LabCoP Waste Management Session on 2 May!

ASLM

MAY 2024 WASTE MANAGEMENT SESSION

CARTRIDGE WASTE MANAGEMENT IN VIRAL LOAD TESTING: THE MOUSE IN THE ROOM

In this session, we share the latest information and bulletin on GeneXpert products, review occupational and environmental risks considering the unique design and use of Xpert cartridges, review treatment options and potential for holistic waste management schemes-treating at the point of generation, versus collecting and processing at regional or central treatment centres.

PRESENTERS

- **Edward Krisiunas**
  President, Waste Not Want Not International (WNWN)
- **Rumbidzai Ndungwani**
  Public Health Programmes Manager, Europe, Middle East & Africa, Cepheid

zoom :https://us02web.zoom.us/j/83903262588

JOIN US ON 2 MAY 2024, 16:00 TO 17:00 EAST AFRICA TIME

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Lab CoP ASLM

CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries. Not available in the United State

Objective

- Discuss Cepheid cartridge waste management
- Discuss risks associated with cartridge waste management
- Discuss the strategy/options of cartridge treatment

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Collins Otieno


Anafi Mataka


Pascale Ondoa


BEATRICE PUIJE


Adisu Kebede

CDC


David Bressler
ILB
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EDWARD KRISIUNAS

USA/ Lead / Public Health - HCW Mgt Consultant


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USA/ Chemist/ Instructor of Green Chemistry


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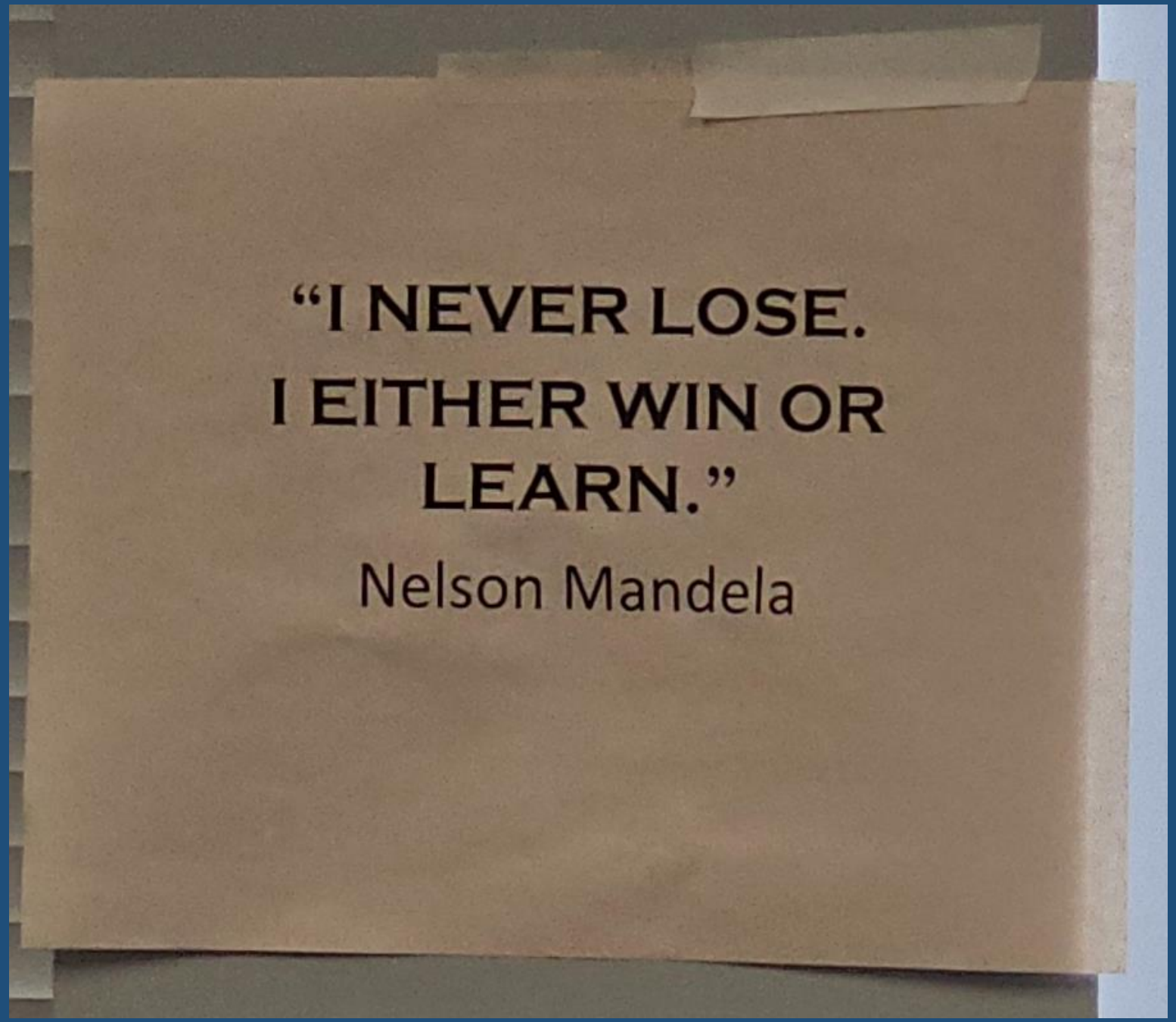
Macedonia / Environmental-HCW Mgt Consultant


SLOBODANKA PAVLOVIC - BOBA
Bosnia/ Environmental Sustainability consultant

No “I” in TEAM


"I NEVER LOSE.
I EITHER WIN OR
LEARN."
Nelson Mandela

FEATURE

Measuring toxic gases generated from reaction of guanidine isothiocyanate-containing reagents with bleach

Chemical Health & Safety, July/August 2005

How did we come to be here today?

Table 2. Resulting Gases from Reactions Between Test Solutions and Mixing Solutions

Test solution + mixing solution	HCl	HCN	Cl_2	NO	NO_2	CO
Reagent A + bleach	O	O	X	X	O	O
Reagent B + bleach	O	O	X	X	O	O
Waste + bleach	O	O	X	O	X	O
Waste + acid	X	O	X	O	O	O
Waste + base	X	X	X	X	O	X

X: not detected; O: observed.

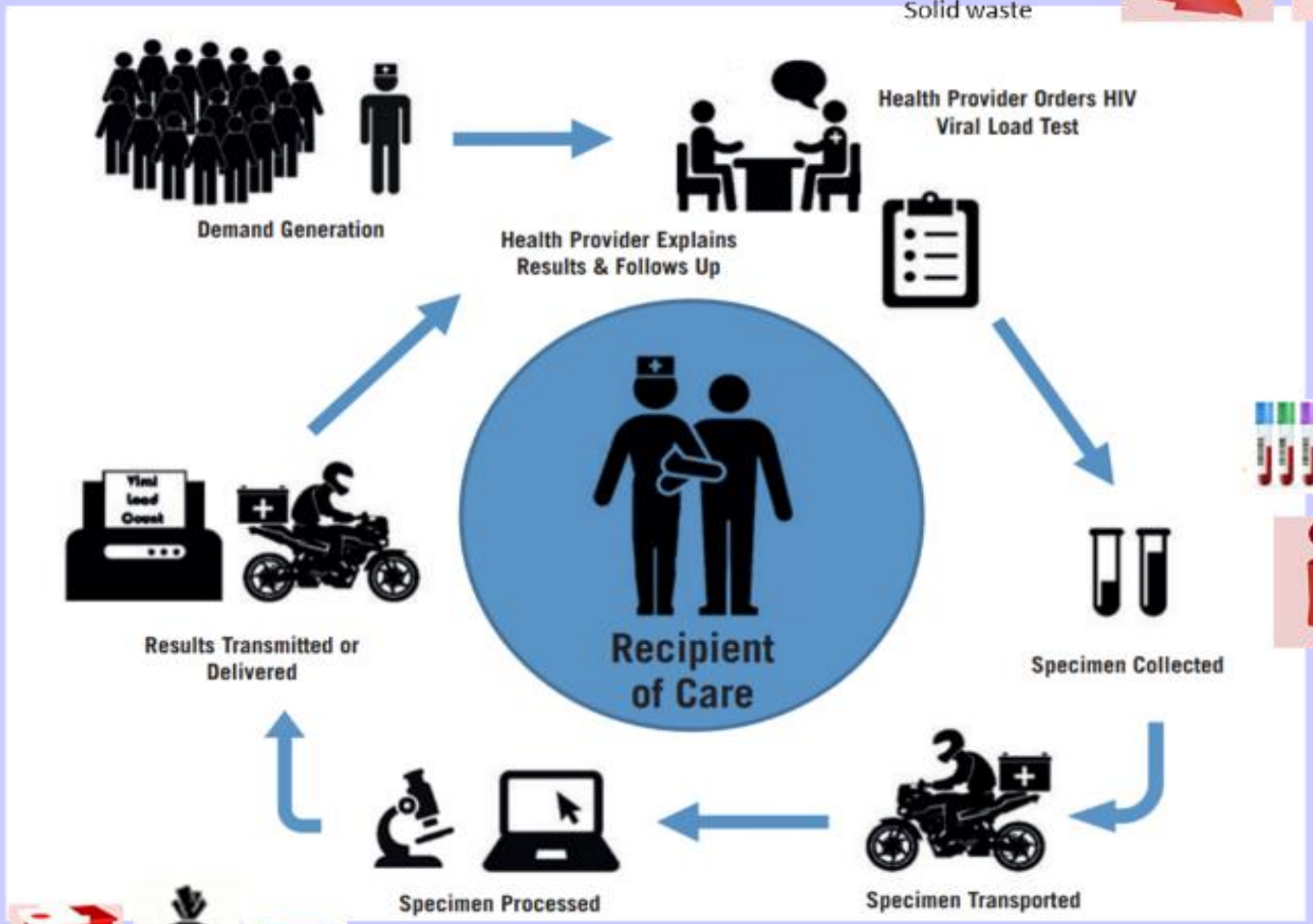
(Note no reaction with alkaline material)

https://www.researchgate.net/publication/240911954_Measuring_toxic_gases_generated_from_reaction_of_guanidine_isothiocyanate-containing_reagents_with_bleach

Cyanide Evolution from GTC Waste+ bleach @ CDC - Atlanta

A holistic approach to clinical lab waste management!

Waste cascade from HIV VL/EID programs



Infectious waste
Sharps
PPE
Solid waste

Infectious waste
Sharps
PPE

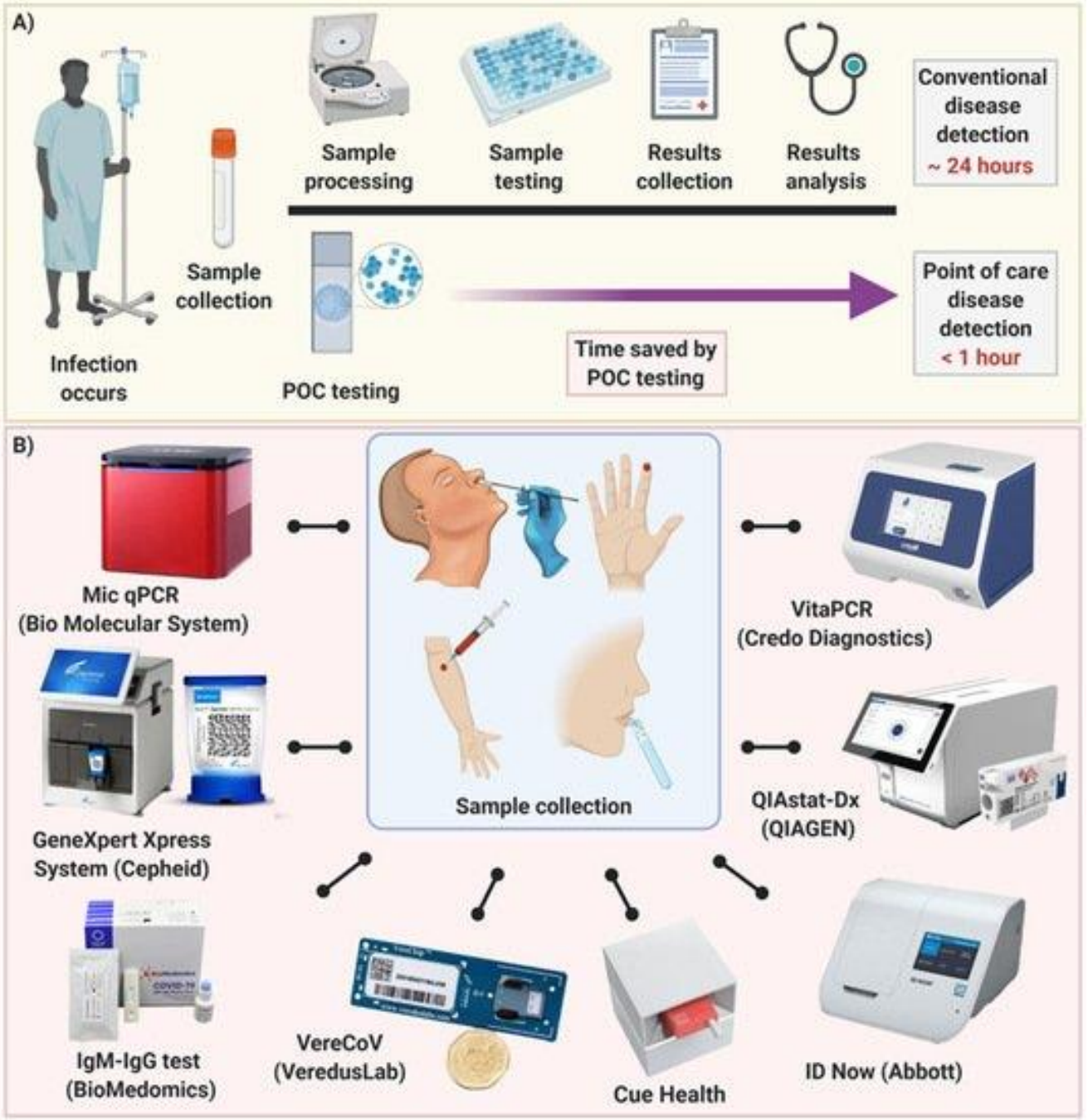
Chemical Waste
Infectious waste
Sharps
PPE
Liquid chemical waste
Solid waste

Infectious waste
Sharps
PPE
Solid waste

Pieces of the lab waste management puzzle over the past 6 years…

COVID19 testing

- (**A**) Schematic illustration of disease detection using conventional methods relied on centralized laboratories and POC testing approaches. POC devices can drastically reduce the amount of time needed to detect disease.
- (**B**) Current rapid commercially available POC devices that possess FDA approval for COVID-19. After sample collection and processing, these devices are capable of testing the sample in a time frame of mostly less than 30 min.



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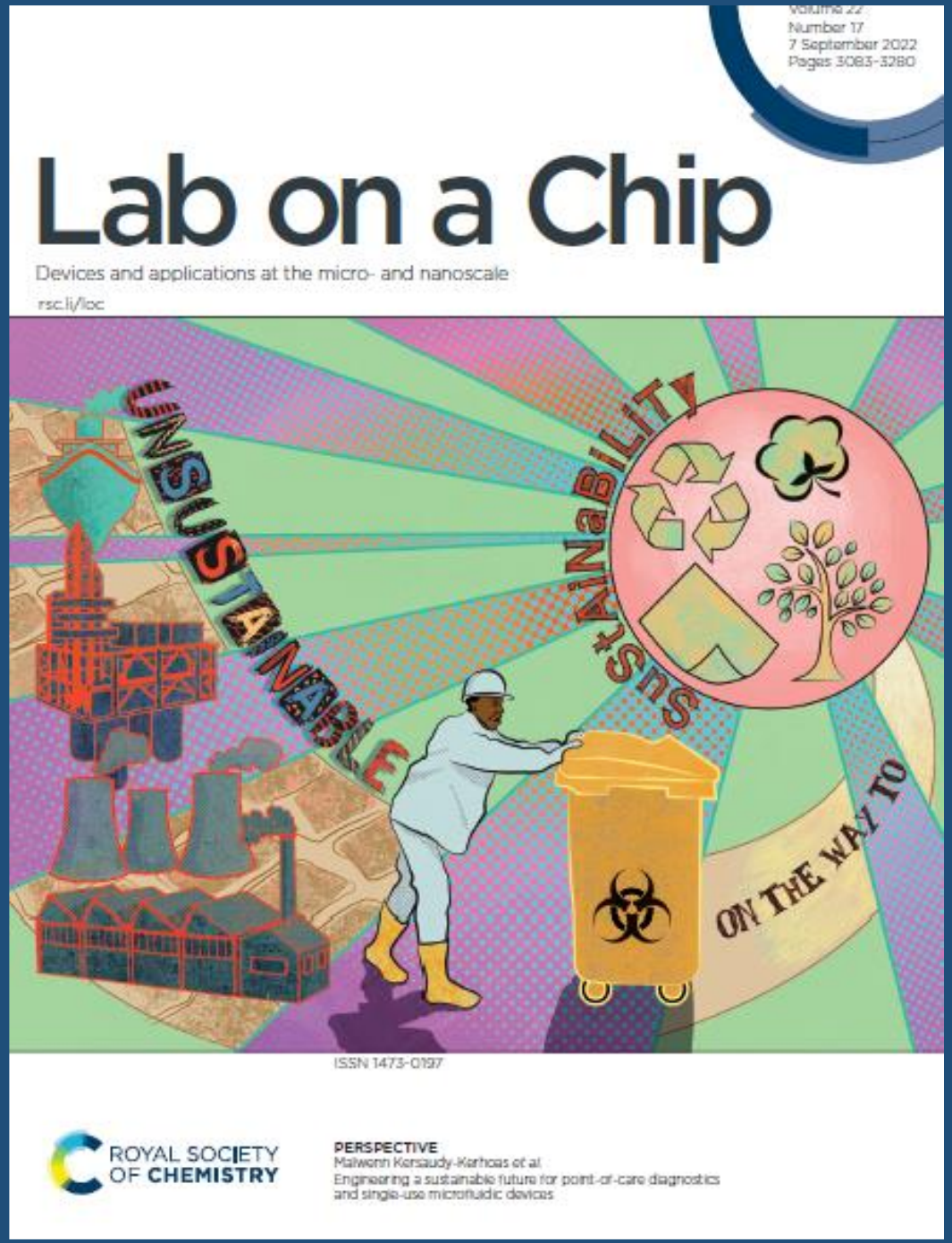


Engineering a sustainable future for point-of-care diagnostics and single-use microfluidic devices

Alfredo Edoardo Ongaro, [a] Zibusiso Ndlovu, [b] Elodie Sollier, [c] Collins Otieno, [d] Pascale Ondoa, [d] Alice Street [e] and Maïwenn Kersaudy-Kerhoas *[fg]

Cite this: Lab Chip, 2022, 22, 3122

Cover: Val Myburgh, South Africa

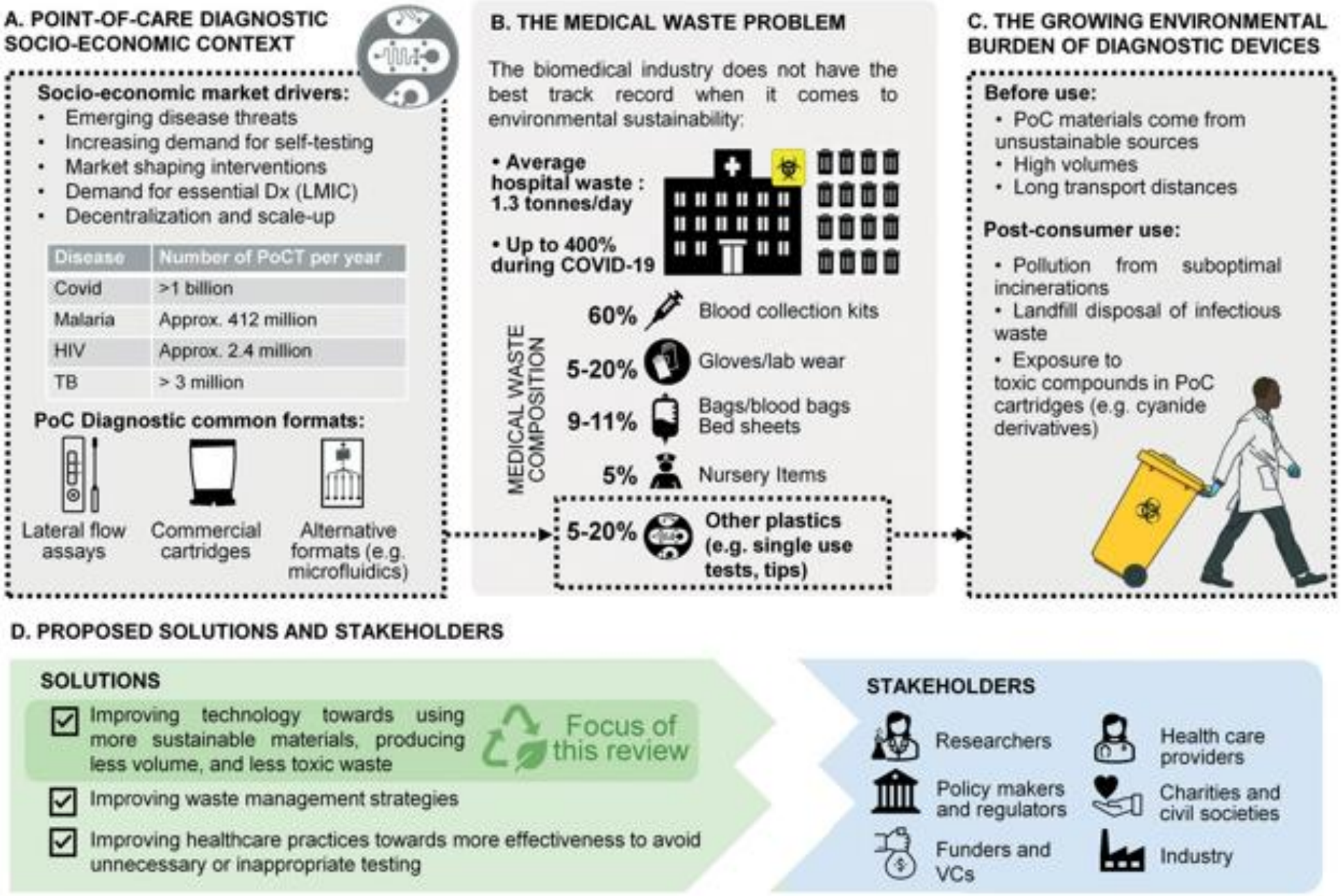
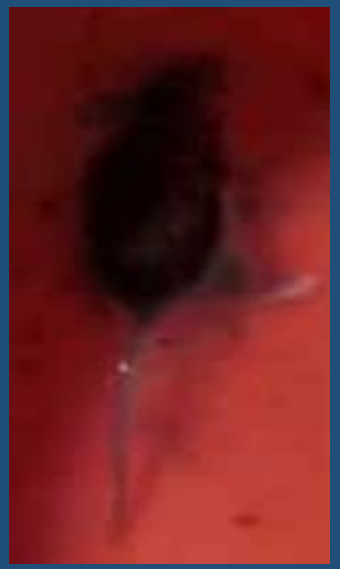


Fig. 1 Overview of the challenges and solutions in single-use diagnostic devices. A) Point-of-care diagnostic socio-economic context.[13–15] B) The medical waste problem.[16,17] C) Growing burden of waste from diagnostic devices. D) Proposed solutions and stakeholders.



Risk Assessment

- Identify hazards
- Assess the risks
- Control the risks
- Review the controls

Physical…Biological…Chemical….Environmental

CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries. Not available in the United State

Viral Load program and Viral Load Waste

Blood samples Collection

Blood samples transport

Hospitals, clinics, health stations, ambulances etc.

Samples Preparation for Analysis

VL Analytical Platforms

Analysis of the samples

Reference and Mini Laboratories

Input values*	
Liquid waste per test (grams/test)	21
Genexpert cartridges (grams/test)	37
Alere Q Cartridge (grams/test)	18
Solid infectious waste per test (grams/test)	120

* References for input values can be shared

SOLID INFECTIOUS WASTE

LIQUID/CHEMICAL AND INFECTIOUS WASTE

CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries. Not available in the United State

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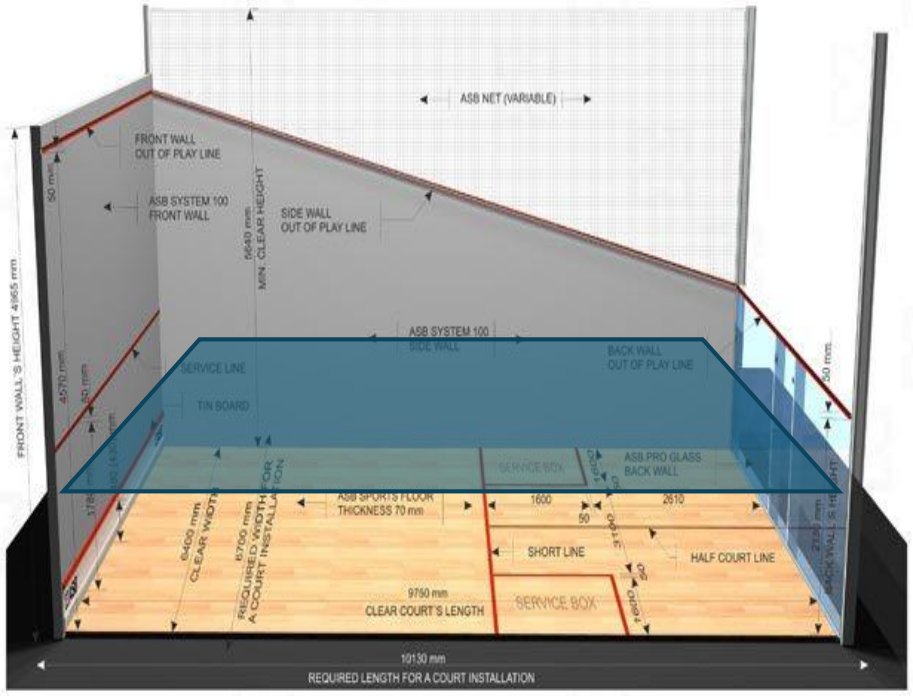
Weight vs. Volume of waste… Examples

In Kenya, 35045 liters of Liquid waste with GTC was generated in 2019 only from HIV VL/EID program.

That is enough to fill squash court in height of 1 meter



200 tons of solid infectious waste was generated from the same program.

That is enough to fill American football pitch with waste up to 6.5 meters in height (with approximate waste density 150kg/m3)

Volume of liquid in Xpert® cartridge

Product	Volume Before Test (mL)	Volume After Test (mL)	PH (Before Test)	Off Board Hazardous Substance	GTC Volume (mL)	Comment*
Xpert® HIV-1 Qual	6.88	≤ 10	7.86	None	0.66	- pH would not change significantly after test - Volume after test will increase by a 1 or 2 mL - Main hazard is GTC (10% to 40%) and bio sample
Xpert® HIV-1 VL	6.88	≤ 10	7.45	None	0.94	- pH would not change significantly after test - Volume after test will increase by a 1 or 2 mL - Main hazard is GTC (10% to 40%) and bio sample
Xpert® HBV VL	6.88	≤ 10	7.45	None	0.94	- pH would not change significantly after test - Volume after test will increase by a 1 or 2 mL - Main hazard is GTC (10% to 40%) and bio sample
Xpert® HCV	6.88	≤ 10	?	None	0.94 (est)	
Xpert® MTB		≤ 10				
Xpert® C. DIF		≤ 10				

HBV, HIV, and HCV Xpert® tests do not contain NaOH

- GTC concentration does vary among cartridges
- Inactivation of infectious agents

Will never have more than 10ml total in each cartridge (5 chemical ingredients)

2000 Xpert® cartridges would have approximately 20 liters of fluid

*Reference: Product CD provided with Xpert® cartridges

Xpert® HIV-1 Viral Load; Xpert® HBV Viral Load

Composition					
Chemical Name	**Identifiers**	**%**	**LD50/LC50**	**Classifications According to Regulation/Directive**	**Comments**
Guanidinium thiocyanate	**CAS:** 593-84-0 **EINECS:** 209-812-1	10-20%	See Section 11.1	**UN GHS:** Acute Tox. 5 (Orl); Skin Irrit. 5; Eye Irrit. 2B; **EU CLP:** Acute Tox. 5, H302, H313, H320 **OSHA HCS 2012:** Acute Tox. 5 (Orl); Eye Irrit. 2B	NDA

6 Reagents and Instruments

6.1 Materials Provided

The HIV-1 Quant Assay kit contains sufficient reagents to process 10 specimens or quality control samples. The kit contains the following:

HIV-1 Quant Assay Cartridges with Integrated Reaction Tubes	**10**
• Bead 1, Bead 2, and Bead 3 (freeze-dried)	1 of each per cartridge
• Lysis Reagent	2 mL per cartridge
• Guanidinium Thiocyanate	
• Rinse Reagent	0.5 mL per cartridge
• Elution Reagent	1.5 mL per cartridge
• Binding Reagent	2.4 mL per cartridge
• Proteinase K Reagent	0.48 mL per cartridge
Disposable 1 mL Transfer Pipettes	**10 per kit**
CD	**1 per kit**
• Assay Definition File (ADF)	
• Instructions to import ADF into GX software	
• Package Insert	

6 Reagents and Instruments

6.1 Materials Provided

The HBV VL assay kit contains sufficient reagents to process 10 samples and/or quality control samples. The kit contains the following:

HBV VL Assay Cartridges with Integrated Reaction Tubes	**10**
• Bead 1, Bead 2 and Bead 3 (freeze-dried)	1 of each per cartridge
• Lysis Reagent (Guanidinium Thiocynate)	1.7 mL per cartridge
• Rinse Reagent	0.5 mL per cartridge
• Elution Reagent	1.5 mL per cartridge
• Binding Reagent	1.5 mL per cartridge
• Proteinase-K Reagent	0.48 mL per cartridge
Disposable 1 mL Transfer Pipettes	**10 per kit**

*Reference: Product CD provided with Xpert® cartridges

Xpert® HCV-1 Viral Load; Xpert® HCV VL Fingerstick

Composition					
Chemical Name	**Identifiers**	**%**	**LD50/LC50**	**Classifications According to Regulation/Directive**	**Comments**
Guanidinium thiocyanate	**CAS:** 593-84-0 **EINECS:** 209-812-1	10-20%	See Section 11.1	**EU CLP:** Acute Tox. 5, H302, H313, H320 **UN GHS Revision 3:** Acute Tox. 5 (Orl); Skin Irrit. 5; Eye Irrit. 2B; **OSHA HCS 2012:** Acute Tox. 5 (Orl); Eye Irrit. 2B	NDA

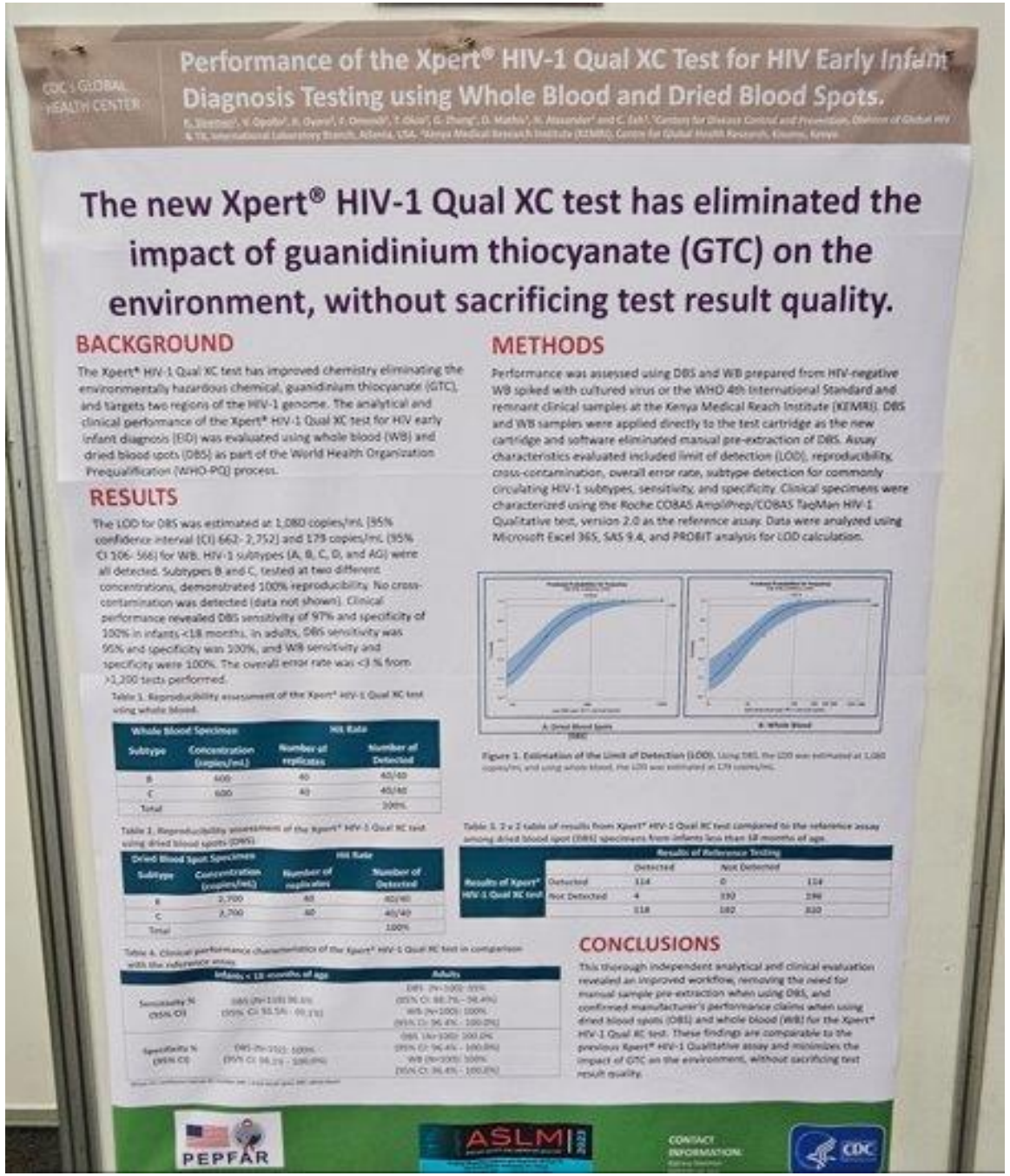
6 Reagents

6.1 Materials Provided

Σ The HCV VL assay kit contains sufficient reagents to process 10 specimens or quality control samples. The kit contains the following:

HCV VL Assay Cartridges with Integrated Reaction Tubes	**10**
• Bead 1, Bead 2, and Bead 3 (freeze-dried)	1 of each per cartridge
• Lysis Reagent (Guanidinium Thiocyanate)	2.0 mL per cartridge
• Rinse Reagent	0.5 mL per cartridge
• Elution Reagent	1.5 mL per cartridge
• Binding Reagent	2.4 mL per cartridge
• Proteinase K Reagent	0.48 mL per cartridge
Disposable 1 mL Transfer Pipettes	**10 per kit**

*Reference: Product CD provided with Xpert® cartridges



Performance of the Xpert® HIV-1 Qual XC Test for HIV Early Infant Diagnosis Testing using Whole Blood and Dried Blood Spots.

CDC | GLOBAL HEALTH CENTER

E. Stevens[1], V. Opollo[2], B. Gyarel[1], F. Omondi[2], T. Okia[2], G. Zhang[1], D. Mathis[1], N. Alexander[1] and C. Eshi[1], [1]Centers for Disease Control and Prevention, Division of Global HIV & TB, International Laboratory Branch, Atlanta, USA, [2]Kenya Medical Research Institute (KEMRI), Centre for Global Health Research, Kisumu, Kenya

The new Xpert® HIV-1 Qual XC test has eliminated the impact of guanidinium thiocyanate (GTC) on the environment, without sacrificing test result quality.

BACKGROUND

The Xpert® HIV-1 Qual XC test has improved chemistry eliminating the environmentally hazardous chemical, guanidinium thiocyanate (GTC), and targets two regions of the HIV-1 genome. The analytical and clinical performance of the Xpert® HIV-1 Qual XC test for HIV early infant diagnosis (EID) was evaluated using whole blood (WB) and dried blood spots (DBS) as part of the World Health Organization Prequalification (WHO-PQ) process.

METHODS

Performance was assessed using DBS and WB prepared from HIV-negative WB spiked with cultured virus or the WHO 4th International Standard and remnant clinical samples at the Kenya Medical Reach Institute (KEMRI). DBS and WB samples were applied directly to the test cartridge as the new cartridge and software eliminated manual pre-extraction of DBS. Assay characteristics evaluated included limit of detection (LOD), reproducibility, cross-contamination, overall error rate, subtype detection for commonly circulating HIV-1 subtypes, sensitivity, and specificity. Clinical specimens were characterized using the Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative test, version 2.0 as the reference assay. Data were analyzed using Microsoft Excel 365, SAS 9.4, and PROBIT analysis for LOD calculation.

RESULTS

The LOD for DBS was estimated at 1,080 copies/mL (95% confidence interval [CI] 662- 2,752) and 179 copies/mL (95% CI 106- 566) for WB. HIV-1 subtypes (A, B, C, D, and AG) were all detected. Subtypes B and C, tested at two different concentrations, demonstrated 100% reproducibility. No cross-contamination was detected (data not shown). Clinical performance revealed DBS sensitivity of 97% and specificity of 100% in infants <18 months. In adults, DBS sensitivity was 95% and specificity was 100%, and WB sensitivity and specificity were 100%. The overall error rate was <3 % from >1,200 tests performed.

Figure 1. Estimation of the Limit of Detection (LOD). Using DBS, the LOD was estimated at 1,080 copies/mL and using whole blood, the LOD was estimated at 179 copies/mL.

Table 1. Reproducibility assessment of the Xpert® HIV-1 Qual XC test using whole blood.

Whole Blood Specimen			Hit Rate
Subtype	Concentration (copies/mL)	Number of replicates	Number of Detected
B	600	40	40/40
C	600	40	40/40
Total			100%

Table 2. Reproducibility assessment of the Xpert® HIV-1 Qual XC test using dried blood spots (DBS)

Dried Blood Spot Specimen			Hit Rate
Subtype	Concentration (copies/mL)	Number of replicates	Number of Detected
B	2,700	40	40/40
C	2,700	40	40/40
Total			100%

Table 3. 2 x 2 table of results from Xpert® HIV-1 Qual XC test compared to the reference assay among dried blood spot (DBS) specimens from infants less than 18 months of age.

		Results of Reference Testing		
		Detected	Not Detected	
Results of Xpert® HIV-1 Qual XC test	Detected	114	0	114
	Not Detected	4	192	196
		118	192	310

Table 4. Clinical performance characteristics of the Xpert® HIV-1 Qual XC test in comparison with the reference assay.

	Infants < 18 months of age	Adults
Sensitivity % (95% CI)	DBS (N=110) 96.4% (95% CI: 91.5% - 99.1%)	DBS (N=100) 95% (95% CI: 88.7% - 98.4%) WB (N=100) 100% (95% CI: 96.4% - 100.0%)
Specificity % (95% CI)	DBS (N=192) 100% (95% CI: 98.1% - 100.0%)	DBS (N=100) 100.0% (95% CI: 96.4% - 100.0%) WB (N=100) 100% (95% CI: 96.4% - 100.0%)

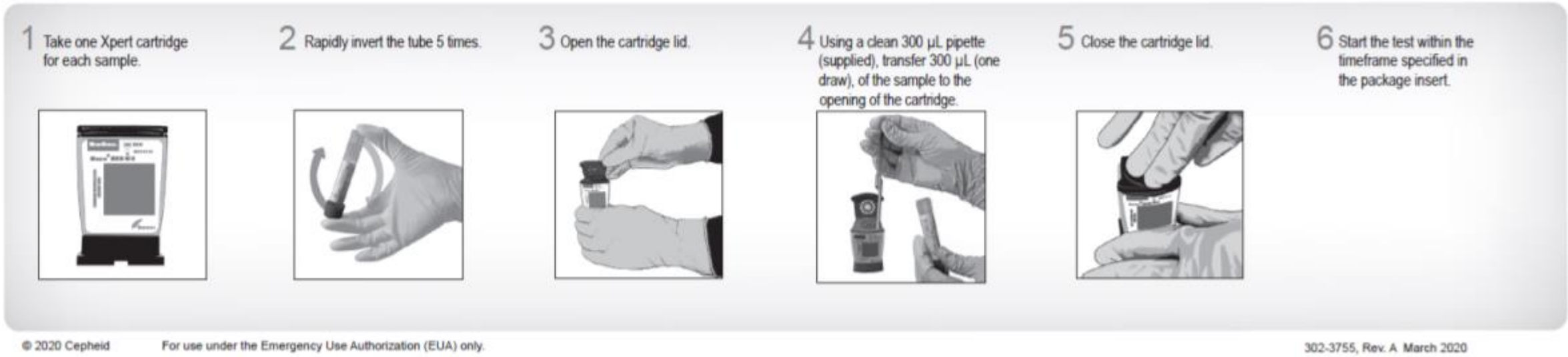
CONCLUSIONS

This thorough independent analytical and clinical evaluation revealed an improved workflow, removing the need for manual sample pre-extraction when using DBS, and confirmed manufacturer's performance claims when using dried blood spots (DBS) and whole blood (WB) for the Xpert® HIV-1 Qual XC test. These findings are comparable to the previous Xpert® HIV-1 Qualitative assay and minimizes the impact of GTC on the environment, without sacrificing test result quality.

PEPFAR ASLM CONTACT INFORMATION: CDC

ASLM 2023
Poster 318

Waste Generation Cepheid Cartridges



POC staff have no access / exposure to Xpert® liquid contents

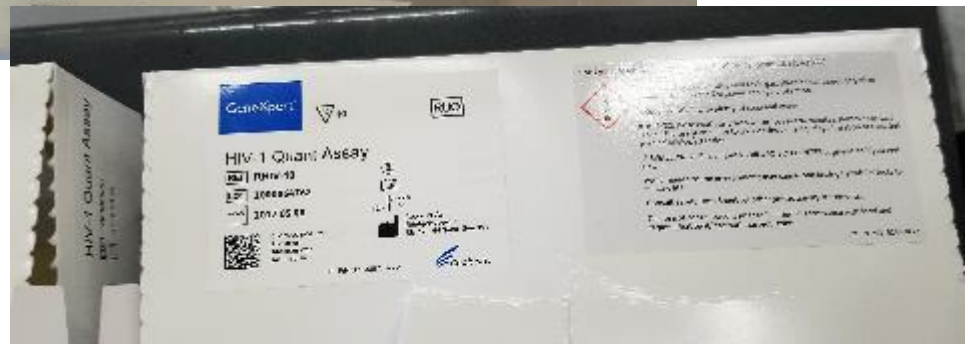
CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries. Not available in the United State

- Low weight
- Low volume of liquid
- Sealed to prevent exposure
- Inactivation of infectious agents?

Cartridge polypropylene construction – Will not create dioxins if incinerated (Not a halogen containing polymer. Emissions can still be toxic if combustion is not efficient

Key issue Treatment capacities

- Logistics of transporting waste liquid if onsite processing is not available
- Storage of large volumes of waste as been proposed but then how is this managed for disposal?
- Atomization of liquid waste is one option or fuel blending (Used in the US for GTC liquid waste but unclear in Africa)
- Disposal of cartridges – different material/liquid quantity



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July 16 2019 Autoclaving Cepheid cartridges

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TEST REPORT

Shredding & autoclaving of Cepheid's GeneXpert cartridges with a Tesalys biohazard waste treatment system

Saint-Jean (France), April 5, 2013

Miquel Lozano – Tesalys

miquel.lozano@tesalys.fr

www.tesalys.fr

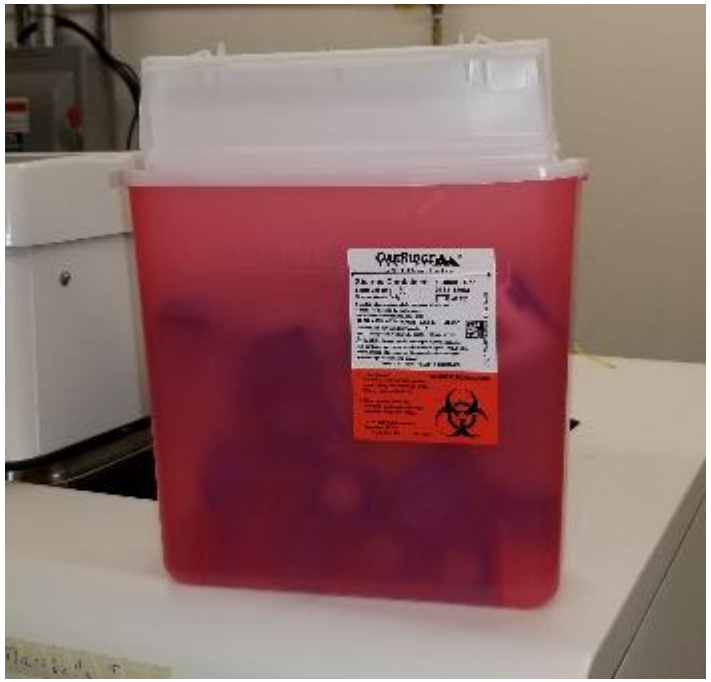
Tesalys

Tesalys biomedical waste treatment machines

- 20 liter or 40 liter treatment capacity
- Shredding of waste
- Prevacuum with air filtration (HEPA)
- Thermal treatment (sterilization/autoclaving) at 134/135°C for solid, liquid waste and machine effluents

- 2 min. Video presentation : http://tesalys.fr/videos.html

www.tesalys.fr



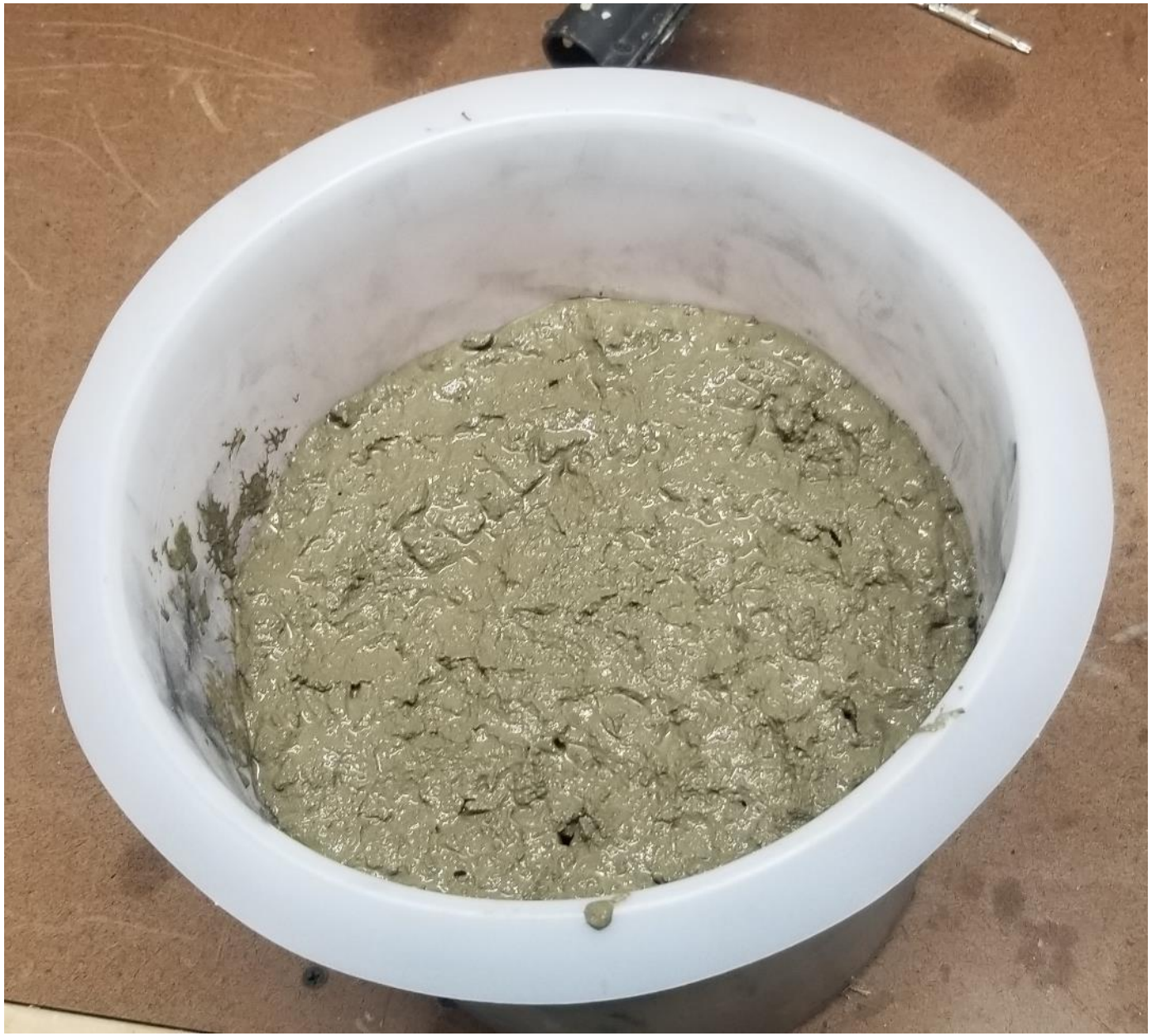
Untreated cartridge liquid CN concentration –

25,000 PPM

Processed cartridge CN concentration –

20 PPM CN

CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries. Not available in the United State



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Cartridge waste

- Incineration
- Pyrolysis

Treatment - Incineration vs Incineration?

South Sudan

The country has 2 Abbott platforms (centrally located) & 40 Xpert® platforms (2 16-modules, 38 4-modules)
Functional Xpert® test sites - 33 (including 3 reference labs)
Xpert® rolled out since 2018 for only TB; EID & SARS-COV2 tests added in 2020 and VL in 2021.
Estimated # of cartridges accumulated between Jan-Aug 2021 - 17,310 for 31 sites

Lessons learned

A. General Requirements

It was critical to develop waste management standard operation procedures and tools specifically for:

- Equipment operation and routine maintenance
- Waste management register
- Waste weighing scale
- Waste transportation - as some wastes have to be transported from across the country.
- Use of personal protective equipment by equipment operators and waste handlers

B. Hardware and software components support

- The equipment is fully automated and hence requires skilled workforce for maintenance of the primary to secondary loader system and alignment of the base and the blower.
- It is also important to establish service maintenance contract.

Lessons learned

Key recommendations for operations:

i. Install a chimney to the incinerator that should be raised to above 6 meters (at least up to 12 meters) and anchored to the Incinerator container.
ii. Train local service provider to be able to conduct maintenance and repairs.
iii. Build capacity of users through trainings, mentorship and exchange visits.
iv. Establish regular audit of documentation, technical support and constant supervision.
v. Ensure timely maintenance of the incinerators to ensure efficiency of operations.
vi. Adhere to maintenance schedules, servicing and daily checkup of all components before running the machine.
vii. Develop waste management plan, adequate training tools for the managers, waster handlers and infection prevention and control teams to empower the knowledge and promote skills transfer.
viii. Develop job aids/posters for waste handlers and personnel operating the equipment

Key issue Treatment capacities

- Logistics of **transporting** waste liquid if onsite processing is not available
- **Storage of large volumes of waste as been proposed but then how is this managed for disposal?**

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Cepheid Cartridges

- Incineration locally
- Incineration – Cement plant
- Pyrolysis
- Transboundary movement to country with treatment and disposal methods (South Africa)
- Autoclaving via process such as Tesalys (Internal shredding system)
- Encapsulation is an option for very small volumes (placing cartridges in plastic drums that would be filled with cement and buried)

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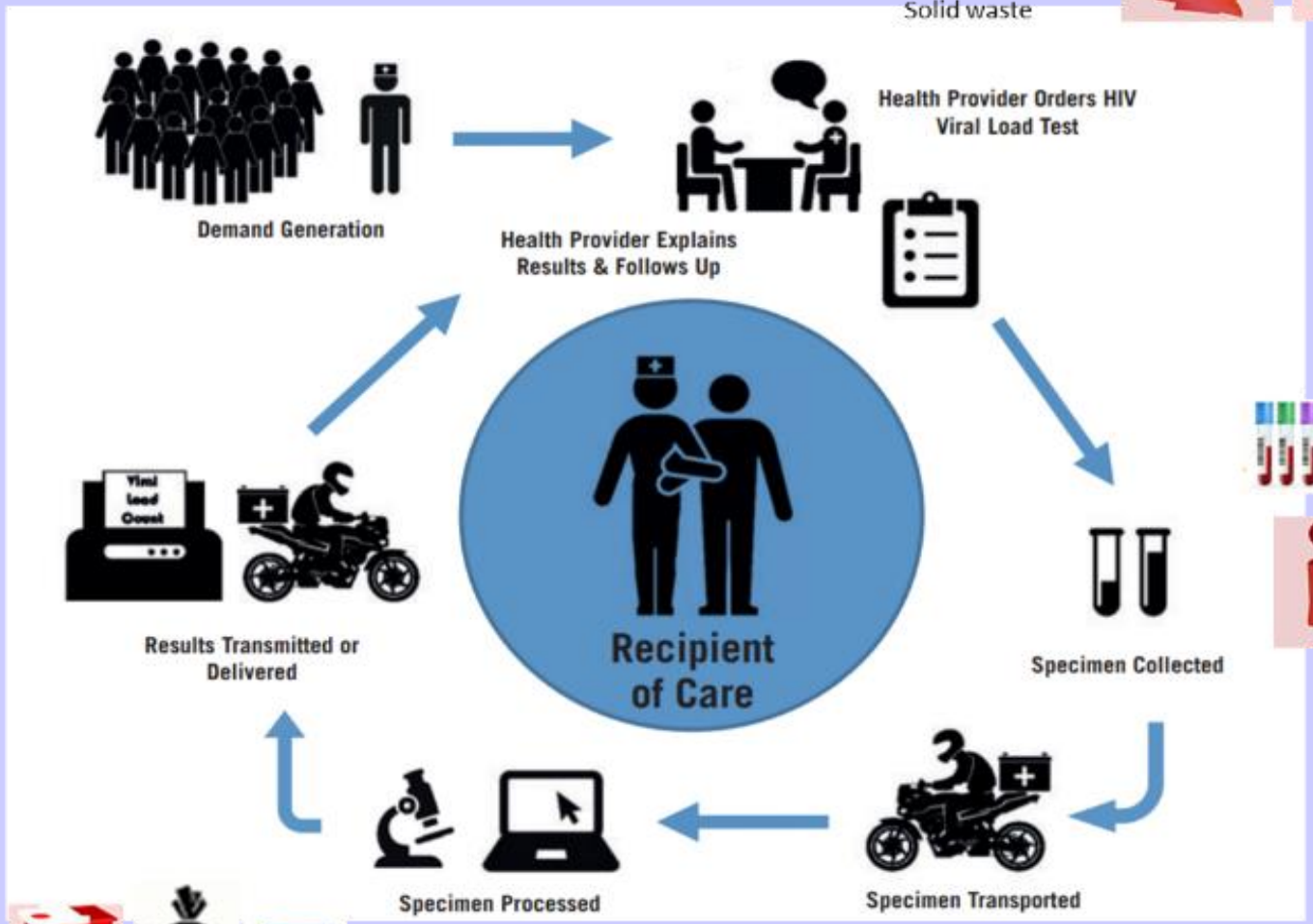
A holistic approach to clinical lab waste management!

Waste cascade from HIV VL/EID programs



Infectious waste
Sharps
PPE
Solid waste

Infectious waste
Sharps
PPE

Chemical Waste
Infectious waste
Sharps
PPE
Liquid chemical waste
Solid waste

Infectious waste
Sharps
PPE
Solid waste

Thank – you!

Ngiyabonga!

Asante Sana / Merci beaucoup / Obrigado

ASLM

CDC

and

all our Africa based laboratory colleagues!