**Performance for Sentebiolab Senteligo™ SARS-CoV-2 (COVID-19) Multiplex qPCR Detection Kit**

|  |  |  |  |
| --- | --- | --- | --- |
| Application | Specimen | Strain | Estimated LOD |
| Limit of Detection  (Analytical Sensitivity)  (copies/mL) | Bronchoalveolar Lavage, Nasopharyngeal fluid | SARS-CoV-2  (Synthetic RNA) | 50 copies/mL |
| Characteristics | | | |
| Intended Use | Qualitative detection of Coronavirus disease 2019 (COVID-19) strain SARS- CoV-2, in patients that meet the clinical criteria for COVID-19 (e.g. fever, cough, shortness of breath, travel history to China) in lower respiratory tract (bronchoalveolar lavage (BAL), tracheal aspirate), and upper respiratory tract (nasopharyngeal and oropharyngeal fluids, nasal swab). | | |
| User | Trained technician in molecular diagnostics procedures | | |
| Analytical Specificity (*in silico* analysis) | **DOES NOT** cross-react with the following microorganisms:  SARS-CoV, MERS-CoV, Human coronaviruses (HCoV-229E, HCoV-OC43, HCoV-NL63, HCoV-HKU1), Adenovirus, Influenza A H3N2, Novel Influenza A H1N1, Influenza B, Influenza C, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Respiratory syncytial virus (subtype A), Respiratory syncytial virus (subtype B), Parechovirus, *Candida albicans*, *Corynebacterium diphtheriae*, Legionella non-pneumophila, *Bacillus anthracis*, *Moraxella catarrhalis*, *Neisseria elongata*, *Neisseria meningitides*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Streptococcus salivarius*, Leptospirosis, *Chlamydia psittaci*, *Coxiella burnetii* (Q- Fever), *Staphylococcus epidermidis,* Enterovirus, Rhinovirus, *Haemophilus Influenzae*, *Mycobacterium tuberculosis*, *Bordetella parapertussis*, *Mycoplasma pneumoniae*, *Chlamydia pneumoniae*, and *Legionella pneumophila* | | |
| Specificity | 100.00% | | |
| Diagnostic Sensitivity | >99% | | |
| Detection details | N1 and N2 regions of Nucleocapsid of strain SARS-CoV-2 responsible for Coronavirus disease 2019 (COVID-19) | | |
| Time to detection | 60-90 minutes, depending on the thermocycler used | | |