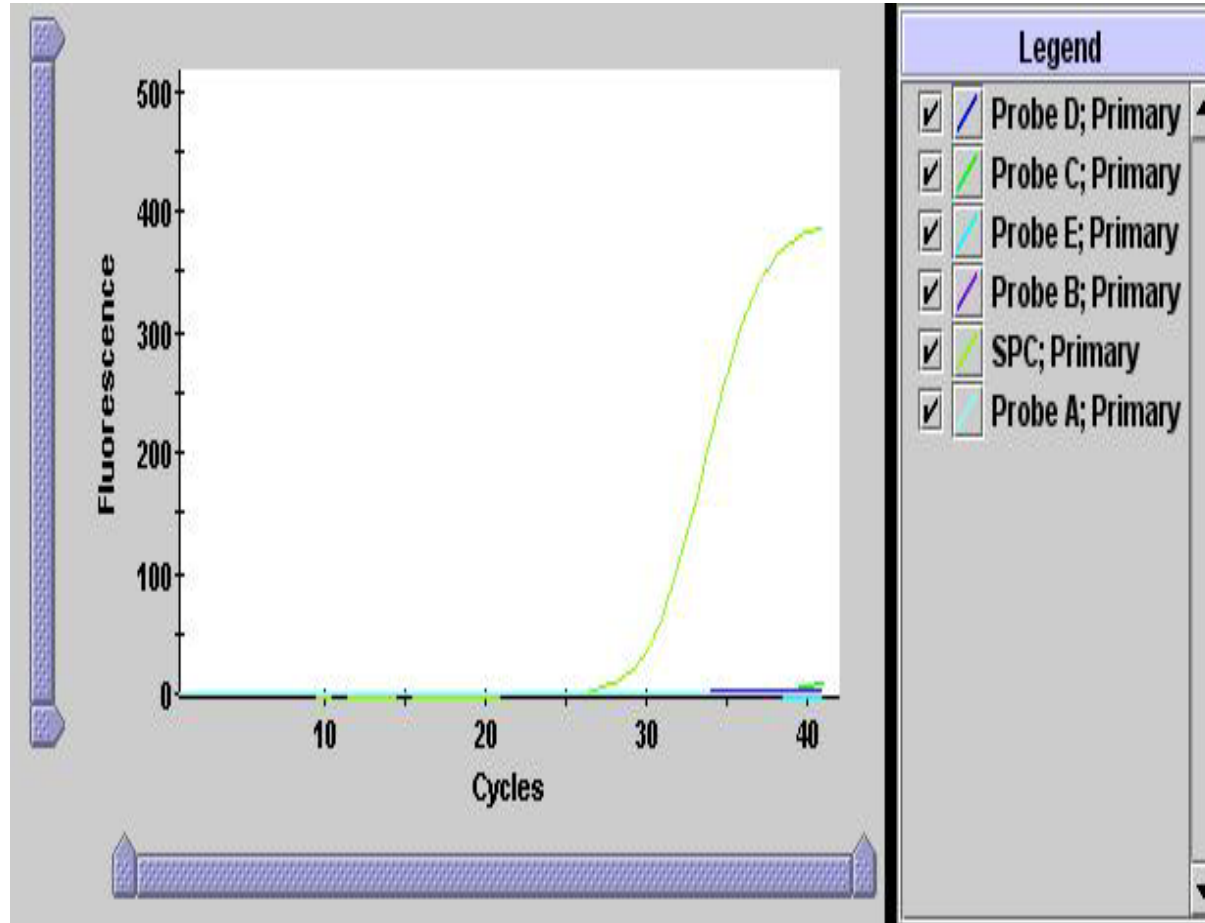
# Cepheid MTB: positive result

- five probes

-assay has an Internal PCR Control (for inhibition assessment)



# Cepheid MTB: negative result



# Validation: Sensitivity; culture positive for MTB:

--13/13 smear numerous, culture  
positives: 100%

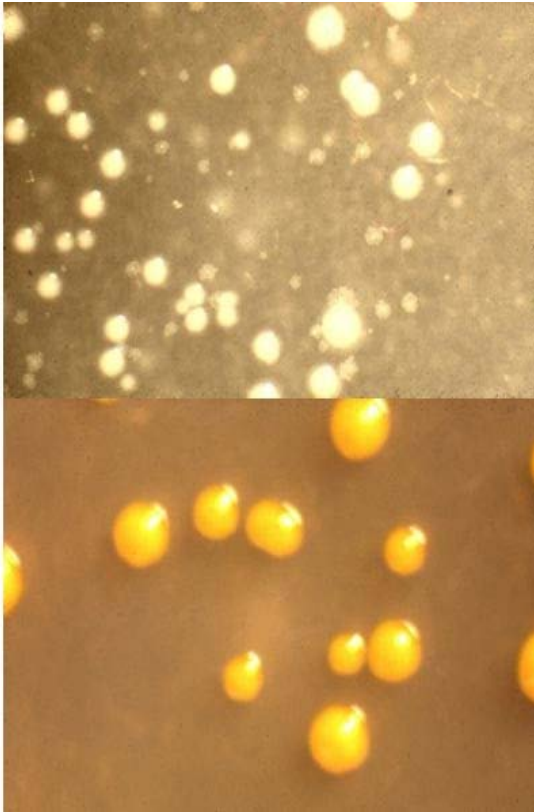
--30/32 smear few / rare: 94%  
(missed one "few" and one "rare")

--29/40 smear negative, culture  
positives: sensitivity: 72.5%

(Sm. Neg/Cult Pos sensitivity of  
**MTD** test: ~72%  
(package insert)



# Specificity



- 30 negative sputum
  - 0/30 positive

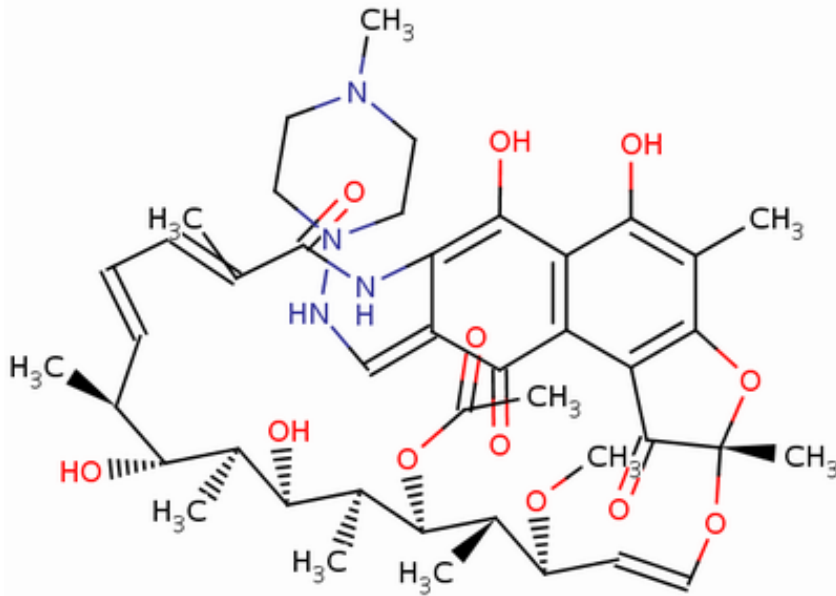
Of those:

- 10 smear+ / culture positive  
MOTTs tested:

0 were reactive

--100% specificity

# Rif Resistance



- In search of specimens
- 3 MGIT samples of resistant isolates tested: all three were called correctly
- 3/85 Rif-susceptible (sputum) specimens were called Rif resistant—*phenotype testing showed otherwise*
- (96.6% specific, so far)

# How we are using it now

- Sputum only
- Test is run: 3 days per week
  - Results follow: depending on when we get specimens: either same day or next day
- All requests must go through public health TB control dept.
- No RIF susceptibility results right now: not validated