

### CovClear COVID-19 Rapid Antigen Test – Canada PCR Comparison

The CovClear COVID-19 Rapid Antigen test was compared against a high-sensitivity RT-PCR test in an over-the-counter trial. At the request of HealthCanada, Empowered Diagnostics sought the one of the highest-sensitivity comparators available to conduct a rigorous assessment of CovClear’s performance.

Not all RT-PCR tests are equally sensitive. The US FDA conducted a reference panel to assess the sensitivity, based on limit of detection, of authorized RT-PCR tests. The limit of detection represents the smallest amount of viral material that can be detected by the test, where a lower limit of detection indicates a more sensitive test. The Viracor Eurofins RT-PCR test was found to be one of the two most sensitive RT-PCR tests on the FDA’s reference panel.<sup>1</sup>

In an over-the-counter trial, CovClear was compared to the Viracor Eurofin RT-PCR test. 477 subjects were tested, including 360 asymptomatic subjects. CovClear tests were self-administered, while RT-PCR tests were administered by a healthcare provider. The study demonstrated a 96% sensitivity (Positive Percent Agreement) and 100% specificity (Negative Percent Agreement). CovClear matched RT-PCR results in 474 out of 477 subjects.

CovClear™ COVID-19 Antigen	Comparator (RT-PCR)		
	Positive	Negative	Total
Positive	63	0	63
Negative	3	411	414
Total	66	411	477
Positive Percent Agreement (PPA)	95.5% (95% CI:88.4%-98.7%)		
Negative Percent Agreement (NPA)	100% (95%CI:99.4%-100%)		

Cycle threshold (Ct) values are commonly used to estimate the amount of viral material in a sample. A Ct value is inversely related to the volume or viral material, where a higher Ct value indicates a relatively lower presence of virus. In the same trial, CovClear demonstrated 100% agreement among subjects with Ct values under 33.

	PCR Positive	CovClear Positive	Agreement
Ct < 20	18	18	100%
20 < Ct < 25	10	10	100%
25 < Ct < 30	22	22	100%
30 < Ct < 33	5	5	100%
33 < Ct < 36.8	11	8	72.7%



RT-PCR is useful when 100% accuracy is needed – for example, when determining medical treatment options in a clinical setting. CovClear’s performance against Viracor Eurofins – one of the most sensitive RT-PCR tests available – indicates that CovClear can be a cost-effective alternative to RT-PCR testing in many scenarios where ease of use and rapid results are top priority.

References:

[1] <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data>