

HIV Testing of Dried Blood Spots: An Evaluation of HIV Kits in Botswana

Rachanee Cheingsong, PhD (CDC)

Sarah Gaolekwe, BSc, MSc,

Wilson Kalake, OND MLT (NBTC)

Presented by:

Kyle Bond, M.S. (CDC)

Acknowledgements

- T Bokete (MOH)
- K Masupu (NACA)
- L Manthe (MOH)
- C Mwangi (NRHL)
- NBTC, BOTUSA, Harvard staff
- T Kenyon (BOTUSA)
- H Jaffe, M Rayfield, K Bond, T Grenade, J Mei, Li Xia (CDC)

Dried Blood Spots

- An easy way to collect and transport blood specimens for investigational purposes
- Blood collected and dried on FDA-approved blood collection device
- 100 ul/spot
- Plasma + cells
- Source of antibody, DNA, RNA

Applications of Testing Dried Blood Spots

Newborn babies screening program in the US

Over 30 inherited and metabolic disorders

Maternal HIV antibodies

Potential applications:

1. HIV surveillance and VCT program
2. Newborn babies screening (PMCT)
 - HIV infection
3. HIV Drug Resistance

HIV Surveillance and VCT Program

1. On-site HIV rapid testing
2. Dried blood spots (DBS) collection for HIV testing at reference labs

HIV Testing of DBS in VCT setting

- Quality control purposes
- Performance of rapid tests and personnel
- Self monitoring and evaluating of the program

HIV Testing of DBS: A Pilot Study in Atlanta

- DBS seroconversion panels (A-E)
- Ugandan DBS panel (n=186)
- Mock DBS
- 7 HIV EIA kits (FDA and non-FDA approved)
- 5 Were not validated for DBS
- The accuracy of the kits was high >97%.

Objective

1. To determine the accuracy of HIV EIA testing on DBS
2. To evaluate the performance of HIV kits for testing DBS in a laboratory setting in Botswana.

Action Plans

July 23rd -Aug. 17th 2001: Pilot Activities

1. Discussion, planning
2. Protocol preparation
3. Generating a panel of DBS
4. Storage and record of specimens
5. HIV Testing
6. Data entry/analysis
7. Comparison of DBS data against serum results
8. Summary

Collection of EDTA blood at National Blood Transfusion Center, Gaborone

Week	Blood Donors	Surveillance
1	227	0
2	46	88
3	38	35
Total	311	123

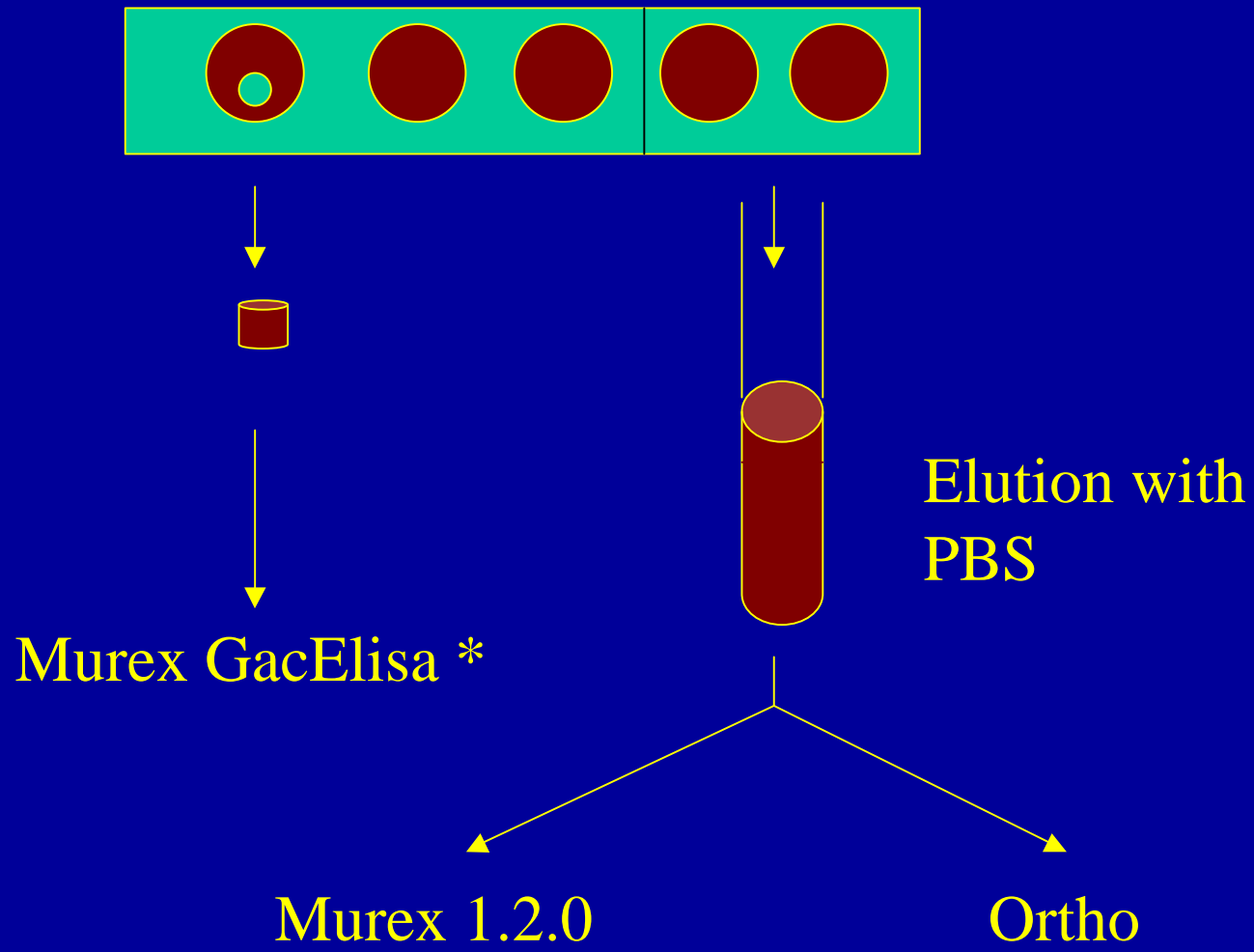
HIV Testing in Botswana

Serum/plasma: 1. Murex 1.2.0
2. Ortho

DBS : 1. Murex 1.2.0
2. Ortho
3. Murex GacElisa
(validated)

HIV Status

Source	HIV +ve/Tested	% prevalence
Blood Donors	11/311	3.5
Sentinel Surveillance	51/123	41.5



Flow Chart of DBS Testing

Mean Absorbance of HIV-ve DBS (n=300) increased

HIV kits	Mean OD Units	
	Serum	DBS
Murex 1.2.0	0.106	0.135
Ortho	0.010	0.047
GacElisa	N/A	0.070

HIV Testing of DBS by GacElisa

Serum HIV	DBS +ve	DBS -ve
HIV +ve n=62	61	1
HIV -ve n=372	1	371

HIV testing of DBS by Murex 1.2.0

Serum HIV	DBS +ve	DBS -ve
HIV +ve n=62	61	1
HIV -ve n=372	4	368

HIV testing of DBS by Ortho

Serum HIV	DBS +ve	DBS -ve
HIV +ve n=62	61	1
HIV -ve n=372	0	372

Performance of HIV kits on DBS

HIV Kits	Sensitivity (%)	Specificity (%)
Murex 1.2.0	98.3	98.9
Ortho	98.3	100
GacElisa*	98.3	99.7

Summary

1. Results of DBS were reasonably comparable to serum results with an exception of one weakly +ve sample.
2. The three kits evaluated with DBS gave comparable results (98% sensitivity, 98-100% specificity).
3. Among three kits evaluated, only GacElisa is validated for DBS.

Plan for weakly +ve samples

- Start collecting this type of samples
- Generating a panel
- Evaluating HIV kits
- Increase sensitivity of HIV kits
- Feed back to manufacturers

Selection of HIV kit(s) for DBS

GacElisa vs Ortho vs Murex 1.2.0 ?

-- Assay validation

- Practical issues
- Dilution factors (Murex and Ortho)
- 1 or 2 assays ?
- Evaluating more HIV kits that use the same format as GacElisa ?

Proposal for Future Activities

- Prospective collection of DBS at VCT sites
- Large sample size
- Evaluation of selected kits with DBS
- Compare results with rapid tests
- Generating a QC panel
- Testing algorithm for DBS