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Letter of confirmation

Date: 24th May 2021

To whom it may concern

Recently SARS-CoV-2 variant with multiple spike protein mutations has been observed in the United Kingdom, South Africa, Brazil and India.

According to WHO, the new strain of SARS-CoV-2 was found to affect the performance of some diagnostic assays with an S gene target.

Using the gene sequence published through GISAID [1] and the strain sequence used in the development stage, GCMS R&D team internally analyzed the reactivity of the GENEDIA W COVID-19 and the new strains of SARS-CoV-2 (VOC-202012/01, 501.V2, Lineage P.1, and Lineage B.1.617) through in-silico analysis.

1.1 Methods

The antigen used in the development of this product is ATCC VR-1986HK(NCBI Accession No: MN985325.1) and sequence alignment was performed based on this sequence.

Four SARS-CoV-2 variants sequence are obtained via GISAID.

Sequence of lineage B.1.1.7(GISAID accession ID: EPI_ISL_601443, British variant) and lineage B.1.351(GISAID accession ID: EPI_ISL_678597, South African variant) and lineage P.1(GISAID accession ID: EPI_ISL_792680, Brazil variant) and lineage B.1.617(GISAID accession ID: EPI_ISL_1595896, India variant) are analyze with corresponding sequence(MN985325.1).

The sequence analysis was performed in two ways, entire sequence alignment and nucleocapsid protein sequence alignment (28,274-29,533 bp).

The study was conducted in-silico analysis using the basic local alignment search tool (BLAST) function of NCBI webpage [2]. The BLAST is an algorithm and program for comparing primary biological sequence information. This program search enables a researcher to compare a subject sequence with an object sequence, and calculate similarity.

<https://blast.ncbi.nlm.nih.gov/>

1.2 Information of sequence

| Source | Sequence information | Accession No | Division |
|--------|--|----------------|-----------------------|
| NCBI | SARS-CoV-2/human/USA/WA-CDC-WA1/2020 | MN985325.1 | Reference material |
| GISAID | hCoV-19/England/MILK-9E05B3/2020 | EPI_ISL_601443 | British variant |
| GISAID | hCoV-19/South Africa/KRISP-EC-K005299/2020 | EPI_ISL_678597 | South African variant |

| | | | |
|--------|------------------------------------|-----------------|----------------|
| GISAID | hCoV-19/Japan/IC-0561/2021* | EPI_ISL_792680 | Brazil variant |
| GISAID | hCoV-19/India/KA-NIMH-SEQ-280/2021 | EPI_ISL_1595896 | India variant |

* Airport Quarantine Station in Japan. COVID-19 positive case who entered from Brazil.

1.3 Results

| Sequence | Accession No | Range | Similarity | Result |
|--|---|----------------------|------------|------------|
| Lineage B.1.1.7 (British variant) | GISAID accession ID: EPI_ISL_601443 | Whole sequence | 99.83 % | Conformity |
| | | Nucleocapsid protein | 99.66 % | |
| Lineage B.1.351 (South African variant) | GISAID accession ID: EPI_ISL_678597 | Whole sequence | 99.86 % | Conformity |
| | | Nucleocapsid protein | 99.92 % | |
| Lineage P.1 (Brazil variant) | GISAID accession ID: EPI_ISL_792680 | Whole sequence | 99.84 % | Conformity |
| | | Nucleocapsid protein | 99.49 % | |
| Lineage B.1.617 (India variant) | GISAID accession ID: EPI_ISL_1595896 | Whole sequence | 99.87 % | Conformity |
| | | Nucleocapsid protein | 99.75 % | |

As a result of in-silico analysis using the above two tools, GENEDIA W COVID-19 Ag are expected to have almost the same nucleocapsid protein reactivity against British, South African, Brazil and India strains as the USA/WA/01 strain used as a standard material.

However, the above prediction based on data analysis, therefore it cannot be assured of its applicability. So, the appropriate test for new strain of SARS-CoV-2 is necessary to conduct.

Sincerely,

Jin-woo Jeon

Jin-Woo Jeon

Leader of Immuno-diagnostics team, R&D center

Reference.

- [1]. GISAID.org
- [2]. Blast.ncbi.nlm.nih.gov

Raw data

| Sequence | Lineage B.1.1.7 (British variant) GISAID accession ID: EPI_ISL_601443 | Range | Whole sequence | | | | | | | | | | | | | | | | | | |
|--|---|--|----------------|------------------|-----------------|----------------|--|--|--|--|---------|-----------|--|--|-------|-------|-----|-----|--------|-------|-------------|
| Job Title MN985325.1 Severe acute respiratory syndrome RID 4EF3JP9N114 <small>Search expires on 03-10 16:14 pm</small> Download All ▼ Program Blast 2 sequences Citation ▼ Query ID Icl Query_43237 (dna) Query Descr MN985325.1 Severe acute respiratory syndrome coronavir ... Query Length 29882 Subject ID Icl Query_43239 (dna) Subject Descr hCoV-19/England/MILK-9E05B3/2020 EPI_ISL_601443 2020-09-20 ... Subject 29764 Length Other reports MSA viewer ? | <div style="border: 1px solid #ccc; padding: 5px;"> Filter Results <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Percent Identity</td> <td style="width: 33%;">E value</td> <td style="width: 33%;">Query Coverage</td> </tr> <tr> <td><input type="text"/> to <input type="text"/></td> <td><input type="text"/> to <input type="text"/></td> <td><input type="text"/> to <input type="text"/></td> </tr> <tr> <td colspan="3" style="text-align: right;"> <input type="button" value="Filter"/> <input type="button" value="Reset"/> </td> </tr> </table> </div> | | | Percent Identity | E value | Query Coverage | <input type="text"/> to <input type="text"/> | <input type="text"/> to <input type="text"/> | <input type="text"/> to <input type="text"/> | <input type="button" value="Filter"/> <input type="button" value="Reset"/> | | | | | | | | | | | |
| Percent Identity | E value | Query Coverage | | | | | | | | | | | | | | | | | | | |
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| <input type="button" value="Filter"/> <input type="button" value="Reset"/> | | | | | | | | | | | | | | | | | | | | | |
| <div style="border: 1px solid #ccc; padding: 5px; background-color: #f0f0f0;"> Descriptions Graphic Summary Alignments Dot Plot </div> | | | | | | | | | | | | | | | | | | | | | |
| <div style="border: 1px solid #ccc; padding: 5px; background-color: #e0e0e0;"> Sequences producing significant alignments Download ▼ New Select columns ▼ Show <input type="text" value="100"/> ? </div> | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> select all 1 sequences selected Graphics New MSA Viewer | | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width: 100%; border-collapse: collapse; font-size: 0.8em;"> <thead> <tr> <th style="width: 45%;">Description</th> <th style="width: 15%;">Scientific Name</th> <th style="width: 5%;">Max Score</th> <th style="width: 5%;">Total Score</th> <th style="width: 5%;">Query Cover</th> <th style="width: 5%;">E value</th> <th style="width: 5%;">Per Ident</th> <th style="width: 5%;">Acc Len</th> <th style="width: 10%;">Accession</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> hCoV-19/England/MILK-9E05B3/2020 EPI_ISL_601443 2020-09-20</td> <td></td> <td>54706</td> <td>54706</td> <td>99%</td> <td>0.0</td> <td>99.83%</td> <td>29764</td> <td>Query_43239</td> </tr> </tbody> </table> | | | | Description | Scientific Name | Max Score | Total Score | Query Cover | E value | Per Ident | Acc Len | Accession | <input checked="" type="checkbox"/> hCoV-19/England/MILK-9E05B3/2020 EPI_ISL_601443 2020-09-20 | | 54706 | 54706 | 99% | 0.0 | 99.83% | 29764 | Query_43239 |
| Description | Scientific Name | Max Score | Total Score | Query Cover | E value | Per Ident | Acc Len | Accession | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> hCoV-19/England/MILK-9E05B3/2020 EPI_ISL_601443 2020-09-20 | | 54706 | 54706 | 99% | 0.0 | 99.83% | 29764 | Query_43239 | | | | | | | | | | | | | |

| Sequence | Lineage B.1.1.7 (British variant) GISAID accession ID: EPI_ISL_601443 | Range | Nucleocapsid protein | | | | | | | | | | | | | | | | | | |
|--|---|--|----------------------|------------------|-----------------|----------------|--|--|--|--|---------|-----------|--|--|------|------|-----|-----|--------|-------|-------------|
| Job Title MN985325.1 Severe acute respiratory syndrome RID 4EF571GF114 <small>Search expires on 03-10 16:15 pm</small> Download All ▼ Program Blast 2 sequences Citation ▼ Query ID Icl Query_15485 (dna) Query Descr MN985325.1 Severe acute respiratory syndrome coronavir ... Query Length 1260 Subject ID Icl Query_15487 (dna) Subject Descr hCoV-19/England/MILK-9E05B3/2020 EPI_ISL_601443 2020-09-20 ... Subject 1259 Length Other reports MSA viewer ? | <div style="border: 1px solid #ccc; padding: 5px;"> Filter Results <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Percent Identity</td> <td style="width: 33%;">E value</td> <td style="width: 33%;">Query Coverage</td> </tr> <tr> <td><input type="text"/> to <input type="text"/></td> <td><input type="text"/> to <input type="text"/></td> <td><input type="text"/> to <input type="text"/></td> </tr> <tr> <td colspan="3" style="text-align: right;"> <input type="button" value="Filter"/> <input type="button" value="Reset"/> </td> </tr> </table> </div> | | | Percent Identity | E value | Query Coverage | <input type="text"/> to <input type="text"/> | <input type="text"/> to <input type="text"/> | <input type="text"/> to <input type="text"/> | <input type="button" value="Filter"/> <input type="button" value="Reset"/> | | | | | | | | | | | |
| Percent Identity | E value | Query Coverage | | | | | | | | | | | | | | | | | | | |
| <input type="text"/> to <input type="text"/> | <input type="text"/> to <input type="text"/> | <input type="text"/> to <input type="text"/> | | | | | | | | | | | | | | | | | | | |
| <input type="button" value="Filter"/> <input type="button" value="Reset"/> | | | | | | | | | | | | | | | | | | | | | |
| <div style="border: 1px solid #ccc; padding: 5px; background-color: #f0f0f0;"> Descriptions Graphic Summary Alignments Dot Plot </div> | | | | | | | | | | | | | | | | | | | | | |
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| <input checked="" type="checkbox"/> select all 1 sequences selected Graphics New MSA Viewer | | | | | | | | | | | | | | | | | | | | | |
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| Sequence | Lineage B.1.351 (South African variant) GISAID accession ID: EPI_ISL_678597 | Range | Whole sequence | | | | | | | | | | | | | | | | | | |
|---|---|-----------|----------------|-------------|-----------------|-----------|-------------|-------------|---------|-----------|---------|-----------|--|--|-------|-------|-----|-----|--------|-------|-------------|
| Job Title MN985325.1 Severe acute respiratory syndrome RID 4EF9BPCM114 Search expires on 03-10 16:17 pm Download All ▾ Program Blast 2 sequences Citation ▾ Query ID lc Query_30611 (dna) Query Descr MN985325.1 Severe acute respiratory syndrome coronav ... Query Length 29882 Subject ID lc Query_30613 (dna) Subject Descr hCoV-19/South Africa/KRISP-EC-K005299/2020 EPI_ISL ... Subject 29856 Length Other reports MSA viewer ? | Filter Results Percent Identity <input type="text"/> to <input type="text"/> E value <input type="text"/> to <input type="text"/> Query Coverage <input type="text"/> to <input type="text"/> <input type="button" value="Filter"/> <input type="button" value="Reset"/> | | | | | | | | | | | | | | | | | | | | |
| Descriptions Graphic Summary Alignments Dot Plot | | | | | | | | | | | | | | | | | | | | | |
| Sequences producing significant alignments Download ▾ New Select columns ▾ Show 100 ▾ ? | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> select all 1 sequences selected Graphics New MSA Viewer | | | | | | | | | | | | | | | | | | | | | |
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| Description | Scientific Name | Max Score | Total Score | Query Cover | E value | Per Ident | Acc Len | Accession | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> hCoV-19/South Africa/KRISP-EC-K005299/2020 EPI_ISL_678597 2020-11-19 | | 54824 | 54824 | 99% | 0.0 | 99.96% | 29856 | Query_30613 | | | | | | | | | | | | | |
| Job Title MN985325.1 Severe acute respiratory syndrome RID 4EF75C27114 Search expires on 03-10 16:16 pm Download All ▾ Program Blast 2 sequences Citation ▾ Query ID lc Query_20487 (dna) Query Descr MN985325.1 Severe acute respiratory syndrome coronav ... Query Length 1260 Subject ID lc Query_20489 (dna) Subject Descr hCoV-19/South Africa/KRISP-EC-K005299/2020 EPI_ISL ... Subject 1259 Length Other reports MSA viewer ? | Filter Results Percent Identity <input type="text"/> to <input type="text"/> E value <input type="text"/> to <input type="text"/> Query Coverage <input type="text"/> to <input type="text"/> <input type="button" value="Filter"/> <input type="button" value="Reset"/> | | | | | | | | | | | | | | | | | | | | |
| Descriptions Graphic Summary Alignments Dot Plot | | | | | | | | | | | | | | | | | | | | | |
| Sequences producing significant alignments Download ▾ New Select columns ▾ Show 100 ▾ ? | | | | | | | | | | | | | | | | | | | | | |
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| Description | Scientific Name | Max Score | Total Score | Query Cover | E value | Per Ident | Acc Len | Accession | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> hCoV-19/South Africa/KRISP-EC-K005299/2020 EPI_ISL_678597 2020-11-19 | | 2235 | 2235 | 96% | 0.0 | 99.92% | 29856 | Query_20489 | | | | | | | | | | | | | |
| Job Title MN985325.1 Severe acute respiratory syndrome RID 4EF75C27114 Search expires on 03-10 16:16 pm Download All ▾ Program Blast 2 sequences Citation ▾ Query ID lc Query_20487 (dna) Query Descr MN985325.1 Severe acute respiratory syndrome coronav ... Query Length 1260 Subject ID lc Query_20489 (dna) Subject Descr hCoV-19/South Africa/KRISP-EC-K005299/2020 EPI_ISL ... Subject 1259 Length Other reports MSA viewer ? | Filter Results Percent Identity <input type="text"/> to <input type="text"/> E value <input type="text"/> to <input type="text"/> Query Coverage <input type="text"/> to <input type="text"/> <input type="button" value="Filter"/> <input type="button" value="Reset"/> | | | | | | | | | | | | | | | | | | | | |
| Descriptions Graphic Summary Alignments Dot Plot | | | | | | | | | | | | | | | | | | | | | |
| Sequences producing significant alignments Download ▾ New Select columns ▾ Show 100 ▾ ? | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> select all 1 sequences selected Graphics New MSA Viewer | | | | | | | | | | | | | | | | | | | | | |
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| Description | Scientific Name | Max Score | Total Score | Query Cover | E value | Per Ident | Acc Len | Accession | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> hCoV-19/South Africa/KRISP-EC-K005299/2020 EPI_ISL_678597 2020-11-19 | | 2235 | 2235 | 96% | 0.0 | 99.92% | 29856 | Query_20489 | | | | | | | | | | | | | |

| Sequence | Lineage P.1 (Brazil variant) GISAID accession ID: EPI_ISL_792680 | Range | Whole sequence | | | | | | | | | | | | | | | | | | |
|---|---|-----------|----------------|-------------|-----------------|------------|-------------|-------------|---------|------------|----------|-----------|--|--|-------|-------|-----|-----|--------|-------|-------------|
| Job Title MN985325.1 Severe acute respiratory syndrome RID 5V3S3S2D114 <small>Search expires on 03-27 15:36 pm</small> Download All ▾ Program Blast 2 sequences Citation ▾ Query ID Icl Query_29181 (dna) Query Descr MN985325.1 Severe acute respiratory syndrome coronavi ... Query Length 29882 Subject ID Icl Query_29183 (dna) Subject Descr hCoV-19/Japan/IC-0561/2021 EPI_ISL_792680 2021-01-02 Subject Length 29733 Other reports MSA viewer ⓘ | <div style="border: 1px solid #ccc; padding: 5px;"> Filter Results Percent Identity <input type="text"/> to <input type="text"/> E value <input type="text"/> to <input type="text"/> Query Coverage <input type="text"/> to <input type="text"/> <div style="text-align: right;"> Filter Reset </div> </div> | | | | | | | | | | | | | | | | | | | | |
| <div style="background-color: #007bff; color: white; padding: 2px; display: flex; justify-content: space-between; align-items: center;"> Descriptions Graphic Summary Alignments Dot Plot </div> | | | | | | | | | | | | | | | | | | | | | |
| <div style="background-color: #e9ecef; padding: 5px; display: flex; justify-content: space-between; align-items: center;"> Sequences producing significant alignments Download ▾ New Select columns ▾ Show 100 ▾ ⓘ </div> | | | | | | | | | | | | | | | | | | | | | |
| <div style="display: flex; justify-content: space-between; align-items: center;"> <input checked="" type="checkbox"/> select all 1 sequences selected Graphics New MSA Viewer </div> | | | | | | | | | | | | | | | | | | | | | |
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| Description | Scientific Name | Max Score | Total Score | Query Cover | E value | Per. Ident | Acc. Len | Accession | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> hCoV-19/Japan/IC-0561/2021 EPI_ISL_792680 2021-01-02 | | 54645 | 54645 | 99% | 0.0 | 99.84% | 29733 | Query_29183 | | | | | | | | | | | | | |

| Sequence | Lineage P.1 (Brazil variant) GISAID accession ID: EPI_ISL_792680 | Range | Nucleocapsid protein | | | | | | | | | | | | | | | | | | |
|---|---|-----------|----------------------|-------------|-----------------|------------|-------------|-------------|---------|------------|----------|-----------|--|--|------|------|-----|-----|--------|-------|-------------|
| Job Title MN985325.1 Severe acute respiratory syndrome RID 5V430FXR114 <small>Search expires on 03-27 15:42 pm</small> Download All ▾ Program Blast 2 sequences Citation ▾ Query ID Icl Query_45279 (dna) Query Descr MN985325.1 Severe acute respiratory syndrome coronavi ... Query Length 1260 Subject ID Icl Query_45281 (dna) Subject Descr hCoV-19/Japan/IC-0561/2021 EPI_ISL_792680 2021-01-02 Subject Length 1259 Other reports MSA viewer ⓘ | <div style="border: 1px solid #ccc; padding: 5px;"> Filter Results Percent Identity <input type="text"/> to <input type="text"/> E value <input type="text"/> to <input type="text"/> Query Coverage <input type="text"/> to <input type="text"/> <div style="text-align: right;"> Filter Reset </div> </div> | | | | | | | | | | | | | | | | | | | | |
| <div style="background-color: #007bff; color: white; padding: 2px; display: flex; justify-content: space-between; align-items: center;"> Descriptions Graphic Summary Alignments Dot Plot </div> | | | | | | | | | | | | | | | | | | | | | |
| <div style="background-color: #e9ecef; padding: 5px; display: flex; justify-content: space-between; align-items: center;"> Sequences producing significant alignments Download ▾ New Select columns ▾ Show 100 ▾ ⓘ </div> | | | | | | | | | | | | | | | | | | | | | |
| <div style="display: flex; justify-content: space-between; align-items: center;"> <input checked="" type="checkbox"/> select all 1 sequences selected Graphics New MSA Viewer </div> | | | | | | | | | | | | | | | | | | | | | |
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| Description | Scientific Name | Max Score | Total Score | Query Cover | E value | Per. Ident | Acc. Len | Accession | | | | | | | | | | | | | |
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| Sequence | Lineage B.1.617 (India variant) GISAID accession ID: EPI_ISL_1595896 | Range | Whole sequence | | | | | | | | | | | | | | | | | | |
|--|---|-----------|----------------|-------------|-----------------|------------|-------------|--------------|---------|------------|----------|-----------|---|--|-------|-------|-----|-----|--------|-------|--------------|
| Job Title MN985325.1 Severe acute respiratory syndrome RID 7THCU7Y611N Search expires on 04-20 07:49 am Download All <input type="checkbox"/> Program Blast 2 sequences Citation <input type="checkbox"/> Query ID Icl Query_393529 (dna) Query Descr MN985325.1 Severe acute respiratory syndrome coronavir ... Query Length 29882 Subject ID Icl Query_393531 (dna) Subject Descr hCoV-19/India/KA-NIMH-SEQ-280/2021 EPI_ISL_1595896 ... Subject 29865 Length Other reports MSA viewer <input type="checkbox"/> | Filter Results Percent Identity <input type="text"/> to <input type="text"/> E value <input type="text"/> to <input type="text"/> Query Coverage <input type="text"/> to <input type="text"/> <input type="button" value="Filter"/> <input type="button" value="Reset"/> | | | | | | | | | | | | | | | | | | | | |
| Descriptions Graphic Summary Alignments Dot Plot | | | | | | | | | | | | | | | | | | | | | |
| Sequences producing significant alignments Download <input type="button" value="New"/> Select columns <input type="button" value="Show"/> 100 <input type="button" value="Help"/> | | | | | | | | | | | | | | | | | | | | | |
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| Descriptions Graphic Summary Alignments Dot Plot | | | | | | | | | | | | | | | | | | | | | |
| Sequences producing significant alignments Download <input type="button" value="New"/> Select columns <input type="button" value="Show"/> 100 <input type="button" value="Help"/> | | | | | | | | | | | | | | | | | | | | | |
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| <table border="1"> <thead> <tr> <th>Description</th> <th>Scientific Name</th> <th>Max Score</th> <th>Total Score</th> <th>Query Cover</th> <th>E value</th> <th>Per. Ident</th> <th>Acc. Len</th> <th>Accession</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> hCoV-19/India/KA-NIMH-SEQ-280/2021 EPI_ISL_1595896 2021-03-19</td> <td></td> <td>2241</td> <td>2241</td> <td>96%</td> <td>0.0</td> <td>99.75%</td> <td>29865</td> <td>Query_408533</td> </tr> </tbody> </table> | | | | Description | Scientific Name | Max Score | Total Score | Query Cover | E value | Per. Ident | Acc. Len | Accession | <input checked="" type="checkbox"/> hCoV-19/India/KA-NIMH-SEQ-280/2021 EPI_ISL_1595896 2021-03-19 | | 2241 | 2241 | 96% | 0.0 | 99.75% | 29865 | Query_408533 |
| Description | Scientific Name | Max Score | Total Score | Query Cover | E value | Per. Ident | Acc. Len | Accession | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> hCoV-19/India/KA-NIMH-SEQ-280/2021 EPI_ISL_1595896 2021-03-19 | | 2241 | 2241 | 96% | 0.0 | 99.75% | 29865 | Query_408533 | | | | | | | | | | | | | |