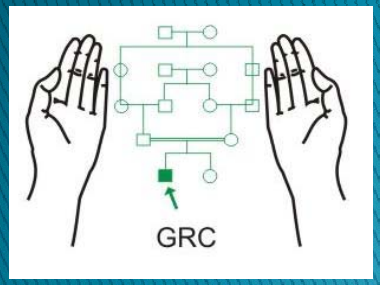
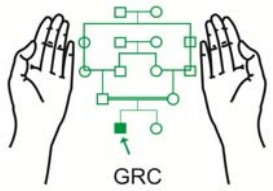
Blood Donor Screening & Quality Control

Maj Gen (R) Suhaib Ahmed, HI (M)
MBBS; FCPS (Pak); PhD (London)
Genetics Resource Centre (GRC)
Rawalpindi



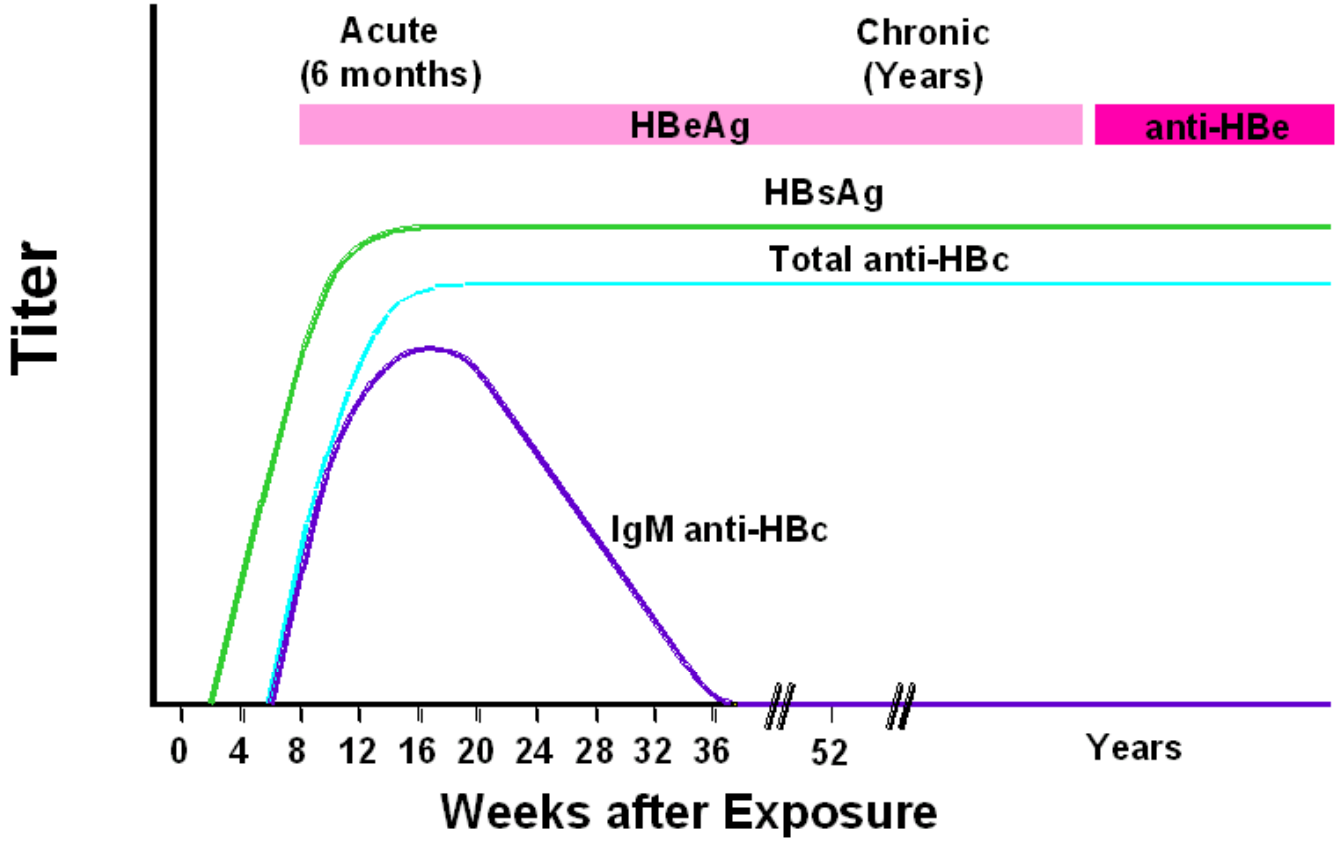
www.grcpk.com

Challenges

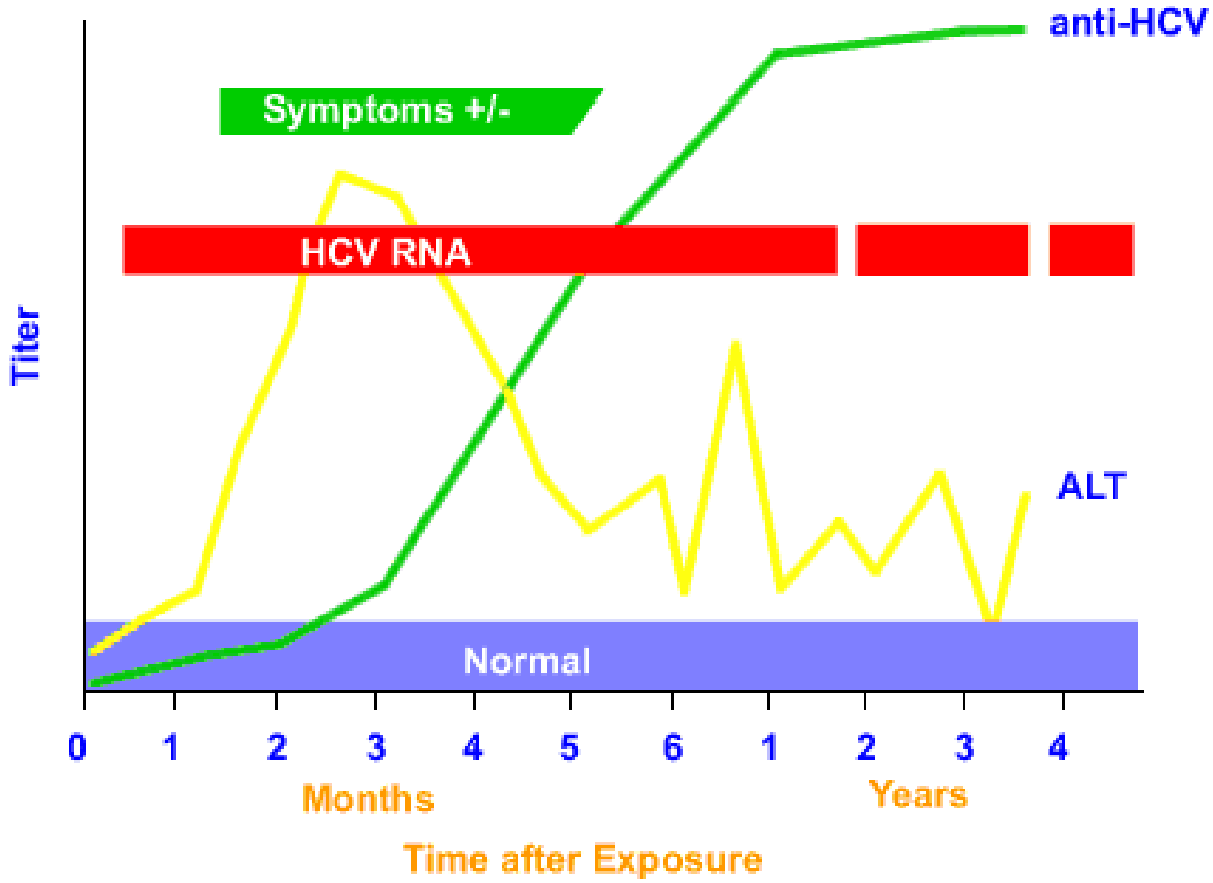


- Low percentage of volunteer donors
- Disorganized (fragmented) blood transfusion services
- High prevalence of HCV and HBV
- Limited resources
- Window period

Progression to Chronic Hepatitis B Virus Infection
Typical Serologic Course



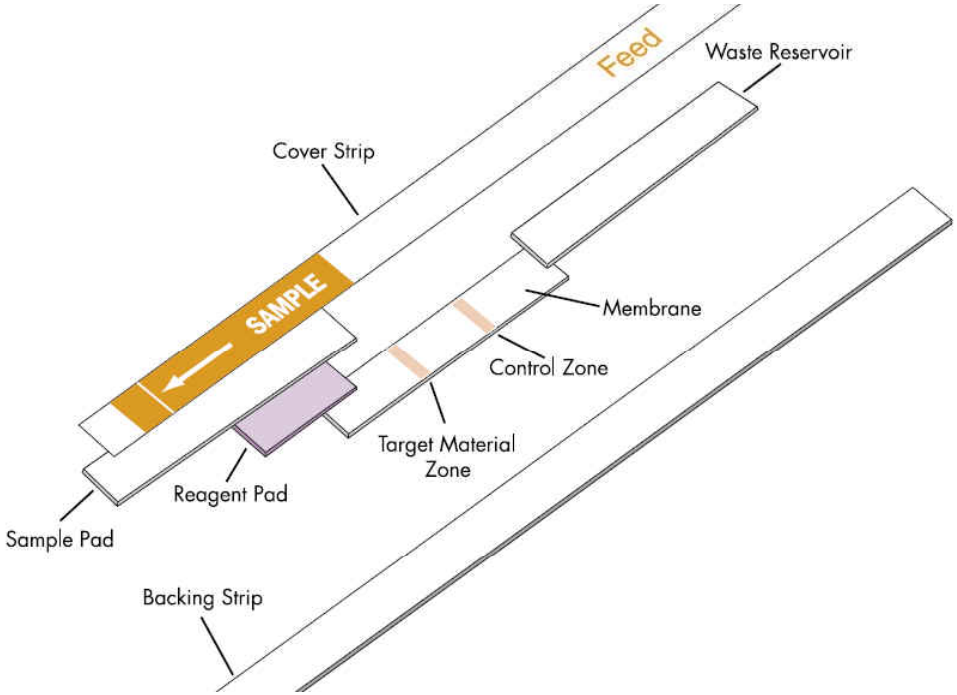
Serologic Pattern of Acute HCV Infection with Progression to Chronic Infection

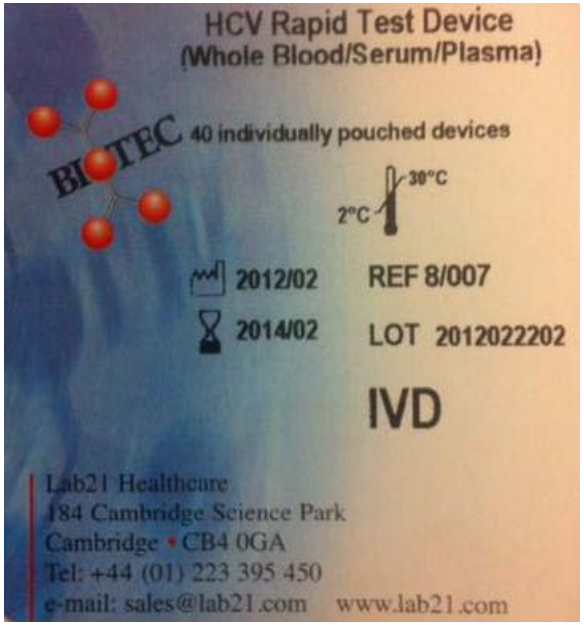


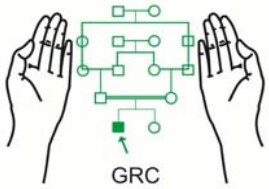
Testing Method

Sensitivity

Specificity

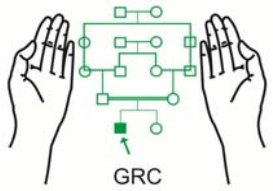

Feed
Waste Reservoir
Cover Strip
SAMPLE
Membrane
Control Zone
Target Material Zone
Reagent Pad
Sample Pad
Backing Strip


HCV Rapid Test Device
(Whole Blood/Serum/Plasma)
BIOTEC
40 individually pouched devices
2°C
30°C
2012/02
REF 8/007
2014/02
LOT 2012022202
IVD
Lab21 Healthcare
184 Cambridge Science Park
Cambridge • CB4 0GA
Tel: +44 (01) 223 395 450
e-mail: sales@lab21.com
www.lab21.com


GRC


HBsAg
HBsAg

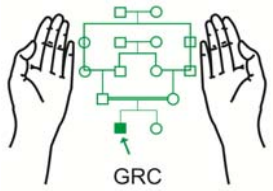
Device Vs ELISA (HBV)



Device Make		Reactive (ELISA) n=100	Non Reactive (ELISA) n=100
ACON	Reactive Non Reactive	95 5	– 100
NOBIS	Reactive Non Reactive	98 2	– 100
MEMBRANE	Reactive Non Reactive	98 2	– 100

(Hayder et al, (2012) PJMR 51: 72-75)

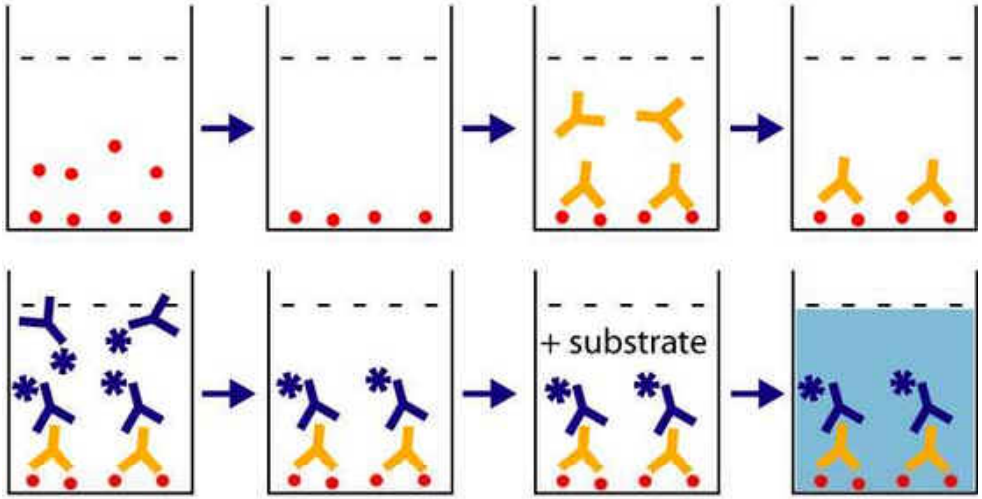
Device Vs ELISA (HCV)

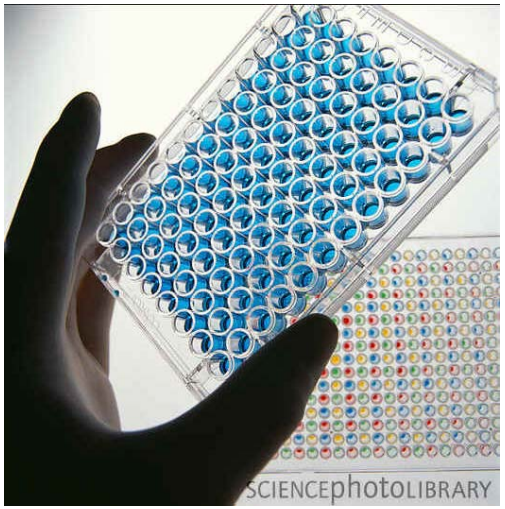


Make		Reactive (ELISA) n=100	Non Reactive (ELISA) n=100
ACON	Reactive Non Reactive	93 7	7 93
NOBIS	Reactive Non Reactive	86 14	4 96
MEMBRANE	Reactive Non Reactive	89 11	3 97

(Hayder et al, (2012) PJMR 51: 72-75)

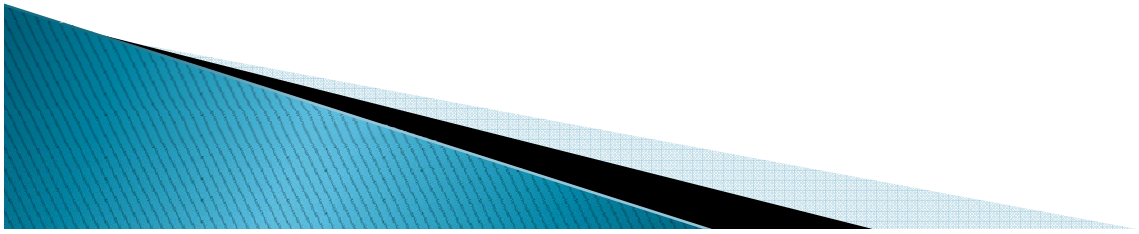
ELISA

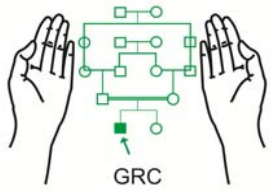




ELISA: Reduction in Mean Window Period

- HIV: 22 days
- HBV: 59 days
- HCV: 70 days

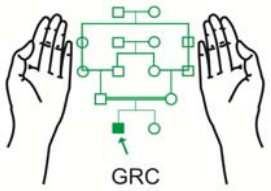




Chemiluminescence Methods

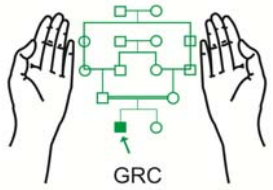
GRC

Nucleic Acid Testing (NAT)

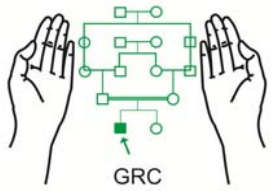


- Individual Donor NAT
  - HCV: the "window period“ is reduced from an average of 72 days to 5 days
  - HIV: the “window period” is reduced from 22 days to 5.6 days
- Pooled Sample NAT
  - HCV from 70-80 days to 10 days
  - HIV from 16 days to 10 days
  - HBV from 56 days to 20-30 days

NAT: Made in Pakistan

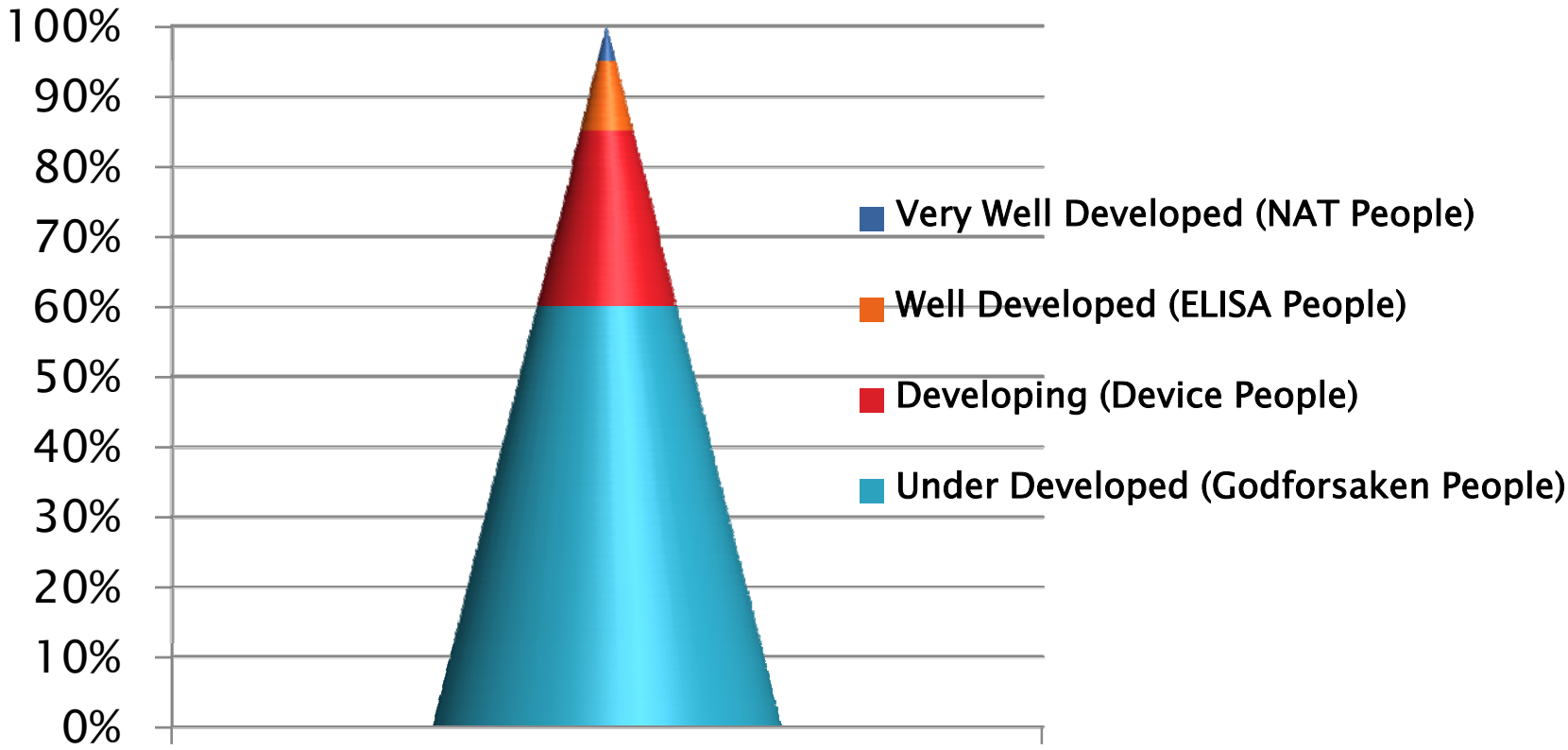


	Surgical	Gynae	Medical	Paeds
Total (270)	54 (20%)	81 (30%)	58(21%)	77 (29%)
Routine 67/270 (25%)	4/54 (7%)	9/81 (11%)	8/58 (14%)	46/77 (60%)
Urgent 203/270 (75%)	50/54 (93%)	72/81 (89%)	50/58 (86%)	31/77 (40%)
Packed Cells 163/270 (60%)	11/54 (20%)	35/81 (43%)	42/58 (72%)	75/77 (97%)
Whole Blood 107/270 (40%)	43/54 (80%)	46/81 (57%)	16/58 (28%)	2/77 (3%)
Hb (Mean) (Range)	9.3 g/dl (4.9-12.2)	8.3 g/dl (4.4-11.1)	7.0 g/dl (4.1-10.6)	7.3 g/dl (2.6-9.6)

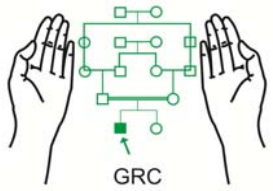


Choice of Screening Method(s) for Pakistani Setting

Population of Pakistan



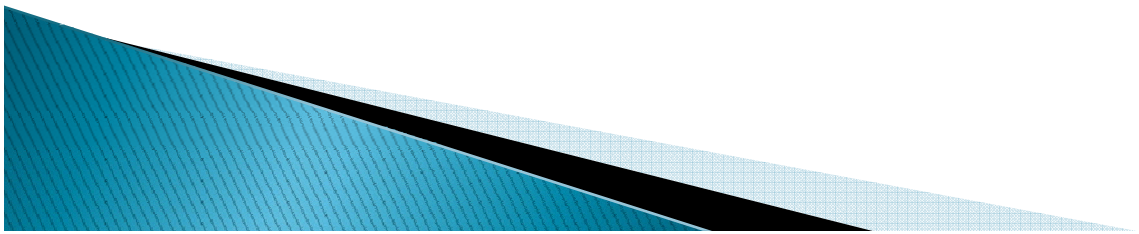
Some critical questions?

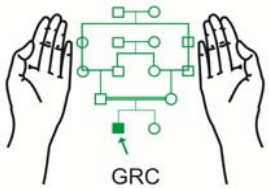


- Getting carried away by the low cost and the ease with which a rapid device can be used?
- Ignoring the large gap in the sensitivity of the rapid devices?
- Concentrating too much on the window period?

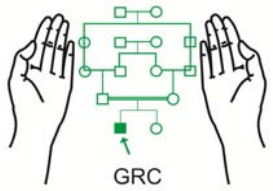
Quality Control of Screening Methods

- Standardization of
  - Screening Kits and reagents
  - Procedures and SOPs
- Internal Quality Control
- External Quality Control
  - National
  - International
- Reference material

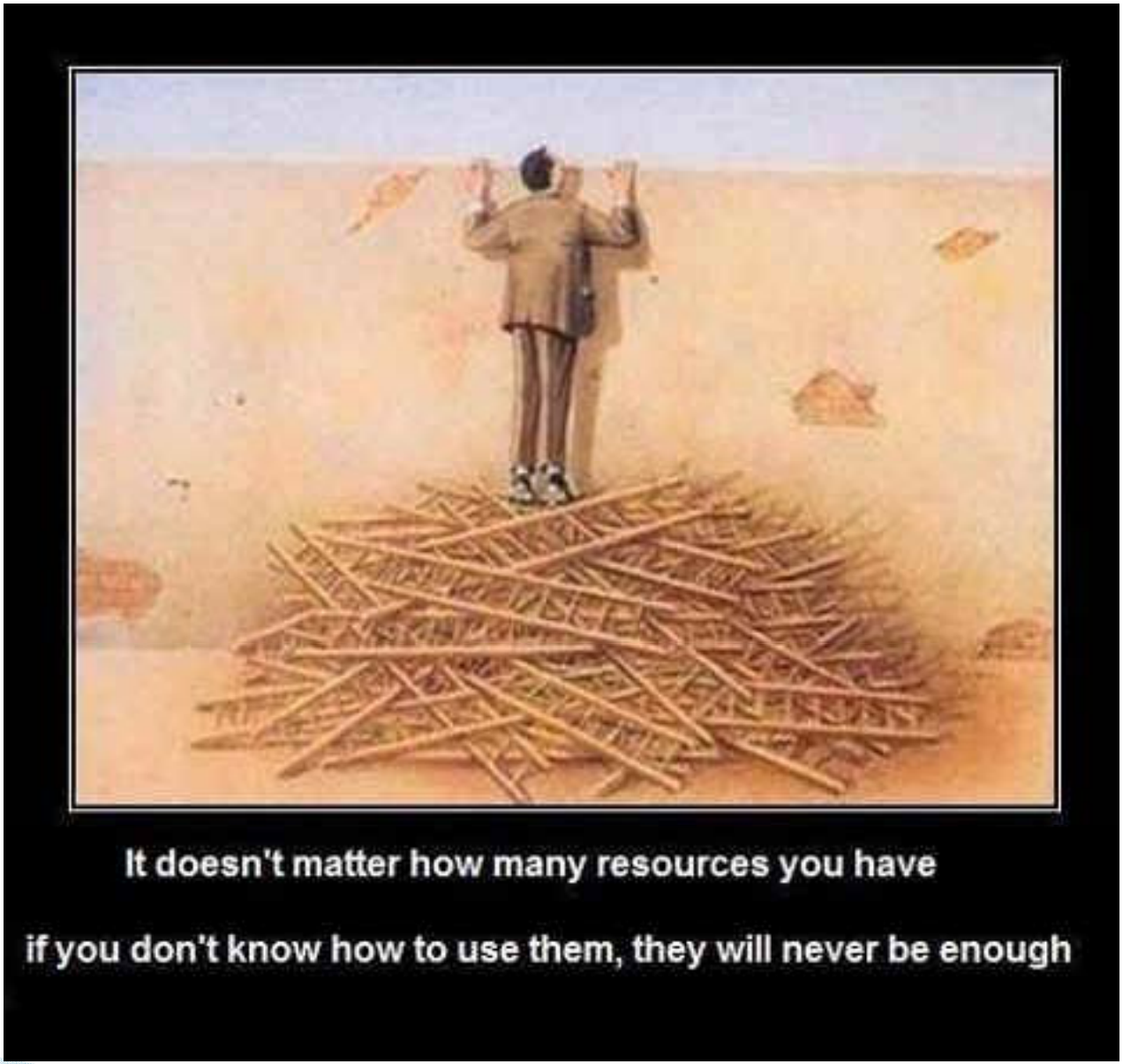




Recommendations



- Minimize the use of Blood and its products
- Standardization of screening kits
  - ELISA or Chemiluminescence is the method of choice
  - Rapid Devices are not recommended
  - PCR not recommended for large scale use
- Internal and external quality assurance


It doesn't matter how many resources you have
if you don't know how to use them, they will never be enough