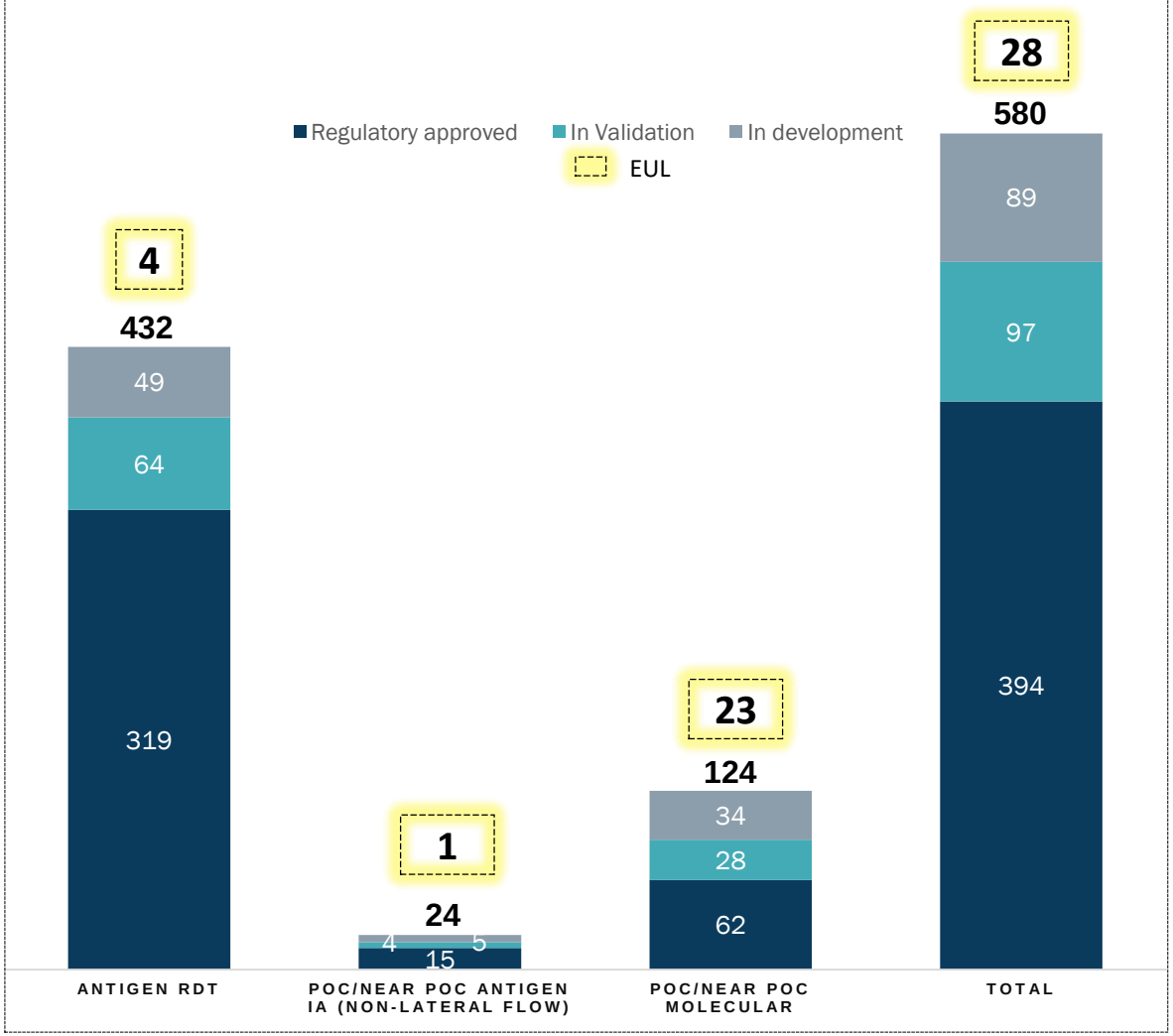
The pipeline of diagnostic tools remains robust with progress still needed on affordability and EUL

ACTaccelerator
ACCESS TO COVID-19 TOOLS
Hosted by World Health Organization

COVID-19 Antigen and Molecular Diagnostic Tools *(Number of tools)*



Tools in market

Ag RDTs
Multiple suppliers
EUL=4
~US$3 per test, with goal of $1 per test

Near-patient molecular/PCR
Only one supplier with EUL; *pricing still high (US$15–20+)*

Lab-based molecular/PCR
Multiple suppliers
<US$15 per test

Near-POC automated PCR
Single supplier (Cepheid)
US$14.90 per test

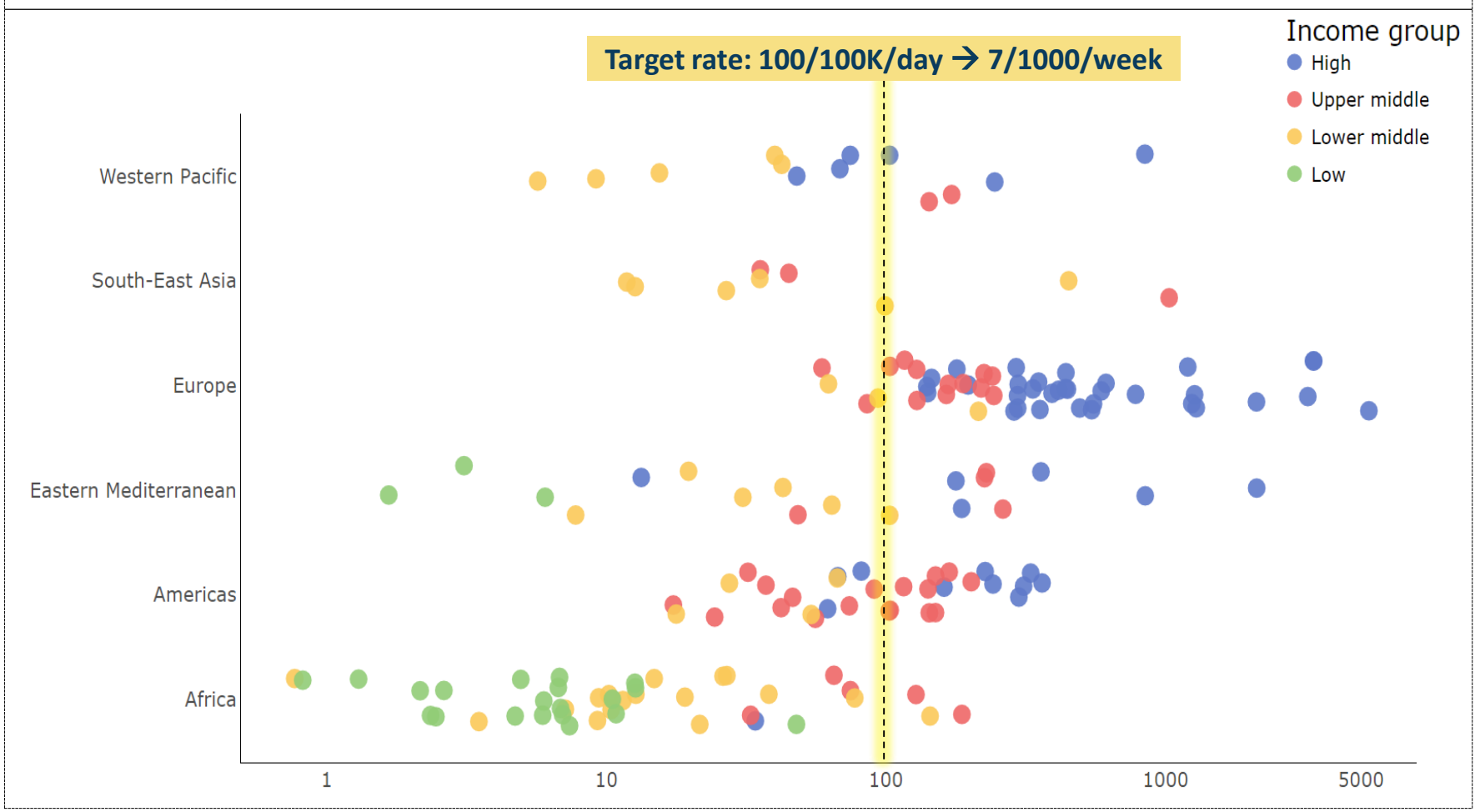
Source: FIND market research, WHO EUL for IVDs Detecting SARS-CoV2 as of 30 Apr 2021

Despite the availability of tools, testing remains inadequate in LMICs

ACTaccelerator
ACCESS TO COVID-19 TOOLS
Hosted by World Health Organization

Average daily COVID-19 testing rates (Jan-Jul 21)

Number of tests per 100K population



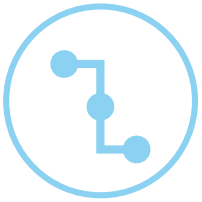
Source: Avg daily tests per capita pulled from FIND test tracker (as of 12 August 2021)

There are multiple drivers contributing to the inequity in testing rates

ACTaccelerator
ACCESS TO COVID-19 TOOLS
Hosted by World Health Organization

R&D

- Challenges in **manufacturing & supply** with limited local manufacturing



Market shaping

- Limited **regulatory review** and approval

Procurement

- Challenges **in supply chain**
- High **pricing** of tools & **shipping costs**

In-country delivery

- Gaps in **in-country governance** and financing structures
- Lack of or **insufficient national testing strategy** followed by public health actions
- Largely **centralized testing**
- **Competing priorities** with other tools & disease areas
- Limited trained **human capital**
- Challenges in **data management**

Lack of funding

ACT-A Dx partners are coordinating to address these barriers and ensure adequate testing to limit transmission, support test & treat strategies, and link to care

ACT-A Dx pillar refreshed priorities for 2021-22

01 Ensure a **reliable supply of accurate, affordable diagnostic tools** through expanded local manufacturing and support for market entry.

02 Scale **procurement of diagnostic tools** based on policy and the evolving evidence of their optimal use.

03 **Expand capacity** for countries to deploy quality-assured diagnostic tools throughout the health system and **increase community-based testing with clear link to public health interventions.**

04 Support the expansion of global disease surveillance, including strengthening the integration of epidemiological and genomic sequencing data.

Ensure equitable access to tests by supporting the procurement and use of **1 bn tests in LMICs in 2021-22**

Ensure increased testing is part of a comprehensive testing **strategy linked to public health action**

Strengthen linkages between testing, surveillance, treatment, and vaccination strategies

Appendix

ACTaccelerator
ACCESS TO COVID-19 TOOLS
Hosted by World Health Organization

Upstream success with tool development needs to be translated into higher testing rates and linkages to care in 2021-2022

ACT accelerator
ACCESS TO COVID-19 TOOLS
Hosted by World Health Organization

Category	What we've achieved	Plan for 2021-22
1 **Research & development**	Executed **4 investments to bring QA, lower-cost antigen RDTs** with regionalized manufacturing in 2021 **RFP for low-cost, QA self-tests:** 6 manufacturers selected. Self-test needs assessment completed, values & preferences work underway **Refreshed R&D product pipeline**; RFP on innovative molecular solutions recently closed with 47 applicants **RFP on digital reader apps:** first award issued with others in review; Conducting regional workshops on digital tools	1. Invest in **R&D and expanded local manufacturing** capacity to optimize existing products and bring additional POC molecular tests to market 2. Ensure diagnostic tools remain effective by **supporting the external evaluation of products against variants**
2 **Market shaping**	Maintained a robust pipeline of diagnostic tools with **394 approved products** **Agreements** signed to enable expanded production of Ag RDTs in Africa. Partnership announced to enable commercialization and distribution of high-quality Ag RDTs in LMICs.	3. Support **EUL of 4 additional tools** and deploy market shaping interventions to support expanded access
3 **Procurement**	Procured **over 39M molecular tests and 62.4M Ag RDTs**; supported prices reductions down to 2.5-3 for Ag RDTs, $6-10 for manual PCR, $10-20 for automated PCR	4. Support the **procurement and optimal use** of 988 M diagnostic tools
4 **In country delivery**	**Operational research studies planning in 20+ countries** and launch of Ag RDT modelling consortium **Launched Genomic Surveillance Working Group** to coordinate global efforts; **conducted baseline mapping** of global sequencing capacity **Trained 42,200+ health care workers** in nearly 200 countries and **deployed catalytic tests to 20+ countries**	5. Aid **evidence generation** required to support the expansion and de-centralization of testing use cases, policies and guidance 6. Ensure all countries have an **effective, QA program for testing** 7. Invest in **workforce development** to expand community-based testing 8.Provide **technical assistance and operational support** to **expand decentralized testing** 9. Enhance **testing through advocacy, communication, and community engagement efforts** underpinned by local context 10. **Support efforts to expand genomic sequencing capacity and build** in-country policies, laboratory and digital infrastructure