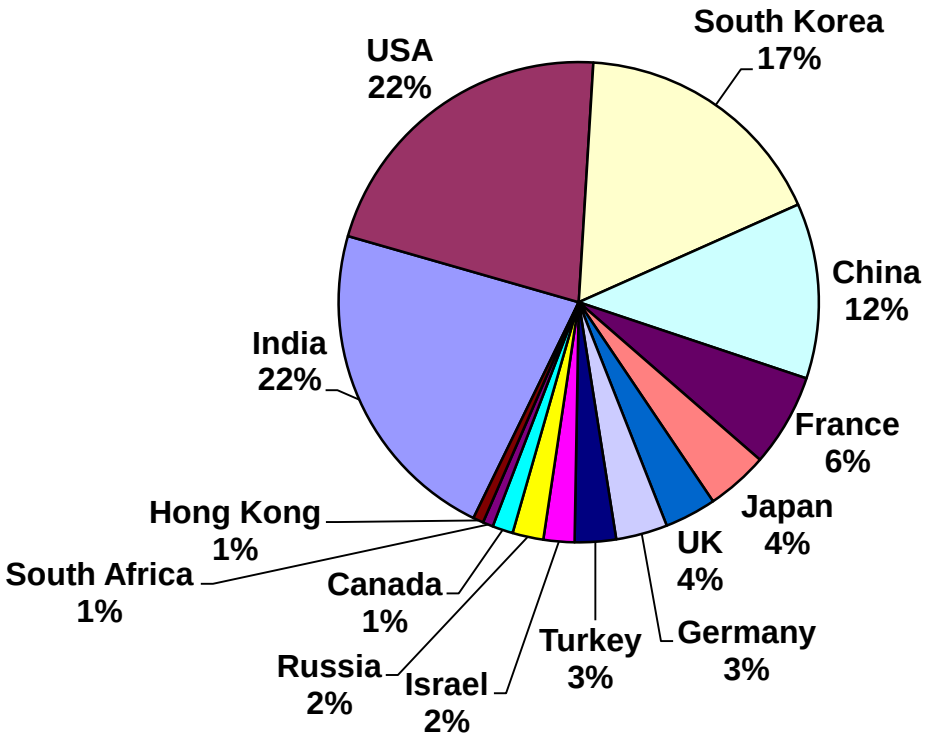
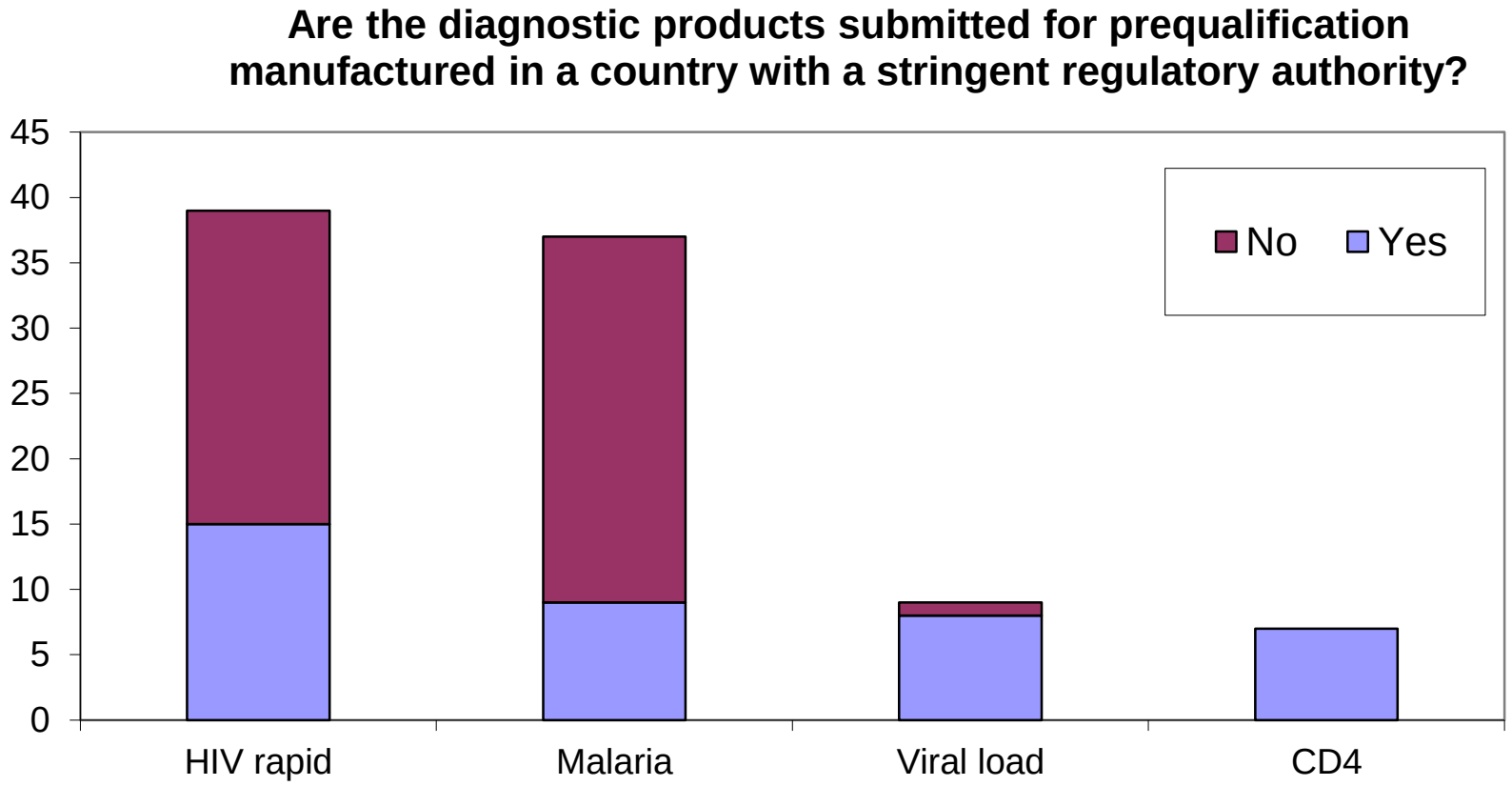
PQ Dx country of manufacture (detail)

Where are products manufactured?
(breakdown by country and % of total, total n=144)



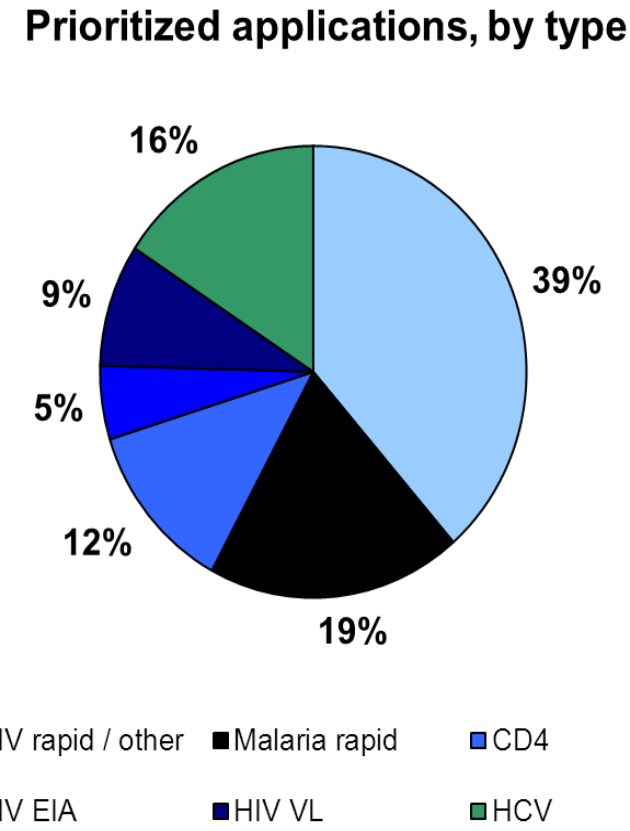
Based on analysis conducted 30 Sept 2011.

PQ Dx country of manufacture (SRA vs. non, by product type)



* SRA: Stringent regulatory authority. For this analysis, a country is considered to have strict diagnostic regulation if a founding members of the Global Harmonization Task Force (GHTF) – i.e., European Union, United States, Canada, Australia and Japan.
Based on analysis conducted 30 Sept 2011.

PQ Dx progress: applications and dossiers



Applications (April 2010 - May 2011):

- 61 priority applications accepted
- 10 applications closed

Dossiers:

- 47 dossiers received (5 pending)
  - 21 HIV – 7 CD4
  - 11 malaria – 4 VL
  - 3 HCV – 1 HBV
- 37 dossiers screened
  - All required amendments
- 9 full dossier assessments completed

Status as of 25 Aug 2011, based on analysis of PQ tracking document

WHO Pre-Qualification (1)

- In your view, what are the key diagnostic related challenges and priorities today and for the next 5 years?
- How can WHO contribute to meeting this challenge by facilitating the availability of quality new diagnostic products?
- How best can the PQ Dx process be Fast-Tracked without compromising the quality of the PQ procedure?

WHO Pre-Qualification (2)

- How better to collaborate with other National Regulatory Authorities?
- How can PQ Dx timelines be better aligned with those of stringent National Regulatory Authorities?
- What operations could be decentralized or outsourced?

WHO Pre-Qualification (3)

- With which other entities should WHO strengthen its collaboration, and in what ways, to improve the effectiveness of its diagnostics PQ services?
- What IT solution support would increase effectiveness of the program?
- Possible funding options to ensure PQ self- sustainability?
- How to improve diagnostics developer's manufacturing capabilities?
- Expansion the PQ process for diseases other than infectious diseases?