

Untitled study

Influenza A antigen · Qualitative agreement × Criteria not met

6 of 6 questions judged · 4 questions not met · Positive agreement / sensitivity (%) and Overall / exact agreement (%) met

Study date **Not recorded**

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
Positive agreement / sensitivity (%)	≥ 90%		90.00% 45/50 · 78.64–95.65	✓ Met
Positive agreement / sensitivity (%)	> 90%		90.00% 45/50 · 78.64–95.65	✗ Not met
Negative agreement / specificity (%)	≥ 95%		94.00% 47/50 · 83.78–97.94	✗ Not met
Overall / exact agreement (%)	≥ 92%		92.00% 92/100 · 85.00–95.89	✓ Met
Positive agreement / sensitivity, lower bound (%)	≥ 80%		78.64%	✗ Not met
Negative agreement / specificity, lower bound (%)	≥ 85%		83.78%	✗ Not met

Comparative method →			
Test method ↓	Negative	Positive	Total
Negative	47	5	52
Positive	3	45	48
Total	50	50	100

Figure 1. Initial results; shaded cells agree.

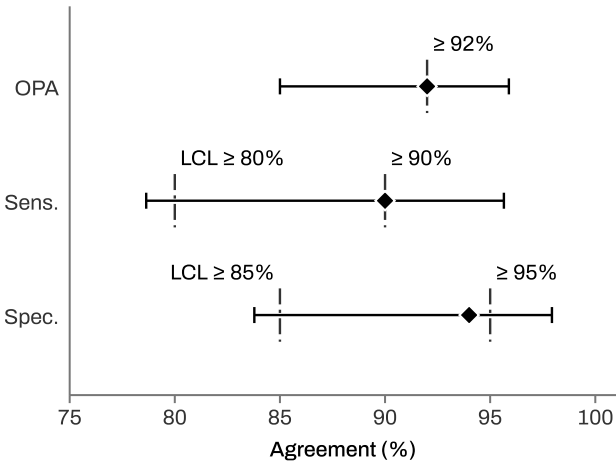


Figure 2. Agreement, 95% CI; dash-dot: goals; LCL: lower confidence limit.

Study details

Pairs **100**

Positive category **positive**

Signed off by

Date

A Data listing

Source: manual entry. 100 rows, all included.

Study row	Specimen	Comparative	Test
1	S001	positive	positive
2	S002	positive	positive
3	S003	positive	positive
4	S004	positive	positive
5	S005	positive	positive
6	S006	positive	positive
7	S007	positive	positive
8	S008	positive	positive
9	S009	positive	positive
10	S010	positive	positive
11	S011	positive	positive
12	S012	positive	positive
13	S013	positive	positive
14	S014	positive	positive
15	S015	positive	positive
16	S016	positive	positive
17	S017	positive	positive
18	S018	positive	positive
19	S019	positive	positive
20	S020	positive	positive
21	S021	positive	positive
22	S022	positive	positive
23	S023	positive	positive
24	S024	positive	positive
25	S025	positive	positive
26	S026	positive	positive
27	S027	positive	positive
28	S028	positive	positive
29	S029	positive	positive
30	S030	positive	positive
31	S031	positive	positive
32	S032	positive	positive
33	S033	positive	positive
34	S034	positive	positive
35	S035	positive	positive
36	S036	positive	positive
37	S037	positive	positive
38	S038	positive	positive
39	S039	positive	positive
40	S040	positive	positive
41	S041	positive	positive
42	S042	positive	positive
43	S043	positive	positive

Study row	Specimen	Comparative	Test
44	S044	positive	positive
45	S045	positive	positive
46	S046	negative	positive
47	S047	negative	positive
48	S048	negative	positive
49	S049	positive	negative
50	S050	positive	negative
51	S051	positive	negative
52	S052	positive	negative
53	S053	positive	negative
54	S054	negative	negative
55	S055	negative	negative
56	S056	negative	negative
57	S057	negative	negative
58	S058	negative	negative
59	S059	negative	negative
60	S060	negative	negative
61	S061	negative	negative
62	S062	negative	negative
63	S063	negative	negative
64	S064	negative	negative
65	S065	negative	negative
66	S066	negative	negative
67	S067	negative	negative
68	S068	negative	negative
69	S069	negative	negative
70	S070	negative	negative
71	S071	negative	negative
72	S072	negative	negative
73	S073	negative	negative
74	S074	negative	negative
75	S075	negative	negative
76	S076	negative	negative
77	S077	negative	negative
78	S078	negative	negative
79	S079	negative	negative
80	S080	negative	negative
81	S081	negative	negative
82	S082	negative	negative
83	S083	negative	negative
84	S084	negative	negative
85	S085	negative	negative
86	S086	negative	negative
87	S087	negative	negative
88	S088	negative	negative
89	S089	negative	negative

	Study row	Specimen	Comparative	Test
	90	S090	negative	negative
	91	S091	negative	negative
	92	S092	negative	negative
	93	S093	negative	negative
	94	S094	negative	negative
	95	S095	negative	negative
	96	S096	negative	negative
	97	S097	negative	negative
	98	S098	negative	negative
	99	S099	negative	negative
	100	S100	negative	negative

1 Results

1.1 Discordant and nonreportable results

Table 2. Discordant and nonreportable initial results

	Row	Specimen	Comparative	Test
	46	S046	Negative	Positive
	47	S047	Negative	Positive
	48	S048	Negative	Positive
	49	S049	Positive	Negative
	50	S050	Positive	Negative
	51	S051	Positive	Negative
	52	S052	Positive	Negative
	53	S053	Positive	Negative

1.2 Supporting statistics

Table 3. Statistics without an acceptance limit

Statistic	Estimate	95% CI
Cohen kappa (unweighted)	0.840	0.734 to 0.946
Positive-proportion difference, test – comparative (percentage points)	–2.00	–7.74 to 3.78
McNemar exact p (b = 3, c = 5)	0.727	

1.3 Predictive values · All specimens · Modeled at prevalence 10.00%. Intervals propagate simultaneous exact sensitivity and specificity bounds; prevalence is treated as fixed.

Table 4. Modeled predictive values at entered prevalence

Measure	Estimate (%)	95.00% CI (%)
Modeled positive predictive value (PPV)	62.50	31.80–91.81
Modeled negative predictive value (NPV)	98.83	96.89–99.69

2 Study notes

1. Sensitivity and specificity rely on the comparative method being a reference standard.