DIAGNOSTICS REPRESENTATION IN SCIENTIFIC LITERATURE

FINAL PRESENTATION

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February 10th, 2025

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STRATEGIC ANALYSIS, RESEARCH & TRAINING CENTER
Department of Global Health | University of Washington

Photo: Jessica Amdur, BII

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START OVERVIEW

Leverages leading content expertise from across the University of Washington

Provides high-quality research and analytic support to the Gates Foundation and global and public health decision-makers

Provides structured mentorship and training to University of Washington graduate research assistants

BACKGROUND

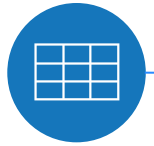
REASON FOR THE REQUEST

The representation of diagnostics in scientific literature is fragmented, with unclear trends and gaps across the value chain.

KEY PROJECT OBJECTIVES

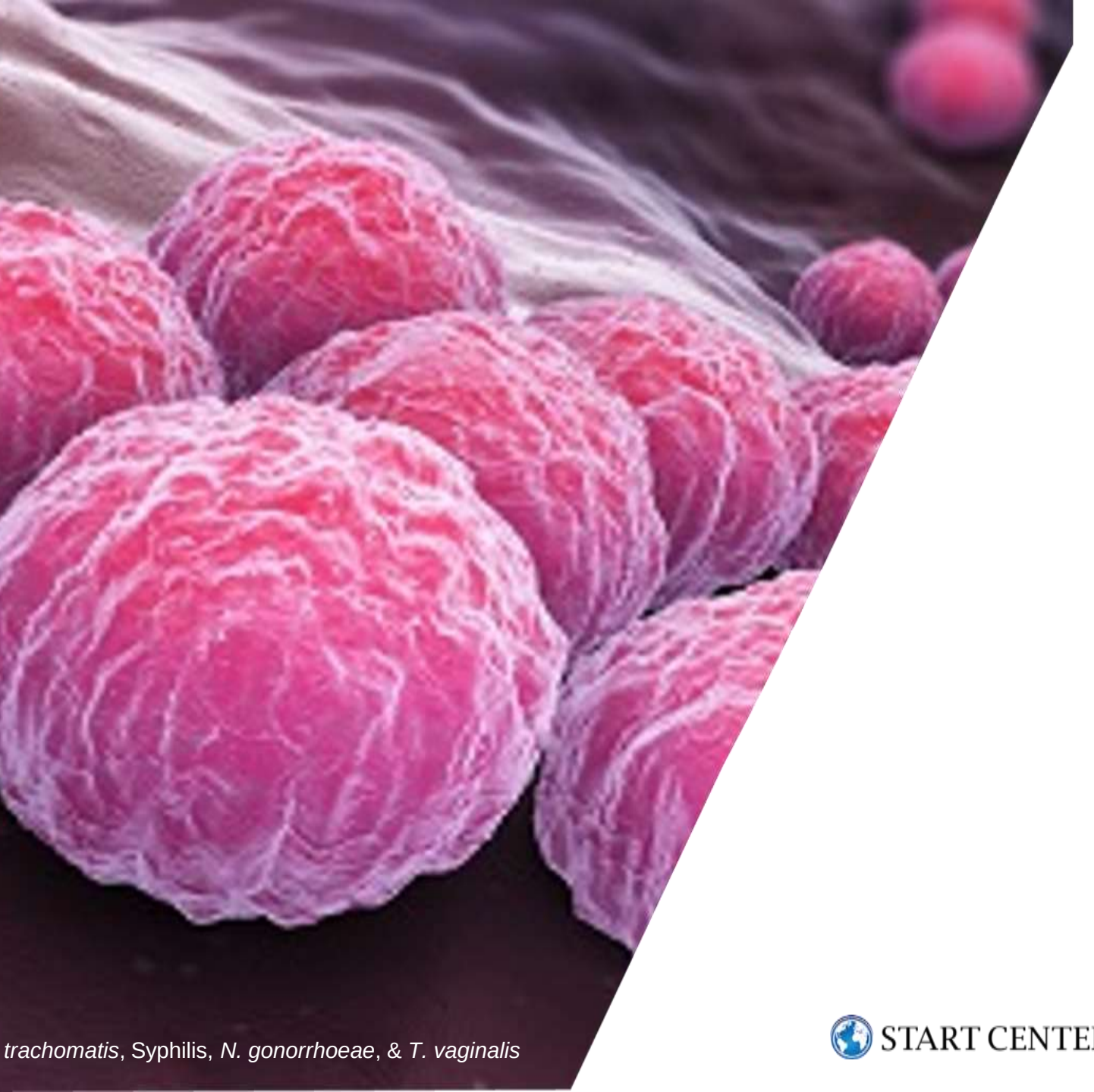
Analyze diagnostics literature to assess representation, focus areas, and LMIC considerations.

Evaluate diagnostics across the value chain, identifying gaps and momentum



Assess diagnostics in global health innovation research

Compare disease-specific vs. agnostic research and highlight key diseases



KEY INFECTIOUS DISEASE AREAS

- *HIV*
- *Tuberculosis*
- *Malaria*
- *HPV/Cervical Cancer*
- *STIs**
- *Anemia*
- *NTDs*

trachomatis, Syphilis, *N. gonorrhoeae*, & *T. vaginalis*

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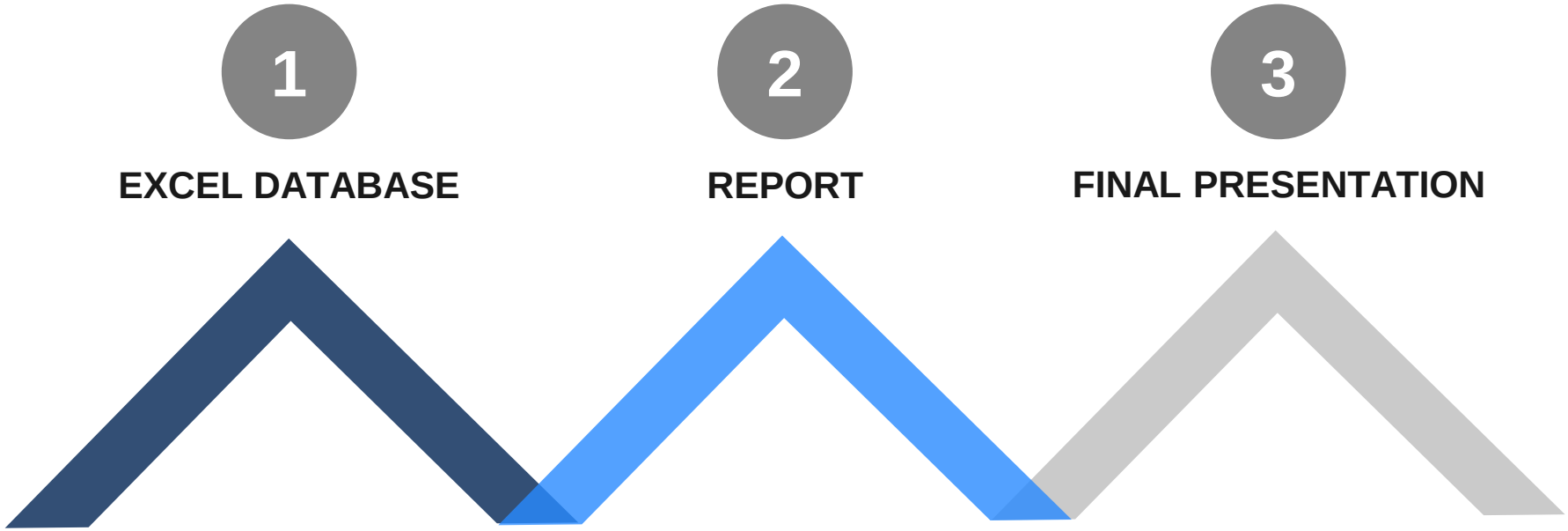
PROJECT DELIVERABLES

SUMMARIZING DIAGNOSTICS REPRESENTATION



Detailing:

- Diagnostic value chain components
- Relevant information for diseases of focus
- LMIC Considerations

- Project methodology
- Findings

- Final slide deck

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PRESENTATION OVERVIEW

OBJECTIVE: DETERMINE DIAGNOSTICS PROMINENCE AND HIGHLIGHT RECOMMENDATIONS FOR FUTURE DIAGNOSTIC INVESTMENT PATHWAYS

KEY PROJECT MESSAGES

KEY PROJECT MESSAGES

1

DIAGNOSTIC PROMINENCE

Despite the critical need for diagnostics in LMICs, scientific literature is disproportionately focused on high-income settings, with molecular and immunologic diagnostics; Malaria and NTDs, remaining underrepresented.

2

MOMENTUM AREAS

Push in task-shifting, POC testing, and decentralized diagnostic models, particularly for HIV viral load monitoring, TB screening, and STI diagnostics

3

GAPS / LIMITATIONS

Structural barriers to timely and equitable diagnostic access including high cost of advanced diagnostics, logistical constraints, and reliance on centralized laboratories.

METHODOLOGY

OVERALL PROJECT PROCESS

Developed separate search strings for diagnostics, infectious diseases, and LMICs and retrieved PubMed articles

Title and Abstract Screening (2,235 articles published between 2022- 2024)

Numeric analysis to assess diagnostics prominence

Data extraction in Excel from 263 articles discussing at least one value chain component

Content Analysis and Synthesis using Miro

Development of Deliverables

Presentation of Findings

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QUANTITATIVE FINDINGS

NUMERIC ANALYSIS

KEY QUANTITATIVE TAKEAWAYS

1

Molecular and Immunologic Diagnostics Underrepresented in LMIC-Focused Literature

Molecular and Immunologic diagnostics account for just 5.4% of LMIC-focused diagnostic-related articles (despite their importance for precision diagnostics).

2

Underrepresentation of Malaria and NTD Diagnostics

HPV (21.8%), TB (21.3%), and STIs (21.4%) had the highest diagnostic representation, followed by Anemia (18.6%) and HIV (17.1%), while Malaria (13.4%) and NTDs (12.2%) were underrepresented relative to their broader disease research landscape.

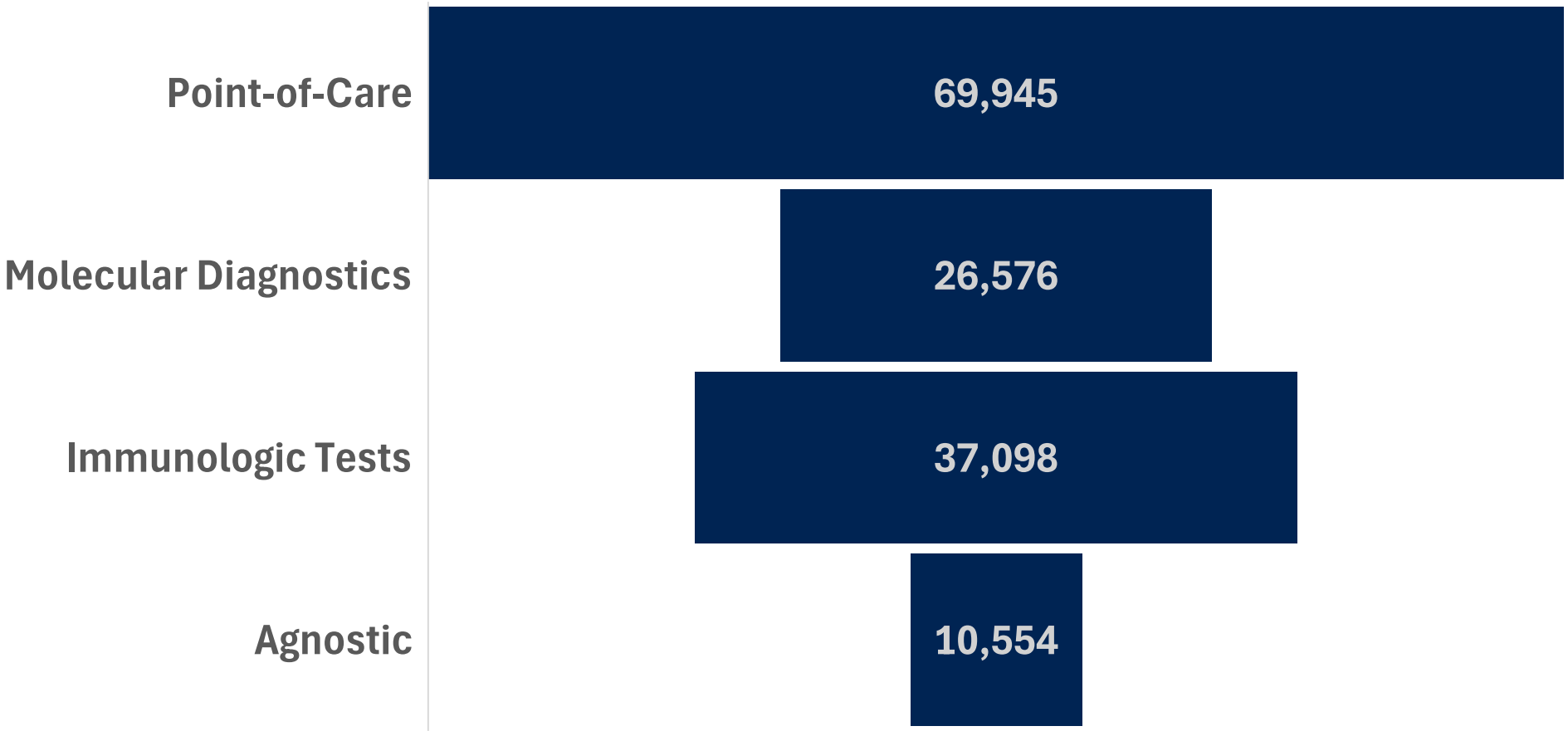
3

LMIC-Focused Diagnostic Research is Extremely Limited

Only 1% of all broad diagnostics-related articles (encompassing any diagnostic-related topic) consider LMICs, indicating a disproportionate emphasis on high-income settings.

RESEARCH EMPHASIS: POINT-OF-CARE, MOLECULAR, IMMUNOLOGIC TESTS AND AGNOSTIC

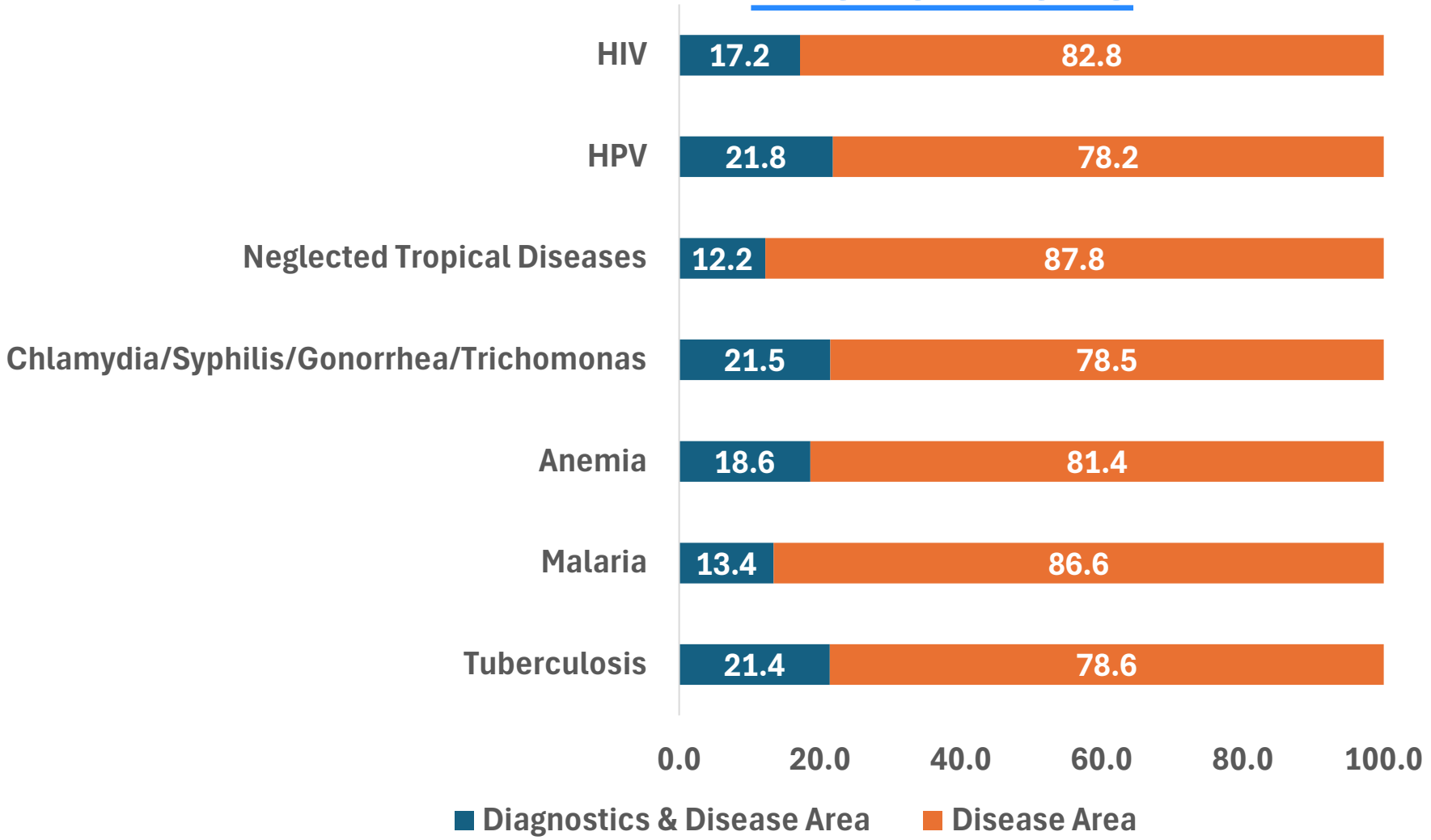
ARTICLE COUNTS



Within the ~ 1.3M articles very broadly including a focus on diagnostic techniques and procedures, Immunologic tests featured more prominently in research than molecular

RESEARCH EMPHASIS BY DISEASE AREA

PROPORTIONS



Diagnostics make up ~12-22% of articles within each disease area, with bars representing 100% of articles per disease

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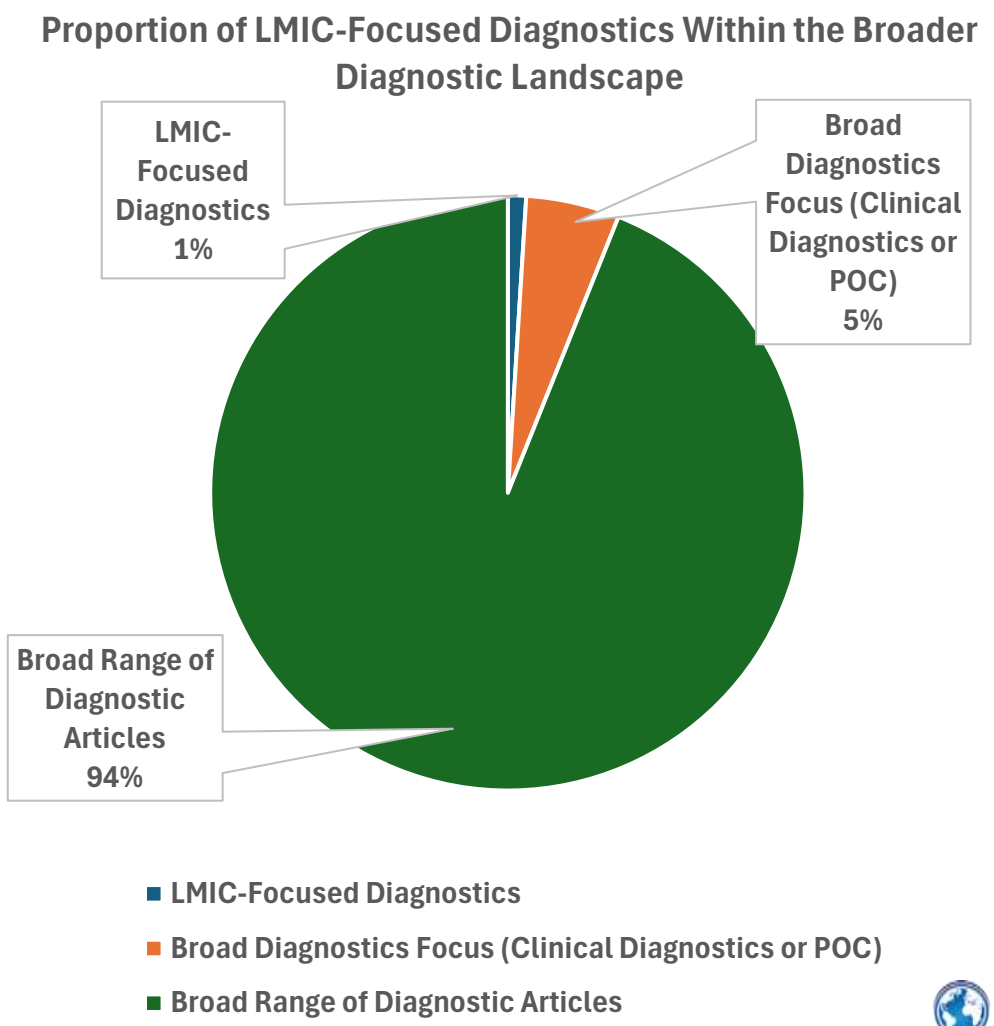
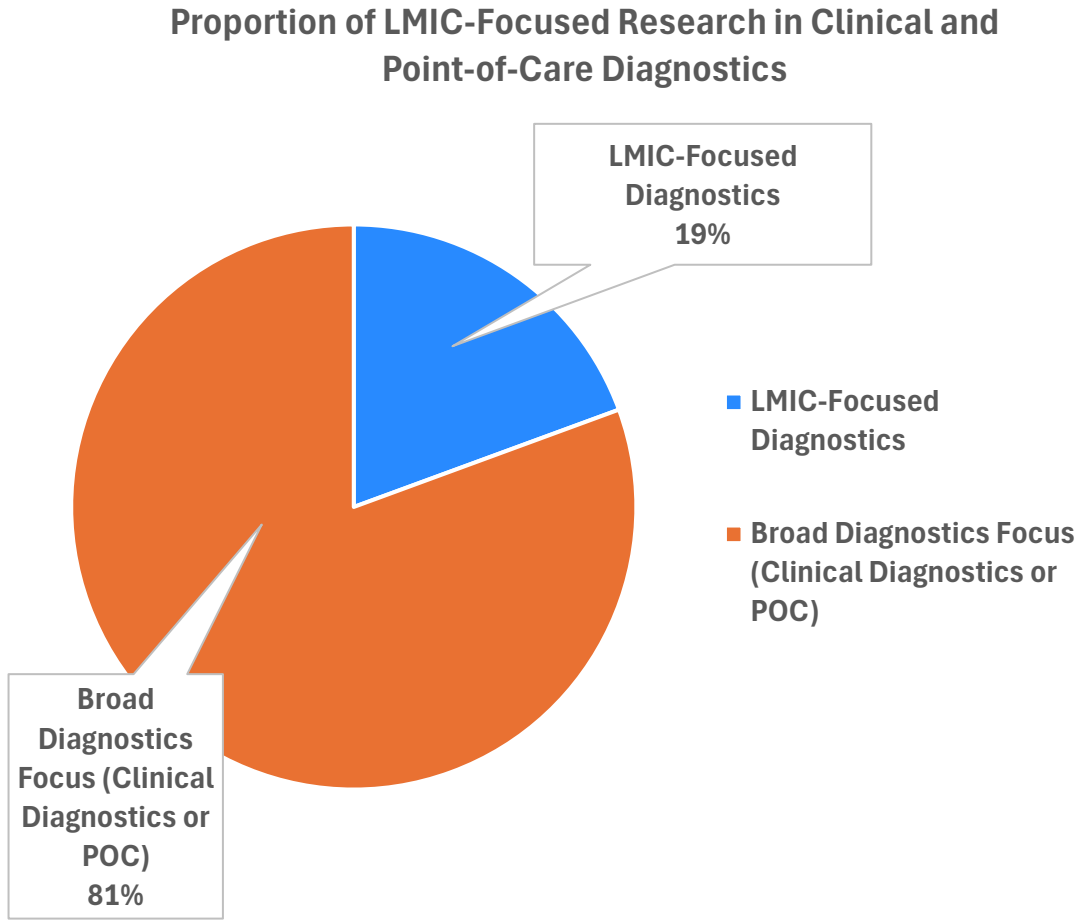
LMIC-FOCUSED REPRESENTATION

SUB-SAHARAN AFRICA AND ASIA





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LMIC Search terms

("Africa South of the Sahara"[MeSH Terms] OR "Developing Countries"[MeSH Terms])

QUALITATIVE FINDINGS

DIAGNOSTICS VALUE CHAIN

KEY QUALITATIVE TAKEAWAYS

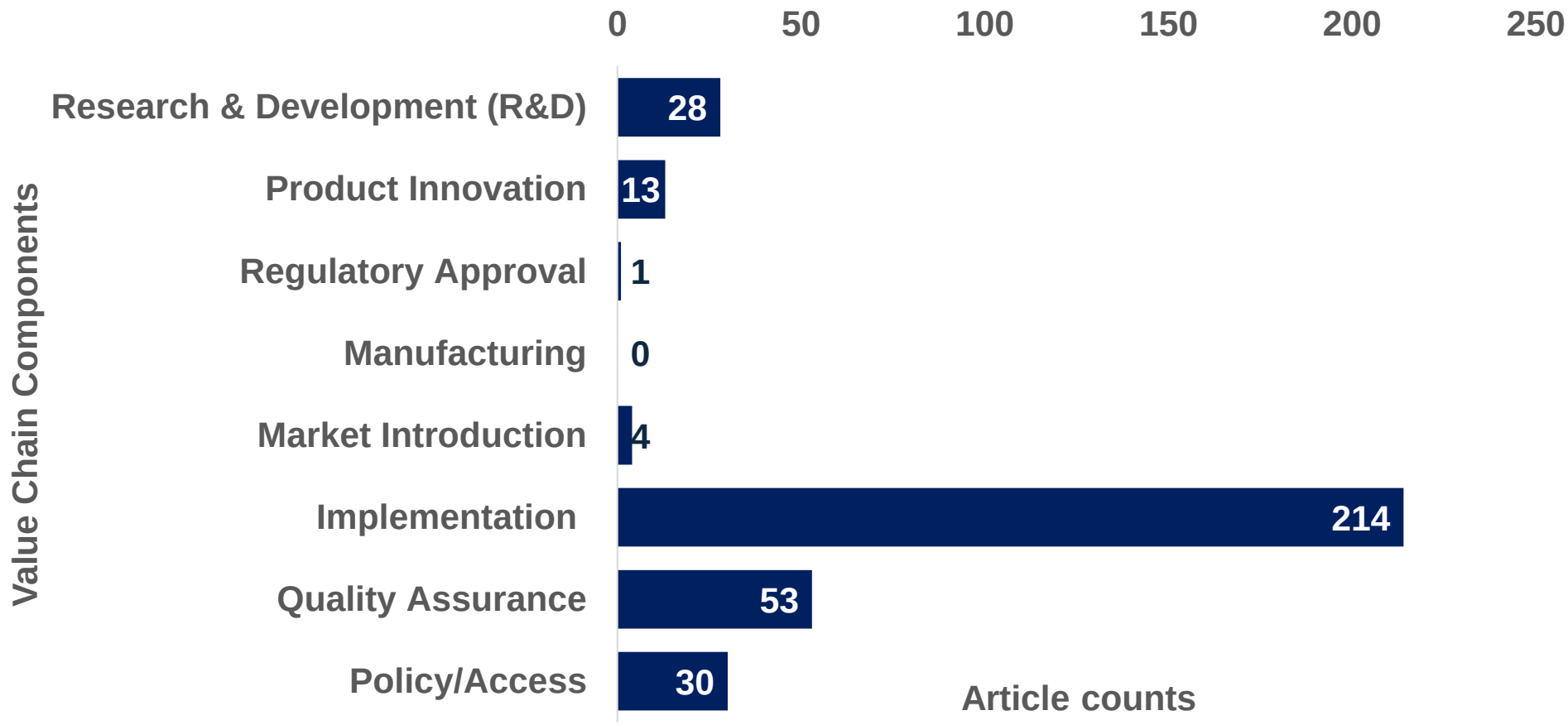
1. HIV and TB have the highest representation in the diagnostic landscape across the value chain, Malaria, HPV, and STIs show lower but noticeable research emphasis, (implementation and policy/access). Anemia and NTDs have minimal representation

2. Strong emphasis on Implementation, Quality Assurance, and Policy/Access compared to upstream components

3. In-vitro diagnostics dominate across the value chain components, Near/POC diagnostics are concentrated on HIV and STIs; meanwhile, agnostic diagnostics remain largely underrepresented.

RESEARCH EMPHASIS BY DIAGNOSTIC VALUE CHAIN

INDEPENDENT, NON-OVERLAPPING ARTICLE COUNTS



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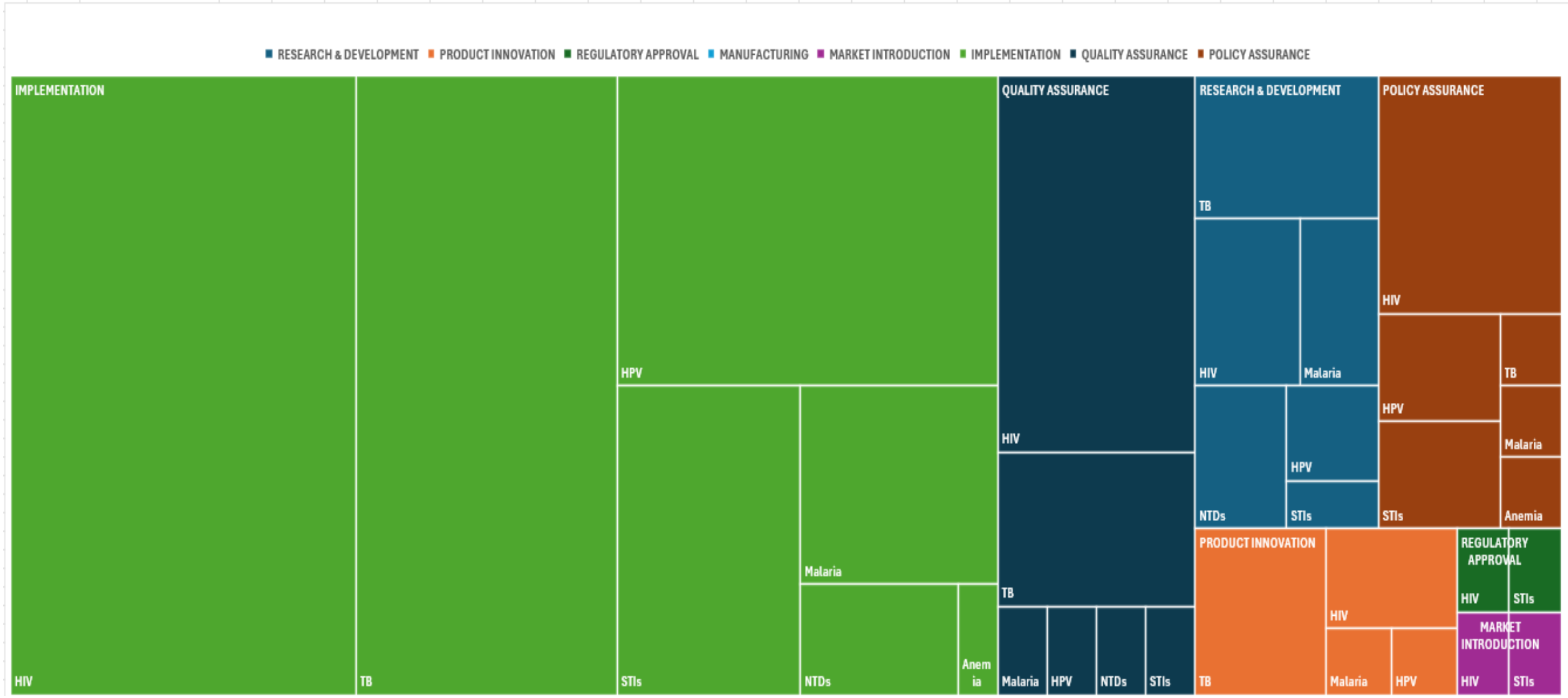
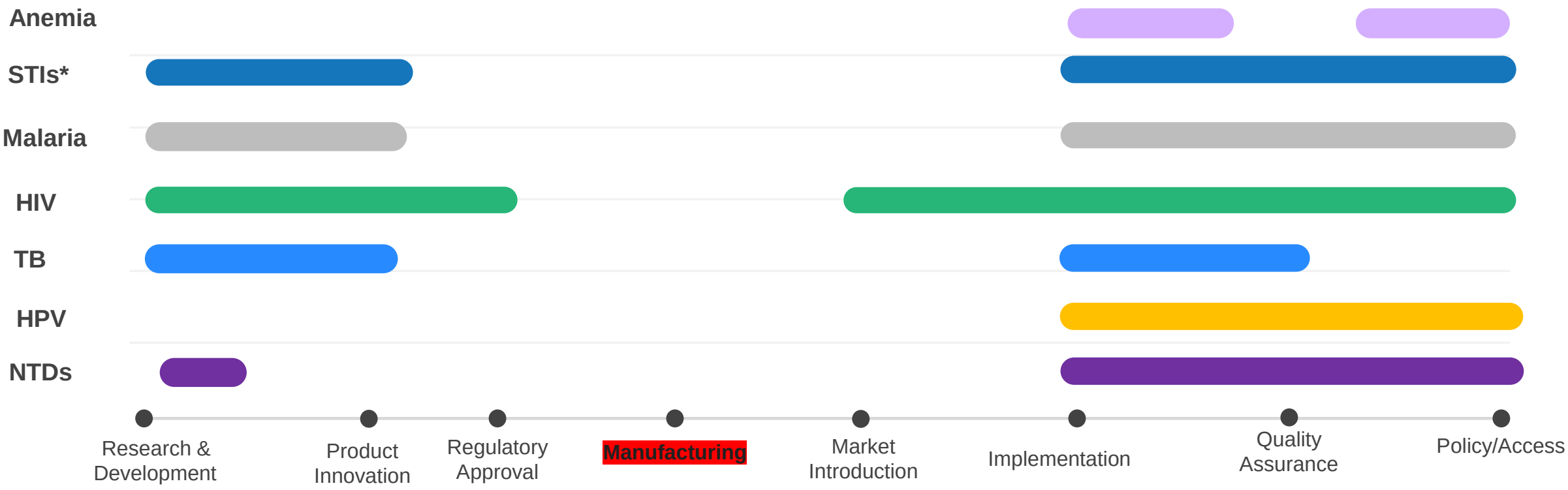
RESEARCH EMPHASIS

DIAGNOSTIC VALUE CHAIN AND DISEASE AREA



RESEARCH EMPHASIS

DIAGNOSTIC VALUE CHAIN AND DISEASE AREA



*C. trachomatis, Syphilis, N. gonorrhoeae, &/or T vaginalis

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RECOMMENDATIONS

DISEASE-SPECIFIC RECOMMENDATIONS

HIV

- Scale up POC diagnostics and support multiplex diagnostic platforms (such as m-PIMA™ HIV1/2 VL (Abbott) for detection and quantification of HIV-1 and HIV-2 viral loads)

TB

- Development and adoption of non-invasive, more reliable diagnostic methods such as non-sputum-based tests to improve early TB detection

Malaria

- Integrate molecular diagnostics, strengthen microscopy, and RDT accuracy via routine refresher training for laboratory personnel.

HPV

- Enhance screen-and-treat strategies using HPV self-sampling, VIA, and thermal ablation which could reduce loss to follow-up and provide same-day treatment.

DISEASE-SPECIFIC RECOMMENDATIONS

STIs

- Accelerate the shift from syndromic to diagnostic-based STI management (POC), while increasing affordability and access

NTDs

- Prioritize multiplex diagnostics capable of detecting multiple NTDs in co-endemic areas.

Anemia

- Expand POC testing access for anemia, particularly in districts with high HIV and malaria burdens and **conduct further research** that independently assesses anemia measurements, diagnostic accuracy

STRATEGIC RECOMMENDATIONS 1/2

CROSS-CUTTING

Patient-Level

- Expand the use of **POC diagnostics** and **multiplex diagnostic devices**
- **Diversify specimen collection methods** to enhance diagnostic accessibility and accuracy

Clinical-Level

- **Task-shifting** and training of frontline HCWs to operate **POC diagnostics**
- Accelerate diagnostic TAT to improve treatment precision

Lab-Level

- Facilitate collaboration between **private-sector diagnostic companies** and public health laboratories
- Enhance laboratory efficiency via process optimization and continuous skill-building

Public Health-Level

- Advocate for policies that prioritize integrating cost-effective, decentralized diagnostic solutions into national health strategies
- **Enhance Disease Surveillance** (WGS) and **Targeted Interventions** to improve disease control and therapeutic response

STRATEGIC RECOMMENDATIONS 2/2

OVER-ARCHING

1

Access to Diagnostics

Increase affordability and availability of POC diagnostics to facilitate early detection and timely treatment initiation

2

Advancing the Integration of Diagnostics

Foster multiplex diagnostic solutions that allow for co-infection screening to improve diagnostic efficiency and reduce overall testing costs

3

Local Innovation and Manufacturing

Prioritized to reduce dependency on imported diagnostics and increase affordability and access in LMICs.

THANK YOU

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QUESTIONS & DISCUSSION

APPENDIX

BROAD DIAGNOSTICS AND LMIC FOCUS- Search String Refinement

Diagnostic techniques OR Diagnostic procedures **OR** Clinical Lab Techniques OR Point-of-Care *Captures a broad range of diagnostic articles (those with any diagnostic-related topic)*	*Diagnostic techniques **OR** Diagnostic procedures **AND** Clinical Lab Techniques **OR** Point-of-Care*	*Diagnostic techniques **OR** Diagnostic Procedures **AND** Clinical Lab Techniques **OR** Molecular Diagnostic Techniques*	Diagnostic techniques **OR** Diagnostic procedures **AND** Clinical Lab Techniques **OR** Immunologic Tests
Column Header above **Hits = 1,292,873**	*Column Header above* **A: 69,945**	*Column Header above* **G: 26,576**	*Column Header above* **M: 37,098**
[Modified Column header] AND *POC* *(Moving away from the broader categories above, the column headers were modified by replacing "AND" with "OR") – to increase breadth and specificity*	**B:** Diagnostic techniques **OR** Diagnostic procedures **OR** Clinical Lab Techniques **AND** Point-of-Care **Hits = 20,381**	***H:*** Diagnostic techniques **OR** Diagnostic Procedures **OR** Clinical Lab Techniques **OR** Molecular Diagnostic Techniques **AND** Point-of-Care **Hits: 20,192**	***N:*** Diagnostic techniques **OR** Diagnostic procedures **OR** Clinical Lab Techniques **OR** Immunologic Tests **AND** Point-of-Care **Hits: 20,266**
[Modified Column header] **AND** *Rapid Diagnostic Test)* *These strings specify mentions of "RDT only" but do not entirely exclude "POC", as most RDTs are POC tests*	**C:** Diagnostic techniques **OR** Diagnostic procedures **OR** Clinical Lab Techniques **AND** Rapid Diagnostic Test **Hits: 7,700**	***I:*** Diagnostic techniques **OR** Diagnostic Procedures **OR** Clinical Lab Techniques **OR** Molecular Diagnostic Techniques **AND** Rapid Diagnostic Test **Hits: 7649**	***O:*** Diagnostic techniques **OR** Diagnostic procedures **OR** Clinical Lab Techniques **OR** Immunologic Tests **AND** Rapid Diagnostic Test **Hits: 7760**
[Modified Column header] **AND** *(POC* **OR** *Rapid Diagnostic Test)*	**D:** (Diagnostic techniques **OR** Diagnostic procedures **OR** Clinical Lab Techniques) **AND**	**J:** (Diagnostic techniques **OR** Diagnostic Procedures **OR** Clinical Lab Techniques **OR** Molecular Diagnostic	**P:** (Diagnostic techniques **OR** Diagnostic procedures **OR** Clinical Lab Techniques **OR** Immunologic Tests)

	(Point-of-Care **OR** Rapid Diagnostic Test) **Hits: 26, 570**	(Point-of-Care OR Rapid Diagnostic Test) **Hits: 26,378**	**AND** (Point-of-Care OR Rapid Diagnostic Test) **Hits: 26,544**
Agnostic/other	E: A - D **Hits: 8,798**	K: G – J **Hits: 198**	Q: M - P **Hits: 10,554**
[Column] **AND** *LMIC**	**F:** (Infectious Disease Diagnosis) **AND** (Clinical Lab Techniques OR Point-of-Care Testing OR Diagnostic Techniques) **AND** ("Africa South of the Sahara"[MeSH Terms] OR "Developing Countries"[MeSH Terms]) **Hits: 4,443** *This string is infectious disease-focused. It ensures that "developing countries" includes Southeast Asia.* *To be used for phase II (screening)*	**L:** (Diagnostic techniques OR Diagnostic Procedures AND Clinical Lab Techniques OR Molecular Diagnostic Techniques) **AND** ("Africa South of the Sahara"[MeSH Terms] OR "Developing Countries"[MeSH Terms]) **Hits: 276**	**R:** (Diagnostic techniques OR Diagnostic procedures AND Clinical Lab Techniques OR Immunologic Tests) **AND** ("Africa South of the Sahara"[MeSH Terms] OR "Developing Countries"[MeSH Terms]) **Hits = 456**
Alternative for Cell F (Diagnostic techniques OR Diagnostic Procedures **AND** (Clinical Lab Techniques OR Point-of-Care Testing OR Diagnostic Techniques) **AND** ("Africa South of the Sahara"[MeSH Terms] OR "Developing Countries"[MeSH Terms]) **Hits = 13,631** *This looks at diagnostics more broadly (no disease-focus). String ensures that "developing countries" includes Southeast Asia.*			

NB: Pubmed last used 11/15/2024

DISEASE-SPECIFIC DIAGNOSTICS vs DISEASE GROUP

Number of Hits: Diagnostics + Disease Group	Number of hits: Disease Group Only
*(Diagnostic techniques **OR** Diagnostic procedures **OR** Clinical Lab Techniques **OR** Point-of-Care **AND** Tuberculosis OR tuberculosis)* ***Hits* = 12,415**	Tuberculosis **Hits = 45,652**
*(Diagnostic techniques **OR** Diagnostic procedures **OR** Clinical Lab Techniques **OR** Point-of-Care **AND** Malaria OR malaria)* ***Hits* = 3,508**	Malaria **Hits = 22,648**
(Diagnostic techniques OR Diagnostic procedures OR Clinical Lab Techniques OR Point-of-Care AND Anemia) ***Hits = 10,325***	Anemia **Hits = 45,132**
(diagnostic techniques OR diagnostic procedures OR clinical lab techniques OR point-of-care) AND [Column] **AND** *(Chlamydia OR Syphilis OR Gonorrhea OR Trichomonas vaginalis)* ***Hits = 3057***	Chlamydia OR Syphilis OR Gonorrhea OR Trichomonas vaginalis ***Hits = 11, 181***
((Diagnostic techniques OR Diagnostic procedures OR Clinical Lab Techniques OR Point-of-Care diagnostics) AND (Lymphatic filariasis OR Onchocerciasis OR Onchocerca volvulus OR schistosomiasis OR Schistosoma mansoni OR Schistosoma haematobium OR guinea worm OR HAT OR human African trypanosomiasis OR soil-transmitted helminths OR trachoma OR visceral leishmaniasis OR dengue OR chagas disease OR chikungunya OR zika)) ***Hits = 4866***	Lymphatic filariasis OR Onchocerciasis OR Onchocerca volvulus OR schistosomiasis OR Schistosoma mansoni OR Schistosoma haematobium OR guinea worm OR dracunculiasis OR HAT OR human African trypanosomiasis OR soil-transmitted helminths OR trachoma OR visceral leishmaniasis OR kala-azar OR dengue OR chagas disease OR Trypanosoma cruzi OR chikungunya OR zika **Hits = 34,947**
(Diagnostic techniques OR Diagnostic procedures OR Clinical Lab Techniques OR Point-of-Care AND Human Papilloma Virus OR HPV)	HPV or Human Papilloma Virus

***Hits* = 4,998**	**Hits = 17,901**
(Diagnostic techniques OR Diagnostic procedures OR Clinical Lab Techniques OR Point-of-Care HIV AND Human Immunodeficiency Virus) **Hits = 16,806**	HIV or Human Immunodeficiency Virus **Hits = 81,099**

DIAGNOSTIC VALUE CHAIN 1/5

COMPONENT	AREA OF RESEARCH EMPHASIS
Research & Development	**HIV**: Understanding the dynamics of HIV-1 reservoirs in infants and the application of next-generation sequencing for high-resolution reservoir profiling in HIV-1 as well as accelerating POC for VL monitoring
	Tuberculosis: The focus is on stool-based qPCR assays for TB detection as a non-invasive alternative to sputum testing, especially for populations with difficulty producing sputum
	Malaria: Growing focus on advanced molecular diagnostic techniques like multiplex real-time PCR, LAMP, and CRISPR-based methods to improve sensitivity and specificity for low parasitemia infections
	HPV: Emphasizes the need for advanced diagnostics and vaccines covering the circulating HR-HPV infections with increasing prevalence of high-risk HPV genotypes
	STIs: Advocacy for novel biomarker-based POC diagnostic being evaluated to detect inflammatory cytokines (IL-1α, IL-1β, and IP-10) linked to STIs and bacterial vaginosis (BV).
	NTDs: Development of novel diagnostic tools (multiplex PCR, peptide microarrays, isothermal recombinase polymerase amplification-lateral flow for leishmaniasis and serological profiling for schistosoma species).

Anemia: No data

DIAGNOSTIC VALUE CHAIN 2/5

COMPONENT	AREA OF RESEARCH EMPHASIS
Product Innovation*	**HIV:** Development of cost-effective and user-friendly multiplex RDTs for simultaneous HIV, HCV, and HBV in resource-limited settings. POC technology integration (for both VL and EID monitoring)
	TB: Novel TB-focused POC ultrasound approach is being evaluated for its potential as a non-invasive diagnostic, particularly where microbiological confirmation is challenging
	HPV: Introducing self-collection for HPV testing including urine based Hr-HPV assays and use of AI-based automated visual evaluation tool for cervical cancer screening.
	STIs: Xpert CT/NG (cepheid) and other molecular assays being positioned for routine STI diagnosis and antimicrobial resistance detection in chlamydia and gonorrhea
Regulatory Approval#	**HIV:** Streamlining regulatory processes for co-infection diagnostics (HIV, syphilis, and HBV) into routine HIV care - e.g chembio dual path platform (DPP) for syphilis, Pima™ for CD4 count, and COBAS® TaqMan HIV-1 test for VL testing
Market Introduction	**HIV:** Evaluating the acceptability and usability of POC and RDTs (such as cepheid Xpert HIV-1 VL assay, accu-Tell® combo rapid test cassette) among patients and HCWs
	STIs: Syphilis self-testing using RDTs demonstrated high user acceptance, with 74% uptake compared to 58% for facility-based testing

TB#, HPV#, Malaria*#, STIs#, NTDs*#, Anemia: *No data*

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DIAGNOSTIC VALUE CHAIN 3/5

COMPONENT	AREA OF RESEARCH EMPHASIS
Implementation	**HIV:** Expanding and supporting POC CD4 testing for Advanced HIV Disease and POC VL testing in ART programs to align with global HIV management goals and improve turnaround times
	TB: Implementing simultaneous TB and HIV testing using POC to improve early detection. Assessing the financial feasibility of implementing sputum-based and POC diagnostics
	Malaria: High prevalence of submicroscopic infections that are undetected by routine microscopy and RDT and low sensitivity of these methods in detecting low-density infections
	HPV: Integrating HPV DNA testing with other testing methods - VIA and colposcopy into a single-visit screen and treat strategy focusing on target groups (AGWY and PLHIV).
	STIs: Programs are moving away from syndromic management and integrating POC molecular tests (e.g., GeneXpert) into routine STI screening
	Anemia: Expanding POC and RDTs for anemia, particularly in pregnant women and malaria co-infected individuals
	NTDs: Deployment of diagnostic tests in endemic areas (mobile clinics for both HIV and schistosomiasis screening, use of circulating anodic antigen lateral flow assays and PCR for Schistosomiasis

DIAGNOSTIC VALUE CHAIN 4/5

COMPONENT	AREA OF RESEARCH EMPHASIS
Quality Assurance	**HIV:** Standardization and harmonization of internationally recognized QA processes. Establishing routine proficiency testing and external quality assurance
	TB: Accuracy assessment of WHO's TB symptom screening criteria and its integration with Xpert MTB/RIF testing
	Malaria: Emphasis on the role of sensitive molecular methods to address limitations in conventional diagnostics (microscopy and RDT)
	HPV: Comparison of testing / screening and treatment approaches demonstrated superiority of HPV DNA testing and thermal ablation respectively
	STIs: Strengthening quality assurance for syphilis, CT, and NG POC via better training, internal quality checks, and improved test reliability
	NTDs: Validation of diagnostic performance and accuracy (use of fluorescence intensity thresholds and diverse settings.

Anemia: No data

DIAGNOSTIC VALUE CHAIN 5/5

COMPONENT	AREA OF RESEARCH EMPHASIS
Policy/Access	**HIV:** Advocating for the widespread integration of POC HIV diagnostics including CD4 testing, VL testing, and EID into national health policies and programs
	TB: The use of saliva as a viable alternative sample type for GeneXpert MTB/RIF ultra, which could increase accessibility for patients who cannot produce sputum
	Malaria: Implications of submicroscopic infections on malaria treatment and control and need to integrate molecular diagnostic methods to detect subclinical malaria.
	HPV: Scaling up new screening and treatment strategies within existing health systems and increasing national HPV screening and vaccination coverage
	STIs: Integrating POC molecular tests into national STI programs to replace syndromic management; advocating for lower-cost diagnostics through concessional pricing, local production, and improved funding mechanisms
	NTDs: Adoption of new diagnostics in policy frameworks, - integrating PCR for Schistosoma DNA detection and self-sampling methods into routine diagnostics
	Anemia: Emphasis on the need to increase the number of healthcare facilities offering POC tests for anemia in remote and underserved areas.

DIAGNOSTIC VALUE CHAIN 1/6

COMPONENT	GAPS / LIMITATIONS
Research and Development	**HIV:** Insufficient knowledge on HIV-1 reservoirs in children
	TB: Low sensitivity of stool-based qPCR assays and limited applicability of microscopy and GeneXpert MTB/RIF (sputum-based diagnostics) in pediatric and immunocompromised groups
	Malaria: Limited diagnostic assays to detect and distinguish rare malaria species (P. *Ovalecurtisi* and for malaria diagnosis in duffy-negative individuals (a receptor for *Plasmodium vivax*)
	STIs: Further research is needed to confirm the specificity of cytokine-based STI biomarker testing, as inflammation markers may not be STI-specific.
	HPV: Limited research and availability of HPV DNA tests and HPV genotype testing and in particular the HR-HPV genotypes which have been shown to be in high circulation.
	NTDs: Cross-reactivity and poor diagnostic performance of peptides in microarray technologies for schistosomiasis and low sensitivity of microscopy for chronic cases of cutaneous leishmaniasis

Anemia: No data

DIAGNOSTIC VALUE CHAIN 2/6

COMPONENT	GAPS / LIMITATIONS
Product Innovation	**HIV:** Limited data on use of non-serum as opposed to serum samples
	TB: Despite improved sensitivity, gene-expression-based diagnostics like Xpert MTB/RIF Ultra stool testing and other MTB-HR assays are not widely accessible and have limited validation in clinical and real-world settings.
	Malaria: While PCR-based methods remain the gold standard, they are not feasible for use in many malaria-endemic settings due to high cost and infrastructure requirements.
	HPV: Limited availability of HPV self-sampling / self-collection tests and hybrid screening strategy combining HPV testing with reflex biomarker testing like correlation of HPV infection with MMP biomarkers of epithelial barrier integrity
	STIs: Limited adoption of molecular diagnostics in routine STI care due to cost and accessibility barriers and a need for integrated anti-microbial resistance detection within existing STI tests to guide treatment decisions.

Anemia, NTDs: No data

DIAGNOSTIC VALUE CHAIN 3/6

COMPONENT	GAPS / LIMITATIONS
Regulatory Approval*	**HIV:** Lack of alignment between international regulatory bodies and local approval processes leading to discrepancies in the speed and approval of essential diagnostic tools
Market Introduction#	**HIV:** Shortage of trained personnel and diagnostic tools and infrastructural limitations for POC testing (such as biosafety hoods for plasma separation)
	STIs: Current syphilis self-tests cannot distinguish active from past infections and require confirmatory testing, and scale up will depend on the availability of affordable dual RDTs and clear policies for integration into national STI programs.

TB*#, HPV*, Malaria*#, STIs*, NTDs*#, Anemia*#: *No data*

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DIAGNOSTIC VALUE CHAIN 4/6

COMPONENT	GAPS / LIMITATIONS
Implementation	**HIV:** The universal test and treat strategy has deprioritized CD4 testing which is critical for identifying advanced HIV disease, and the current standard-of-care VL testing and EID practices linked to reference laboratories lead to diagnostic delays.
	TB: Many TB cases remain undiagnosed, especially where POC tests are not widely implemented, and POC C-reactive protein testing for TB detection fails to meet WHO's minimum sensitivity criteria, limiting its widespread use.
	Malaria: Inadequacy of diagnostic tools with good performance in detecting and accurately identifying malaria species in clinical settings and including the need to strengthen routine malaria laboratory diagnostic methods
	STIs: Over -reliance on syndromic management which misses asymptomatic infections which leads to untreated STIs or antibiotic overuse and some POC tests are costly and have long turnaround times
	HPV: There is high loss to follow up rates for detecting of HPV and cervical cancer cases especially in cases where same day results are not available, and limited STI screening leading to untreated co-infections increases HPV persistence
	Anemia: Limited availability and uptake of innovative diagnostics, including POC like RDTs, limits diagnostic coverage and accessibility especially for pregnant women and individuals with co-morbid infections
	NTDs: Current widespread use of outdated methods like stool microscopy underestimates disease prevalence and lack of effective self-sampling as well as HCW-collected sampling methods for diagnosing female genital schistosomiasis

DIAGNOSTIC VALUE CHAIN 5/6

COMPONENT	GAPS / LIMITATIONS
Quality Assurance	**HIV:** Limited availability of strong QA frameworks, lack of routine proficiency testing participation or external QA programs and insufficient specialized training on the latest diagnostic technologies.
	TB: Despite the availability of Xpert MTB host response assay, 30% of TB cases remain undiagnosed, partly due to inconsistent diagnostic performance and limited implementation in clinical settings
	Malaria: Poor sample quality e.g poor quality of dried blood spot samples hindered DNA analysis while limited expertise in microscopy and high degradation rates of RDTs hinders accurate malaria diagnosis
	HPV: Limited sensitivity and specificity in current screening strategies like VIA which have high false positive rates and limited HPV diagnostic reliability for self- collected samples due to poor collection technique or mishandling and the fact that HPV DNA can degrade quickly, affecting test performance.
	STIs: Efforts still underway to strengthen QA for syphilis, chlamydia and gonorrhea POC testing through better training, internal quality checks, and improved test reliability.
	NTDs: Conventional diagnostics still have low sensitivity, particularly for chronic cases of cutaneous leishmaniasis.

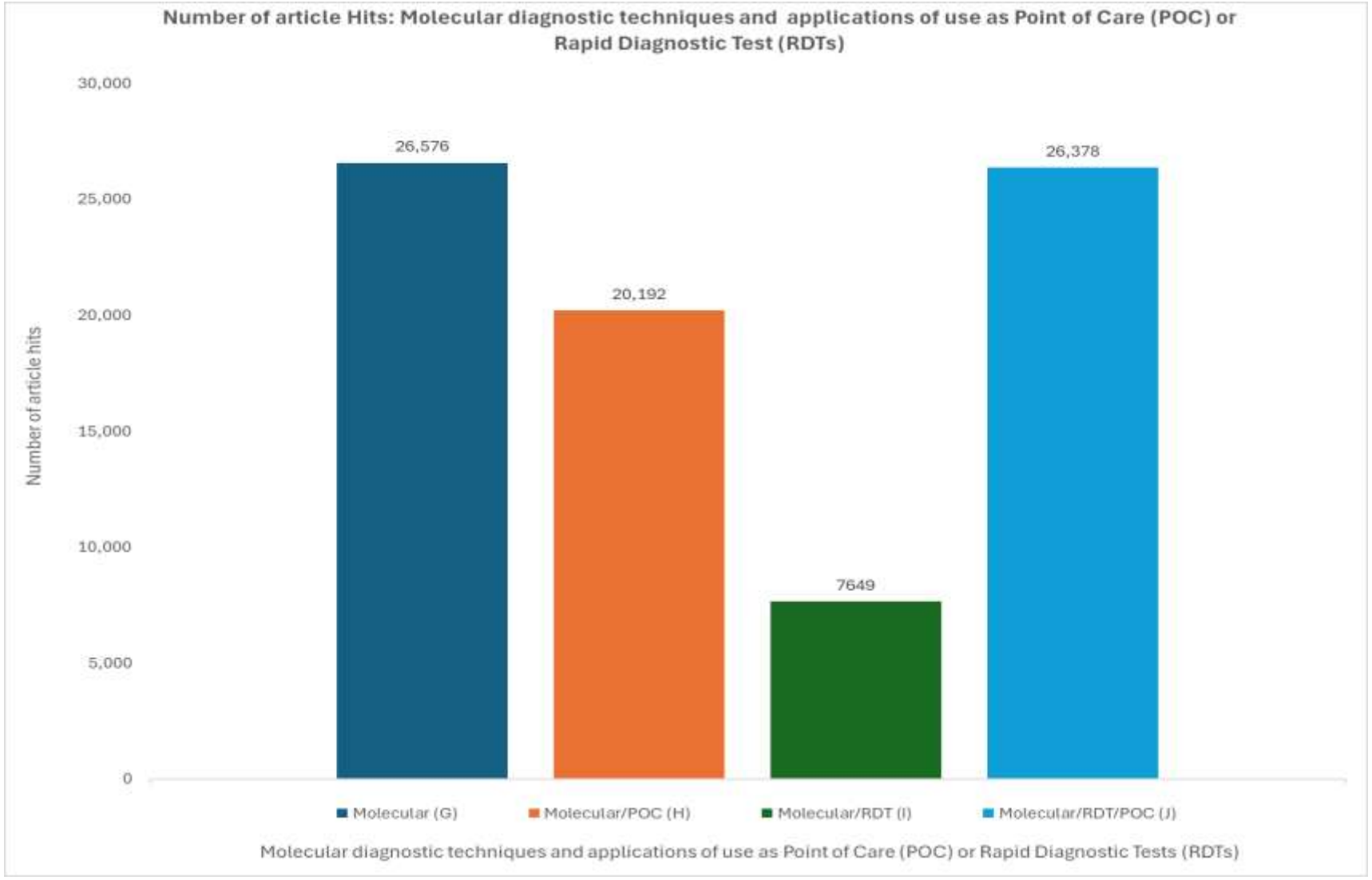
Anemia: No data

DIAGNOSTIC VALUE CHAIN 6/6

COMPONENT	GAPS / LIMITATIONS
Policy/Access	**HIV:** Delays in turnaround time for standard-of-care VL testing results (up to 143 days) compared to same-day results with POC tests are compounded by limited access to VL testing in rural areas (due to cost, infrastructural challenges)
	TB: While saliva-based GeneXpert MTB/RIF ultra testing has potential for improving TB detection, its feasibility is limited as current studies primarily focus on sputum smear-positive cases.
	Malaria: There is need to strengthen the availability and quality of routine malaria data to assess and estimate the current supply, demand and unmet needs of various RDTs.
	HPV: Lack of integration of routine HPV DNA testing into national cervical cancer screening programs and limited scale up of vaccination and screen-and-treat strategies using HPV self-sampling and thermal ablation to reduce loss to follow-up and provide same-day treatment.
	Anemia: Limited access to anemia screening and POC tests in routine maternal and child health services leads to missed diagnostic opportunities.
	STIs: Many health systems still lack policies supporting routine molecular STI testing, slowing adoption and scale-up.

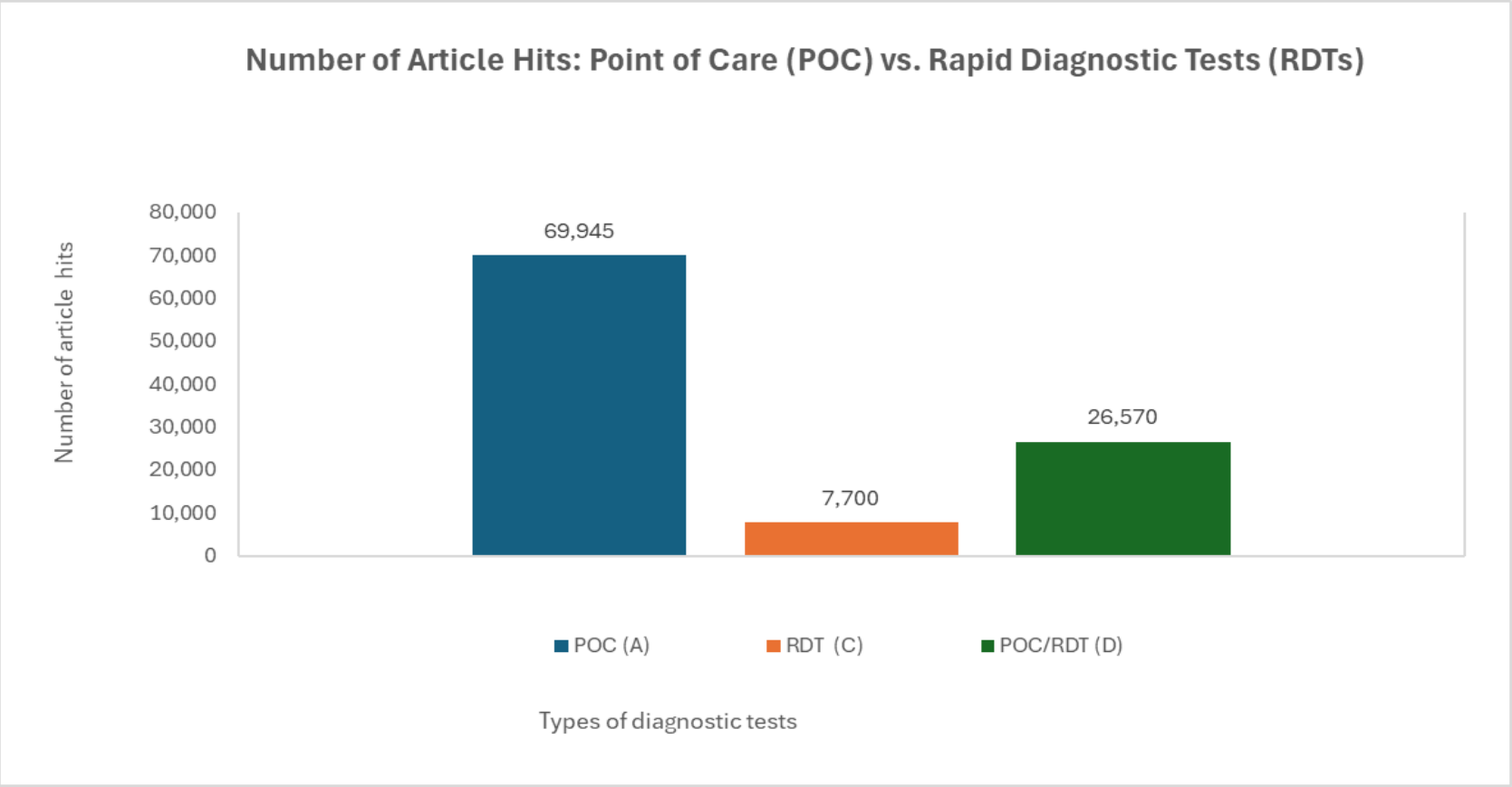
Anemia: No data

Article Frequencies for Molecular Diagnostics Sub-groups



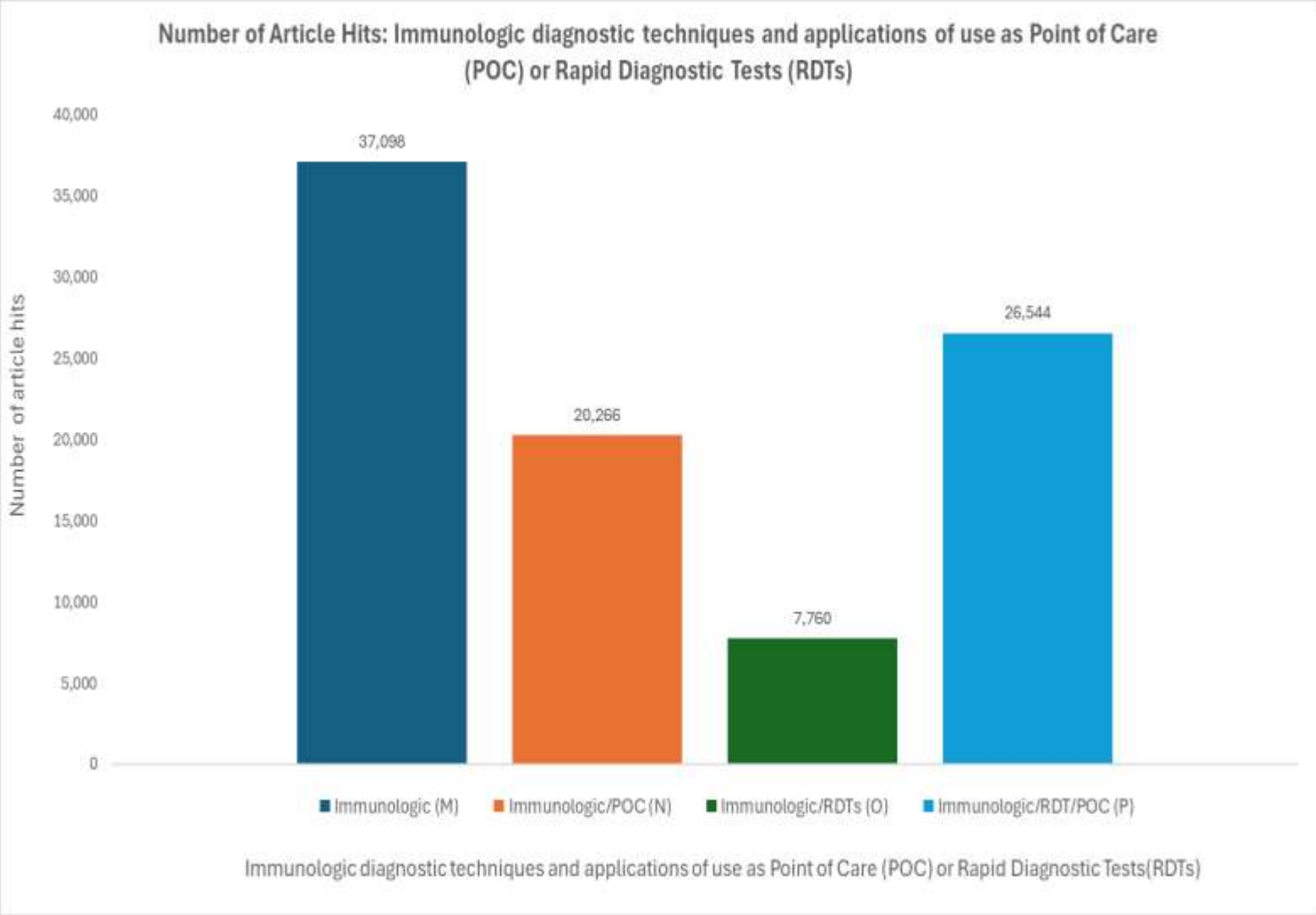
Articles focusing on molecular diagnostic methods used as rapid diagnostic tests (RDTs) had the fewest PubMed search hits, while those focused on either point-of-care (POC) or RDTs had the highest number of hits within the spectrum of molecular diagnostics.

Article Frequencies by Point-of-Care Diagnostic Sub-groups



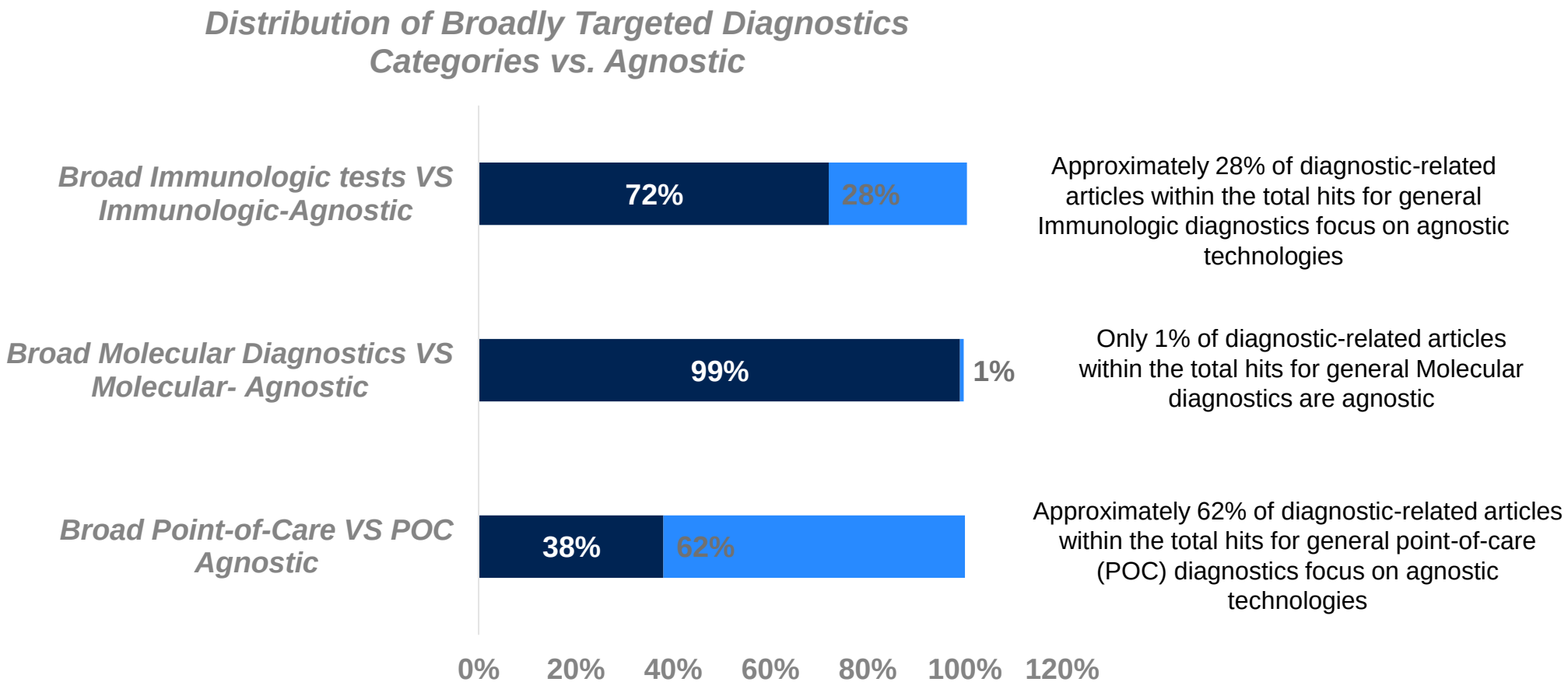
Articles broadly addressing various diagnostic methods and their applications as point-of-care (POC) tests yielded more PubMed search hits than those specifically focused on rapid diagnostic tests (RDTs) alone or on both RDTs and POC.

Article Frequencies for Immunologic Diagnostic Sub-groups



Similarly, articles focusing on immunologic diagnostic methods and their use as rapid diagnostic tests (RDTs) had fewer PubMed search hits, while those focused on either point-of-care (POC) tests or RDTs had the highest number of hits within the spectrum of immunologic diagnostics

Representation of Agnostic Diagnostics



Approximately 28% of diagnostic-related articles within the total hits for general Immunologic diagnostics focus on agnostic technologies

Only 1% of diagnostic-related articles within the total hits for general Molecular diagnostics are agnostic

Approximately 62% of diagnostic-related articles within the total hits for general point-of-care (POC) diagnostics focus on agnostic technologies

GLOSSARY OF ACRONYMS

Acronym	Full meaning
POC	Point-of-Care
WGS	Whole Genome Sequencing
VIA	Visual Inspection with Acetic Acid
TAT	Turn-around-time
RDTs	Rapid Diagnostic Tests
HPV	Human Papilloma Virus
TB	Tuberculosis
HCW	Healthcare worker
VL	Viral Load
UTT	Universal Test-and-Treat
PCR	Polymerase Chain Reaction
CT	*Chlamydia trachomatis*
NG	*Neisseria gonorrhea*
TV	*Trichomonas vaginalis*