

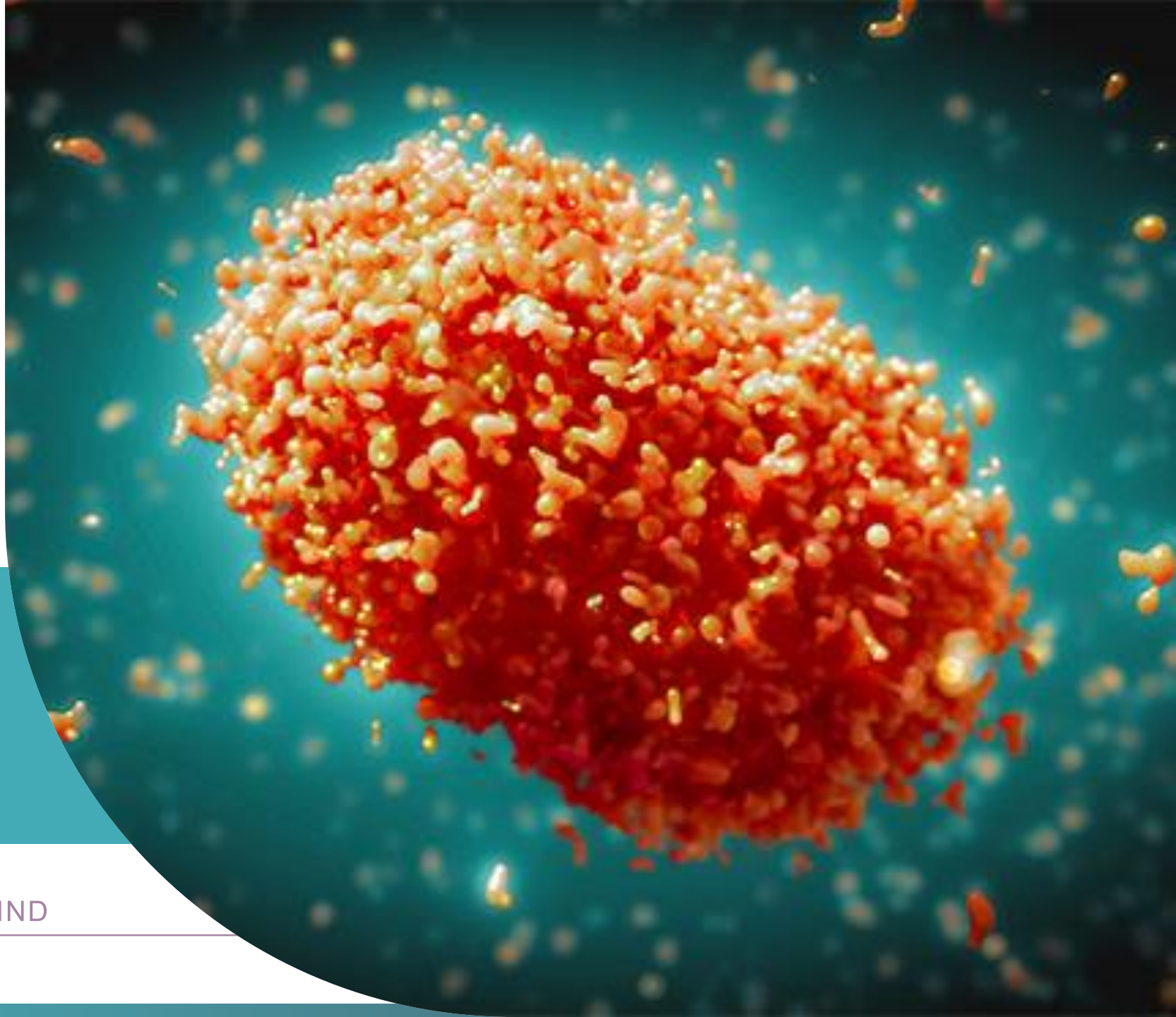


UPDATE OF MPOX DX LANDSCAPE

29 August 2024

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DIAGNOSTIC TOOLS FOR MPOX DETECTION

Molecular tests - Confirmation based on nucleic acid amplification tests (NAATs) using either PCR or sequencing

Assays should target conserved orthopoxvirus (OPXV) and MPXV genes

- Lab-based PCR kits
- POC molecular
- Sequencing – protocols

Antigens RDTs – Not recommended as primary Dx tool

Recommended specimens

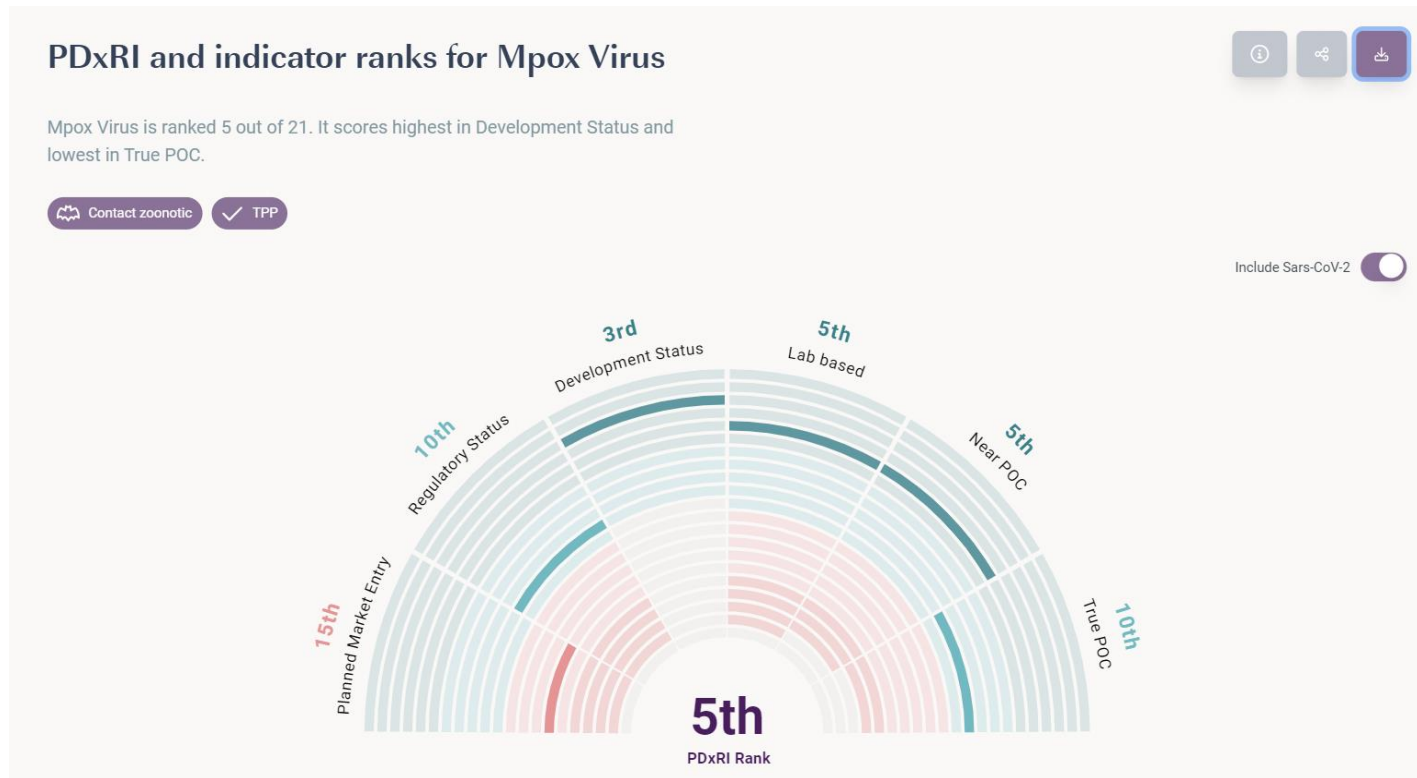
- Lesion swabs, oropharyngeal swab, anorectal swab

Target product profiles available:

- TPP1 – tests for diagnosis in health care settings and laboratories
- TPP2 – tests to aid diagnosis for decentralized use; detect OPXV antigens

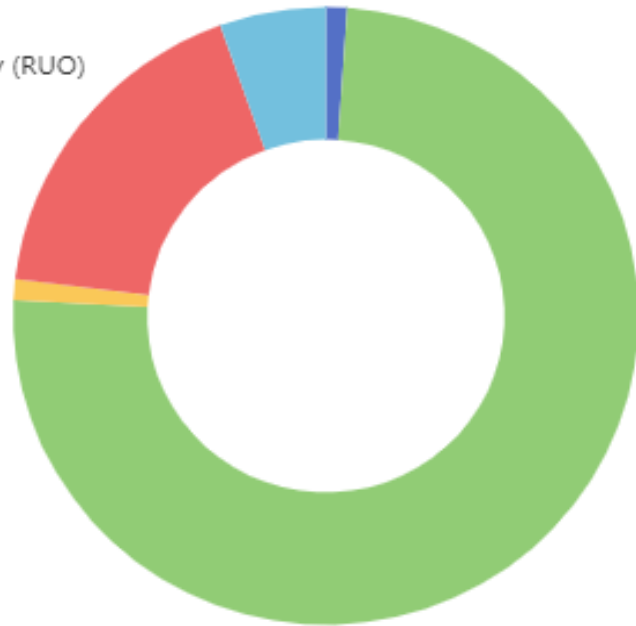
MPOX DIAGNOSTIC READINESS (2022-2023 DATA)

Pathogen name Select to explore	DX Index	Planned Market Entry	Regulatory Status	Development Status	Laboratory based	Near POC	True POC	TPP
Sars-CoV-2	100	2,616	979	138	949	254	1,201	✓
Dengue Virus	70,3	454	28	10	179	26	260	✗
Influenza A	56,6	216	119	7	64	38	112	✗
Influenza B	56,5	215	119	7	64	38	112	✗
Mpox Virus	47,1	44	9	9	93	25	14	✓



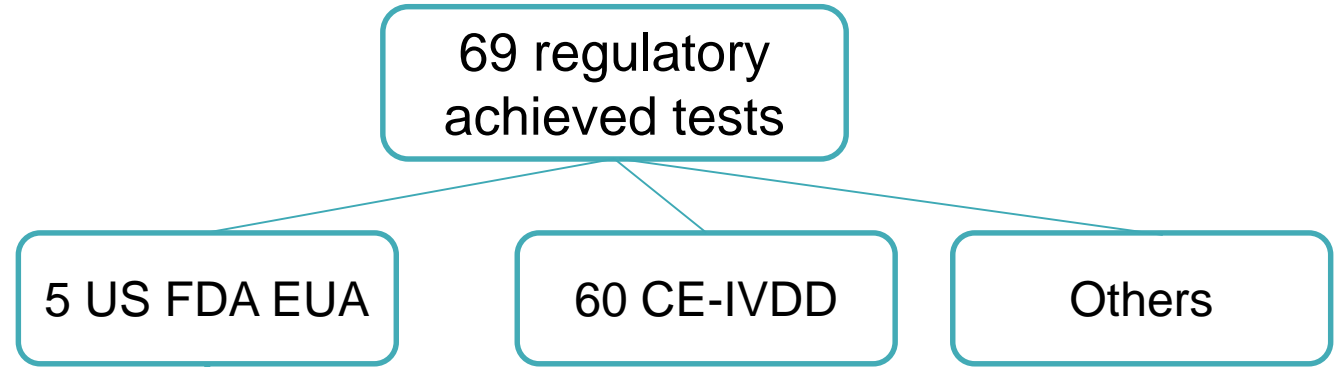
MPOX DIAGNOSTIC LANDSCAPE

91 LAB-BASED MOLECULAR TESTS (2022-2023 DATA)



- No sequencing kits available (only protocols)

Source: <https://www.finddx.org/test-directory/>



	Clade(s) detected	Sensitivity (IFU)	Specificity (IFU)
Alinity m MPXV (Abbott)	MPX Clade I / MPX Clade II	100%	100%
QuantiVirus MPXV Test Kit (Dicarta)	MPX Clade I / MPX Clade II	100%	100%
Monkeypox Virus Qualitative Real-Time PCR (Quest Diagnostics)	MPX Clade II	n/a	n/a
cobas MPXV (Roche)	MPX Clade I / MPX Clade II	100%	100%
Non-variola Orthopoxvirus Real-time PCR Primer and Probe Set (US CDC)	OPX	100%	100%

AFRICA CDC: RECOMMENDED TESTS FOR USE

Manufacturer, country	Name of test	Sample type	Clades	Limit of detection	Regulatory Status	Comments
Abbott, United States of America	ALINITY M MPXV	Lesion swab specimens	Detects clade I and II. Does not distinguish between clades.	200 copies/ml	EUA by US FDA	Limited opportunity for cross-reactivity in silico analysis
Bioperfectus Biotech, China	Bioperfectus MonkeyPox Virus Genotyping RT-PCR kit	Tonsillar swab, Nasopharyngeal swab, lesion exudate, lesion crust, serum, whole blood	Detects and distinguishes between clades I and II.	250 copies/ml	CE-IVDD	
Certest Biotech SL, Spain	Viasure Monkeypox Virus Real Time PCR Detection Kit	skin lesion swab: vesicular fluid, pustular fluid, papules	Detects clades I and II. Does not distinguish between clades.	8 copies/ml	CE-IVDD. EUA by FDA revoked.	
Cue Health, United States	Cue Mpox (Monkeypox) Molecular Test	skin lesion swab: vesicular fluid, pustular fluid, papules	Detects clades I and II. Does not distinguish between clades.	100 copies/ml	EUA by US FDA	'cross reactivity' tested in silico only: No cross reaction with non-orthopox pathogens with similar signs and symptoms. Cross-reaction with cowpox (72-92%)
Daan Gene, China	Detection Kit for Monkeypox Virus DNA (PCR-Fluorescence Probing)	Rashes, scabs, blister fluid, pustular fluid, or whole blood specimens	Detects clades I and II. Does not distinguish between clades.	200 copies/ml	CE, China NMPA	
Diacarta Inc, United States	QuantiVirus MPXV Test Kit	Swabs of acute pustular or vesicular rash	Detects clades I and II. Does not distinguish between clades.	25-80 copies/ml	CE-IVDD and EUA by US FDA	Reagents for extraction not included in the kit.
KH Medical Co.Ltd, South Korea	RADI FAST Mpox detection kit	Skin lesion, crust and swab	Detects clade I, IIb and II.	1000 copies/ml	CE-IVDD	Independently evaluated in DRC. Has local regulatory approval in DRC.
Roche, United States of America	Cobas MPVX	Lesion swab samples	Detect clade I and II. Does not distinguish between clades.	36.5 copies/ml	EUA by US FDA	Limited opportunity for cross-reactivity in silico analysis.
Sansure Biotech, China	Monkey Pox Nucleic Acid Diagnostic Kit	Serum, whole blood, vesicles and pustules, nasopharyngeal swab, oropharyngeal swab	Detects clades I and II. Does not distinguish Clades	200 copies/ml	CE-IVDD	

Table: List of Recommended Real-Time(RT) PCR Tests for Mpox

Collaboration recently initiated between FIND and Africa CDC for the landscape, assessment and recommend **near/true POC tests and RDTs**

15 MOLECULAR POC (2022 & 2024 DATA)

■ True Point of Care
■ near Point of Care



Source: <https://www.finddx.org/test-directory/>

11
near
POC

4 true
POC

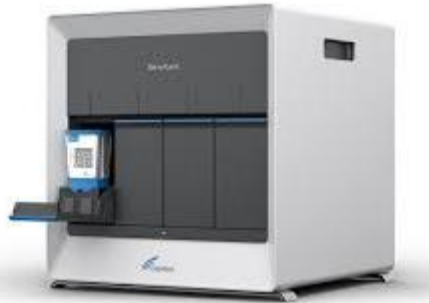
	Stage of development	Clade(s) detected	Sensitivity (IFU)	Specificity (IFU)
Xpert Mpox(Cepheid)	Regulatory Achieved (US FDA EUA)	OPXV*, MPX clade II	100%	96.6%
u-card dx monkeypox virus test(Wondfo Biotech)	Regulatory Achieved (CE-IVDD)	n/a	n/a	n/a
EasyNAT Monkeypox Virus(Ustar)	Regulatory Achieved (CE-IVDD)	n/a	n/a	n/a
FlashDetect LyocartE Monkeypox Assay(Coyote)	Regulatory Achieved (CE-IVDD)	n/a	n/a	n/a
QIAstat-Dx Viral Vesicular Panel(QIAGEN)	Research Use Only (RUO)	OPXV, MPXV clade I**, II, other	n/a	n/a
MPX/OPX Assay on GeneXpert (BioGX)	Late-Stage Development (fully functional prototype)	n/a	98.8%	100%
STANDARD M10 MPX/OPX(SD Biosensor)	Regulatory Status Unknown	OPXV*, MPX clade II	n/a	n/a
GenPad (K.K. Mirai Genomics)	Research Use Only (RUO)	n/a	n/a	n/a
Truenat MPX (Molbio Diagnostics)	Early-stage prototype	MPX J2L gene	n/a	n/a
Sanity 2.0, Monkeypox Virus Test Kit (ProDiag)	Regulatory Achieved (CE-IVDD)	MPX D14L gene; MPX F3L gene;	n/a	n/a
Skin Tropic Virus Panel Drgaonfly (ProtonDx)	Research Use Only (RUO)	n/a	n/a	n/a
DiaxxoPCR-MPXV (Diaxxo AG)	Research Use Only (RUO)	MPX F3L gene	n/a	n/a
Cue Mpox molecular test (Cue Health)	Regulatory Achieved (US FDA EUA)	MPXV clades I, II	100%	100%
Pluslife Monkeypox Virus Card(Pluslife)	Regulatory Achieved (CE-IVDD)	n/a	n/a	n/a
Skin Tropic Virus Panel – Dragonfly (ProtonDx)	Research Use Only (RUO)	OPXV, MPXV clades I, II	n/a	n/a
ZiP-MPx-P2 (ZiP Diagnostics)	Research Use Only (RUO)	MPX J2L gene	n/a	n/a

MPOX DIAGNOSTIC LANDSCAPE
POC PLATFORMS FOR MPOX/OPXV

SD BIOSENSOR Standard M10



Cepheid Xpert



Cue Health



Qiagen - QIAstat-Dx



Near POC

True POC

64 IMMUNOASSAYS (2022 & 2024 DATA)

- IA Reagent Kit
- Rapid diagnostic test (strip or cassette)



2 IA reagent kits: RUO targeting antibody

64 RDTs

	Antigen	Antibody	Antigen + Antibody
Regulatory achieved (CE-IVD)	32	6	
RUO	5	2	1
In development	7	1	1
Regulatory status unknown	5	4	

Source: <https://www.finddx.org/test-directory/>

INDEPENDENT PERFORMANCE EVALUATIONS OF MPOX DIAGNOSTICS**Lab-based PCR:**

- MPX clade 2: 95-100% sensitivity, 100% specificity (Fattouh et al. 2024, de Pace et al. 2024, Mancon et al. 2024)
- MPX clade 1: No clinical performance results

Point-of-care molecular tests:

- MPX clade 2: 89-100% sensitivity, 100% specificity (Mancon et al. 2024, Damhorst et al. 2024, FIND evaluation)
- MPX clade 1: 63-68% sensitivity, 97-100% specificity (FIND evaluation; results to be published)

Rapid diagnostic tests:

- Limited data for both clades, although test sensitivity seems to be low (FIND evaluation; results to be published)

GAPS AND NEEDS FOR MPOX DIAGNOSTICS

Gaps

- Dx Landscape update ongoing
- Few tests, especially point-of-care tests, with independent evaluation data
- Challenging supply of PCR reagents should there be a surge in cases
- Limited testing done in some countries/areas

Needs

- Updated mpox landscape to identify:
 - Point of care tests (molecular and antigen-based)
 - Tests that detect all circulating MPXV clades
- Additional independent performance evaluations
- Improve availability and accessibility to diagnostics through:
 - Emergency use listing for diagnostics
 - Technology transfer of PCR reagents or kits to manufacturers/distributors in region
- Dedicated resources for test procurement, roll-out, and training

NEXT STEPS

FIND'S MPOX DIAGNOSTICS RESPONSE PLAN

Accelerate product Research & Development

- 1 Updating the diagnostic landscape
- 2 Identifying tests for performance evaluations
- 3 Product development (e.g. optimization, new development)

Streamline evidence generation and regulatory approval

- 4 Conduct analytical and clinical evaluations of POC tests
- 5 Support sample banking and characterization
- 6 Support regulatory harmonization

Strengthen surveillance and community-based testing infrastructure

- 7 Generate evidence on uses of POC tests for mpox
- 8 Support laboratory capacity efforts (e.g. testing, sequencing)
- 9 Monitor diagnostic response and benchmark to 100 Days Mission

Establish warm base for manufacturing and reliable pull mechanism

- 10 Support regional manufacturing of priority diagnostics



Internal taskforce to coordinate activities (e.g. advocacy, communications, and partner engagement)

WHERE ARE WE WITH MPOX?
SUMMARY



We are better prepared this time around **BUT** key gaps remain in:

- **Diagnostic data for MPXV clade 1**
- **Availability of point-of-care tests**
- **Access to well-performing diagnostics in Africa**