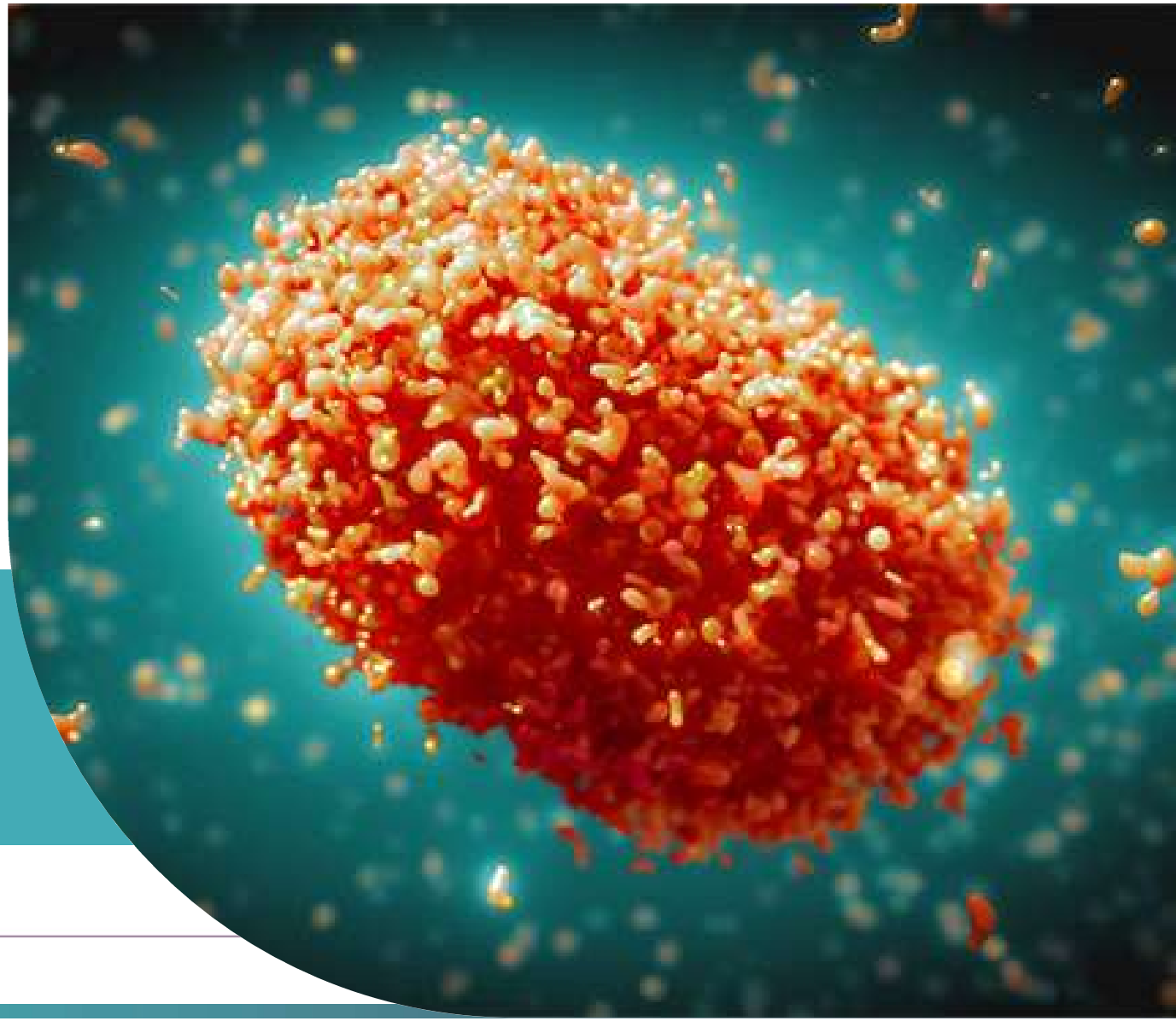
FIND



STATUS OF MPOX DIAGNOSTICS

29 August 2024

Daniel Bausch

100 Days Mission for diagnostics

Safe, effective, and affordable diagnostic tests must be available within 100 days of the identification of a pandemic threat

Where are we with mpox?

DIAGNOSING MPOX

- Confirmation based on nucleic acid amplification tests (NAATs) using either PCR or sequencing
  - Assays should target conserved orthopoxvirus (OPXV) and MPXV genes

Recommended specimens:

- Lesion swab, oropharyngeal swab, anorectal swab

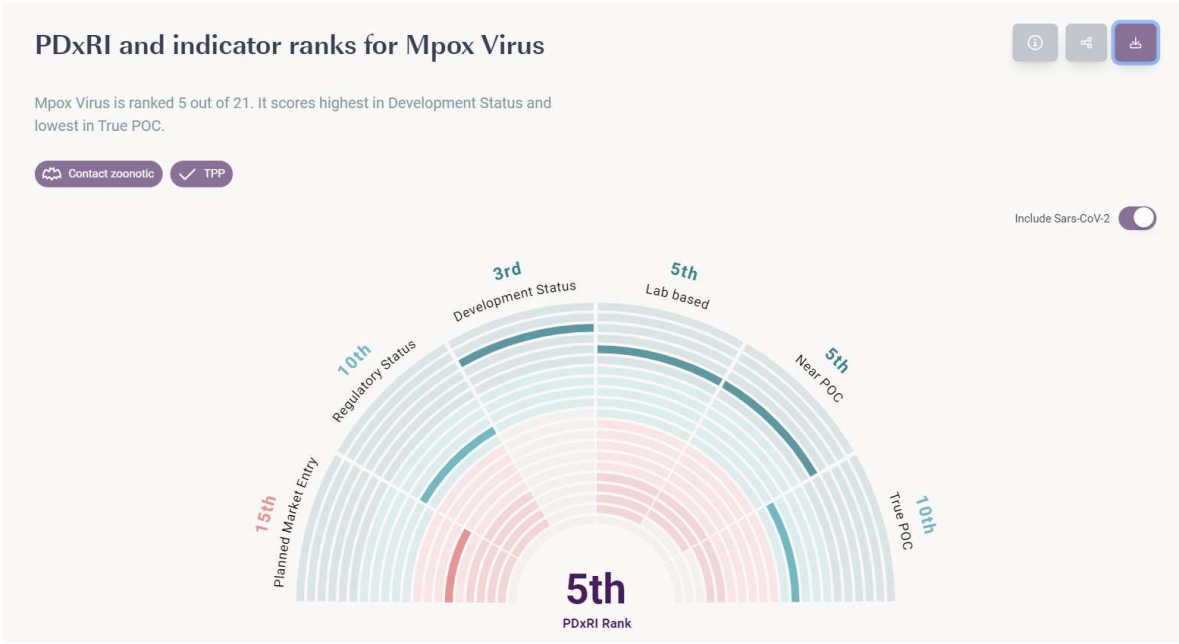
Target product profiles available:

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

https://www.finddx.org/tools-and-resources/dxconnect/test-directories/outbreaks-test-directory/

MPOX DIAGNOSTIC READINESS

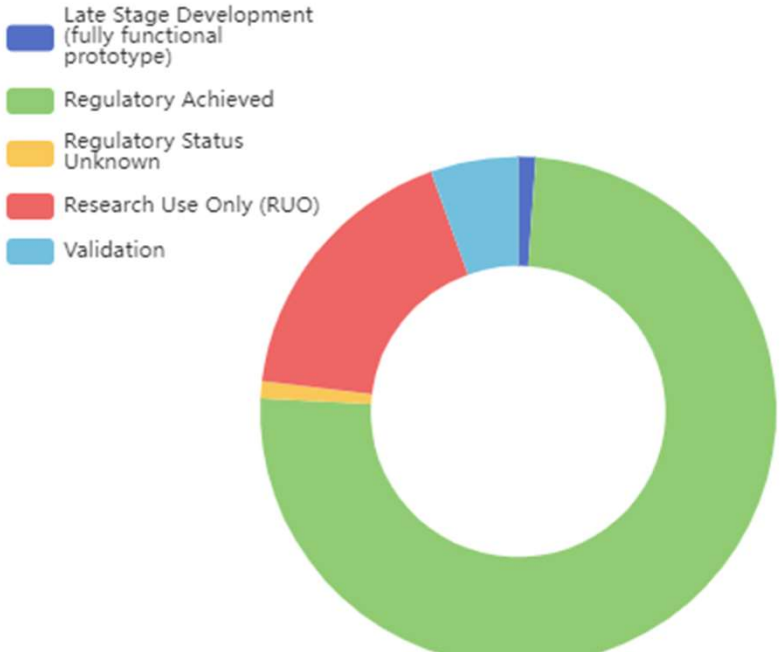
Pathogen name Select to explore	DX Index	Planned Market Entry	Regulatory Status	Development Status	Laboratory based	Near POC	True POC	TPP
Sars-CoV-2	100	2.616	979	138	949	254	1.201	✓
Dengue Virus	70,3	454	28	10	179	26	260	✗
Influenza A	56,6	216	119	7	64	38	112	✗
Influenza B	56,5	215	119	7	64	38	112	✗
Mpox Virus	47,1	44	9	9	93	25	14	✓



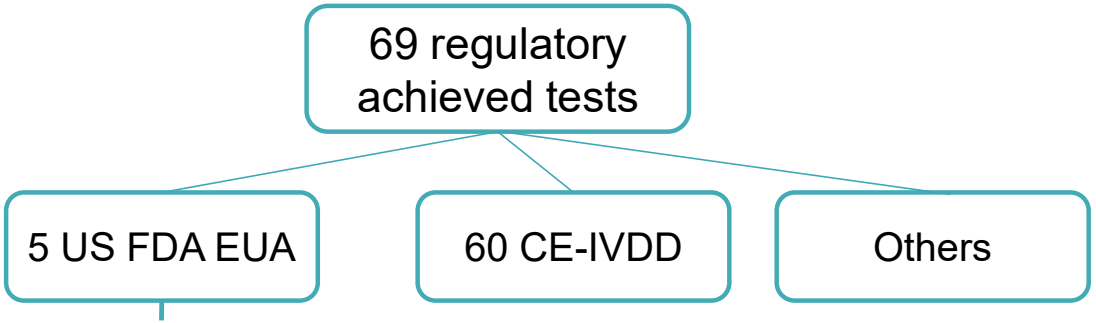
https://www.finddx.org/data-and-impact/dashboards/diagnostic-readiness-index/#/

MPOX DIAGNOSTIC LANDSCAPE

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



- No sequencing kits available (only protocols)

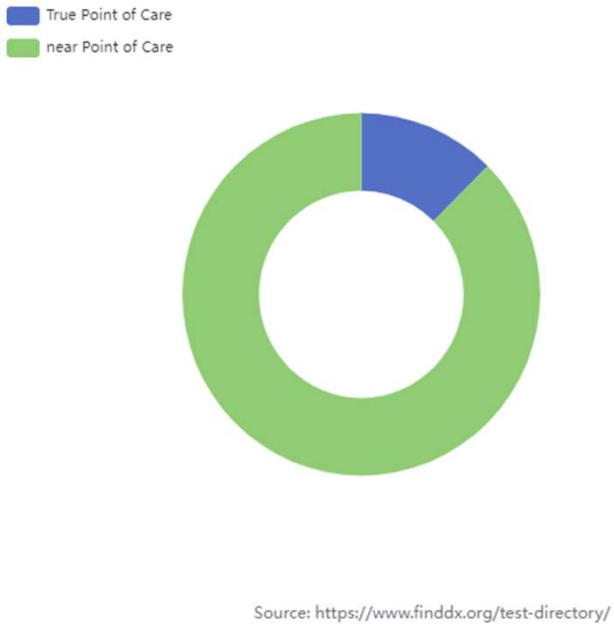


	Clade(s) detected	Sensitivity (IFU)	Specificity (IFU)
Alinity m MPXV (Abbott)	MPX Clade I / MPX Clade II	100%	100%
QuantiVirus MPXV Test Kit (Dicarta)	MPX Clade I / MPX Clade II	100%	100%
Monkeypox Virus Qualitative Real-Time PCR (Quest Diagnostics)	MPX Clade II	n/a	n/a
cobas MPXV (Roche)	MPX Clade I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

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

MPOX DIAGNOSTIC LANDSCAPE

10 MOLECULAR POC (2022-2023 DATA)



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

		Stage of development	Clade(s) detected	Sensitivity (IFU)	Specificity (IFU)
7 near POC	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
3 true POC	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

*OPXV positive and MPXV clade II negative can be considered MPXV clade I.
** Pan OPVX is being added by Qiagen to cover clade Ib

MPOX DIAGNOSTIC LANDSCAPE

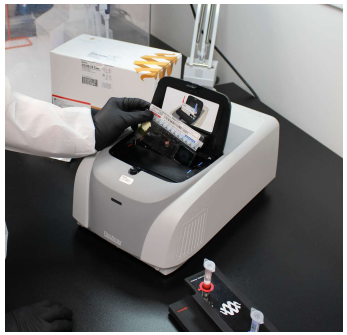
FULLY AUTOMATED PLATFORMS FOR MPOX/OPXV

QIAGEN NeuMoDx 288 workstation

SD BIOSENSOR Standard M10

Cepheid Xpert

BIOFIRE FilmArray



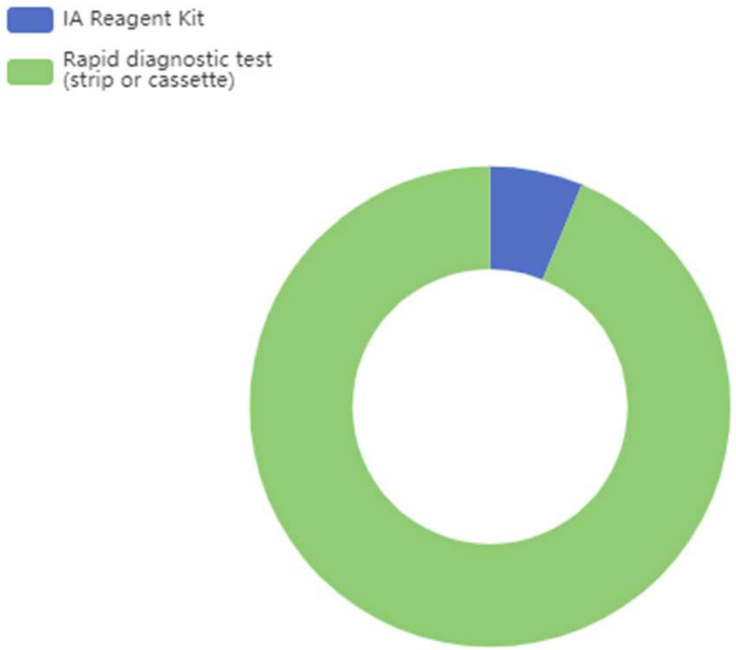
AFRICA CDC: RECOMMENDED TESTS FOR USE

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 Biotec 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 Stated 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, orорharyngeal swab	Detects clades I and II. Does not distinquish Clades	200 copies/ml	CE-IVDD	

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

MPOX DIAGNOSTIC LANDSCAPE

32 IMMUNOASSAYS (2022-2023 DATA)



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

2 IA reagent kits (ELISA): RUO targeting antibody

30 RDTs:

	Antigen	Antibody	Antigen + Antibody
Regulatory achieved (CE-IVD)	14	6	
RUO	2	2	
In development		1	1
Regulatory status unknown	2	2	

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)

NEXT STEPS

GAPS AND NEEDS FOR MPOX DIAGNOSTICS

Gaps

- Landscape report not recently updated
- 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	Streamline evidence generation and regulatory approval	Strengthen surveillance and community-based testing infrastructure	Establish warm base for manufacturing and reliable pull mechanism
1 Updating the diagnostic landscape	4 Conduct analytical and clinical evaluations of POC tests	7 Generate evidence on uses of POC tests for mpox	10 Support regional manufacturing of priority diagnostics
2 Identifying tests for performance evaluations	5 Support sample banking and characterization	8 Support laboratory capacity efforts (e.g. testing, sequencing)	
3 Product development (e.g. optimization, new development)	6 Support regulatory harmonization	9 Monitor diagnostic response and benchmark to 100 Days Mission	

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

NEXT STEPS

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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**