



# Maximizing our resources in LMI Countries: Using existing systems and available resources

## **KEMRI-PD Perspective**

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# KEMRI's Facility for production of health products for LMI Countries

- In 2004/2005 KEMRI constructed and equipped a Production Plant to facilitate translation of its research findings into products for public use and commercialization.
- This facility has instituted the necessary QMS: cGMP-compliance , currently pursuing ISO 13485:2003 and ISO 17024:2003, with an ultimate goal of attaining WHO-Prequalification status of its key products and later passing the technologies to local industries
- This facility is also ANDi Center of Excellence in Development and Production of Diagnostics





# Cost-effective products developed so far by KEMRI-PD

Hemagglutination-based test kit for screening blood for hepatitis B virus (*Hepcell*<sup>®</sup> *RPHA kit*).



Rapid test kits for: HIV 1 & 2 (*Kemcom*<sup>®</sup> *Rapid*), HBV (*Hepcell*<sup>®</sup> *Rapid*) and HCV (*Kempac*<sup>®</sup> *Rapid*). *Awaiting WHO –Prequalification process*



# Cost effective products developed so far by KEMRI-PD

Taq polymerase  
enzyme (*Kemtaq*<sup>®</sup>)



- Alcohol-Based Hand (ABHR) (*KEMrub*<sup>®</sup>).
- Based on WHO Formulation
- Currently distributed in supermarket outlets in Kenya.
- Efficacy studies carried out recently showed that it is the most efficacious ABHR in the Kenyan Market (*welcome to our poster presentation in this conference*)



# Cost effective products developed so far by KEMRI-PD

*The facility also produces HIV Proficiency Testing Panels and plans are currently in place to produce other panel to support EQAS in the region. So far supplying WHO Somalia (more than 600 labs)*



# Culture Media Production line...1

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- The Production line was developed through the support of CDC and Defense Threat Reduction Agency of USA.
- The initiative is driven by the fact that while the culture of microorganisms is a Gold Standard for confirmation of infections, the country and the region lack capacity to produce QUALITY CONTROLLED Media.
- Also the quality Ready-to-Use Media are imported hence quite expensive. Since they have short shelf lives (about 3 months) most of it is lost during transit leading to losses due to expiry.
- Hence the need for local Media Production

# Culture Media Production line...2



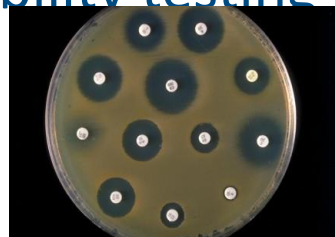
- The new and modern KEMRI Production facility for media production is an automated closed system which ensures that the media is never exposed to contaminations.



# Culture Media Production Capacity



- The culture media production line has a capacity of producing 200,000 petri dishes and 90,000 tubes per month (this is enough to supply the Kenya and the region) at 40% less costly than imported media
- The facility can do practically all the types of culture media that include: *Mac Conkey Agar, Motility Indole Urea Agar, Sabouraud Dextrose Agar, Campylobacter, Karmali Agar Base, T.C.B.S Agar, X.L.D Agar, Mueller Hinton Agar, Urea Agar, Blood Agar Base, TSI Agar, BBL Mannitol Agar and Brain -Heart Infusion Broth*
- The Production facility also has capacity to manufacture drug susceptibility testing media.







# Working with partners in Product development for LMI Countries

## 1. Partner for Appropriate Technology in Health (PATH, USA)

- DNA/RNA extraction kits and upgrade of KEMRI HIV Rapid Test kit to 4<sup>th</sup> Generation

## 2. Japan International Cooperation Agency (JICA)

- Infrastructure development and training of the staff
- Commercialization of sequencing services and real time PCR
- Development of rapid test kits for Yellow Fever and Rift Valley Fever

## 3. Centers for Disease Control and Prevention (USA)

- Culture Media and Hematological Controls
- Buffers, distilled water, molecular grade water
- Support of upgrade of HIV Rapid test kits from 3<sup>rd</sup> to 4<sup>th</sup> Generation
- ISO 17043, ISO 13485 and WHO prequalification

## 4. National Council of Science and Technology (NCST, Kenya)

- Support funding of product development

## 5. Others: Kenya Government and its Agency



## **Current efforts at KPD to improve the increase outcomes using limited resources**

- a. KEMRI is currently working to establish a Public Private Partnership model with Pharmaceutical Industries in Kenya. The Institute is currently producing its disinfectants in collaboration with local pharmaceutical firm
- b. KEMRI is in the process of forming a Business Enterprise Company (KEMRES) to commercialize its products and Services.
- c. KEMRI has developed a draft Revenue Sharing Policy
- d. Funds generated by product commercialization by KEMRI is ploughed back to product development activities (PhD and MSc Students have benefited much on this arrangement)
- e. KEMRI is now focusing on recruitment of more multidisciplinary scientists to support product development and commercialization



Thank You