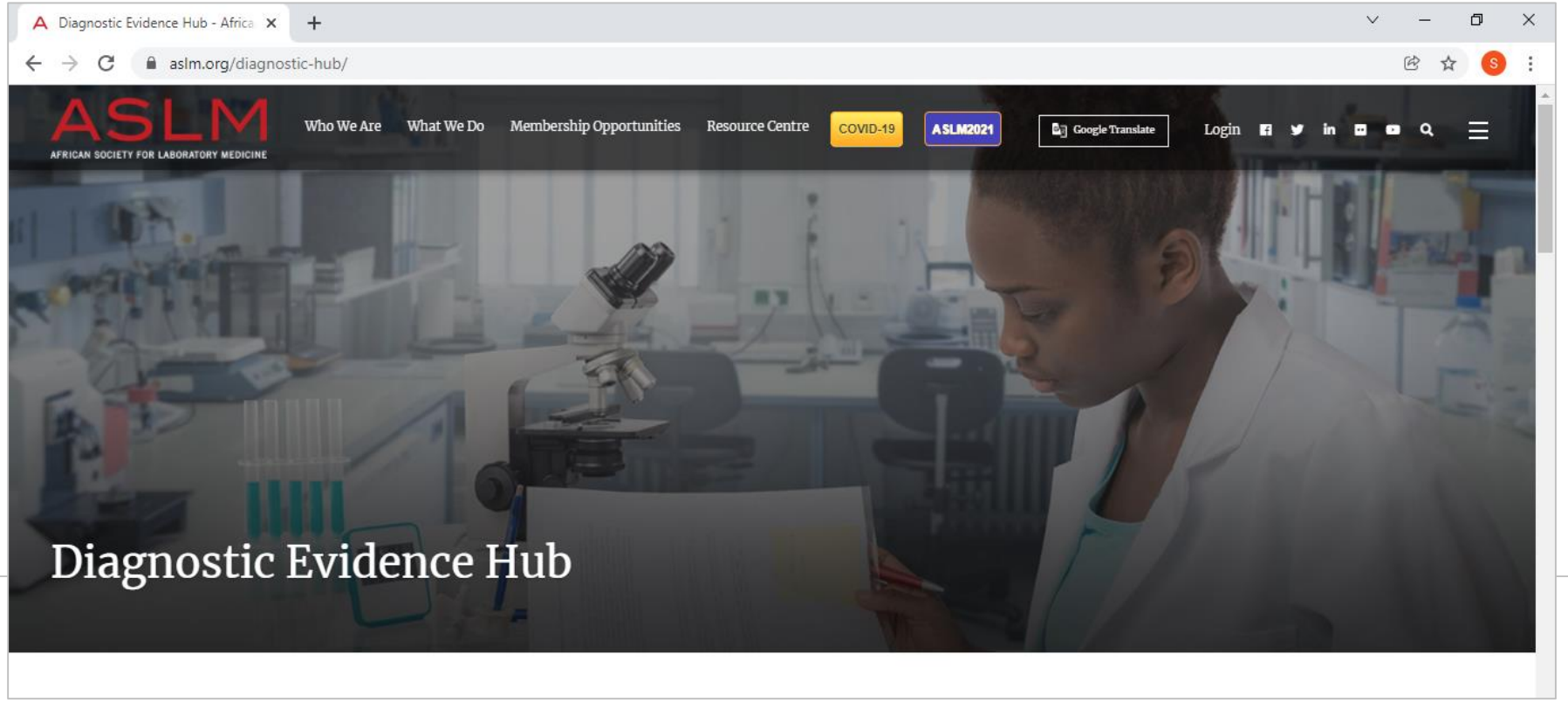
The Diagnostic Evidence Hub: *Its role in Accelerating Uptake of Diagnostic Innovations*



Mashate Silver
Program Manager, LabCoP, ASLM

Special ECHO Session

Dec 08, 2021

Forbes

Oct 6, 2021, 06:35pm EDT | 1,197 views

A Grim Diagnosis - Half The World's Population Has Limited Access To Diagnostics

Madhukar Pai Contributor ⓘ

Healthcare

I write about global health, infectious diseases, and equity

Follow

…… Tremendous effort and innovation has gone into Covid-19 testing. We now have rapid tests as well as home-based, self-tests for Covid-19, and have come up with easier and simpler ways of taking testing closer to people's homes and schools. Mobile testing sites, drive-through testing, and sample collection via community health workers, neighborhood pharmacies, schools and workplaces are all happening. **We need to do the same for many other areas in global health and 'democratize' access to testing…..**

Madhukar Pai

Access to quality diagnostics

47% of global population lack access to basic diagnostics for many common diseases

Gap greatest in primary care => **19%** in LMICs have access to the simplest diagnostic tests (other than for HIV or malaria)

- Easy access to diagnostics is far from guaranteed.
- Global commitments:
  - Universal health coverage (UHC)
  - Health-related Sustainable Development Goals
  - Global Health Security (IHR)

In vitro diagnostic devices (IVD) registration process in Africa

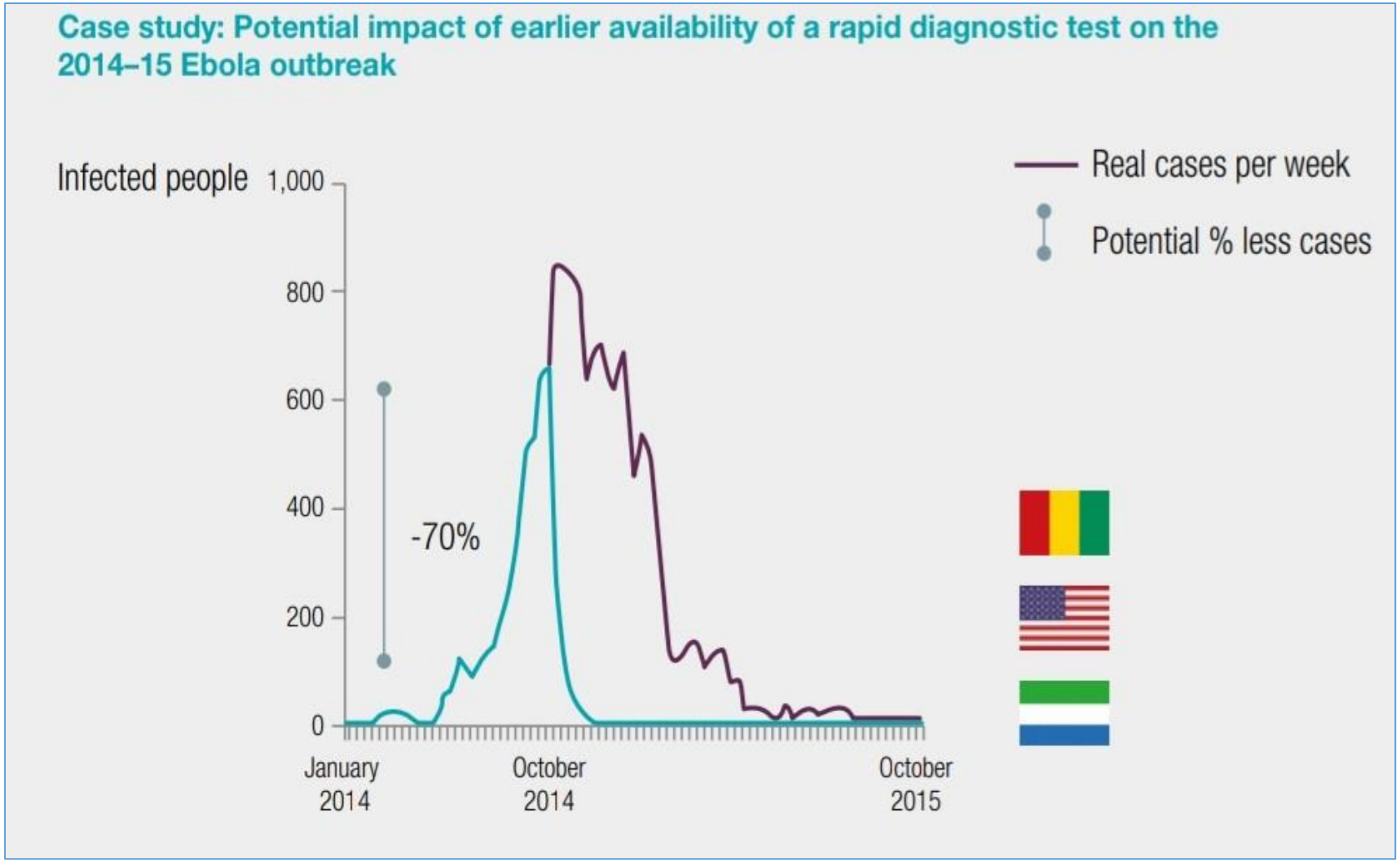
- Highly variable registration process across the regions:
  - ✓ Technical documentation (dossier)
  - ✓ Samples
- Different regulations for registration, renewals and changes
- Import permit issues

- Different lead-time, validity period and costs
- Informal/inaccessible registration regulation in some countries
- Limited human resources capacity/trained personnel

1. Inability to register all product ranges in each country
2. Inability to launch new products in all African countries at the same time
3. Prevent some countries to access to quality innovative and affordable IVD

McNerney R, Sollis K, Peeling RW. Improving access to new diagnostics through harmonised regulation: priorities for action. Afr J Lab Med. 2014;3(1), Art. #123, 7 pages.http://dx.doi.org/10.4102/ajlm.v3i1.123

Impact of early availability of diagnostics….



Models suggest <u>early</u> diagnosis could have controlled 30–70% of cases, potentially saving thousands of lives and billions of dollars in the cost of response alone.

Source: Diagnostics for epidemic preparedness. Outbreak strategy 2018 by FIND

1. Technology introduction pathway

Need assessment

In-country regulatory approval (3 – 6 months)

Supply to the programme (3 months)

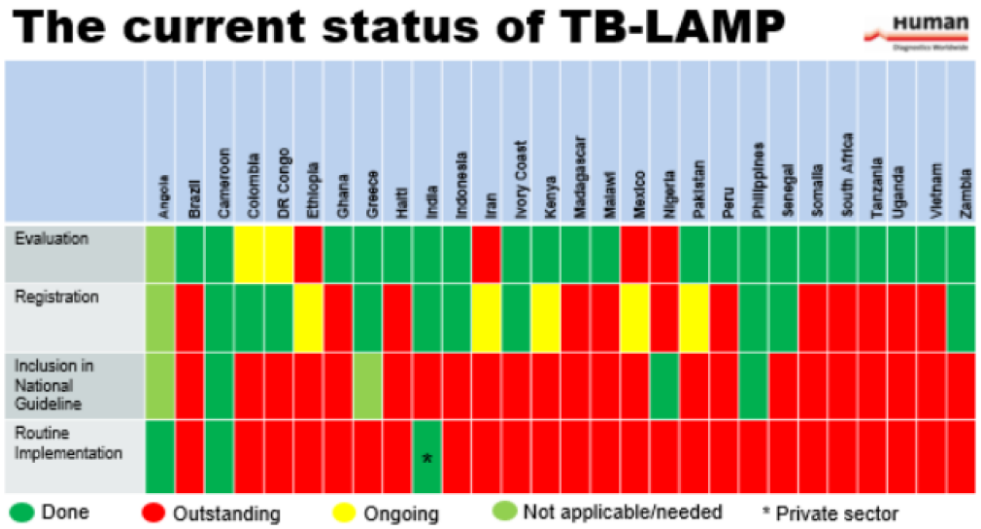
UHC?

Diagnostic product Available

Process time: ~36 months (40% time on validation)

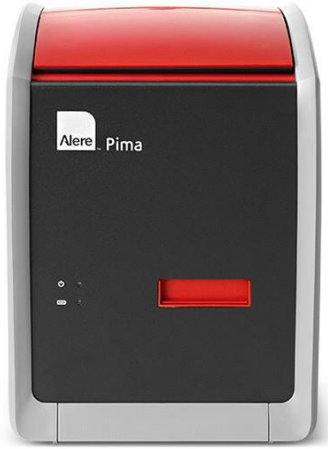
Source: FIND

Some repeat evaluations have not added value !



Poor recognition & reliance leading to multiple, similar laboratory validation studies

PIMA CD 4



Multiple > 20 Countries have conducted the evaluation of the PIMA point-of-care CD4+ count machines in various settings

Source: FIND

Enabling IVD registration process through harmonised regulation will improve access to new diagnostics

- Unified or convergent regulations/process across regions
- Formal, clear and established process
- Adequate human resources capacity/skilled personnel
- Predictable lead-time – short and timely
- Reasonable costs

Regulation of IVDs in Africa

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Regulations	Burundi	Kenya	Rwanda	Tanzania	Tanzania/ Zanzibar	Uganda	Ethiopia	Nigeria	South Africa
Legal framework	✓	✓	✓	✓	✓	–	✓	✓	✓
IVD regulated?	–	✓	–	✓	✓	–	✓	✓	✓
Premarket controls									
Adoption of GHTF classification	–	–	–	✓	✓	–	✓	In process	✓
Registration	–	+	–	✓	–	–	✓	✓	✓
Clinical performance Evaluation capacity	+	✓	–	✓ Limited	–	✓ HIV only	✓ Limited	–	✓
Manufacturing audit	–	–	–	–	–	–	–	–	–
Marketing controls									
Advertising control	✓	+	–	✓	–	✓	✓	✓	✓
Marketing controls	–	+	HIV, TB	✓	–	✓	✓	✓	✓
Postmarketing controls									
Surveillance	–	+	–	✓	–	–	–	–	✓
Accredited laboratories	–	✓	–	✓	–	✓	✓	–	✓
Device reporting	–	+	–	–	–	–	–	–	✓
Corrections/recall	–	+	–	–	–	–	–	–	✓

Abbreviations: GHTF, Global Harmonization Task Force; HIV, human immunodeficiency virus; IVD, in vitro diagnostics; TB, tuberculosis.

McNerney and Peeling Clin Infect Dis 2015;61(S3):S135–40

AUDA-NEPAD AFRICAN UNION DEVELOPMENT AGENCY

Africa Medical Devices Forum

World Health Organization

African Union

AFRICA CDC Centres for Disease Control and Prevention Safeguarding Africa's Health

Technical Assistance

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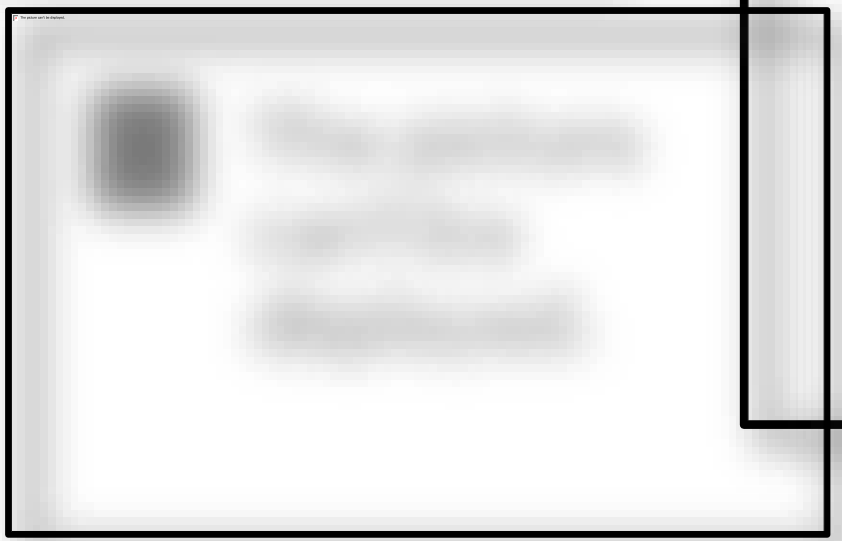
Prequalification of IVDs and the Collaborative Registration Procedure

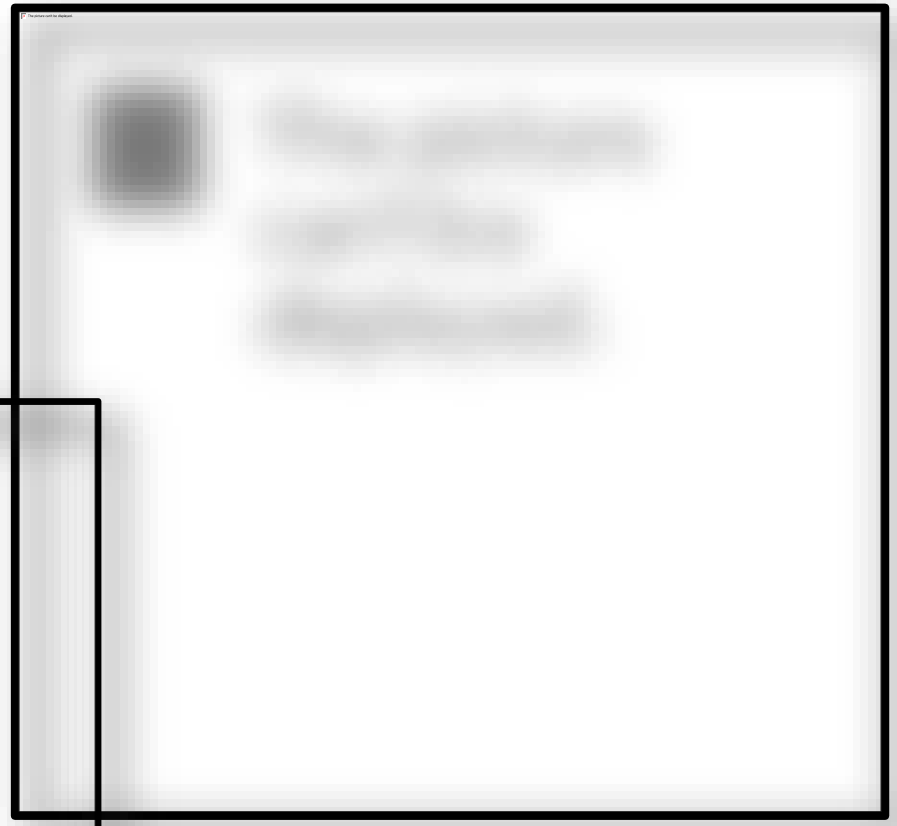
World Health Organization

In vitro Diagnostics assessment Team

Dr Susie Braniff

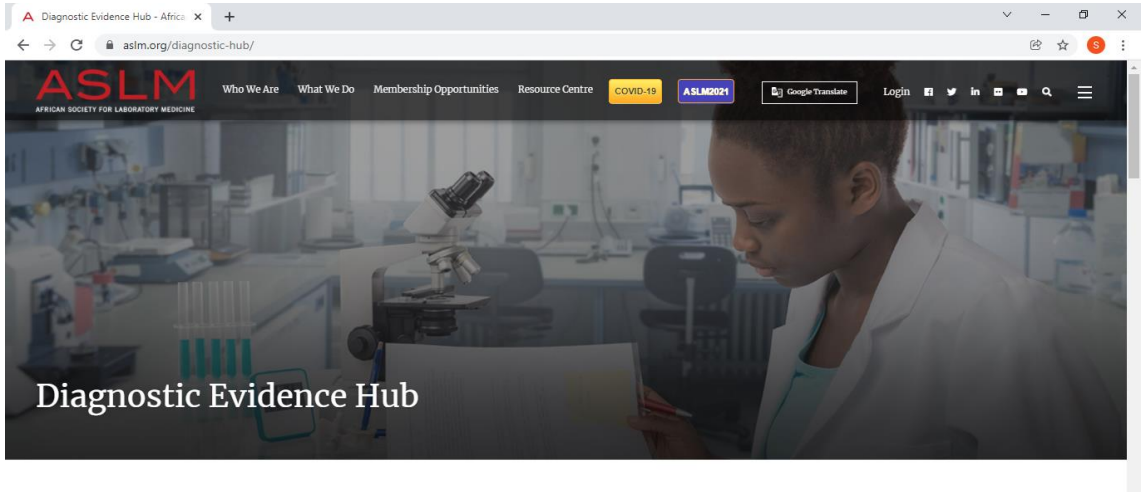
December 2021





The Diagnostic Evidence Hub

Hosted on ASLM's website at
https://aslm.org/diagnostic-hub/



Current products:

- HIV -Already built
- *TB*
- *Malaria*

  In development
- *More diseases to be considered in future*

- Aims to accelerate in-country registration and adoption new diagnostic innovations
- Knowledge **platform** for quick access to to published studies & field evalutaions for diagnostic innovations evaluation studies
- **Target audience:** National regulatory bodies, Policy Makers, Diagnostics experts, Lab. Scientists
- Access to consolidated regulatory and performance data for POC assays/new invitro diagnostic innovations
- Pooled data for **already performed field evaluations** at a one stop point
- Helps stakeholders reduce on time searching for new diagnostic innovations' performance characteristics
- Evaluation data presented at the hub are from published works, field based experiences
- Only data on for WHO PQ & independent re-known bodies is included

- ASLM and its Partners do not necessarily endorse any specific manufacturers
- **Only presents:** facts and data from WHO PQ, Independent bodies & published data sources/ information

Accessing and navigating the Diagnostic Evidence Hub

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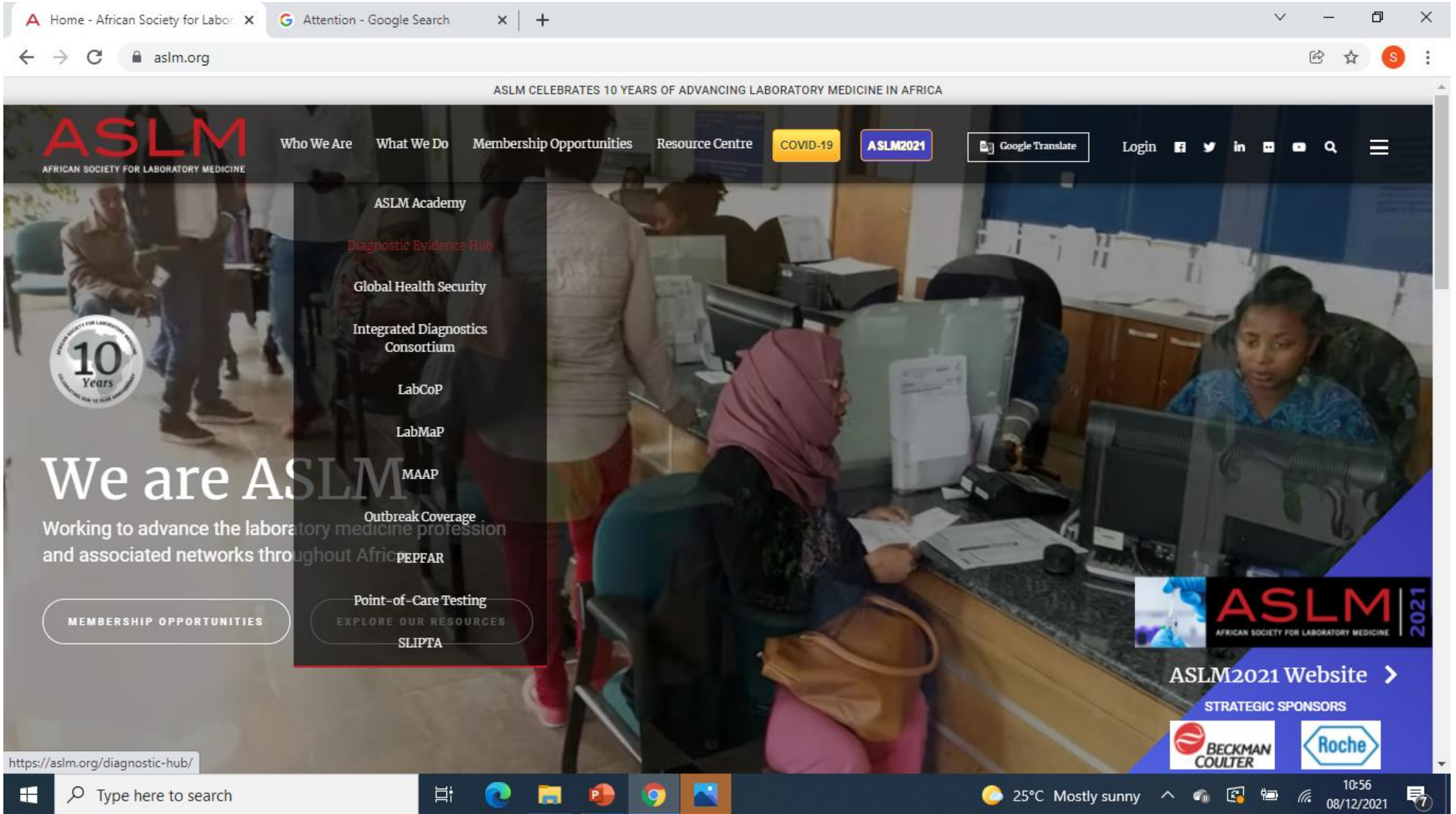

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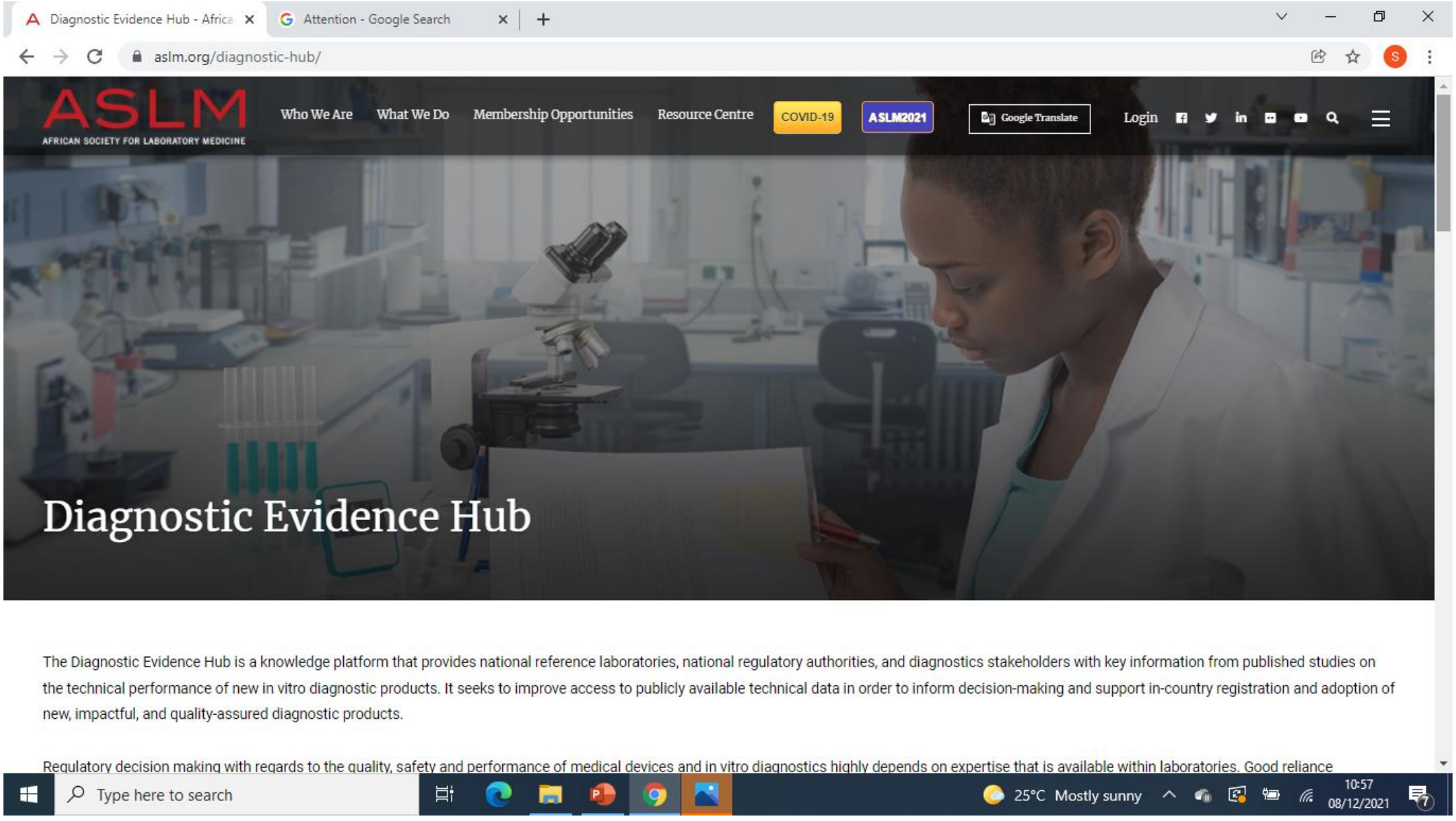

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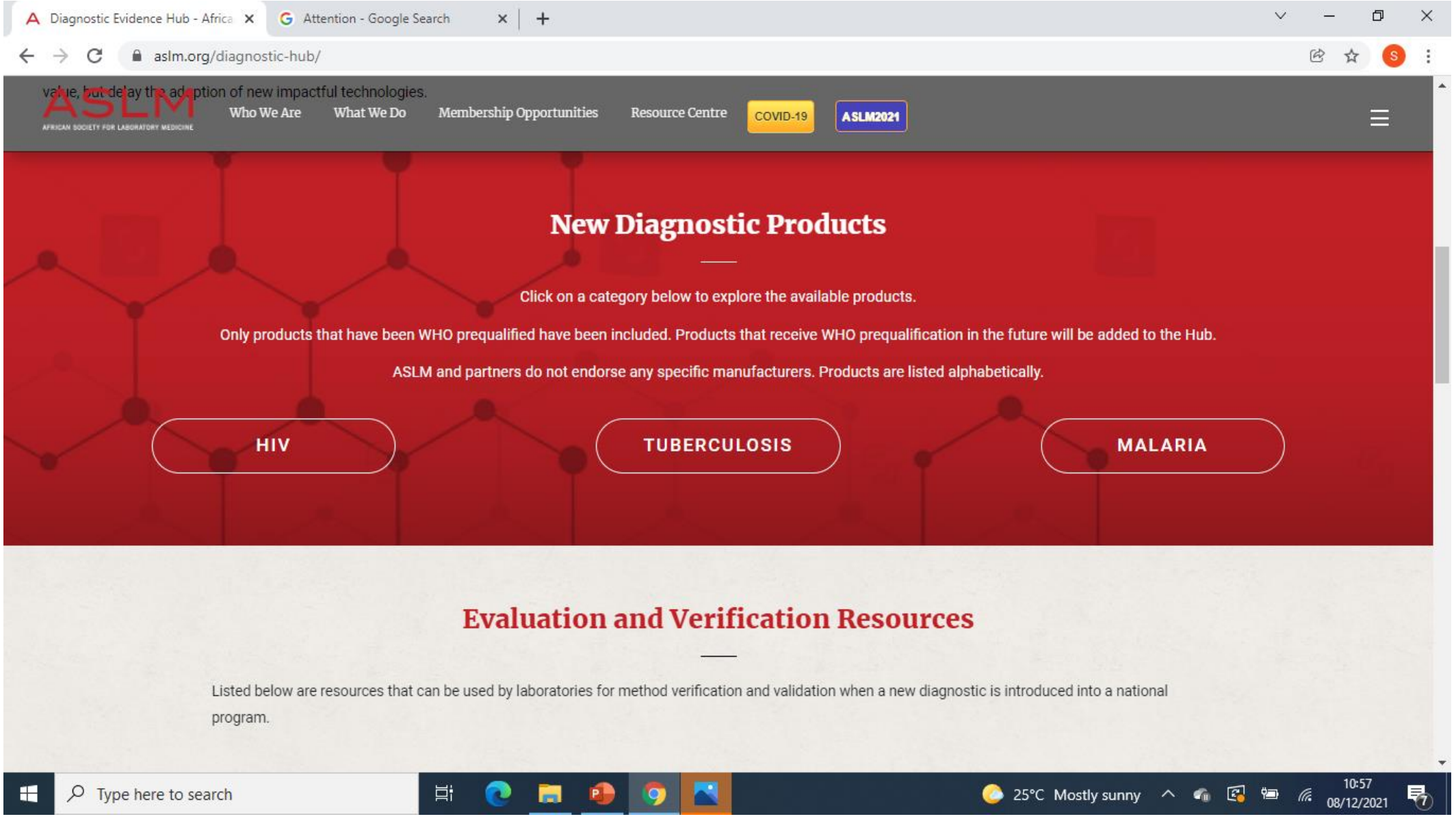

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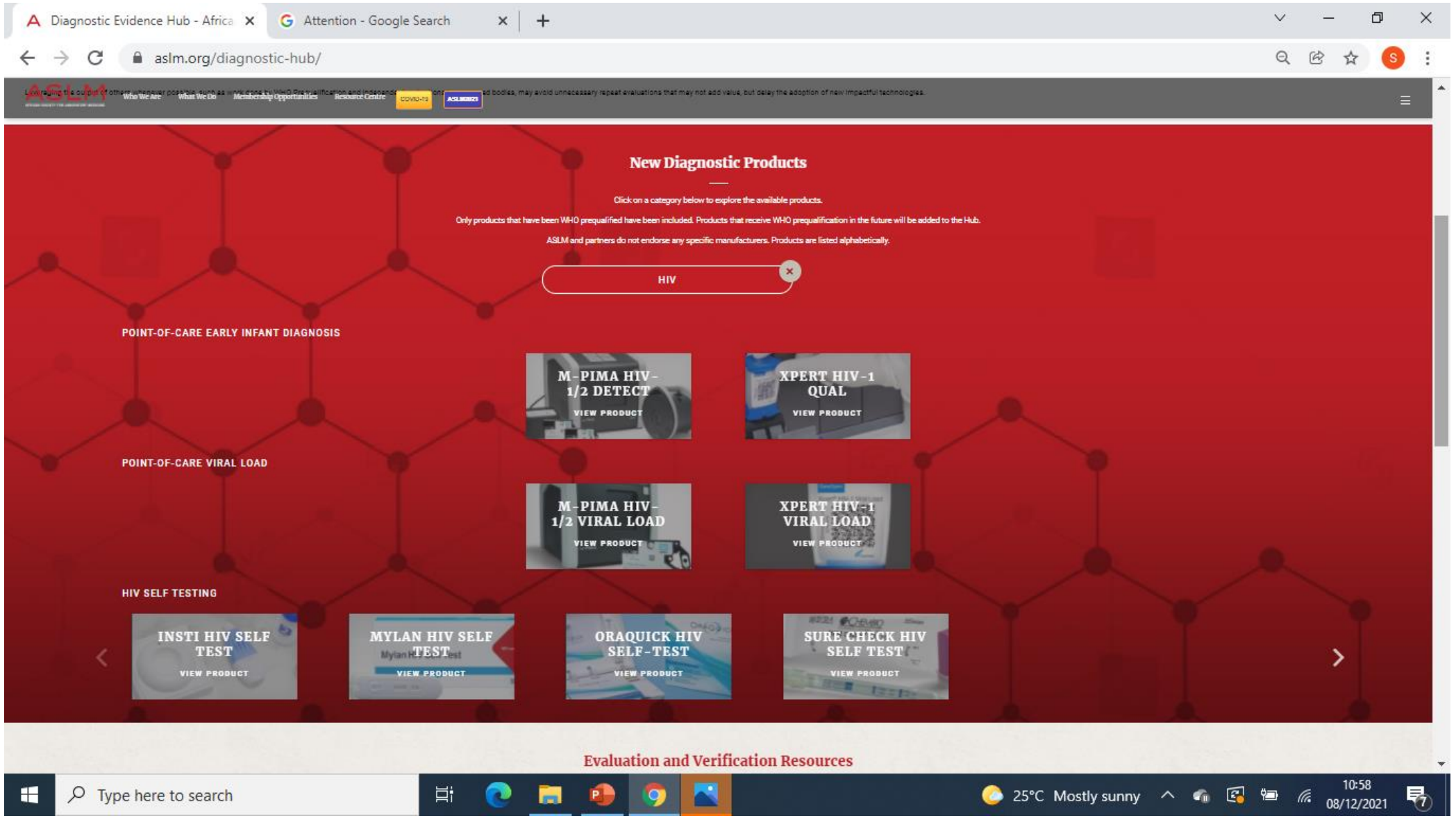

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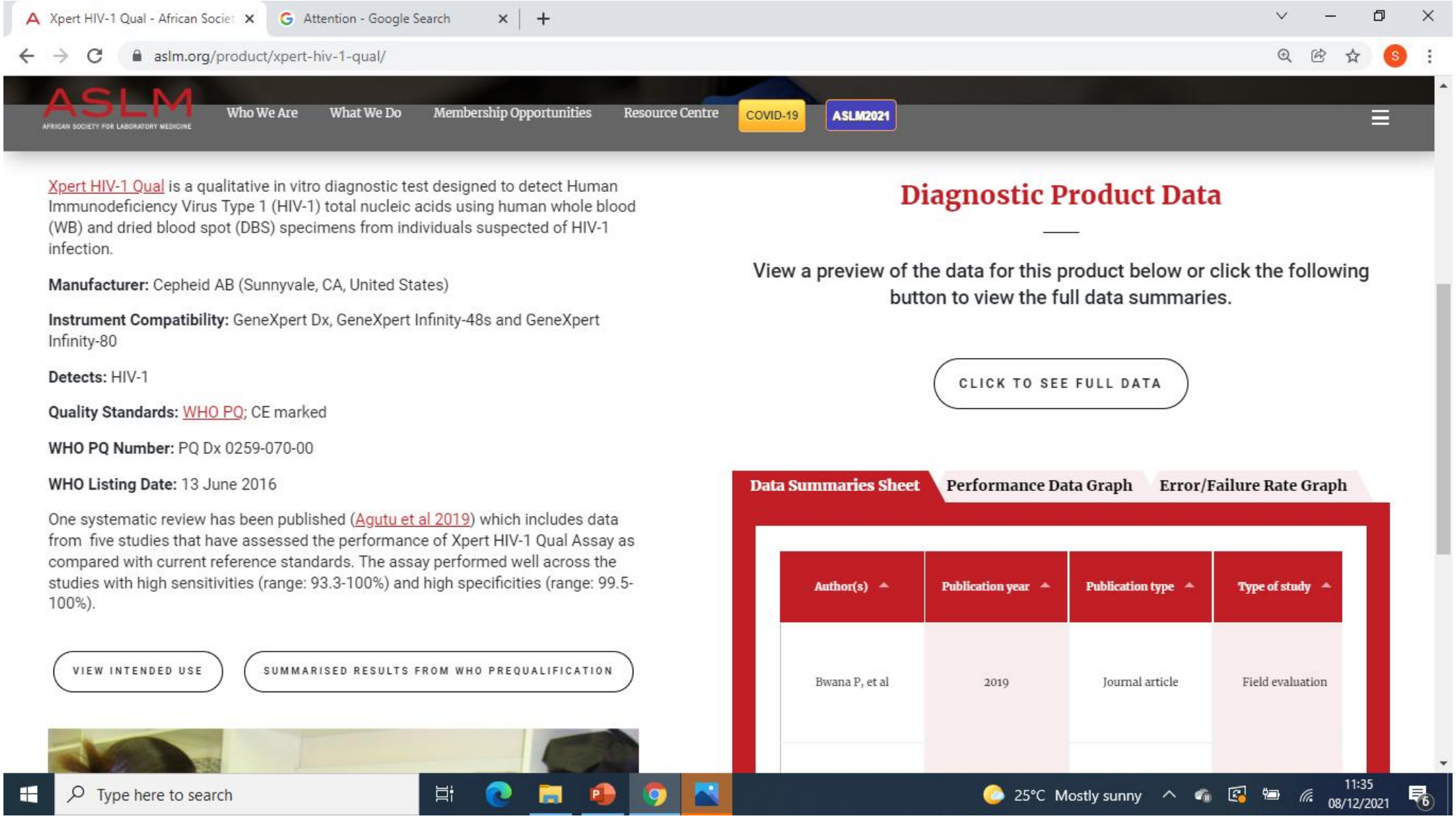

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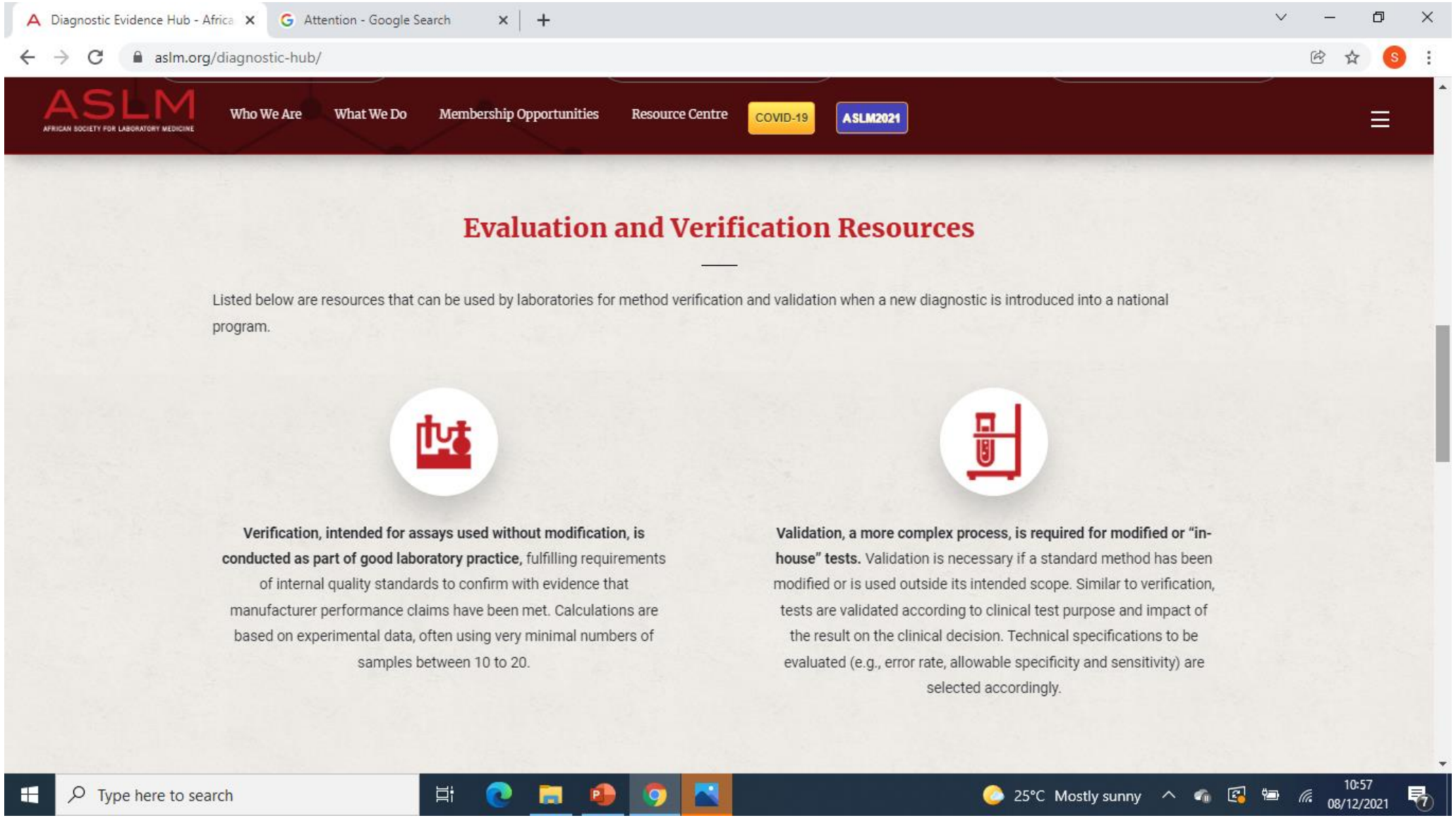

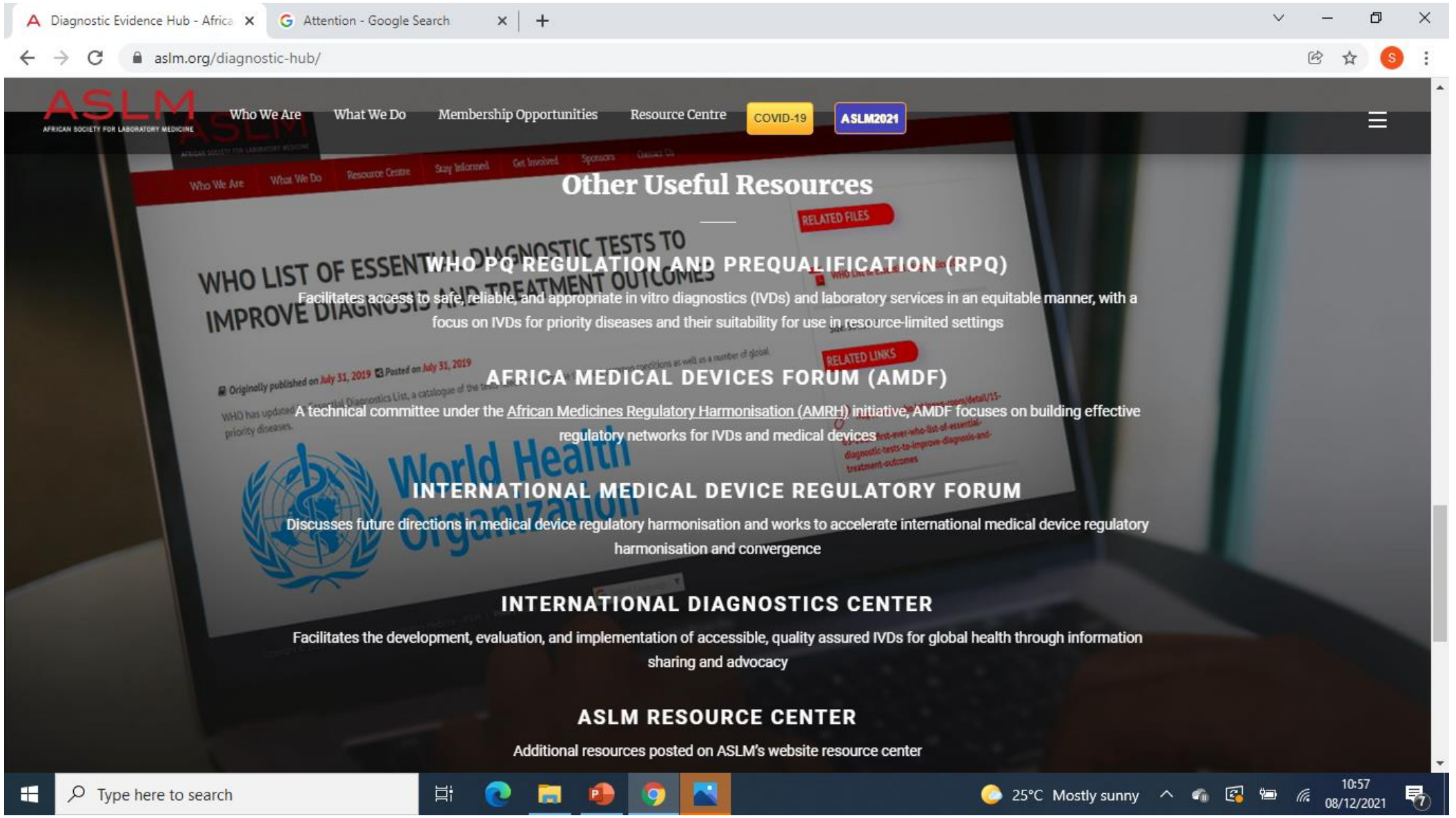
Diagnostic Evidence Hub - Africa
Attention - Google Search
aslm.org/diagnostic-hub/
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What We Do
Membership Opportunities
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Other Useful Resources
RELATED FILES
WHO PQ REGULATION AND PREQUALIFICATION (RPQ)
Facilitates access to safe, reliable, and appropriate in vitro diagnostics (IVDs) and laboratory services in an equitable manner, with a focus on IVDs for priority diseases and their suitability for use in resource-limited settings
RELATED LINKS
AFRICA MEDICAL DEVICES FORUM (AMDF)
A technical committee under the African Medicines Regulatory Harmonisation (AMRH) initiative, AMDF focuses on building effective regulatory networks for IVDs and medical devices
INTERNATIONAL MEDICAL DEVICE REGULATORY FORUM
Discusses future directions in medical device regulatory harmonisation and works to accelerate international medical device regulatory harmonisation and convergence
INTERNATIONAL DIAGNOSTICS CENTER
Facilitates the development, evaluation, and implementation of accessible, quality assured IVDs for global health through information sharing and advocacy
ASLM RESOURCE CENTER
Additional resources posted on ASLM's website resource center
Type here to search
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08/12/2021

ASLM is considering expanding the Diagnostics Evidence Hub and is interested in feedback from stakeholders

- What challenges are countries still facing when trying to introduce a new diagnostic product?

- Which aspects of the Diagnostic Evidence Hub are most helpful in addressing these challenges?

- How can the Diagnostics Evidence Hub be expanded to better support stakeholders to rapidly introduce new diagnostics?
  - Including additional types of HIV diagnostics e.g. dual HIV/syphilis RDTs?
  - Including diagnostics for other diseases e.g. TB?
  - Including evidence and tools for implementation and scale up of new diagnostics?

Partner Acknowledgment

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Thank you…