

Table 1. Negative agreement by specimen category

Negative agreement (pre-COVID-19 outbreak)	Sample number	Reactive	Non-reactive	Negative percent agreement (95% CI)
Sepsis screen	136	2	134	98.5% (94.79% to 99.82%)
Acute respiratory exacerbation	78	1	77	98.7% (93.06% to 99.97%)
HIV positive	43	0	43	100.0% (91.78% to 100.00%)
Total	257	3	254	98.8% (96.63% to 99.76%)
Notes	Reactive samples all IgM only. IgA specificity 100% (95%CI 98.57% to 100.00%), IgM specificity 98.83% (95% CI 96.63% to 99.76%), IgG specificity 100% (95%CI 98.57% to 100.00%).			

Table 2. Negative agreement by IgA, IgM and IgG antibody

Negative agreement (pre-COVID-19 outbreak)	Number of Samples	Number of Patients	IgA			IgM			IgG		
			Reactive (n)	Non-reactive (n)	Cross-reactive (%)	Reactive (n)	Non-reactive (n)	Cross-reactive (%)	Reactive (n)	Non-reactive (n)	Cross-reactive (%)
Sepsis screen	136	33	0	136	0.0%	2	134	1.5%	0	136	0.0%
Acute respiratory exacerbation	78	26	0	78	0.0%	1	77	1.3%	0	78	0.0%
HIV positive	43	43	0	43	0.0%	0	43	0.0%	0	43	0.0%
Total	257	102	0	257	0.0%	3	254	1.2%	0	257	0.0%
Notes	Sepsis screen a total of 33 patients were included with 136 repeat samples on sequential days. Acute respiratory exacerbation includes 18 patients with plasma and serum from same day of collection, demonstrating equivalency. HIV positive includes both seroconversion samples and performance panels.										

Table 3. Positive agreement by days post symptom onset

Positive agreement (COVID-19 outbreak)	Gold standard	Sample number	Reactive	Non-reactive	Positive percent agreement (95% CI)
4–50 days post PCR swab	PCR lab confirmation	108	89	19	82.4%
					(73.90% to 89.06%)
21–27 days post symptom onset	PCR lab confirmation	25	24	1	96.0%
					(79.65% to 99.90%)
14–20 days post PCR swab	PCR lab confirmation	37	36	1	97.3%
					(85.84% to 99.93%)
4–50 days post PCR swab	PCR + ELISA lab confirmation	99	87	12	87.9%
					(79.78% to 93.58%)
21–27 days post symptom onset	PCR + ELISA lab confirmation	24	23	1	95.8%
					(78.88% to 99.89%)
14–20 days post PCR swab	PCR + ELISA lab confirmation	35	35	0	100.0%
					(90.00% to 100.00%)
Notes	ELISA confirmation by Omega IgG. RT-PCR confirmation by Roche cobas ® SARS-CoV-2 Test (E and ORF targets) or Altona Diagnostics RealStar®SARS-CoV-2 RT-PCR Kit (S and E genes).				

Table 4. Comparison of performance between PHE Validation of ELISA antibody tests and Mologic rapid antibody test

Positive agreement (COVID-19 outbreak)	Roche ELISA				Abbott ELISA				Mologic RDT			
	Sample number	Reactive	Non-reactive	Positive percent agreement (95% CI)	Sample number	Reactive	Non-reactive	Positive percent agreement (95% CI)	Sample number	Reactive	Non-reactive	Positive percent agreement (95% CI)
5-65 days post symptom onset	93	78	15	83.9% (74.80% to 90.68%)	96	89	7	92.7% (85.55% to 97.02%)	108	89	19	82.4% (73.90% to 89.06%)
11-20 days post symptom onset	4	3	1	75.0% (19.41% to 99.37%)	5	5	0	100.0% (18.71% to 81.29%)	31	24	7	77.4% (58.90% to 90.41%)
21-30 days post symptom onset	35	28	7	80.0% (63.06% to 91.56%)	31	29	2	93.5% (78.58% to 99.21%)	30	29	1	96.7% (82.78% to 99.92%)
31-40 days post symptom onset	30	28	2	93.3% (77.93% to 99.18%)	37	35	2	94.6% (81.81% to 99.34%)	22	19	3	86.4% (65.09% to 97.09%)
41-50 days post symptom onset	8	8	0	100.0% (63.06% to 100.00%)	8	7	1	87.5% (47.35% to 99.68%)	7	4	3	57.1% (18.41% to 90.10%)
Notes	<p>Comparison of PHE validation data for the Roche and Abbott ELISA laboratory platforms and the Mologic RDT. https://www.gov.uk/government/publications/covid-19-laboratory-evaluations-of-serological-assays</p> <p>Gold standard RT-PCR confirmation by Roche cobas ® SARS-CoV-2 Test (E and ORF targets) or Altona Diagnostics RealStar®SARS-CoV-2 RT-PCR Kit (S and E genes).</p>											

Table 5. Analytical specificity of potentially cross-reacting antibodies

Cross-reactivity panel	Number of Samples	IgA			IgM			IgG		
		Reactive (n)	Non-reactive (n)	Cross-reactive (%)	Reactive (n)	Non-reactive (n)	Cross-reactive (%)	Reactive (n)	Non-reactive (n)	Cross-reactive (%)
Coronavirus panel	41	0	41	0.0%	3	38	7.3%	2	39	4.9%
High prevalence virus panel	108	1	107	0.9%	5	102	4.6%	6	102	5.6%
Other organisms	61	1	60	1.6%	1	60	1.6%	2	59	3.3%
Auto-antibodies	13	0	13	0.0%	1	12	7.7%	1	12	7.7%
Coronavirus panel										
Coronavirus 229	20	0	20	0.0%	3	17	15.0%	2	18	10.0%
Coronavirus HKU1	4	0	4	0.0%	0	4	0.0%	0	4	0.0%
Coronavirus NL63	5	0	5	0.0%	0	5	0.0%	0	5	0.0%
Coronavirus OC43	12	0	12	0.0%	0	12	0.0%	0	12	0.0%
High prevalence virus panel										
Adenovirus	9	0	9	0.0%	1	8	11.1%	0	9	0.0%
EBV	5	0	5	0.0%	0	5	0.0%	0	5	0.0%
Haemophilus influenzae	3	0	3	0.0%	0	3	0.0%	0	3	0.0%
Human Metapneumovirus	9	0	9	0.0%	0	9	0.0%	1	8	11.1%
Influenza A	30	1	29	3.3%	2	27	6.7%	3	27	10.0%
Influenza B	2	0	2	0.0%	0	2	0.0%	0	2	0.0%
Parainfluenza	22	0	22	0.0%	2	20	9.1%	2	20	9.1%
Rhinovirus	14	0	14	0.0%	0	14	0.0%	0	14	0.0%
RSV	14	0	14	0.0%	0	14	0.0%	0	14	0.0%

Other organisms										
Bocavirus	2	0	2	0.0%	0	2	0.0%	0	2	0.0%
Bordatella pertussis	6	0	6	0.0%	0	6	0.0%	0	6	0.0%
Dengue	2	0	2	0.0%	0	2	0.0%	0	2	0.0%
Enterovirus	8	0	8	0.0%	0	8	0.0%	1	7	12.5%
Group A Streptococcus	2	0	2	0.0%	0	2	0.0%	0	2	0.0%
M. tuberculosis	3	0	3	0.0%	0	3	0.0%	0	3	0.0%
Mycoplasma pneumoniae	4	0	4	0.0%	0	4	0.0%	0	4	0.0%
Parechovirus	2	1	1	50.0%	1	1	50.0%	1	1	50.0%
Serum save	31	0	31	0.0%	0	31	0.0%	0	31	0.0%
Strep. Pneumonia	1	0	1	0.0%	0	1	0.0%	0	1	0.0%
Auto-antibodies										
Rheumatoid factor	9	0	9	0.0%	1	8	11.1%	1	8	11.1%
Systemic Lupus Erythematosus	4	0	4	0.0%	0	4	0.0%	0	4	0.0%
Notes	<p>Cross-reactive samples for parechovirus included in the data above were from the same infant, who was also positive for multiple respiratory viruses including coronavirus 43, parainfluenza, enterovirus, and bocavirus.</p> <p>EBV: Epstein Barr Virus; hMPV: human metapneumovirus; RSV: Respiratory syncytial virus; SLE: Systemic Lupus Erythematosus; Serum save represents COVID-19 negative samples from other organisms.</p> <p>Outstanding testing pending on Chlamydia pneumoniae, Legionella, malaria, and Pneumocystis jirovecii pneumonia</p>									