

Reliability of CNEURO hyssops for sample collection in the SARS-CoV-2 diagnosis

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Abstract

Background: The detection of SARS-CoV-2 genetic material from nasopharyngeal swab samples by RT-PCR is the most specific and sensitive way to test suspected cases. However, factors such as the sampling process, type of hyssop used, and the anatomical area from which the sample is collected can distort the result and cause false negatives.

Objective: to evaluate the reliability of CNUERO hyssops for sample collection in the SARS-CoV-2 diagnosis versus IMPROSWAB hyssops.

Methods: To study the reliability of hyssops developed in Cuba for swabbing in the COVID-19 diagnosis, by comparing them to other hyssops successfully used for this task, 2 swabbing samples were obtained from each patient (136). One of these two samples was taken using the hyssops made in Cuba, while the other was taken employing another hyssop imported from Germany.

The positive detections between both hyssops were compared using the Fisher exact test. The result of the detection of each hyssop was evaluated and compared using the ROC curve.

Results: The use of CNEURO hyssops allowed detecting 45 out of 59 positive cases, while IMPROSAWAB hyssops detected 52 out of 59. Non-significant differences were detected between positive cases detected for each hyssop. The sensibility of sample detection using CNEURO hyssops was of 76.3 % and of 88.1 % when using IMPROSWAB hyssops. Hence, no significant differences are detected in the detection of cases using these two hyssops.

Conclusion: CNEURO hyssops are safe and reliable to be used for nasopharyngeal samples taking of COVID-19 patients.



Figure S1. CNEURO Hyssop for nasopharyngeal and oropharyngeal sampling. Cuban`s manufacture.

Table S1. Results of the detections of genetic material of the SARS-CoV-2 virus from nasopharyngeal and oropharyngeal samples by RT-PCR.

Cases	Sex	Age	Double swabs (nasopharyngeal and oropharyngeal) by IMPROSWAB Hyssops (True positive cases)	Nasopharyngeal swabs by CNEURO Hyssops	Nasopharyngeal swabs by IMPROSWAB Hyssops
1	F	74	Negative	Negative	Negative
2	F	58	Positive	Positive	Positive
3	M	59	Positive	Positive	Positive

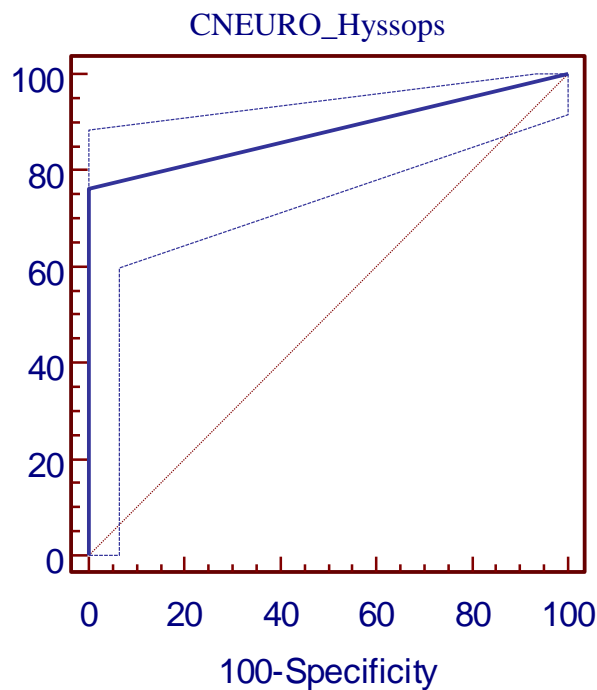
4	F	64	Negative	Negative	Negative
5	F	48	Positive	Negative	Positive
6	M	21	Positive	Negative	Positive
7	F	35	Positive	Negative	Positive
8	F	65	Positive	Positive	Positive
9	F	24	Positive	Positive	Positive
10	M	80	Positive	Positive	Positive
11	F	46	Positive	Negative	Positive
12	F	50	Positive	Negative	Positive
13	M	27	Positive	Positive	Positive
14	F	31	Positive	Positive	Positive
15	F	68	Positive	Positive	Positive
16	M	52	Negative	Negative	Negative
17	M	57	Positive	Positive	Negative
18	M	28	Positive	Positive	Positive
19	F	57	Positive	Positive	Positive
20	F	46	Positive	Positive	Positive
21	F	66	Positive	Positive	Positive
22	F	36	Negative	Negative	Negative
23	F	54	Positive	Positive	Positive
24	F	39	Positive	Positive	Positive
25	F	29	Positive	Positive	Positive
26	F	57	Positive	Positive	Positive
27	F	50	Positive	Positive	Positive
28	F	21	Negative	Negative	Negative
29	F	36	Positive	Positive	Positive
30	M	23	Negative	Negative	Negative
31	M	56	Negative	Negative	Negative
32	F	39	Negative	Negative	Negative
33	M	87	Negative	Negative	Negative
34	F	83	Negative	Negative	Negative
35	M	62	Negative	Negative	Negative
36	F	28	Negative	Negative	Negative
37	F	24	Negative	Negative	Negative
38	F	66	Negative	Negative	Negative
39	M	78	Negative	Negative	Negative
40	M	46	Positive	Positive	Positive
41	M	32	Positive	Positive	Positive
42	M	33	Negative	Negative	Negative
43	F	53	Positive	Positive	Positive
44	F	63	Positive	Negative	Positive

45	F	65	Negative	Negative	Negative
46	F	44	Negative	Negative	Negative
47	F	23	Positive	Positive	Positive
48	M	36	Positive	Negative	Positive
49	M	51	Positive	Positive	Negative
50	M	29	Positive	Positive	Positive
51	M	60	Negative	Negative	Negative
52	M	53	Negative	Negative	Negative
53	M	55	Negative	Negative	Negative
54	F	24	Positive	Negative	Positive
55	M	82	Negative	Negative	Negative
56	M	37	Negative	Negative	Negative
57	M	33	Negative	Negative	Negative
58	M	64	Negative	Negative	Negative
59	M	59	Negative	Negative	Negative
60	M	50	Negative	Negative	Negative
61	M	49	Negative	Negative	Negative
62	F	49	Positive	Positive	Positive
63	F	28	Negative	Negative	Negative
64	M	49	Negative	Negative	Negative
65	F	44	Negative	Negative	Negative
66	F	64	Negative	Negative	Negative
67	F	70	Positive	Positive	Negative
68	M	64	Negative	Negative	Negative
69	F	49	Negative	Negative	Negative
70	F	51	Positive	Positive	Negative
71	F	45	Negative	Negative	Negative
72	M	51	Negative	Negative	Negative
73	F	61	Negative	Negative	Negative
74	M	42	Negative	Negative	Negative
75	M	72	Negative	Negative	Negative
76	M	79	Negative	Negative	Negative
77	F	28	Positive	Negative	Positive
78	F	22	Positive	Positive	Positive
79	F	21	Negative	Negative	Negative
80	M	19	Negative	Negative	Negative
81	F	38	Negative	Negative	Negative
82	M	25	Negative	Negative	Negative
83	F	54	Negative	Negative	Negative
84	F	69	Positive	Positive	Positive
85	M	40	Negative	Negative	Negative

86	F	36	Negative	Negative	Negative
87	F	34	Negative	Negative	Negative
88	F	31	Positive	Positive	Positive
89	M	50	Positive	Positive	Negative
90	M	24	Negative	Negative	Negative
91	F	59	Negative	Negative	Negative
92	M	45	Negative	Negative	Negative
93	F	35	Negative	Negative	Negative
94	M	32	Negative	Negative	Negative
95	F	62	Negative	Negative	Negative
96	F	51	Negative	Negative	Negative
97	M	25	Negative	Negative	Negative
98	F	43	Negative	Negative	Negative
99	F	31	Negative	Negative	Negative
100	F	45	Negative	Negative	Negative
101	F	45	Negative	Negative	Negative
102	M	20	Negative	Negative	Negative
103	F	64	Negative	Negative	Negative
104	F	32	Negative	Negative	Negative
105	F	46	Negative	Negative	Negative
106	F	21	Negative	Negative	Negative
107	F	47	Positive	Positive	Positive
108	M	28	Negative	Negative	Negative
109	M	33	Positive	Positive	Positive
110	M	30	Positive	Positive	Positive
111	M	20	Positive	Positive	Positive
112	F	43	Positive	Positive	Negative
113	F	29	Positive	Negative	Positive
114	M	61	Positive	Positive	Positive
115	M	41	Negative	Negative	Negative
116	F	58	Positive	Negative	Positive
117	F	50	Negative	Negative	Negative
118	M	19	Positive	Positive	Positive
119	M	21	Positive	Negative	Positive
120	F	58	Positive	Positive	Positive
121	F	25	Positive	Positive	Positive
122	F	43	Negative	Negative	Negative
123	F	36	Positive	Positive	Negative
124	F	44	Negative	Negative	Negative
125	F	60	Negative	Negative	Negative
126	F	45	Negative	Negative	Negative

127	M	61	Negative	Negative	Negative
128	F	57	Positive	Positive	Positive
129	F	74	Negative	Negative	Negative
130	F	32	Negative	Negative	Negative
131	F	21	Positive	Positive	Positive
132	M	50	Positive	Negative	Positive
133	F	19	Positive	Negative	Positive
134	M	20	Positive	Positive	Positive
135	F	64	Negative	Negative	Negative
136	F	67	Negative	Negative	Negative

Figure S2. ROC curves analysis for two hyssops type



VARIABLE = CNEURO_Hyssops

CLASSIFICATION VARIABLE
Gold_Standard

POSITIVE GROUP
Gold_Standard = 1
Sample size = 59

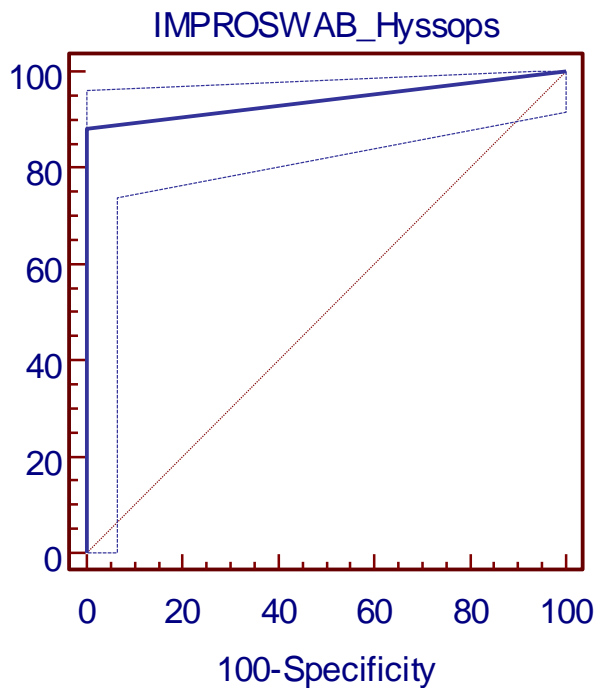
NEGATIVE GROUP
Gold_Standard = 0
Sample size = 77

Disease prevalence unknown.

Area under the ROC curve = 0.881
 Standard error = 0.031
 95% Confidence interval = 0.815 to 0.930
 P (Area=0.5) < 0.0001

Criterion	Sens. (95% C.I.)	Spec. (95% C.I.)	+LR	-LR
≥ 0	100.0 (93.9-100.0)	0.0 (0.0- 4.7)	1.00	
> 0 *	76.3 (63.4-86.4)	100.0 (95.3-100.0)		0.24
> 1	0.0 (0.0- 6.1)	100.0 (95.3-100.0)		1.00

Sens. = Sensitivity
 Spec. = Specificity
 +LR = Positive likelihood ratio
 -LR = Negative likelihood ratio



VARIABLE = IMPROSWAB_Hyssops

CLASSIFICATION VARIABLE

Gold_Standard

POSITIVE GROUP

Gold_Standard = 1

Sample size = 59

NEGATIVE GROUP

Gold_Standard = 0

Sample size = 77

Disease prevalence unknown.

Area under the ROC curve = 0.941

Standard error = 0.022

95% Confidence interval = 0.887 to 0.974

P (Area=0.5) < 0.0001

Criterion	Sens. (95% C.I.)	Spec. (95% C.I.)	+LR	-LR
≥ 0	100.0 (93.9-100.0)	0.0 (0.0-4.7)	1.00	
> 0 *	88.1 (77.1-95.1)	100.0 (95.3-100.0)		0.12
> 1	0.0 (0.0-6.1)	100.0 (95.3-100.0)		1.00

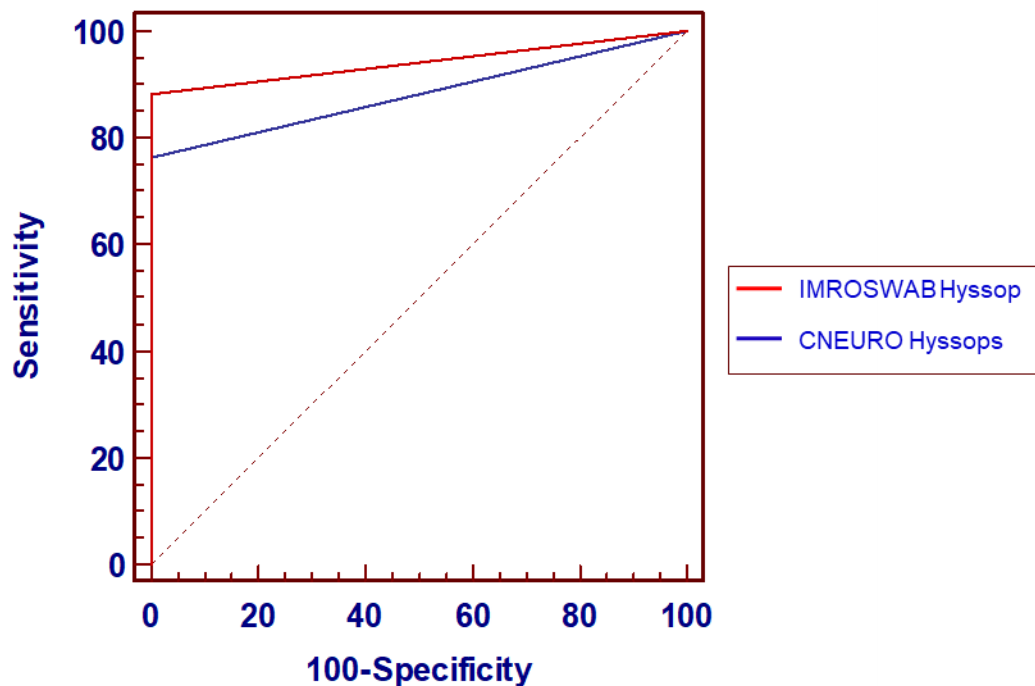
Sens. = Sensitivity

Spec. = Specificity

+LR = Positive likelihood ratio

-LR = Negative likelihood ratio

Figure S3. The pairwise comparison of ROC curves between both hyssops (CNEURO vs. IMPROSWAB)



VARIABLE 1 = CNEURO_Hyssops

VARIABLE 2 = IMPROSWAB_Hyssops

CLASSIFICATION VARIABLE

Gold_Standard

POSITIVE GROUP

Gold_Standard = 1

Sample size = 59

NEGATIVE GROUP

Gold_Standard = 0

Sample size = 77

ROC curve for CNEURO_Hyssops

Area under the ROC curve = 0.881

Standard error = 0.031

95% Confidence interval = 0.815 to 0.930

ROC curve for IMPROSWAB_Hyssops

Area under the ROC curve = 0.941

Standard error = 0.022

95% Confidence interval = 0.887 to 0.974

Pairwise comparison of ROC curves

CNEURO_Hyssops

IMPROSWAB_Hyssops

Difference between areas = 0.059

Standard error = 0.037

95% Confidence interval = -0.014 to 0.133

Significance level P = 0.112

Table S2. Comparison between the samples collected by each technician

Table Analyzed	Data 1		
Fisher's exact test			
P value	0.0254		
P value summary	*		
One- or two-sided	Two-sided		
Statistically significant? (alpha<0.05)	Yes		
Data analyzed	Technician 1	Technician 2	Total
Positives	40	26	66
Negatives	28	42	70
Total	68	68	136