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# Failure of Test kits: Ensuring the quality of HIV testing in Malawi

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# Case Report: HIV test misdiagnosis

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A 43 years old married woman presented to a private clinic with repeated episodes of mouth sores. The clinician diagnosed her with oral candida. Her past medical history was significant only for bronchial asthma since childhood. Her asthma had been poorly controlled in the recent few weeks requiring high doses of oral prednisolone and regular salbutamol inhaler. She had been on this treatment for a month when she presented with these sores. She had neither had a blood transfusion nor experimental HIV vaccine.

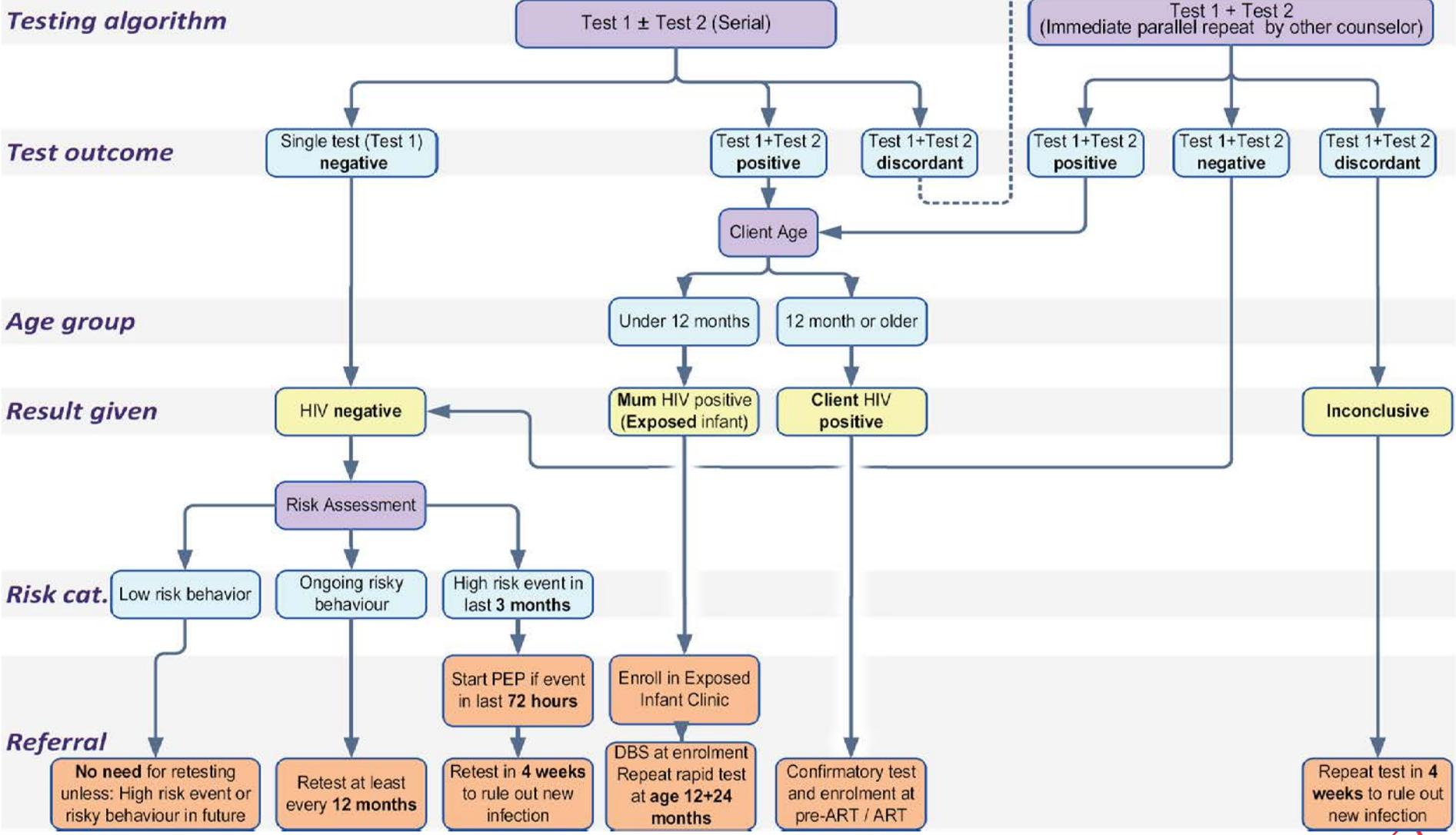


*Fig 2: Excess fat on the back*



# Malawi's algorithm

Most recent HIV test result: **Negative or Never tested**





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# Common Testing Issues

## [Elizabeth Marum, Hetal Patel]

Observed	Recommendations
Disorganized work space	Clean work space
Safety concerns – Inconsistent use of gloves or proper disposal	Universal safety precautions should be followed
Poor finger-prick procedure	Follow job aide
Inadequate sample volume	Follow job aide
Run-time not followed	Mandatory use of timer
Testing algorithm not followed	Re-fresher training
Hand written record keeping	Official register use only
Over burdened sites (ANC, OPD)	No more than 5 clients per Batch





# PEPFAR Policy issues

- Test kit specifications
  - Time to read
  - Storage
- Post-market evaluation
- Task shifting
  - “Health Surveillance Assistants” (HSA)
  - Other duties
- Sheer volume
  - Option B+
  - “Batching”





# Do we know how BIG the problem is?

- No
  - No systemic study as of yet
  - Some clues but hard to interpret and generalize





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# ANC sentinel surveillance: ?apples and oranges

	ANC rapid test	CRL; 4 <sup>th</sup> Generation ELISA
Total tests	23788	23218
Total Positive tests	2215	2532
Percentage	9.3	10.9

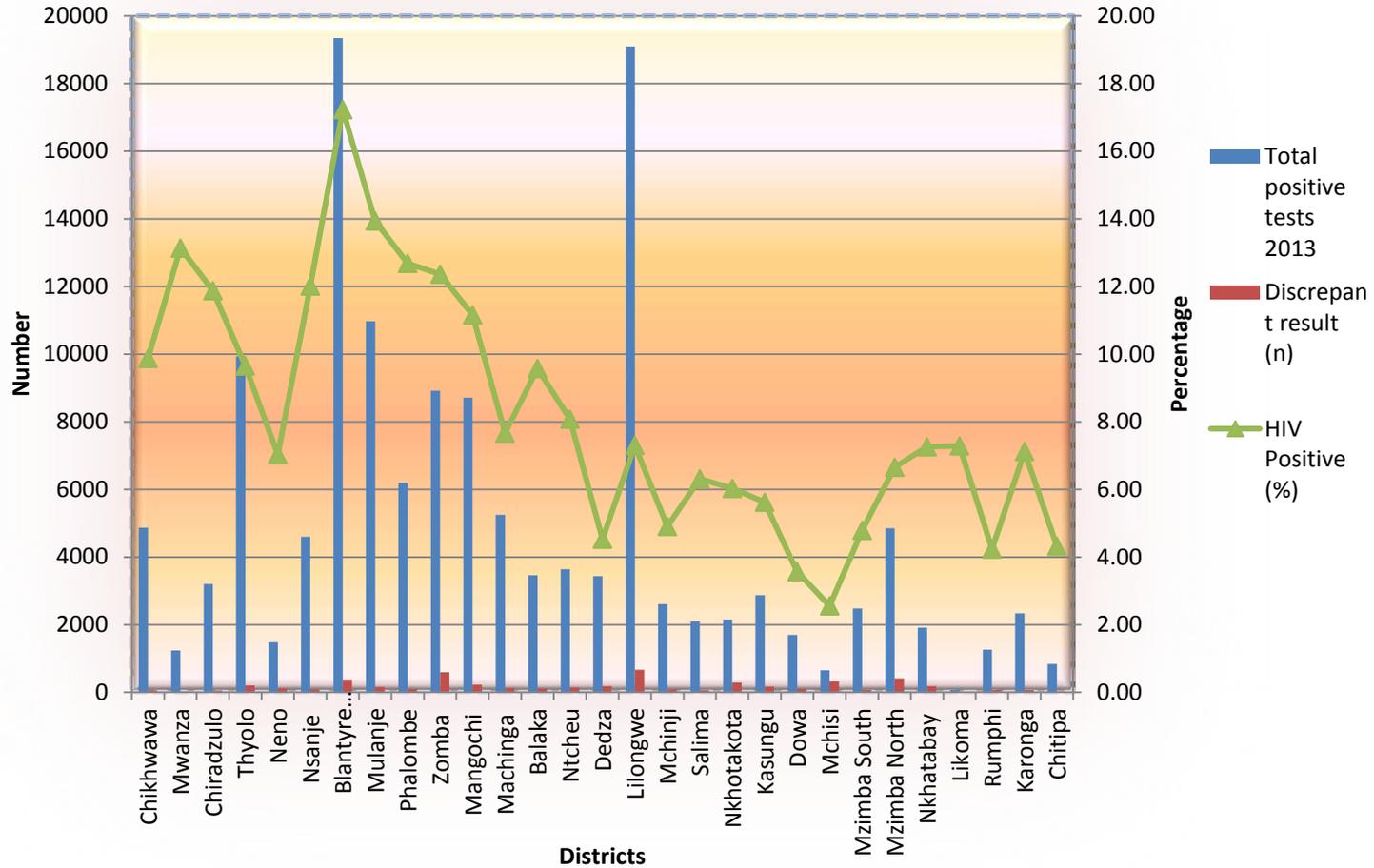
Extrapolate  
national:  
-/+9030





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# HTC 2013



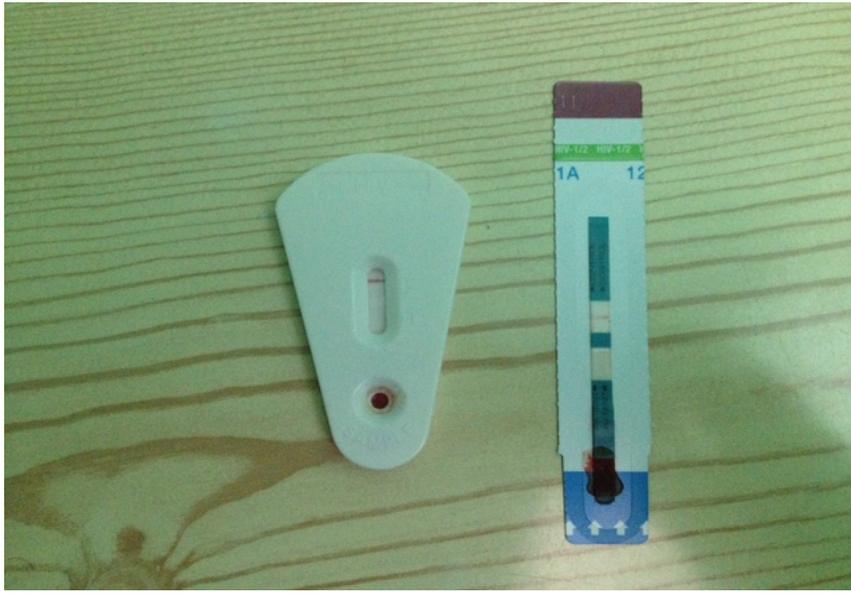
<b>Total tests</b>	<b>1701346</b>
Total Positive	140181
Discordant test	5048
“Confirmatory inconclusive”	745



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- 45 years old
- On ARVs since July 2007, started as “Stage 3”
- 2 VL done
  - LDL
- Re-tested while being screened for “HART vs HEART” study
- *Awaiting a qualitative PCR and Western blot...*





# Implementing a Comprehensive Approach to Ensure Quality

Level	To strengthen Dry Tube Specimen EQA and QC	To strengthen data collection and use
Central	<ul style="list-style-type: none"><li>• Laboratory technologist</li><li>• Supervision to districts</li></ul>	<ul style="list-style-type: none"><li>• M and E (data) position</li><li>• IT equipment</li><li>• IT training</li></ul>
Zonal	<ul style="list-style-type: none"><li>• Training</li><li>• Supervision to Districts/sites</li></ul>	<ul style="list-style-type: none"><li>• IT equipment</li><li>• IT training</li></ul>
District	<ul style="list-style-type: none"><li>• Q- Corps (Supervision)</li><li>• Local IPs</li><li>• Q-Corps for distribution and results collection (?Riders for Health)</li></ul>	<ul style="list-style-type: none"><li>• IT equipment</li><li>• IT training</li></ul>
Sites (Health facility)	<ul style="list-style-type: none"><li>• Q-Corps</li><li>• Involve PEPFAR district implementing partners</li></ul>	<ul style="list-style-type: none"><li>• Monthly reporting to District Lab manager</li></ul>

# Conclusion

- In Malawi as in many countries, patient are started on ARVs based on 2 RTDs with no further confirmation
- There has been no systematic study but anecdotal evidence exists for false positives and false negatives
- EQA and mentorship needs to be intensified in Public health approach programs with task shifting



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