

ROCHE Clinical Evaluation Comparison between FDA EUA and Public Health England

	1. Roche Elecsys Roche Internal		
Date after onset	Total positive	Test positive	Sensitivity
~ 6 days	116	76	65.5%
7~13 days	59	52	88.1%
14~ days	29	29	100.0%
14~ days	29	29	100.0%

	2. Roche Elecsys _ Public Health England		
Date after onset	Total positive	Test positive	Sensitivity
~ 10 days	14	10	71.4%
11~20 days	4	3	75.0%
21~ days	73	64	87.7%
14~ days	77	67	87.0%

Sugentech Clinical Evaluation Comparison between US EUA submission data and Pasteur Institute France

	Sugentech Korean Major Teaching Hospital Clinical Study study (US EUA submission)			Sugentech Result from Pasteur Institute France		
Date after onset	Total positive	Test positive	Sensitivity	Total positive	Test positive	Sensitivity
~ 10 days	23	17	73.9%	4	3	75.0%
11~20 days	31	29	93.5%	15	14	93.3%
21~ days	13	13	100.0%	8	8	100.0%
14~ days	33	32	97.0%	16	16	100.0%

Appendix] Roche Evaluation Result in PHE(Public Health England)

Group	Positive	Negative	Total	Sensitivity (95% CI)
<= 10 from admission	10	4	14	71.4% (42.0-90.4)
11 to 20	3	1	4	75.0% (21.9-98.7)
21 to 30	28	7	35	80.0% (62.5-90.9)
31 to 40	28	2	30	93.3% (76.5-98.8)
41 to 50	8	0	8	100.0% (59.8-100)
Interval not known	1	1	2	50.0% (26.7-97.3)
From 14 days	64	9	73	87.7% (77.9-93.8)
From 21 days	67	19	77	87.0% (67.4-85.8)

Table 4: Assay sensitivity by interval when tested with PHE's sample set

Appendix] Sugentech Pasteur Institute Evaluation Result

Period after onset of symptoms	Serums	POS CNR	POS CNR	POS Kit	POS Kit	Agreement (%)						
						days	(not)	(not)	%	(not)	%	VP
0-5	1	1	100%	0	0%	0	0	1	0	0%	-	0%
6-10	3	3	100%	3	100%	3	0	0	0	100%	-	100%
11-15	7	7	100%	6	86%	6	0	1	0	86%	-	86%
16-20	8	8	100%	8	100%	8	0	0	0	100%	-	100%
> 20	8	8	100%	8	100%	8	0	0	0	100%	-	100%
<i>Subtotal</i>	27	27	100%	25	93%	25	0	2	0	93%	-	93%
unknown	15	15	100%	15	100%	15	0	0	0	100%	-	100%
Total COVID-19 +	42	42	100%	40	95%	40	0	2	0	95%	-	95%
Pre-pdm	38	0	0%	0	0%	0	0	0	38	-	100%	100%
TOTAL	80	42	100%	40	95%	40	0	2	38	95%	100%	98%

Table I-2: Percentage of positivity and agreement between results of the kit (IgM + IgG) and the results of the reference test of the CNR (Igtot / IgG): .VP, true positive; FP, false positive; FN, false negative; VN, true negative.