

November 29, 2021

[Notice] Notification of Omicron variants detection

To WHOM IT MAY CONCERN,

As COVID-19 continues to impact the global community, Seegene wants to update you on the steps we have taken to ensure business continuity for our customers.

We have confirmed the detectability of Allplex™ assays with respect to the Omicron variant, B.1.1.529 of SARS-CoV-2, which has emerged in South Africa.

1. Seegene's one-step solution to Omicron variant

With the Allplex™ SARS-CoV-2 Master Assay, SARS-CoV-2 screening and Omicron variant monitoring can be performed simultaneously with a single test.

Allplex™ SARS-CoV-2 Master Assay targets RdRP, S, E, N gene and all gene can be detected. In in-silico analysis of 66 of Omicron genome sequence (GISAID database, November 26), detectable percentages are as follows:

| Seegene Assay | Detectable Percentage (%) | | | |
|---|---------------------------|-----------|--------|--------|
| | E gene | RdRP gene | S gene | N gene |
| Allplex™ SARS-CoV-2 Master Assay (Cat# RV10285Y/10284X) | 100.0 | 100.0 | 100.0 | 100.0 |

Allplex™ SARS-CoV-2 Master Assay can detect S variants (HV69/70del, N501Y and P681H) out of 34 mutations possessed by Omicron variant. The expected results of the assay on Omicron variant are shown below.

| Seegene Assay | Target | | | | |
|---|--------|---------|--------|-----|-------------|
| | E | Endo IC | RdRP/S | N | S variants* |
| Allplex™ SARS-CoV-2 Master Assay (Cat# RV10285Y/10284X) | POS | POS | POS | POS | POS |

* HV69/70 deletion, Y144 deletion, E484K, N501Y, P681H

2. Seegene's SARS-CoV-2 screening solution

The list of Seegene's SARS-CoV-2 screening products that can detect Omicron variant is as follows;

- 1) Allplex™ 2019-nCoV Assay
- 2) Allplex™ SARS-CoV-2 Assay
- 3) Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay

In in-silico analysis of 66 of Omicron genome sequence (GISAID database, November 26), detectable percentages are as follows:

| Seegene Assay | Detectable Percentage (%) | | | |
|--|---------------------------|-----------|------------|--------|
| | E gene | RdRP gene | S gene | N gene |
| Allplex™ 2019-nCoV Assay (Cat# RP10244Y/10243X) | 100.0 | 100.0 | Non-target | 100.0 |
| Allplex™ SARS-CoV-2 Assay (Cat# RV10247T/10248X) | 100.0 | 100.0 | | 100.0 |
| Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay (Cat# RV10260Y/10259X) | Non-target | 100.0 | 100.0 | 85.7* |

* Due to limited sequence number; coverage information to be updated.

3. Seegene's SARS-CoV-2 variants solution

The list of Seegene's SARS-CoV-2 variants products that can detect Omicron variant is as follows;

- 1) Allplex™ SARS-CoV-2 Variants I Assay
- 2) Allplex™ SARS-CoV-2 Variants II Assay

The expected results of the assays on Omicron variant are shown below.

| Seegene Assay | Allplex™ SARS-CoV-2 Variants I Assay (Cat# RV10287Y/10286X) | | | Allplex™ SARS-CoV-2 Variants II Assay (Cat# RV10306Y/10305X) | | | | Predicted Results |
|---------------------|---|-------|--------------|--|-------|--------------|-------|---------------------------------|
| | HV69/70del | E484K | N501Y | W152C | L452R | K417N | K417T | |
| Omicron (B.1.1.529) | POS | - | POS | - | - | POS | - | HV69/70del, N501Y, K417N |

For more detailed information about this update, please contact your regional manager.



Won-Jun Oh
 Director of Product Marketing Group,
 Seegene Inc.