FIND Evaluation of SD Biosensor STANDARD M10 MPX/OPX

Version 1.1, Date: 2024-09-05

Copyright and use of the report

Evaluation Process – private sector engagement

FIND is a not-for-profit foundation, whose mission is to find diagnostic solutions to overcome diseases of poverty in lower- and middle-income countries. It works closely with the private and public sectors and receives funding from donors and some of its industry partners. It has internal firewalls, policies, and processes to protect it against any undue influence in its work or the publication of its findings.

More information on our policy and guidelines for working with private sector partners can be found here: https://www.finddx.org/policies/

FIND conducted an independent evaluation of Mpox point-of-care tests following an Expression of Interest (EOI) process that was available on FIND's webpage.

Document History

Document Version	Date	Comment
1.0	2024-09-04	Initial version
1.1	2024-09-05	Updated product code. Updated evaluation details.

1.0 **Product info:**

Manufacturer name	SD Biosensor
Test name	STANDARD M10 MPX/OPX
Product code(s)	11MPX10A
Pack size(s)	10 cartridges per kit
Kit content	Cartridge Quick reference instructions
Equipment and consumables required, but not provided	SD Biosensor M10 platform
Product storage (temperature range)	2-28℃ (36-82℉)
Shelf-life (months)	12 months at 2-28℃
Manufacturing site (country)	Republic of Korea

2.0 **Study Details**

Study design	Prospective and retrospective diagnostic evaluation study across multiple, independent sites to determine the accuracy of Mpox point-of-care tests, using consecutive enrolment. Presence
Index assays	Novel point-of-care tests (i.e. point-of-care molecular and rapid diagnostic tests) that detect monkeypox virus (MPXV) sequences or antigens.
Reference method	Results of the index tests are compared to RT-PCR result, which is the recommended test for mpox diagnosis.
Limit of detection	Analytical sensitivity, i.e., the Limit of detection (LOD), was performed at the University Hospital of Geneva, where standardized serial dilutions of cultured viral isolates were prepared. The kit's proprietary swabs were soaked in the viral dilution series. Dilutions were tested in triplicate, and LOD was defined as the last dilution where all repeats were interpreted as positive.
Clinical performance	Sensitivity was calculated as the proportion of true positive results detected by the INDEX TEST among all positives by the reference method and reported as a percentage. Specificity was calculated as the proportion of true negative specimens identified as negative by the INDEX TEST among all negatives by the reference method and reported as a percentage. The 95% confidence intervals were calculated to assess the level of uncertainty introduced by sample size using Wilson’s score method.

3.0 **Evaluation details**

Country of collaborator	**Democratic Republic of the Congo (DRC)**	**United Kingdom (UK)**	**Switzerland (CH)**
Location of clinical site(s) (city, town)	INRB - Goma	Liverpool School of Tropical Medicine	University Hospital of Geneva
Study Period	2023-2024	2023-2024	2023-2024

Study design	Prospective using lesion and oropharyngeal samples in VTM	Retrospective using frozen lesion and respiratory samples	Analytical study using viral cultures
Study cohort inclusion/exclusion	Inclusion: Individuals ≥ 2 years of age suspected to have mpox (and/or specimens collected from them), as per national or WHO case definitions Exclusion: individual with no visible rash or lesions	Inclusion: Individuals ≥ 2 years of age suspected to have mpox (and/or specimens collected from them), as per national or WHO case definitions. Exclusion: individual with no visible rash or lesions	Not applicable
MPXV clade present	Clade 1 (presumed)	Clade 2b (presumed)	Clade 1, Clade 2a, Clade 2b (virus culture)
Sample type, index test	Lesion swab in viral transport media (VTM), Oropharyngeal swab in VTM	Lesion swab in VTM, Oropharyngeal swab in VTM	Virus cultures in PBS
Reference PCR method	Monkeypox virus Nucleic Acid Diagnostic Kit (Sansure Biotech)	Monkeypox virus Nucleic Acid Diagnostic Kit (Sansure Biotech)	Lab-developed protocol[1]
Sample type, PCR test	Lesion swab in VTM, Oropharyngeal swab in VTM	Lesion swab in VTM, Oropharyngeal swab in VTM	Virus cultures in PBS

4.0 **Results**

4.1 Study cohort

Table 1. Study Cohort – **Lesion Sample** Population.

	Overall	**DRC**	**UK**
Total N (Valid PCR Results)	79	68 (86.1%)	11 (13.9%)
Age [mean (min-max), N]	19 (2-46), 79	17 (2-46), 68	34 (24-45), 11
Gender [%F, (n/N)]	43% (34/79)	50% (34/68)	0% (0/11)
Days from symptom onset [median (Q1-Q3); N]	Not applicable	4 (2.75-7), 68	Information not available

[1] https://www.hug.ch/sites/interhug/files/structures/laboratoire_de_virologie/documents/Monkeypox/protocol_for_the_detection_of_monkeypox_by_rt.pdf

Days 0-3 (n, %)	Not applicable	32 (47.1%)	Information not available
Days 4-7 (n, %)	Not applicable	22 (32.4%)	Information not available
Days 8+ (n, %)	Not applicable	14 (20.6%)	Information not available
Positivity [% (n/N)]	36.7% (29/79)	27.9% (19/68)	90.9% (10/11)
PCR Ct [median (Q1-Q3); N]	26.6 (22.7-34.2), 29	26.7 (22.6-34.4), 19	26 (24.3-30.3), 10
Ct ≤ 25, n (%)	25, (86.2%)	16 (84.2%)	9 (90%)
Ct ≤ 30, n (%)	17, (58.6%)	11 (57.9%)	6 (60%)
Ct ≤ 35, n (%)	10, (34.5%)	7 (36.8%)	3 (30%)

Table 2. Study Cohort – **OP Sample** Population

	Overall	**DRC**	**UK**
Total N (Valid PCR Results)	82	68 (82.9%)	14 (17.1%)
Age [mean (min-max), N]	20 (2-58), 82	17 (2-46), 68	36 (24-58), 14
Gender [%F, (n/N)]	41.5% (34/82)	50% (34/68)	0% (0/14)
Days from symptom onset [median (Q1-Q3); N]	Not applicable	4 (2.75-7), 68	Information not available
Days 0-3 (n, %)	Not applicable	32 (47.1%)	Information not available
Days 4-7 (n, %)	Not applicable	22 (32.4%)	Information not available
Days 8+ (n, %)	Not applicable	14 (20.6%)	Information not available
Positivity [% (n/N)]	29.3% (24/82)	20.6% (14/68)	71.4% (10/14)
PCR Ct [median (Q1-Q3); N]	29.4 (25.9-35.8), 24	34.5 (27.7-36.8), 14	28.9 (25-30.2), 10
Ct ≤ 25, n (%)	16 (66.7%)	8 (57.1%)	8 (80%)
Ct ≤ 30, n (%)	13 (54.2%)	6 (42.9%)	7 (70%)
Ct ≤ 35, n (%)	5 (20.8%)	1 (7.1%)	4 (40%)

Table 3. Study Cohort – **population used for OP index test / Lesion reference test performance evaluation**.

Note. Only participants who had a lesion and oropharyngeal sample collected on the same day were eligible to be included in this analysis. This includes 68 participants from INRB and 5 participants from LSTM.

	Overall	DRC	UK
Total N (Valid PCR Results)	73	68 (93.2%)	5 (6.8%)
Age [mean (min-max), N]	18 (2-46), 73	17 (2-46), 68	32 (24-45), 5
Gender [%F, (n/N)]	46.6% (34/73)	50% (34/68)	0% (0/5)
Days from symptom onset [median (Q1-Q3); N]	Not applicable	4 (2.75-7), 68	Information not available
Days 0-3 (n, %)	Not applicable	32 (47.1%)	Information not available
Days 4-7 (n, %)	Not applicable	22 (32.4%)	Information not available
Days 8+ (n, %)	Not applicable	14 (20.6%)	Information not available
Positivity [% (n/N)]	32.9% (24/73)	27.9% (19/68)	100% (5/5)
PCR Ct [median (Q1-Q3); N]	27.3 (22.9-34.4), 24	26.7 (22.6-34.4), 19	30.2 (25.3-33.6), 5
Ct ≤ 25, n (%)	20 (83.3%)	16 (84.2%)	4 (80%)
Ct ≤ 30, n (%)	13 (54.2%)	11 (57.9%)	2 (40%)
Ct ≤ 35, n (%)	8 (33.3%)	7 (36.8%)	1 (20%)

4.2 Estimation of clinical performance

Table 4. Performance evaluation on **lesion sample** (Reference sample is lesion).

	Overall	DRC	UK
Clinical Sensitivity [95% CI], N[1]	**75.86 [57.89-87.78], 29**	**63.16 [41.04-80.85], 19**	**100 [72.25-100.0], 10**
Sensitivity, CT ≤ 35, N	80 [60.87-91.14], 25	68.75 [44.4-85.84], 16	100 [70.09-100.0], 9
Sensitivity, CT ≤ 30, N	100 [81.57-100.0], 17	100 [74.12-100.0], 11	100 [60.97-100.0], 6
Sensitivity, CT ≤ 25, N	100 [72.25-100.0], 10	100 [64.57-100.0], 7	100 [43.85-100.0], 3
Sensitivity, Symptom Onset 0-3 days [95%CI], N	Not applicable	50 [18.76-81.24], 6	Information not available

Sensitivity, Symptom Onset 4-7 days [95%CI], N	Not applicable	83.33 [43.65-96.99], 6	Information not available
Sensitivity, Symptom Onset > 7 days [95%CI], N	Not applicable	57.14 [25.05-84.18], 7	Information not available
Clinical Specificity [95% CI], N[2]	**87.76 [75.76-94.27], 49**	**89.58 [77.83-95.47], 48**	**0 [0.0-79.35], 1**
Invalid rate (%, n/N)	1.27% (1/79)	1.47% (1/68)	0% (0/11)

1. For sensitivity columns, N represents the total number of positives included in the performance evaluation i.e., TP + FN.
2. For specificity columns, N represents the total number of negatives included in the performance evaluation i.e., TN + FP.

Table 5. Performance evaluation on **oropharyngeal samples** (Reference sample is lesion).

Note. Only participants who had a lesion and oropharyngeal sample collected on the same day were eligible to be included in this analysis. This includes 68 participants from INRB and 5 participants from LSTM.

	Overall	**DRC**	**UK**
Clinical Sensitivity [95% CI], N[1]	**68.18 [47.32-83.64], 22**	**66.67 [43.75-83.72], 18**	**75 [30.06-95.44], 4**
Sensitivity, CT ≤ 35, N	73.68 [51.21-88.19], 19	73.33 [48.05-89.1], 15	75 [30.06-95.44], 4
Sensitivity, CT ≤ 30, N	92.31 [66.69-98.63], 13	100 [74.12-100.0], 11	50 [9.45-90.55], 2
Sensitivity, CT ≤ 25, N	100 [67.56-100.0], 8	100 [64.57-100.0], 7	100 [20.65-100.0], 1
Sensitivity, Symptom Onset 0-3 days [95%CI], N	Not applicable	60 [23.07-88.24], 5	Information not available
Sensitivity, Symptom Onset 4-7 days [95%CI], N	Not applicable	83.33 [43.65-96.99], 6	Information not available
Sensitivity, Symptom Onset > 7 days [95%CI], N	Not applicable	57.14 [25.05-84.18], 7	Information not available
Clinical Specificity [95% CI], N[2]	**97.78 [88.43-99.61], 45**	**97.78 [88.43-99.61], 45**	**NaN [NaN-NaN], 0**
Invalid rate (%, n/N)	8.22% (6/73)	7.35% (5/68)	20% (1/5)

1. For sensitivity columns, N represents the total number of positives included in the performance evaluation i.e., TP + FN.
2. For specificity columns, N represents the total number of negatives included in the performance evaluation i.e., TN + FP.

Table 6. Performance evaluation on **oropharyngeal samples** (Reference sample is oropharyngeal)

	Overall	**DRC**	**UK**
Clinical Sensitivity [95% CI], N[1]	**81.82 [61.48-92.69], 22**	**71.43 [45.35-88.28], 14**	**100 [67.56-100.0], 8**

Sensitivity, CT ≤ 35, N	86.67 [62.12-96.26], 15	75 [40.93-92.85], 8	100 [64.57-100.0], 7
Sensitivity, CT ≤ 30, N	100 [75.75-100.0], 12	100 [60.97-100.0], 6	100 [60.97-100.0], 6
Sensitivity, CT ≤ 25, N	100 [56.55-100.0], 5	100 [20.65-100.0], 1	100 [51.01-100.0], 4
Sensitivity, Symptom Onset 0-3 days [95%CI], N	Not applicable	60 [23.07-88.24], 5	Information not available
Sensitivity, Symptom Onset 4-7 days [95%CI], N	Not applicable	83.33 [43.65-96.99], 6	Information not available
Sensitivity, Symptom Onset > 7 days [95%CI], N	Not applicable	66.67 [20.77-93.85], 3	Information not available
Clinical Specificity [95% CI], N[2]	**90.57 [79.75-95.9], 53**	**93.88 [83.48-97.9], 49**	**50 [15.0-85.0], 4**
Invalid rate (%, n/N)	8.54% (7/82)	7.35% (5/68)	14.29% (2/14)

1. For sensitivity columns, N represents the total number of positives included in the performance evaluation i.e., TP + FN.
2. For specificity columns, N represents the total number of negatives included in the performance evaluation i.e., TN + FP.

4.3 Estimation of analytical performance

Verified LOD

MPXV clade	Lowest dilution detected	Verified LOD concentration	Viral copy equivalent
Clade 1	To be determined	To be determined	To be determined
Clade 2a	To be determined	To be determined	To be determined
Clade 2b	To be determined	To be determined	To be determined