# Analytical Evaluation Report of Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test

## 1. Purpose

The purpose of this report is to provide information regarding the analytical performance of the “Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test”.

## 2. Introduction

### 2.1 Description of qSARS-CoV-2 IgG/IgM Cassette Rapid Test

Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is a product for in-vitro analysis of whole blood, serum and plasma, designed to deliver qualitative results for a panel of tests. The resulting complex overflows a nitrocellulose membrane where the specific antigens against IgG or IgM antibodies are immobilized on the test zone and forms the pink to purple line at the “G” or “M” position of the window. The unreacted colloidal gold-labeled antigens react with the antibodies on the control zone and forms the pink to purple line at the “C” position of the window. The intensity and speed at which the color develops depends on the concentration of 2019-nCoV IgG/IgM antibodies in the specimen. The user can get the qualitative result by observing the G/M-line.

**Result Interpretation**

- In addition to the presence of C band, if only G line is developed, the test result indicates the presence of IgG anti- SARS-CoV-2 virus; the result is IgG positive or reactive, suggesting late stage primary, early secondary or previous infection.
- In addition to the presence of C band, if only M band is developed, the test indicates for the presence of IgM anti-SARS-CoV-2 virus. The result is IgM positive or reactive, suggesting a primary SARS-CoV-2 virus infection.
- In addition to the presence of C line, both G and M lines are developed, the test indicates for the presence of IgG and IgM anti-SARS-CoV-2 virus. The result is IgG and IgM positive or reactive, suggesting current primary or early secondary SARS-CoV-2 virus infection.
- If only the C band is present, the absence of any burgundy color in the both test bands (G and M) indicates that no anti-SARS-CoV-2 virus antibodies are detected. The result is negative or non-reactive. However, a negative or non-reactive result does not preclude the possibility of SARS-CoV-2 virus infection.A negative or non-reactive result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limits of the assay, or the viruses have undergone minor amino acid mutation in the epitope recognized by the antibody utilized in the test.

| Product | Lot # | Manufacturer |
|---|---|---|
| qSARS-CoV-2 IgG/IgM Cassette Rapid Test | 20200201, 20200202, 20200203. | Cellex Inc. |

### 2.2 Intended Use

The Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is a lateral flow immunoassay for the qualitative detection of 2019-nCoV IgM/IgG antibodies in serum, plasma or whole blood specimens. It is intended to be used as a screening test and aid in the diagnosis of SARS-CoV-2 viral infections. Any reactive specimen with the Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test must be confirmed with alternative testing method(s).

## 3. Analytical Evaluation Method and Analytical Performance Results

### 3.1 Analytical Sensitivity--Limit of Detection

Four positive samples were serially diluted and tested in 20 replicates. The most diluted replicates at which 19 or 20 replicates were tested positive for these four samples were 1:60,000.

| | Limit of Detection | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Samples | Positive Sample 1 | | Positive Sample 2 | | Positive Sample 3 | | Positive Sample 4 | |
| Dilution ratio | 1:60,000 | 1:80,000 | 1:9,000 | 1:11,000 | 1:2000 | 1:3000 | 1:500 | 1:800 |
| Replicates | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| Positive Results | 20 | 9 | 20 | 18 | 20 | 9 | 20 | 8 |
| Positive Detection Rate | 100.00% | 45.00% | 100.00% | 90.00% | 100.00% | 45.00% | 100.00% | 40.00% |

### 3.2 Analytical Precision-- Intra-Assay Repeatability

One positive sample diluted at low to medium levels of titers were tested along with a negative sample used for this study. The samples were tested with the qSARS-CoV-2 IgG/IgM Cassette Rapid Test (Lot #20200201) over a period of 12 days. Two runs and two replicates per run were performed daily.

| | Intra - Assay Repeatability | | |
|---|---|---|---|
| Samples | Positive Sample 1 | | Negative Sample |
| Dilution ratio | 1:60,00 | 1:600 | 1:1 |
| Replicates | 48 | 48 | 48 |
| Positive Results | 48 | 48 | 0 |
| Positive Detection Rate | 100.00% | 100.00% | 0.00% |

### 3.3 Analytical Precision-- Inter-Assay Precision

One positive sample diluted at low to medium levels of titers were tested along with a negative sample used for this study. The samples were tested with three different batches of qSARS-CoV-2 IgG/IgM Cassette Rapid Test (Lot #20200201, #20200202. #20200203) over a period of 5 days. Two runs and two replicates per run were performed daily.

| | Inter-Assay Precision | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Samples | Positive Sample 1 | | | | | | Negative Sample | | |
| Dilution ratio | 1:60,00 | | | 1:600 | | | 1:1 | | |
| Lot No. | 20190201 | 20190202 | 20190203 | 20190201 | 20190202 | 20190203 | 20190201 | 20190202 | 20190203 |
| Replicates | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| Positive Results | 20 | 20 | 20 | 20 | 20 | 20 | 0 | 0 | 0 |
| Positive Detection Rate | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 0.00% | 0.00% | 0.00% |

### 3.4 Analytical Precision-- Site-to-Site Reproducibility

One positive sample diluted at low to medium levels of titers were tested along with a negative sample used for this study in three sites over a period of five days. Two operators were involved in the study in each site. Each operator tested three replicates each day.

| | Site-to-Site Reproducibility | | |
|---|---|---|---|
| Samples | Positive Sample 1 | | Negative Sample |
| Dilution ratio | 1:60,00 | 1:600 | 1:1 |
| Replicates | 90 | 90 | 90 |
| Positive Results | 90 | 90 | 90 |
| Positive Detection Rate | 100.00% | 100.00% | 0.00% |

### 3.5 Analytical Specificity--Cross Reactivity

Negative serum or plasma samples containing antibodies reactive to one of the following pathogens were tested along with unspiked samples in multiple replicates. No false positivity was found:

| | Assay Cross Reactivity | |
|---|---|---|
| Potentially Cross-Reactivity Substances | with the antibodies to potentially cross-reactivity substances | without the antibodies to potentially cross-reactivity substances |
| Human coronavirus (collected before Oct 2019) | - | - |
| HBV | - | - |
| HCV | - | - |

| | | |
|---|---|---|
| HIV-1 | - | - |
| HIV-2 | - | - |
| Adenovirus | - | - |
| Human Metapneumovirus (hMPV) | - | - |
| Parainfluenza virus 1-4 | - | - |
| Influenza A | - | - |
| Influenza B | - | - |
| Enterovirus 71 | - | - |
| Respiratory syncytial virus | - | - |
| Rhinovirus | - | - |
| Chlamydia pneumoniae | - | - |
| Streptococcus pneumoniae | - | - |
| Mycobacterium tuberculosis | - | - |
| Mycoplasma pneumoniae | - | - |
| EB Virus | - | - |

### 3.6 Hook Effects

Positive samples with titers up to 1:60,000 were found to be still reactive when tested with the qSARS-CoV-2 IgG/IgM Rapid Test. Therefore, antibody titers up to 1:60,000 may not have a hook effect.

### 3.7 Test Effectiveness of Whole Blood Samples

50 negative whole blood samples were spiked with positive serum at 1:100. Another 50 whole blood specimens were spiked with negative serum at same dilution. These 100 specimens were tested with the qSARS-CoV-2 IgG/IgM Rapid Test. All spiked samples were correctly identified by the test except for one of the negative samples, which was tested positive with the test.

| | Test Effectiveness of Whole Blood Samples | |
|---|---|---|
| Negative whole blood samples | With positive serum | With negative serum |
| Total | 50 | 50 |
| Positive Results | 50 | 1 |
| Concordance Rate | 100.00% | 98.00% |
| Total Concordance Rate | 99.00% | |

### 3.8 Sample Storage Conditions

A low tier positive serum sample which stored at 2-8℃ were tested over a period of 5 days. Two replicates were performed daily. As expected, the activity of sample was retained after storage for up to 120 hours (5 days) at 2-8℃.

| Sample Storage Conditions Validation | |
|---|---|
| Storage days at 2-8℃ | Results |
| 1 | Weakly Positive |
| 2 | Weakly Positive |
| 3 | Weakly Positive |
| 4 | Weakly Positive |
| 5 | Weakly Positive |

## 4. Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.