Emergency Use Authorized (EUA) COVID-19 testing modalities and 510K respiratory assays

Medical and Scientific Affairs, Respiratory Areas of Interest- 2022

Background

Medical and Scientific Affairs focuses on evidence that relates to **access**, **innovation**, data needed for **launch success**, and evidence that will **transform clinical decisions**. Roche is passionate about evidence generation for respiratory pathogens. This document indicates the areas of interest for clinical research projects to evaluate the implementation, clinical utility, and economic impact of products listed in the table below. Proposals can be submitted immediately and will be evaluated on a rolling basis. Please submit proposals via https://medical-and-scientific-affairs.roche.com/us/en/start-a-study/msa-submit-proposal-form.html.

Areas of Interest

- Concepts that contribute to our understanding of SARS-CoV-2 infection dynamics
- Studies that illustrate the interplay of molecular assays concurrent with serology results
- Studies investigating co-infection and/or medical value of conducting multiplex testing
- Studies assessing the HECON, workflow, and/or medical value of diagnostic tests
- Establishing the optimal use cases and placement locations for diagnostic instruments and assays to support the pandemic response
- Studies examining the potential of alternative sample types (inclusive of specimen type, self/at home collection, defining appropriate window of testing/kinetics and digital biomarkers)
- Studies investigating the longevity, clinical utility, or durability of antibody response after vaccination, booster and/or infection
- Relationship of quantitative value and disease severity, therapeutic monitoring, isolation or quarantine and public health benefit with clinical utility endpoints
- Comparative studies of EUA and IVD products
- Studies utilizing Roche digital solutions with Point of Care testing workflow, credential verification, utilization at events, venues, workplace and for public health reporting

Assay	Platform	Sample Type	Method
SARS-CoV-2 + Influenza A/B	cobas® 5800/6800/8800	Nasal (self/clinician), NP, OP	RT-PCR
SARS-CoV-2	cobas® 5800/6800/8800	Nasal (self/clinician), NP, OP	RT-PCR
SARS-CoV-2 Variant Set 1 (RUO)	cobas® 5800/6800/8800	N/A	RT-PCR
Influenza A/B + RSV (RUO)	cobas® 5800/6800/8800	N/A	RT-PCR
SARS-CoV-2 Duo assay*	cobas® 5800/6800/8800	TBD	RT-PCR
Strep A	cobas® Liat	throat swab	RT-PCR
Influenza A/B & RSV	cobas® Liat	NP	RT-PCR
SARS-CoV-2 & Influenza A/B	cobas® Liat	Nasal (self/clinician), NP	RT-PCR
SARS-CoV-2	cobas® Liat	Nasal (self/clinician), NP, mid turbinate	RT-PCR
Bordetella pertussis (Bp), *Bordetella holmesii* (Bh) and *Bordetella parapertussis* (Bpp)*	cobas® Liat	TBD	RT-PCR
Anti-SARS-CoV-2 S (semi-quant)	Elecsys	Plasma/Serum	Immunoassay
Anti-SARS-CoV-2 N (qualitative)	Elecsys	Plasma/Serum	Immunoassay
COVID-19 AT HOME test	COVID-19 At Home TEST	Nasal (self)	Lateral Flow
Respiratory Pathogens Panel : Adenovirus, Coronavirus (229E, HKU1, NL63, OC43), Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza A H1, Influenza A H1-2009, Influenza A H3, Influenza B, Parainfluenza 1, 2, 3, 4, Respiratory Syncytial Virus A and B, *Chlamydia pneumoniae, Mycoplasma pneumoniae*	GenMarkDx ePlex	NPS	
Respiratory Pathogens Panel 2: Adenovirus, Coronavirus (229E, HKU1, NL63, OC43), Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza A H1, Influenza A H1-2009, Influenza A H3, Influenza B, Parainfluenza 1, 2, 3, 4, Respiratory Syncytial Virus A and B, *Chlamydia pneumoniae, Mycoplasma pneumoniae,* SARS-CoV-2	GenMarkDx ePlex	NPS	
NAVIFY Pass**	N/A	N/A	Digital Solution
iThemba module**	N/A	N/A	Digital Solution

*Assay in development not currently FDA approved; RUO: Research Use Only; TBD: To Be Determined Upon FDA approval

** Not launched in the US