EIKEN CHEMICAL CO.,LTD.

Loopamp™ SARS-CoV-2 Detection Kit - Performance Data

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Specimens from the National Institute of Infectious Diseases (Japan), 10 positive and 15 negative samples, processed according to “Manual for the Detection of Pathogen 2019-nCoV Ver.2.6 (National Institute of Infectious Diseases), February 17, 2020” were measured by turbidity detection using Real-Time Turbidimeter LA-500 and visual fluorescence detection.

Positive samples were positive in 9 out of 10 samples. All 15 negative samples were negative. A 90% (9/10) positive agreement, a 100% (15/15) negative agreement, and a 96% (24/25) overall agreement were obtained for the infection laboratory PCR assay. One sample that tested positive by the Infectious Research Institute for PCR and negative by the product had concentrations below the detection limit of the product.

The reagent was found to be as detectable as PCR testing by the Infectious Laboratory with a short reaction time of 35 minutes.

The results of real-time turbidimetry and fluoroscopic detection were 100% in agreement. (in-house data)

		Products (LAMP)		
		Positive	Negative	Total
Reference product (PCR assay)	Positive	9	1	10
	Negative	0	15	15
	Total	9	16	25

(In-house data)

Extraction: QIAamp Viral RNA Mini Kit

19 SARS-CoV-2 negative confirmed saliva samples collected from healthy volunteers were divided into 2 sample groups, concretely 10 SARS-CoV-2 spiked saliva samples and 19 SARS-CoV-2 negative saliva samples. Positive samples were prepared at the concentrations described in "Evaluation of performance of genetic testing for new coronavirus (2019-nCoV)” at National Institute of Infectious Diseases (https://www.niid.go.jp/niid/ja/diseases/ka/corona-virus/2019-ncov/9482-covid14-15.html) were measured similarly by turbidity detection using Real-Time Turbidimeter LA-500 and visual fluorescent detection. The results showed that the positive concordance rate was 90% (9/10), the negative concordance rate was 100% (19/19), and the overall concordance rate was 97% (28/29) for both turbidity detection and visual detection. The negative samples were below the detection limit of the product. (in-house data)

	Number of studies	Number of positives
Positive samples	10	9
Negative samples	19	0

(In-house data)

Extraction: QIAamp Viral RNA Mini Kit