

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

	Summary																																																																																																																																																												
Analytical Sensitivity	Limit of Detection <ul style="list-style-type: none">IgG: 1:20,000 for positive specimenIgM: 1:10,000 for positive specimen																																																																																																																																																												
Analytical Specificity	Cross-reactivity <ul style="list-style-type: none">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 <ul style="list-style-type: none">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 (80 IU/ml), EDTA (2.5 mg/ml), Sodium citrate (10 mg/ml), Heparin sodium (1 mg/ml)																																																																																																																																																												
Precision	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	Clinical performance was evaluated in three different institutions in comparison with RT-PCR positive cases. For IgM only, 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%.																																																																																																																																																												
	<table><tr><th colspan="2" rowspan="3">COV03</th><th colspan="4">IgM</th><th colspan="4">IgG</th><th colspan="4">IgM/IgG</th></tr><tr><th colspan="2">RT-PCR</th><th rowspan="2">PPA (%)</th><th rowspan="2">PNA (%)</th><th colspan="2">RT-PCR</th><th rowspan="2">PPA (%)</th><th rowspan="2">PNA (%)</th><th colspan="2">RT-PCR</th><th rowspan="2">PPA (%)</th><th rowspan="2">PNA (%)</th></tr><tr><th>Pos</th><th>Neg</th><th>Pos</th><th>Neg</th><th>Pos</th><th>Neg</th></tr><tr><td rowspan="3">Site1</td><td>Pos</td><td>10</td><td>0</td><td rowspan="3">90.91</td><td rowspan="3">100</td><td>9</td><td>0</td><td rowspan="3">81.82</td><td rowspan="3">100</td><td>10</td><td>0</td><td rowspan="3">90.91</td><td rowspan="3">100</td></tr><tr><td>Neg</td><td>1</td><td>81</td><td>2</td><td>81</td><td>2</td><td>81</td></tr><tr><td>Total</td><td>11</td><td>81</td><td>11</td><td>81</td><td>11</td><td>81</td></tr><tr><td rowspan="3">Site2</td><td>Pos</td><td>50</td><td>0</td><td rowspan="3">68.49</td><td rowspan="3">100</td><td>64</td><td>2</td><td rowspan="3">87.67</td><td rowspan="3">98.67</td><td>64</td><td>2</td><td rowspan="3">87.67</td><td rowspan="3">98.67</td></tr><tr><td>Neg</td><td>23</td><td>150</td><td>9</td><td>148</td><td>9</td><td>148</td></tr><tr><td>Total</td><td>73</td><td>150</td><td>73</td><td>150</td><td>73</td><td>150</td></tr><tr><td rowspan="3">Site3</td><td>Pos</td><td>64</td><td>1</td><td rowspan="3">60.95</td><td rowspan="3">99.88</td><td>64</td><td>5</td><td rowspan="3">60.95</td><td rowspan="3">99.41</td><td>79</td><td>5</td><td rowspan="3">75.24</td><td rowspan="3">99.41</td></tr><tr><td>Neg</td><td>41</td><td>849</td><td>41</td><td>845</td><td>26</td><td>845</td></tr><tr><td>Total</td><td>105</td><td>850</td><td>105</td><td>850</td><td>105</td><td>850</td></tr><tr><td rowspan="3">Total</td><td>Pos</td><td>124</td><td>1</td><td rowspan="3">65.61</td><td rowspan="3">99.91</td><td>137</td><td>7</td><td rowspan="3">72.49</td><td rowspan="3">99.35</td><td>153</td><td>7</td><td rowspan="3">80.95</td><td rowspan="3">99.35</td></tr><tr><td>Neg</td><td>65</td><td>1080</td><td>52</td><td>1074</td><td>37</td><td>1074</td></tr><tr><td>Total</td><td>189</td><td>1081</td><td>189</td><td>1081</td><td>189</td><td>1081</td></tr></table>													COV03		IgM				IgG				IgM/IgG				RT-PCR		PPA (%)	PNA (%)	RT-PCR		PPA (%)	PNA (%)	RT-PCR		PPA (%)	PNA (%)	Pos	Neg	Pos	Neg	Pos	Neg	Site1	Pos	10	0	90.91	100	9	0	81.82	100	10	0	90.91	100	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	75.24	99.41	Neg	41	849	41	845	26	845	Total	105	850	105	850	105	850	Total	Pos	124	1	65.61	99.91	137	7	72.49	99.35	153	7	80.95	99.35	Neg	65	1080	52	1074	37	1074	Total	189	1081	189	1081	189	1081
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	Clinical performance after seroconversion (10 days after RT-PCR confirmed) was evaluated in three different institutions in comparison with RT-PCR positive cases. This time we only used seroconverted samples (average seroconversion days is 10 days after symptom or diagnosis). For IgM only, clinical sensitivity is 70.59 % and specificity is 99.91%. For IgG only, clinical sensitivity is 87.39% and clinical specificity is 99.35%. For the sample with IgM or IgG positives, clinical Sensitivity is 90.76% and clinical Specificity is 99.35%.																																																																																																																																																												
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Shelf-life Stability	For the shelf-life stability of the PCL COVID19 IgG/IgM Rapid Gold, accelerated aging test was performed using 3 lots. If stored and handled as directed, the products are stable for up to 758 days and we guarantee the shelf-life as for 2 years based on the test results.																																																																																																																																																												