



# Loopamp™



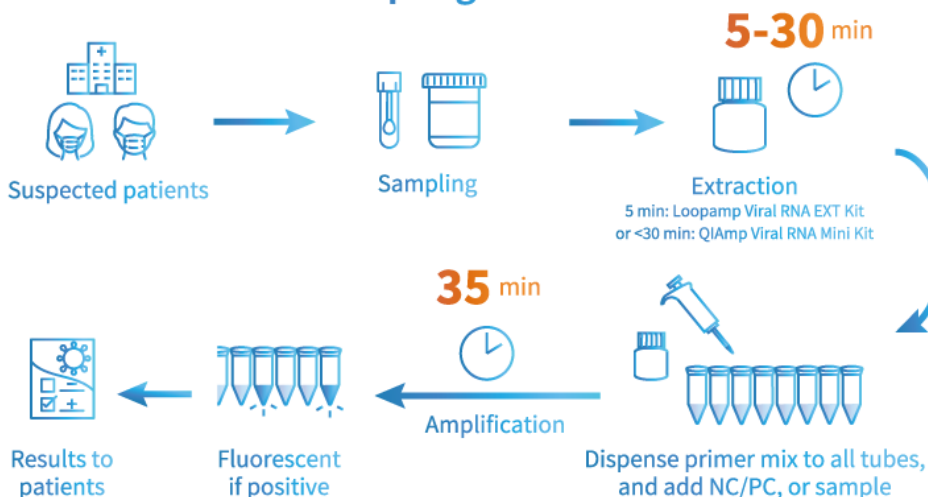
LAMP (Loop-mediated Isothermal Amplification) method

## Loopamp™ SARS-CoV-2 Detection Kit



- Detect SARS-CoV-2 using RT-LAMP reaction
- Ready to use dried reagent and primer set
- Simple operation and result in approximately 60 min.
- Visual fluorescence detection available

### Sampling to result



#### **[Attention]**

1. SARS-CoV-2 infection can not be denied even if negative result observed by this product..
2. Diagnosis should be determined by the latest case definition and clinical symptoms released by the authority.
3. Take appropriate biohazard precautions and be careful of infection during specimen collection and operation.  
Please refer to the latest safety management manual released by WHO.

## Components

Dried RNA Amplification Reagent (dRMR)	48 tubes × 1
Primer Mix. 2019-nCoV (PM nCV19)	0.72 mL × 1
Positive Control 2019-nCoV (PC nCV19)	0.16 mL × 1
Negative Control (NC)	0.16 mL × 1

※ Virus RNA Extraction reagent is NOT INCLUDED in this kit  
 1) Loopamp™ Viral RNA Extraction Kit (EIKEN)  
 2) QIAamp Viral RNA Mini Kit (QIAGEN)

### (Optional)

#### Loopamp™ Viral RNA Extraction Kit

A designated extraction reagent can easily extract SARS-CoV-2 virus from Throat, Nasopharyngeal Swab and Saliva

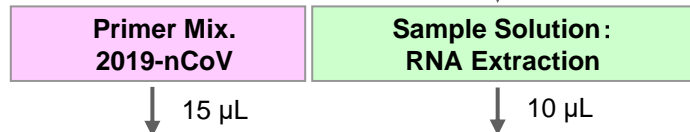
Code: LMC801 (48 tests)  
 Contents: 4ml x 48 vials  
 Storage: Room temperature  
 Shelf Life : 18 months



Designated use for Loopamp™ SARS-CoV-2 Detection Kit

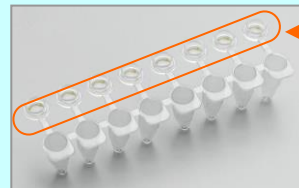
## Operation Manual

### Extract RNA from specimen



#### 【Operation on ice】

- Dispense **Primer Mix. 2019-nCoV** into reaction tube
- Dispense Sample solution or Control



Dried RNA Amplification Reagent is fixed on inner side of the lid.

- After closing caps of reaction tubes, invert reaction tubes to collect solution in lids. Leave tubes standing upside down **on ice for 2 minutes**.
- Mix solution by inversion of tubes and then spin down tubes.

Set the reaction tubes into a turbidimeter or incubator

**RT-LAMP Reaction**  
**62.5°C for 35min.**

Result

※ For result by fluorescent visual detection, please see more details from instruction.

## Performance Data with Loopamp™ Viral RNA Extraction Kit

Spiked samples: Dispense 24, 100, 240 virus genome copies into nasopharyngeal swab or throat swab collected from healthy volunteers, and analyse all samples after being treated with Loopamp™ Viral RNA Extraction Kit.

Virus Genome Copies /Reaction	Loopamp™ SARS-CoV-2 Detection Kit	
	Throat Swab (Pos. / Tests)	Nasopharyngeal Swab (Pos. / Tests)
240	10/10	10/10
100	10/10	10/10
24	9/10	6/10
0	0/10	0/10

(In house data)

Suspected positive specimen with 100 & 240 virus copies, were determined positive.

Evaluation of 2019-nCoV Genome diagnostic methods published by NIID, defines that LOD less than 100 virus copies is ACCEPTABLE when the reaction time is between 15 to 60 minutes..

Our results meet the criteria above, thus Loopamp™ SARS-CoV-2 Detection Kit using Loopamp™ Viral RNA Extraction Kit can be applied to detection of SARS-CoV-2.

## Product information

Product Name	Contents	Storage	Shelf Life	Code
Loopamp™ SARS-CoV-2 Detection Kit	48 tests	2~8°C	12 months	LMC403

Please see Eiken GENOME SITE: <http://loopamp.eiken.co.jp/e> for further information about LAMP method.  
 Please read the instructions for use carefully before using these products.



Eiken Corporate Website  
<https://www.eiken.co.jp/en/products/lamp/covid19test/>



EIKEN CHEMICAL CO.,LTD.



8197 AMK

October 2020