


Summarized results of **CoVID-19 dtect-RT-qPCR Test** validation according with the guidelines of the UNE/EN ISO/IEC 17025:2005 and ISO/IEC 15189:2012, and acceptance criteria adopted.

Term of validation	Obtained values	Acceptance criteria	Result
<b>Specificity</b>	<b>Positive:</b> SARS-CoV-2 isolate Australia/VIC01/2020 (GenBank No.: MT007544.1) and isolate Wuhan-Hu-1 (GenBank No.: MN908947.3)	<b>Inclusiveness:</b> Positive for both SARS-CoV-2 strains	<b>ACCEPTED</b>
	<b>Negative:</b> 39 negative specimens from ISCI, previously characterized by reference protocol [12]	<b>Exclusiveness:</b> Negative for all negative specimens,	<b>ACCEPTED</b>
<b>Standard curve</b>	$Y = -3.534 \cdot m + 37.534$ $a = -3.534$ $R^2 = 0.9986$	$-3.587 < a < -3.103$	<b>ACCEPTED</b>
	$F_{\text{assay}} = 0.014$ $F_{\text{fisher}} = 5.318$	$F_{\text{assay}} < F_{\text{fisher}}$	<b>ACCEPTED</b>
	Efficiency (e) = 93.1 %	$90 \% < e < 110\%$	<b>VALIDATED</b>
<b>Reliability</b>	<b>Repeatability</b>		
	Conc.	CV (%)	
	10 <sup>6</sup> copies	1.18	
	10 <sup>5</sup> copies	1.08	
	10 <sup>4</sup> copies	0.68	CV < 10%
	10 <sup>3</sup> copies	0.53	
	10 <sup>2</sup> copies	0.54	
	10 copies	1.31	
	<b>Reproducibility</b>		
Conc.	CV (%)		
10 <sup>6</sup> copies	1.13		
10 <sup>5</sup> copies	0.91		
10 <sup>4</sup> copies	0.93	CV < 10%	
10 <sup>3</sup> copies	0.59		
10 <sup>2</sup> copies	0.66		
10 copies	1.83		
		<b>REPRODUCIBLE</b>	
<b>Limit of Detection (LOD)*</b>	10 copies	Positive = 15/15 (100%)	Positives ≥ 90 % <b>ACCEPTED</b>
<b>Limit of Quantification (LOQ)*</b>	10 copies	$t_{\text{value}} = 0.582$ $t_{\text{student}} = 2.145$	$t_{\text{value}} < t_{\text{student}}$ <b>ACCEPTED</b>
<b>Diagnostic Validation</b>	Diagnostic Specificity: 100% Diagnostic Sensitivity: 100% Diagnostic Efficiency: 100%	≥ 90 %	<b>ACCEPTED</b>

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