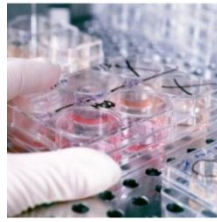




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Field Evaluations of the Alere q point-of-care system for EID

Dr Marvin Hsiao

ASLM 2014 conference Cape Town



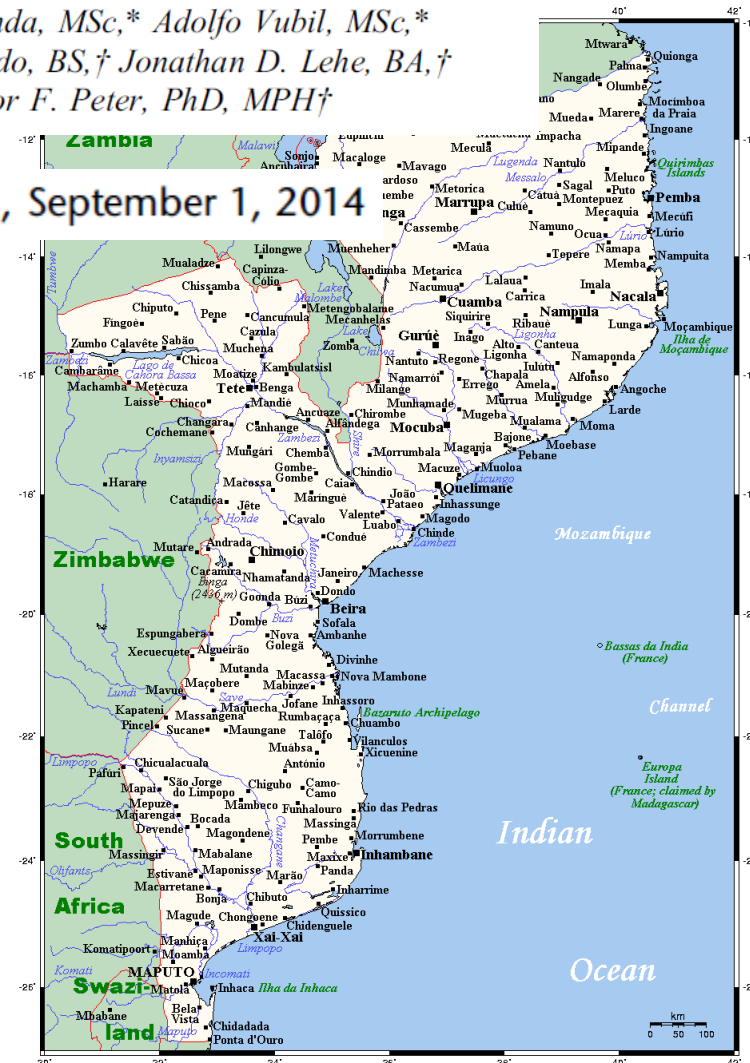
No conflict of interest declared

Accurate Early Infant HIV Diagnosis in Primary Health Clinics Using a Point-of-Care Nucleic Acid Test

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- Field evaluation – 4 primary care Clinic and 1 Hospital at Maputo
- Compared against SOC Lab testing
- Roche CAP/CTM HIV-1 Qual (DBS)
- N= 872
- Sensitivity 98.5%
- Specificity 99.9%



Alert Evaluation Cape Town

NHLS Grootes Schoor Laboratory

- Performed by Laboratory staff
- Birth – 18 months children

Mowbray Maternity Hospital

- Performed by clinical staff
- Birth PCR setting

Gugulethu Infant Clinic

- Performed by clinical staff
- Mostly infant 6-10 weeks





Methods

Sampling

- EDTA samples taken through heel prick or venepuncture from
 - Primary Care clinics – typically 6-10 weeks
 - Hospitals – wide range of ages include some birth PCR's

Testing

- Sample received at NHLS regional laboratory
- Parallel testing done on
 - Roche CAP/CTM HIV-1 Qual V1
 - Alere q Detect

Resulting

- Concordance: no further test
- Discordance: follow up sample – 2 sample positive confirms HIV infection

Results

- Samples tested N=1057
- Children tested n=1004, median age 47 days
- Of the tested sample, the Roche CAP/CTM result were
 - Positive: 161/1057 (15%)
 - Negative: 885/1057 (84%)
 - Equivocal: 11/1057 (1%)

Evaluation of Alere q as early infant diagnosis tool

	Alere q point-of-care HIV PCR			
	Error	Negative	Positive	Total
Roche CAP/CTM HIV-1 PCR				
Negative	55	828	2	885
Positive	10	5	146	161
Equivocal	0	5	6	11
Total	65	838	154	1057

- 6% error rate; 66% of the errors resolved on the 2nd attempt
 - Sensitivity 96.7% Specificity 99.4%
- Excluding error 99.3% concordance



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See Oral session 3.3 Advances in Early Infant
Diagnosis for further analysis

Wednesday 3 Dec 11:00-12:45



Summary of studies

	Mozambique	Cape Town	
N	827	1057	
N – HIV infected	65 (7.7%)	161(15%)*	*Extra PCR pos infant tested
PMTCT	WHO A	WHO B+	
Gold standard	DBS sample	EDTA sample	
Sensitivity	98.5%	96.7%	
Specificity	99.9%	99.4%	
Concordance	99.7%	99.3%	

- Alere q performed well in both EID studies
- Slightly lower sensitivity in our Cape Town study
 - Maternal ART and infant prophylaxis?
 - Different gold standard EDTA vs DBS?



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