

Performance summary of the PCL COVID19 IgG/IgM Rapid Gold (COV03)

	Summary													
Analytical Sensitivity	Limit of Detection IgG: 1:20,000 for positive specimen IgM: 1:10,000 for positive specimen													
Analytical Specificity	Cross-reactivity No cross-reaction between IgG and IgM. None of the viruses listed below showed cross reactivity in the assay. Influenza A, Influenza B, Respiratory syncytial virus, Parainfluenza and Adenovirus, hepatitis B virus and hepatitis C virus Interference None of the substances listed below showed interference in the assay. Hemoglobin (12 mg/ml), Bilirubin (24 mg/dL), Triglycerides (30 mg/ml), Cholesterol (20 mg/ml), Rheumatoid factor (8													
Precision	IU/ml), EDTA (2.5 mg/ml), Sodium citrate (10 mg/ml), Heparin sodium (1 mg/ml) In order to assure the reproducibility of the PCL COVID19 IgG/IgM Rapid Gold, the reproducibility between the lots, the operators, and the laboratories were evaluated. All of the test delivered the same results for all reference panels tested affirming reproducibility of the product.													
	Clinical performance was evaluated in three different institutions in comparison with RT-PCR positive cases. For IgM on clinical sensitivity is 65.61% and specificity is 99.91%. For IgG only, clinical sensitivity is 72.49% and clinical specificity is 99.35%. For the sample with IgM or IgG positives, clinical sensitivity is 80.95% and specificity is 99.35%.													
					M			_	G			IgM,		
	CO	V03		PCR	PPA	PNA		PCR	PPA	PNA	RT-I		PPA	PNA
		D	Pos	Neg	(%)	(%)	Pos	Neg	(%)	(%)	Pos	Neg	(%)	(%)
	C:1-1	Pos	10	0	90.91	100	9	0	81.82	100	10	0	90.91	100
	Site1	Neg	1	81			2	81			2	81		
		Total	11	81			11	81			11	81		
	Site2	Pos	50	0	68.49	100	64	2	87.67	98.67	64	2	87.67	98.67
		Neg	23	150			9	148			9	148		
		Total	73	150			73	150			73	150		
	Site3	Pos	64	1	60.95	99.88	64	5	60.95	99.41	79	5	75.04	99.42
		Neg	41	849			41	845			26	845	75.24	
		Total	105	850			105	850			105	850		
	ll <u> </u>	Pos	124	1	65.61	99.91	137	7	72.49	99.35	153	7	80.95	99.35
	11			1 1000			52	1074			37	1074		
	Total	Neg	65	1080							189	1001		
Clinical	Clinical p	Neg Total performa	189 nce after	1081 serocon	-	-			-		ted in thi			
	Clinical processing comparists after symmetric	Neg Total Derforma son with I nptom or 6 and clir ty is 99.35	189 nce after RT-PCR po diagnosis nical spec 5%.	1081 serocon ositive cas s). For IgN ificity is S	ses. This t 1 only, cli 9.35%. F	ime we on ical sense or the sa	after RT-F only used sitivity is a mple wit	CR confi seroconv 70.59 % a h IgM or	erted san nd specifi IgG posit	nples (ave city is 99 ives, clin	ted in thierage sero .91%. For	ree differ oconversi IgG only, tivity is 9 IgM,	ion days i clinical s 0.76% an	s 10 da ensitiv nd clini
	Clinical processing comparists after symmetric	Neg Total Derforma son with Inptom or and clir	189 nce after RT-PCR po diagnosis nical spec 5%.	1081 r serocom ositive cas s). For IgN ificity is 9 Ig	ses. This to the ses. This to the ses. This to the ses. T	ime we on ical sensor the sa	ofter RT-F only used sitivity is 7 mple wit RT-	CR confi seroconv 70.59 % a h IgM or Ig PCR	erted san nd specifi IgG posit G PPA	nples (ave icity is 99 ives, clini PNA	ted in thi erage sero .91%. For cal Sensi	ree differ oconversi IgG only, tivity is 9 IgM PCR	ion days i clinical s 0.76% an /IgG PPA	s 10 d ensitiv d clin
	Clinical processing comparists after symmetric	Neg Total Derforma son with Inptom or 6 and clir ty is 99.35	189 nce after RT-PCR podiagnosis nical speces 5%. RT- Pos	serocomositive cases). For IgN	ses. This t 1 only, cli 9.35%. F	ime we on ical sense or the sa	ofter RT-F only used sitivity is 7 mple wit RT- Pos	CR confi seroconv 70.59 % a h IgM or Ig PCR Neg	erted san nd specifi IgG posit	nples (ave city is 99 ives, clin	ted in thi erage sero .91%. For cal Sensi RT-I Pos	ree differ oconversi IgG only, tivity is 9 IgM, PCR Neg	ion days i clinical s 0.76% an	s 10 d ensiti id clin PN/
Clinical erformance	Clinical p comparis after sym is 87.39% Specificit	Neg Total Derforma son with Inptom or 6 and clir ty is 99.35	189 nce after RT-PCR pe diagnosis nical spec 5%. RT- Pos 10	1081 serocon ositive cas s). For IgN ificity is 9 PCR Neg 0	ses. This to the ses. This to the ses. This to the ses. This to the ses. Th	or the sa	ofter RT-F only used sitivity is a mple wit RT- Pos 9	CR confi seroconv 70.59 % a h IgM or Ig PCR Neg 0	erted san nd specifi IgG posit G PPA (%)	nples (ave city is 99 ives, clini PNA (%)	ted in thi erage serv .91%. For cal Sensi RT-I Pos 10	ree differ oconversi IgG only, tivity is 9 IgM, PCR Neg 0	ion days i clinical s 0.76% an /IgG PPA (%)	s 10 d ensiti d clin PN/ (%)
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