

Report about the comparison study of 2 commercial Sars-Cov-2 lateral flow test

Test kits evaluated:

Sienna Covid-19 IgG/IgG Rapid test kit, lot number not provided

Biohit SARS-Cov-2 IgG/IgM antibody test kit (colloidal gold method) lot SA200301, manufacturing day 2020-03-20.

Positive samples

2 serum samples from Biomex GmbH; Sars-Cov-2 IgG and IgM tested with Shenzhen YHLO instrument

Lot No.	Drawn	Date of infection	PCR positive	Corona IgM AU/ml	Corona IgG Au/ml	Location of infection	Gender	Symptoms
64082383	17.4.20	13.3.20	19.3.20	0,94	47,38	Austria	M	2,4,7,8,15
64082836	20.4.20	7-12.3.20	19.3.20	43,31	100,2	Austria	M	13,1,2

Key symptoms: 1 fever, 2 limb pain, 3 muscle pain, 4 headache, 5 backache, 6 shivers, 7 catarrh, 8 anosmia, 9 ache when swallowing, 10 mucous, 11 diarrhoea, 12 breathing difficulties, 13 coughing, 14 tiredness, 15 sore throat

Negative sample

Normal human serum from year 1993; 308-1993-10)

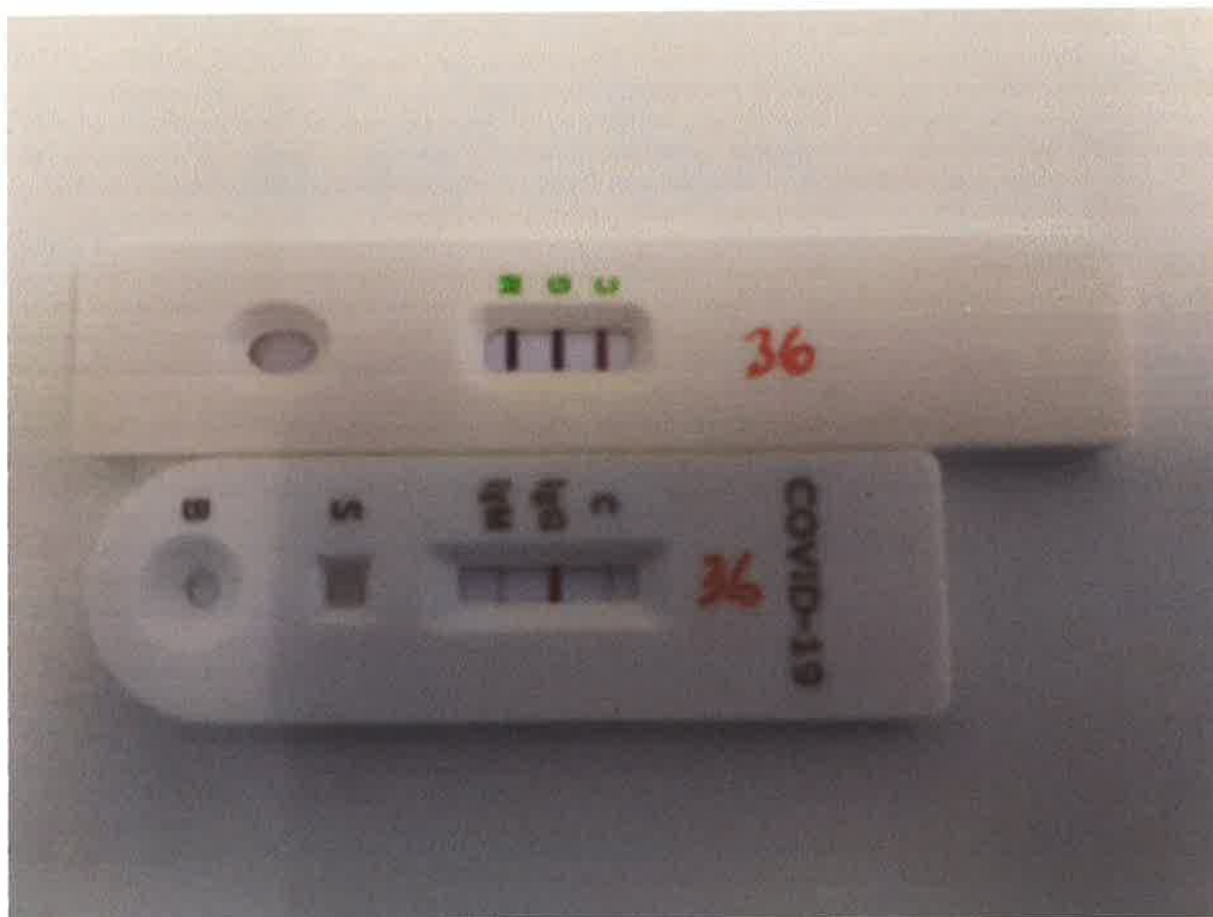
Serum dilution

Both tests were done based to the instruction provided by the manufacturer by adding 10 µl of positive serum either undiluted or diluted with negative serum. Serum samples were diluted by keeping the amount of serum always constant using following dilution scheme

	Positive serum	Negative serum (308-1993-10)
Undiluted	10 µl	0 µl
1:1	5 µl	5 µl
1:2	3,3 µl	6,6 µl
1:4	2 µl	8 µl
1:10	1 µl	9 µl
1:40	1 µl	39 µl
1:80	diluted 1:1 with negative sample from previous sample	
1:160	diluted 1:1 with negative sample from previous sample	
1:320	diluted 1:1 with negative sample from previous sample	

Test results

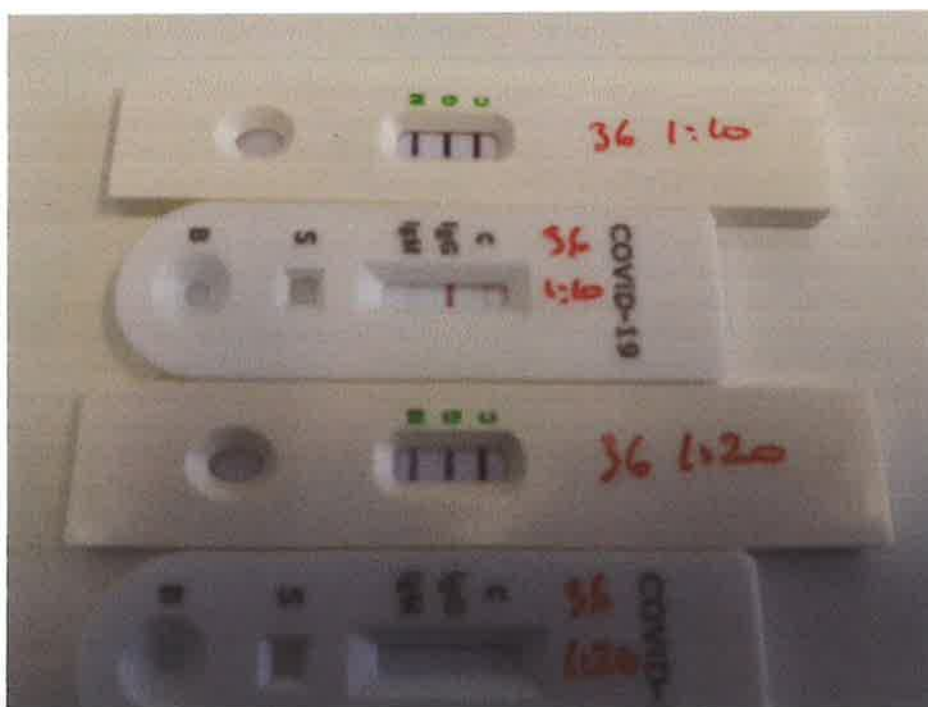
Samples were pipetted simultaneously to both products. Diluent (either Biohit or Sienna) was added after that to both test cassettes. Results were recorder both after 10 and 15 minutes. There was no difference between results after 10 and 15 minutes. Pictures were taken from both tests 15 minutes after adding diluent.



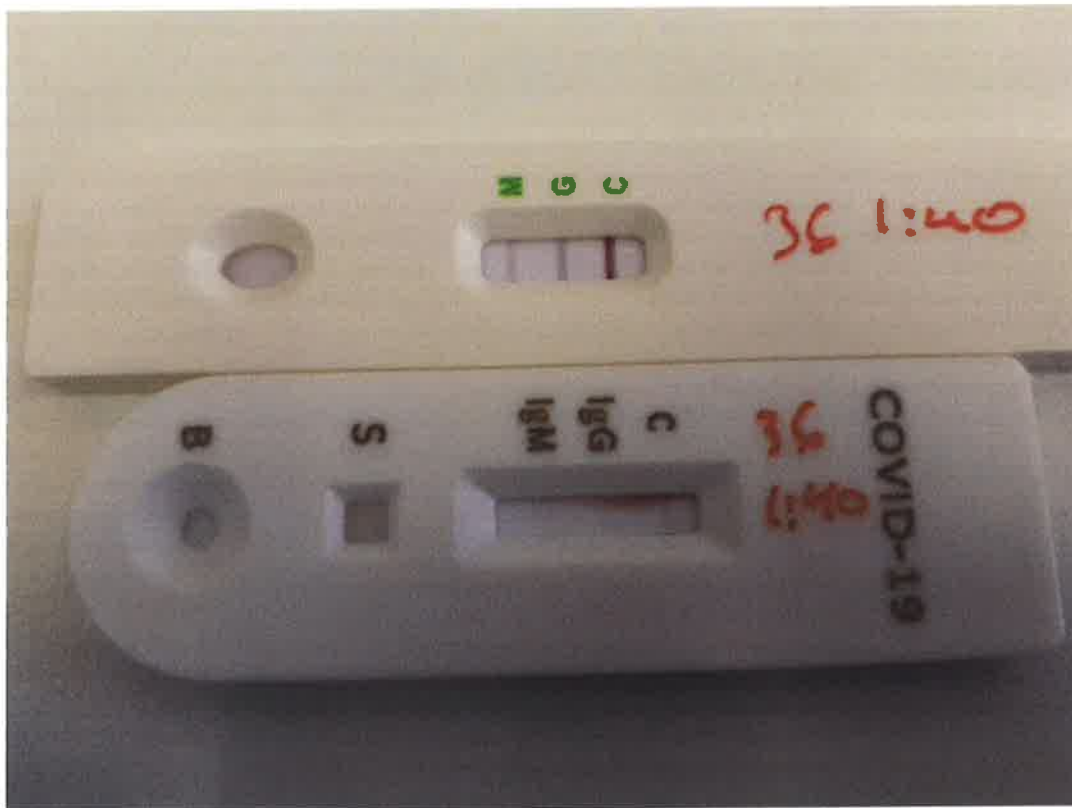
Picture 1: Sample 64082383 undilute



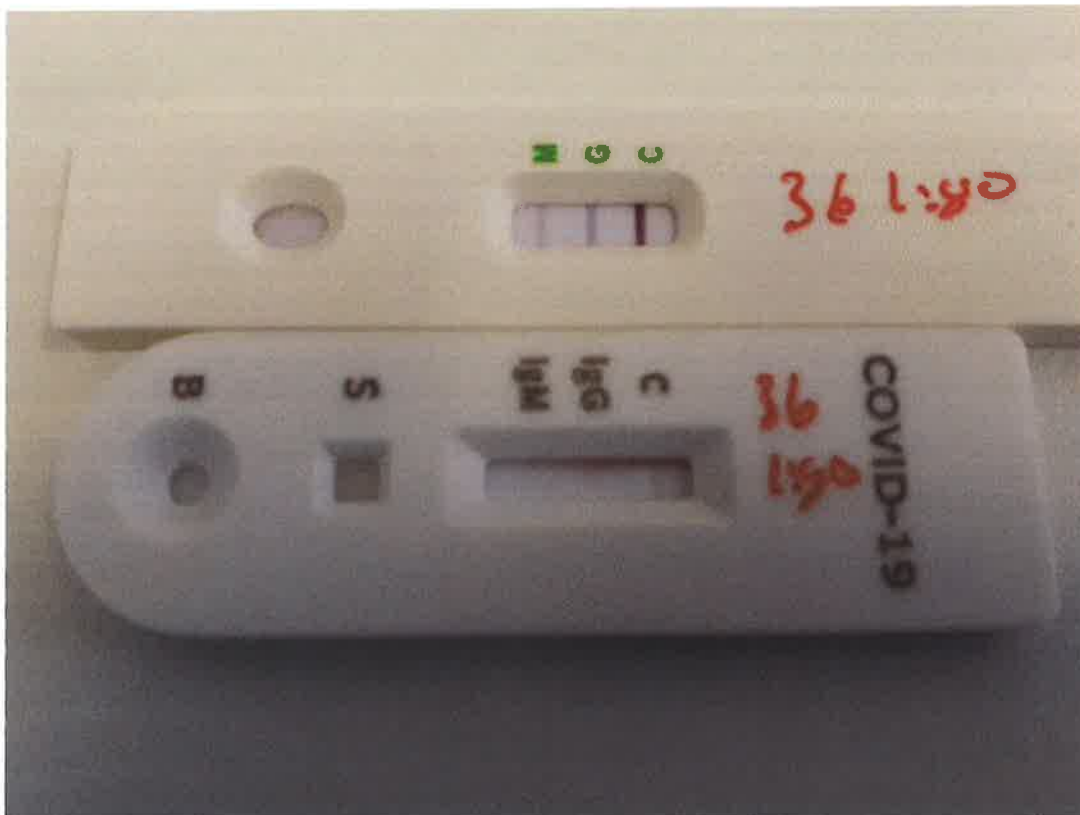
Picture 2: Sample 64082383 dilutions 1:1 and 1:2



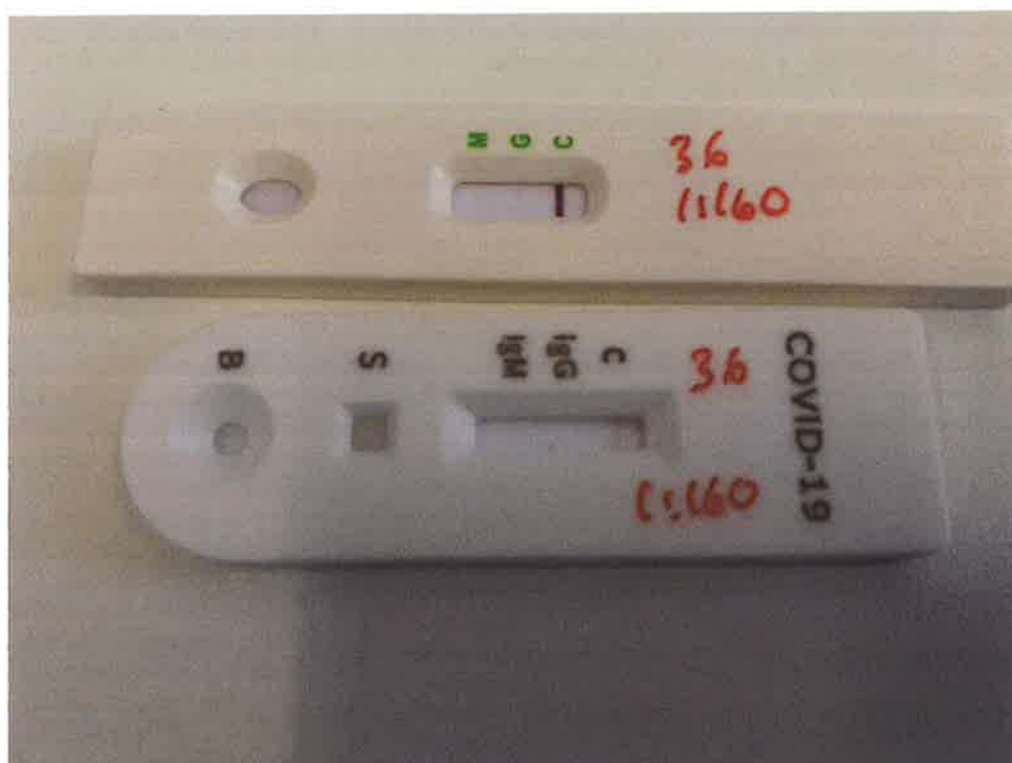
Picture 3: Sample 64082383 dilutions 1:10 and 1:20



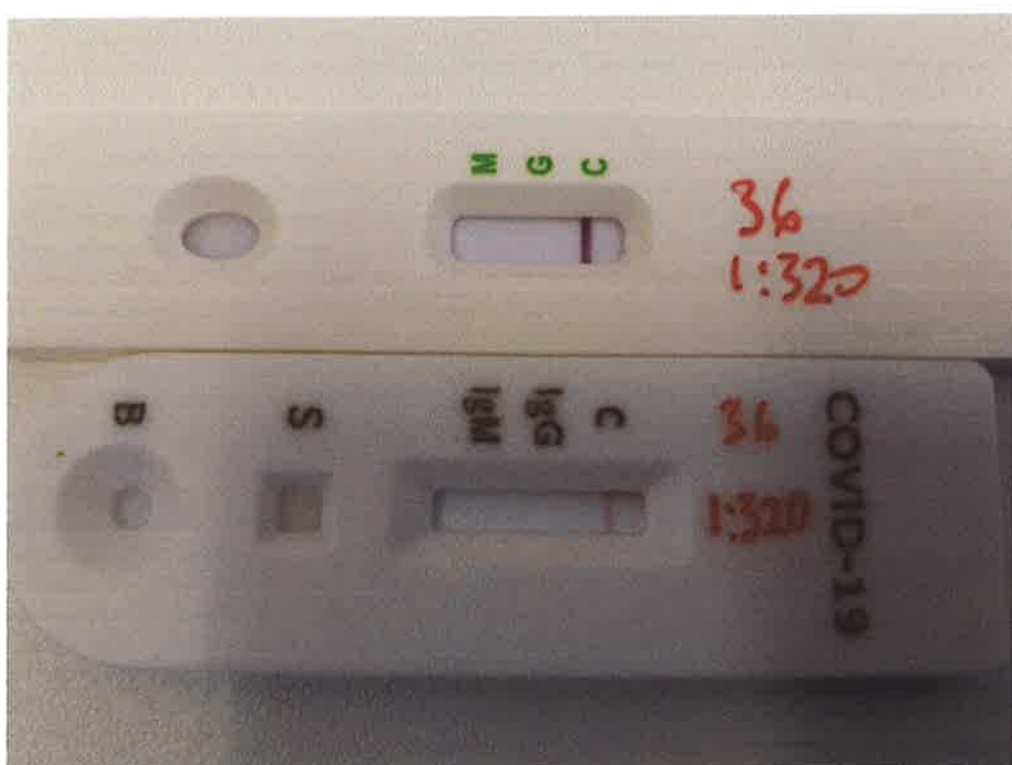
Picture 4: Sample 64082383 dilution 1:40



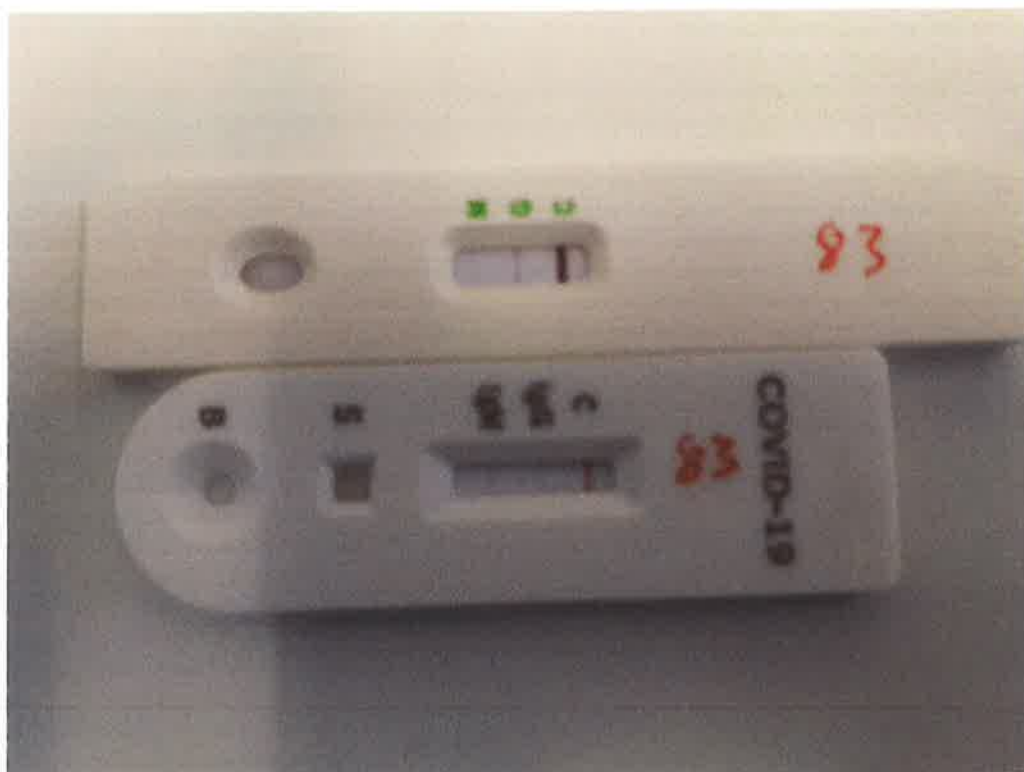
Picture 5: Sample 64082383 dilution 1:80



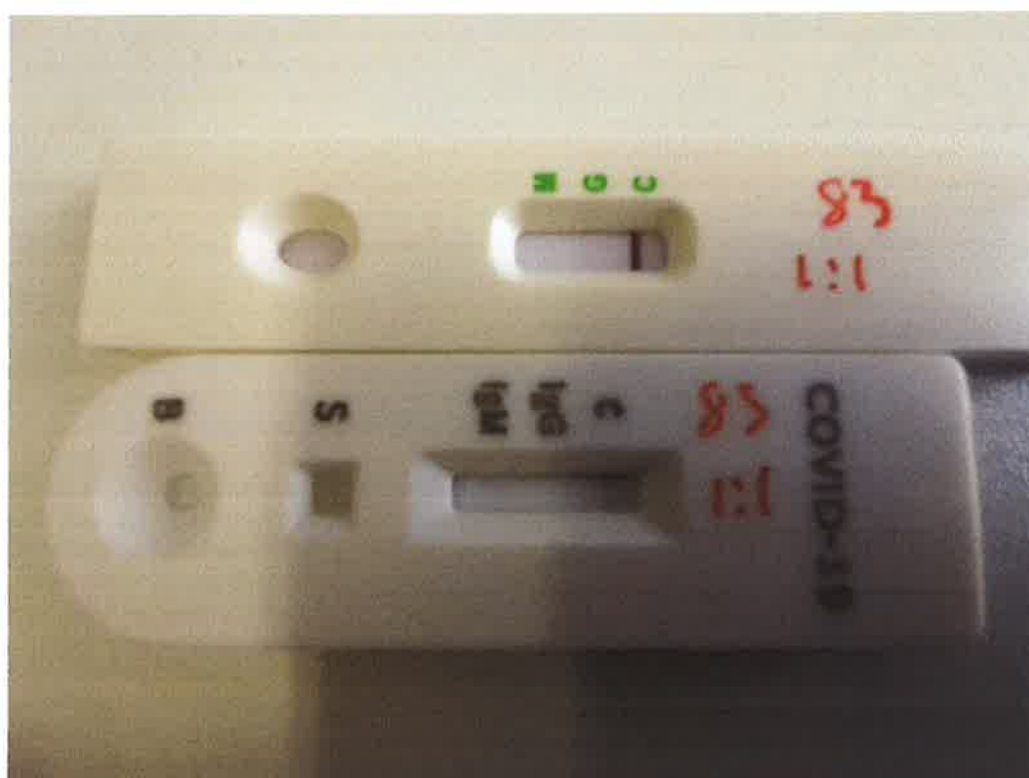
Picture 6: Sample 64082383 dilution 1:160



Picture 7: Sample 64082383 dilution 1:320



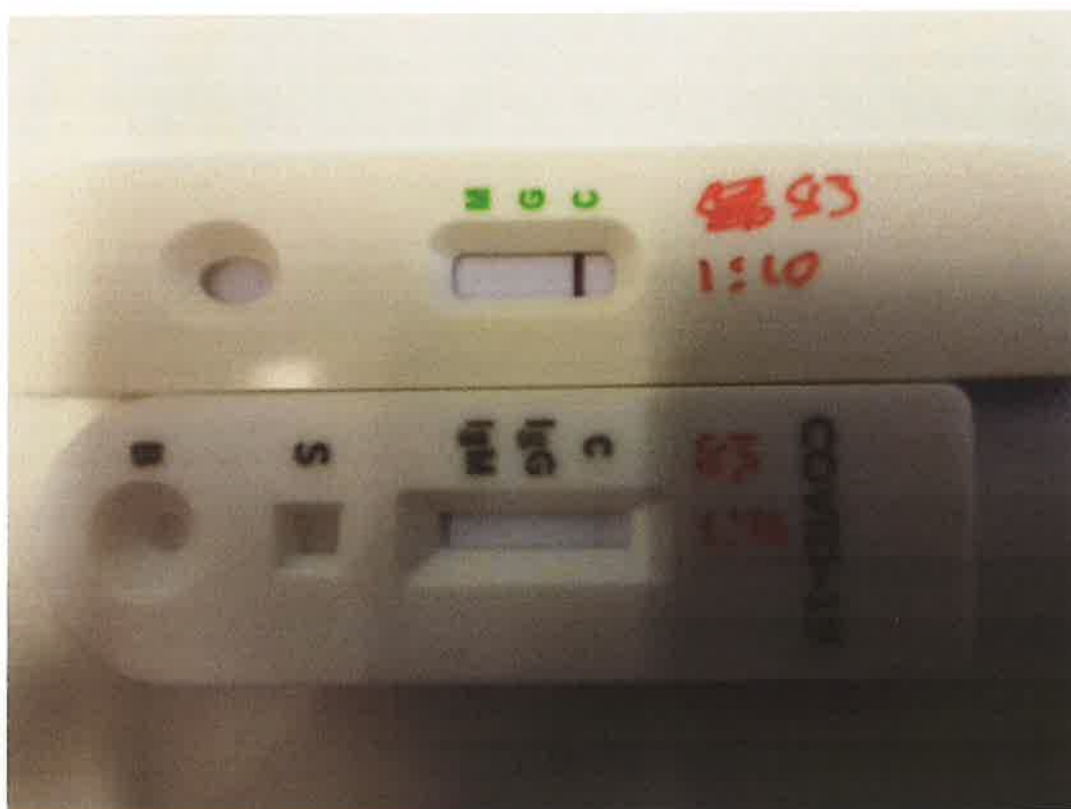
Picture 8: Sample 64082383



Picture 9: Sample 64082383 dilution 1:1



Picture 10: Sample 64082383 dilution 1:4



Picture 11: Sample 64082383 dilution 1:10

Visual Interpretation

Sample	Sienna IgM	Sienna IgG	Biohit IgM	Biohit IgG
64082836	+	+++	++++	++++
64082836 1:1	+	+++	++++	++++
64082836 1:2	+	++	++++	++++
64082836 1:10	+	++	++++	++++
64082836 1:20	+	+	+++	+++
64082836 1:40	+/-	+	++	++
64082836 1:80	-	+/-	++	++
64082836 1:160	-	-	+	+
64082836 1:320	--	-	-	+/-
64082383	+	+/-	+	++
64082383 1:1	+	-	+	+
64082383 1:4	-	-	-	+
64082383 1:10	-	-	-	+/-

Sensitivity

Biohit test is having roughly 4 times better sensitivity with IgG antibodies. Concerning IgM difference is not that big. Biohit is only 2 times more sensitive. Sienna test was barely IgG positive with sample 6408283 although YHLO gave result 47,38 (YHLO has a cut of level for IgG 0,3).

Readability

Biohit test is really easy to read. All lines are dark and very intense. Biohit has clear concentration dependence with both IgG and IgM measurement. Biohit test has plenty of conjugate and because of that it will take while to clear the background.

Sienna test is having good intensity with IgG test line until the cut of level. IgG test line is clearly having concentration dependence. Both IgM and control lines are having really low intensity. In some cassettes control line is so faint that those should be judged as invalid test. With IgM there is no concentration dependence. If IgM is positive it is having always same faint intensity. Conjugate is moving mainly through edges of the test strip. Because of that in some cassettes diluent cannot clear the background and those cassettes have reddish one side.

May 25th, 2020



Mika Saramäki

CEO

Anidiagnostics Oy

Valtatie 26, 03600 Karkkila

Finland

Tel. +358 40 7340 793

Email: mika.saramaki@anidiagnostics.fi