

RDC Medical and Scientific Affairs 2024-2025 Respiratory Disease Areas of Interest

Background:

Medical and Scientific Affairs is committed to supporting evidence generation that improves access to current and future diagnostic solutions. Evidence relating to product performance and its impacts on clinical decision making, improved patient outcomes, and health network economics assists with launch support and drives improved access to these innovative technologies.

Proposals within the scope of the following areas of interest can be submitted at any time and will be evaluated on a rolling basis.

Areas of Interest:

- Clinical utility and health economic impacts of respiratory assays, especially targeted (2-5 pathogens) and expanded/syndromic (6+ pathogens) multiplex PCR solutions, across diverse patient populations and settings of care
 - Outcomes of interest include, but are not limited to: impacts to patient management and clinical outcomes, patient triage, infection control, resource/bed management, and antibiotic/antiviral stewardship
 - Settings of interest include, but are not limited to: non-acute, and/or decentralized settings (emergency department, urgent care clinics, physicians' offices, mobile units, community pharmacies)
 - Populations of interest include, but are not limited to: average risk adults, pediatrics
- Clinical utility of quantitative SARS-CoV-2 measurements in patient management
- Methods to improve diagnostic stewardship in respiratory test ordering
- Mechanisms to increase access to respiratory diagnostic solutions for underserved populations
- Real-world data generation demonstrating the disease burden of respiratory pathogens across diverse patient populations



Respiratory Portfolio:

Platform	Assay Name
cobas [®] Liat	cobas Liat Influenza A/B & RSV Assay
	cobas Liat SARS-CoV-2 & Influenza A/B Assay
	cobas Liat SARS-CoV-2 Assay ¹
	cobas Liat Strep A Assay
	cobas Liat Bordetella Assay² (B. pertussis, B. pertussis, B. holmesii)
GenMark ePlex®	Respiratory Pathogen Panel 2 ¹
cobas [®] 5800/6800/8800 ³	cobas SARS-CoV-2 & Influenza A/B Test ¹
	cobas SARS-CoV-2 Test ¹
	cobas SARS-CoV-2 Qualitative Test
	cobas SARS-CoV-2 Duo Test ¹
	cobas Influenza A/B & RSV UC Test ⁴
	cobas Multiplex Respiratory Test ²
	cobas omni Utility Channel
cobas [®] e 411 analyzer cobas [®] e 601/602 modules cobas [®] e 801 module	Elecsys [®] Anti-SARS-CoV-2 Assay ¹
	Elecsys [®] Anti-SARS-CoV-2 S Assay ¹

¹ This product is authorized for use under the Emergency Use Authorization declaration.

 $^{^{\}rm 2}$ This product is in development; design goals and product name are subject to change.

³ Assay availability varies by platform. Only the **cobas** SARS-CoV-2 Qualitative assay and assays developed on the **cobas** omni Utility Channel are compatible for use on the **cobas** 5800 system.

⁴ This product is for research use only (RUO).