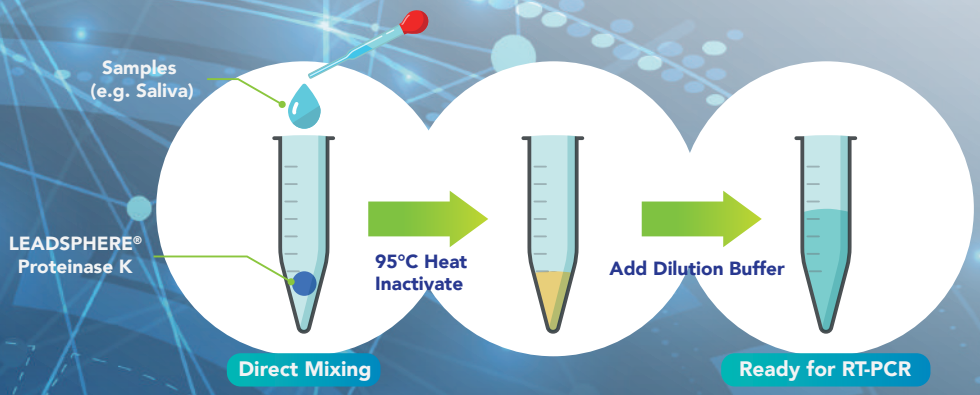
LEADGENE
LEADGENE BIOMEDICAL, INC.

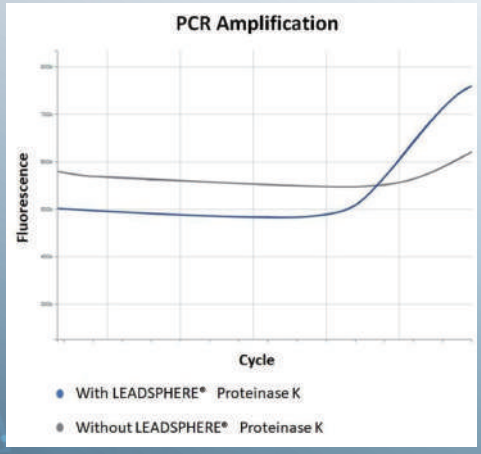
LEADSPHERE® Proteinase K

LEADSPHERE® Proteinase K is provided in a lyophilized sphere format with multiple critical advantages for developing diagnostics assay tools:

- Facilitation of long-term logistics at room temperature.
- Ease in aliquoting and handling during the manufacturing process.
- Simplified point-of-care protocol for end-users

LEADSPHERE® Proteinase K formulation is fine-tuned for direct mixing with and digestion of saliva. A simple protocol is illustrated below.

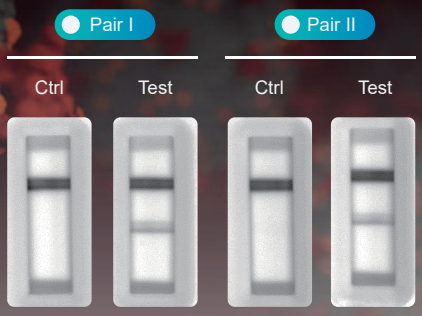




LEADSPHERE® Proteinase K is generated with ISO13485 quality management system and is used specifically for medical devices. Furthermore, it has been widely used in combination with RT-PCR technology.

LEADGENE
LEADGENE BIOMEDICAL, INC.

Antibody Pairs for Omicron Detection



- ✓ Exceptional Sensitivity / Specificity
- ✓ Monoclonal Antibodies
- ✓ Quality Consistency
- ✓ Secured Supply
- ✓ ISO13485 / QMS

COVID-19 rapid antigen tests are found to be less sensitive for the Omicron variant compared to the earlier circulating virus variants (1), necessitating a reassessment of the diagnostic performance of current EUA-approved test devices (2). To ensure tests continue to perform as intended, Leadgene conducted a comprehensive epitope binning study and identified the next-generation of COVID-19's antibody pairs (Table 1).

Antibody Pair	Product Name	Cat. No.
● Pair I	Anti-SARS-CoV-2 NP Antibody [Clone 74-2]	14950
	Anti-SARS-CoV & CoV-2 NP Antibody (Rec mAb)	17900
● Pair II	Anti-SARS-CoV & CoV-2 NP Antibody [Clone 102-7]	18700
	Anti-SARS-CoV & CoV-2 NP Antibody (Rec mAb)	17900

● **Table 1. Anti-SARS-CoV-2 nucleocapsid (NP) antibody pairs for detection of Omicron.** Identified by comprehensive screening, these pairs have been successfully used to develop lateral-flow-based rapid test devices for the Omicron variant (BA.4/BA.5).

Lateral flow assays using these next-generation antibody pairs exhibit outstanding results for the detection towards the inactivated virus of Omicron, with the sensitivity of >95% in samples with a Ct value of less than 27 found in PCR tests. The limit of detection for nucleocapsid protein was reported at a range of 25~100 pg/mL.

References:
1. Microbiol Spectr. 2022 Aug 31;10(4):e0085322.
2. FDA, Medical Devices 09/14/2022

TEL : +886-6-2536677 (Headquarter) +886-2-27065528 (Taipei Office) E-MAIL : info@leadgene.com.tw