

Ministry of Health, Kenya

1. National Public Health Laboratories
2. National AIDS & STI Control Program
3. Kenyatta National Hospital
4. Centre for Disease Control Kenya
5. UNICEF



Performance characteristics of GeneXpert and Alere Q point-of-Care technologies for HIV Early Infant Diagnosis in Kenya

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Disclosure



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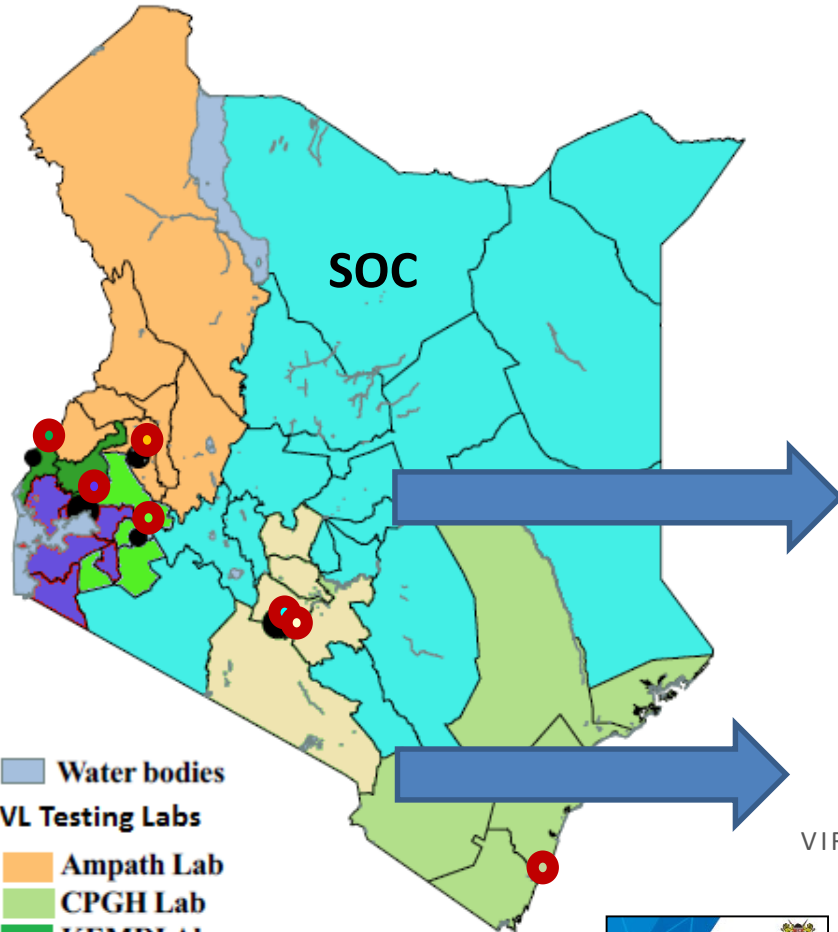
No conflict of interest



EID AND VIRAL LOAD TESTING IN KENYA; Situational Analysis



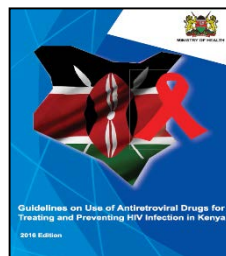
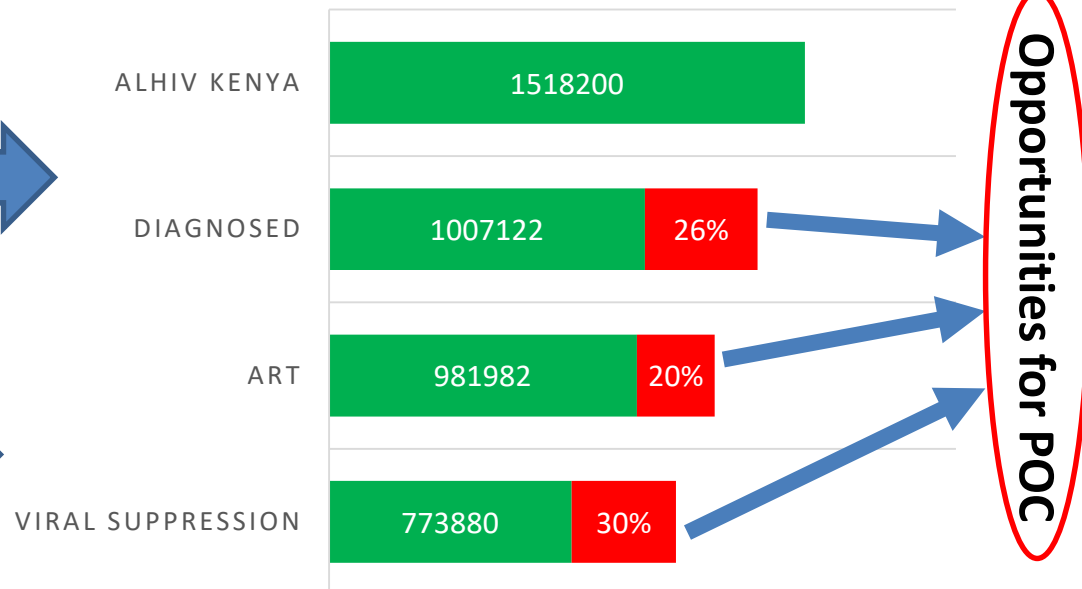
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- Water bodies
- VL Testing Labs**
- Ampath Lab
- CPGH Lab
- KEMRI Alupe
- KEMRI Nairobi
- KEMRI/CDC Lab
- NHRL Nairobi
- WRP Kericho Lab

90-90-90 CASCADE

Reached Unreached



Over 250000 EID tests annually





need to bridge the gap towards attaining the UNAIDS 1ST 90-90-90 targets among children?



WHO pre-qualified EID POC devices
1. Alere Q HIV 1/2 Detect

2. Genexpert HIV 1 Qual assay



very limited in country experiences in quality control and evaluation?



- point-of-care (POC) nucleic acid testing (NAT) technologies can now be used for EID and has the potential to decentralize testing
 - markedly reduce the time taken for results availability



OBJECTIVES



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- To evaluate Alere Q HIV 1 / 2 Detect and Cepheid GeneXpert® HIV 1 Qual assays to assess their performance in local settings
- to ascertain the manufacturer's claims on their sensitivities and specificities.
- To evaluate the users' operational features of the two equipment



METHODS



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- **Period:** Jun 2017 – Aug 2017
- **Design:** Cross sectional prospective
- **Samples:** EDTA whole blood from HIV exposed infants attending routine Kenyatta National Hospital eMTCT clinic.
- **Sample size:** 200 HIV exposed infant
- **Validation Location:** National HIV Reference Lab
- **Gold standard equipment:** Roche CAP/CTM V.2
- QA; any discrepant results between POC and the SOC system were repeated on both platforms.
- **Data analysis:** SAS V.9



RESULTS



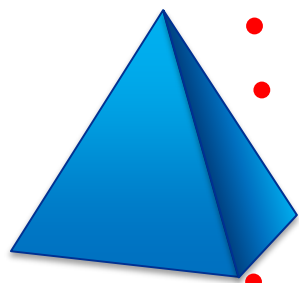
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Performance of Alere Q HIV 1/2 assay against the Standard of Care

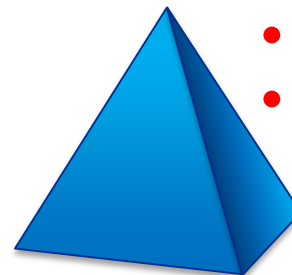
	Roche CAP/CTM		Total
	Positive	Negative	
Alere Q			
Positive	124	0	124
Negative	3	97	100
Total	127	97	224

Performance of Gene expert® HIV 1 Qual assay against the Standard of Care

	Roche CAP/CTM		Total
	Positive	Negative	
Gene expert			
Positive	104	1	105
Negative	1	94	95
Total	105	95	200



- Sensitivity = 97.6%
- Specificity = 100%
 - PPV=100%
 - NPV=97%
- Kappa value=0.966



- Sensitivity = 99.1%
- Specificity = 98.9%
 - PPV=98.9%
 - NPV=99.1%
- Kappa value=0.987



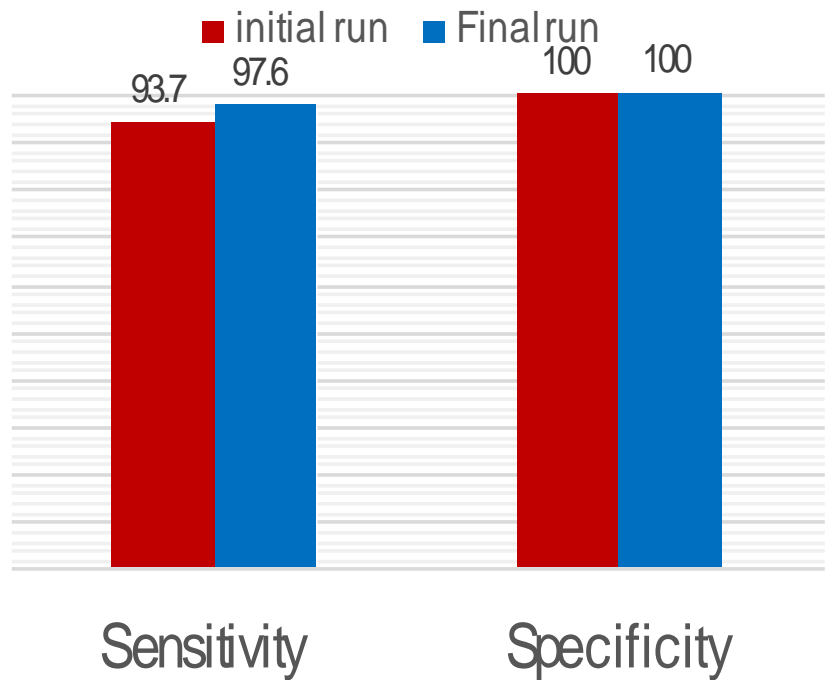


RESULTS

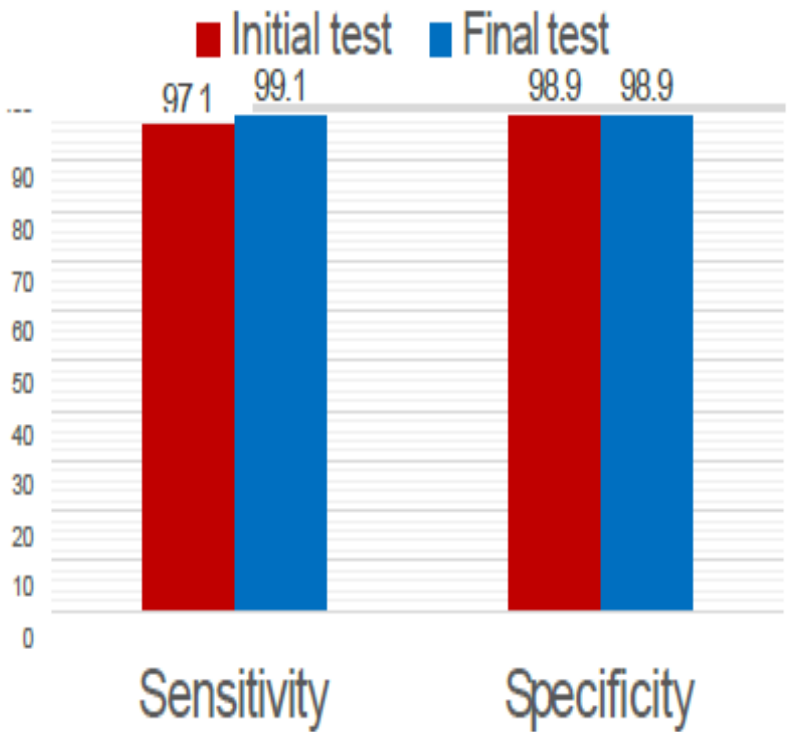


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Summary of sensitivity and specificity of Alere Q in first and final run



Summary of sensitivity and specificity of GeneXpert in first and final run

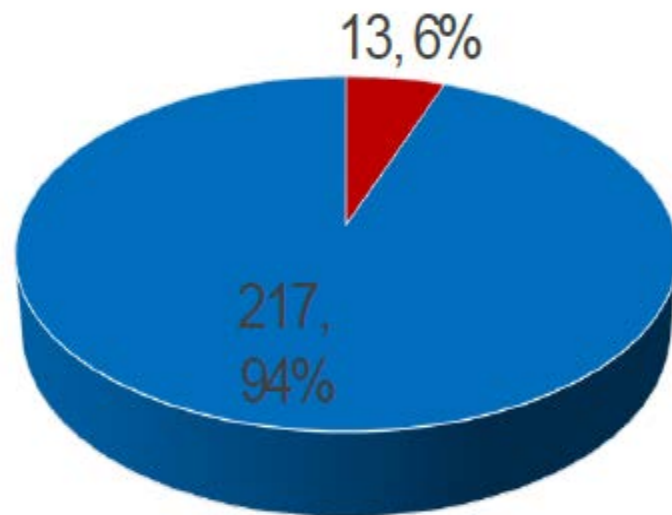


RESULTS



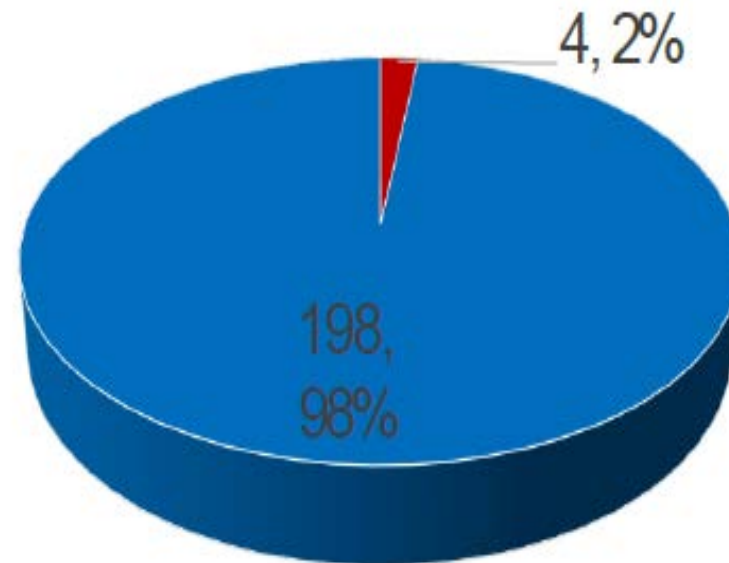
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• Alere Q assay error rate



■ errors ■ passed

GeneXpert assay error rate



■ errors ■ passed



OPERATIONAL DIFFERENCES



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Features	Alere Q	Genexpert
Sample volume	Requires 25 ul	Requires 100 ul
Sample type	Whole blood	DBS, Whole blood
Alternative power source	Comes with a battery pack that can last 8 hrs	Relies on consistent power and a UPS that can last 1 ½ hours
Assay time to results	51 minutes	90 mint
System	Uniplex system	Multiplex system
Ease	Offers Mobile testing – good for Level 1 and 2 health facilities AC/ Battery-operated 7.8 kg in weight	Good for county and referral hospitals. Constant power supply required Bulky
Error rates	Significant error rates	Few error rates
Cost	\$21.4 per test	\$ 22.00 per test
Performance characteristics	Sensitivity – 97.6% Specificity – 100%	Sensitivity – 99.1% Specificity – 98.9%



CONCLUSION



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- The two EID POCs reported a good laboratory performance making their implementation a great initiative for Kenya in trying to race towards the UNAIDS 90-90-90 targets.
- Their ability to relay results to the patients in a single visit could greatly improve the treatment outcomes, provide better linkage to care and minimized loss to follow ups (LTFUs)



NATIONAL POC IMPLEMENTATION



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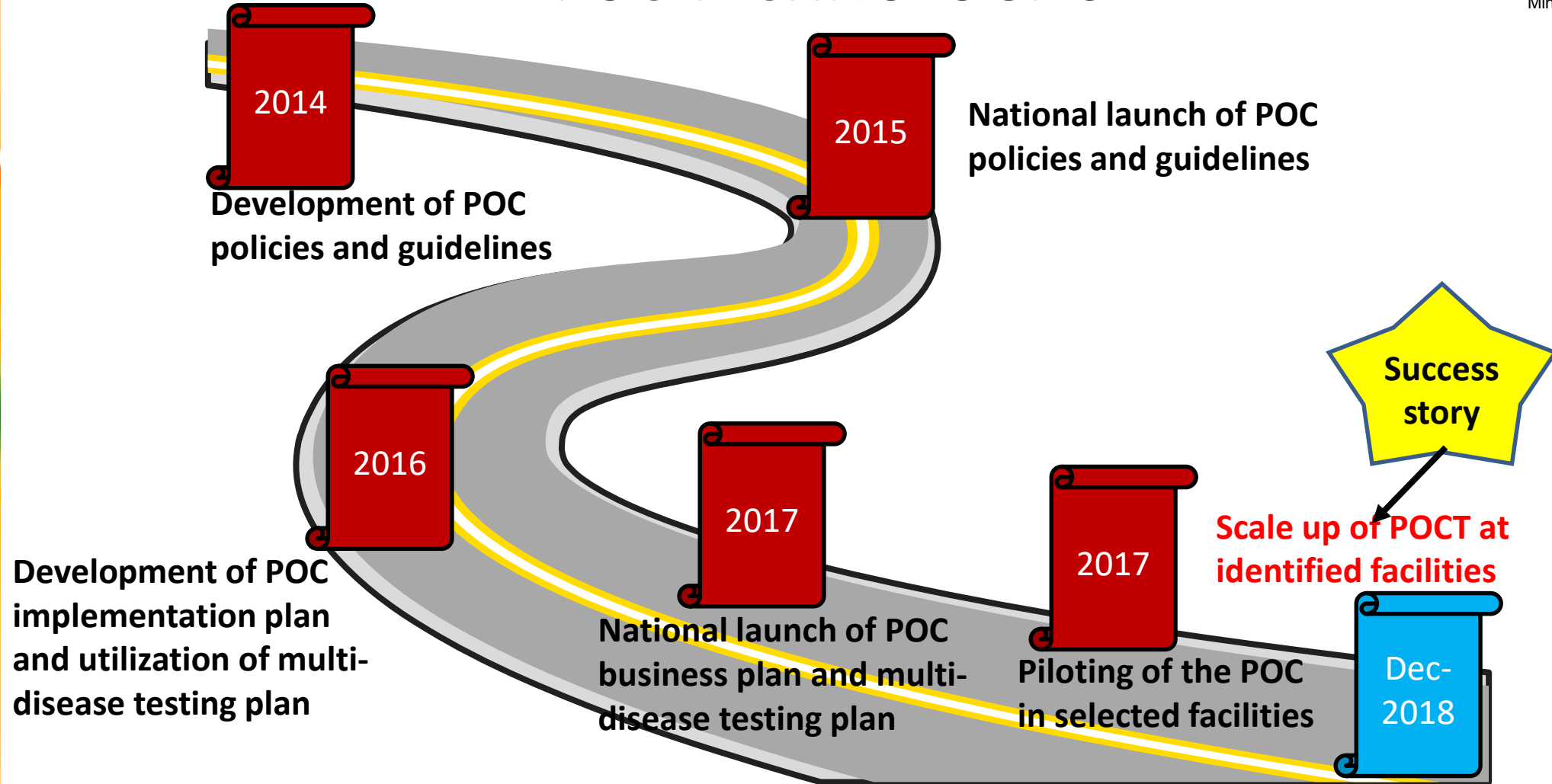
- The two EID POCs have since been piloted at few health care facilities.
- This was followed by roll out and scale up to various healthcare facilities (n=43) country wide based on the unmet needs, turn around time and uptake of EID services



ROADMAP TO IMPLEMENTATION OF POC TECHNOLOGIES



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ACKNOWLEDGEMENTS



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- *Ministry of Health*
- *National Public Health Laboratories*
- *National AIDS and STI Control Program*
- *UNICEF*
- *Kenyatta National Hospital*
- *Division of Global HIV & TB, US Centers for Disease Control & Prevention, Nairobi Kenya*

