cobas® Respiratory flex

Centralized syndromic PCR testing with the flexibility to test just what is relevant and needed

Acute respiratory tract infections are significant causes of worldwide morbidity and mortality.[1-5] Because many acute respiratory illnesses present with similar symptoms and because there are now different types of treatment available for some, it's important to quickly identify the viral pathogen causing symptoms. Quick and accurate identification can lead to proper treatment within an effective time frame and help prevent further transmission.

Intended Use

cobas® Respiratory flex for use on the **cobas®** 5800/6800/8800 systems is an automated, multiplex, nucleic acid test that utilizes real-time polymerase chain reaction (PCR) technology for simultaneous in vitro qualitative detection and differentiation of adenovirus (species B, C and E), common human coronaviruses (229E, HKU1, NL63, OC43), human metapneumovirus, human rhinovirus/enterovirus, influenza A virus, influenza B virus, parainfluenza viruses 1, 2, 3, and 4, respiratory syncytial virus (RSV), and SARS-CoV-2 in nasopharyngeal swab specimens obtained from individuals with signs and symptoms of respiratory tract infections in conjunction with clinical and epidemiological risk factors.

Existing **cobas®** 5800/6800/8800 systems are ready right now.

cobas® Respiratory flex is designed for flexibility - to allow customers to test only what's needed promoting diagnostic stewardship.

Simplify lab logistics by offering a customizable solution out of one test kit.

Key parameters

Targets	Adenovirus (species B, C and E), common human coronaviruses (229E, HKU1, NL63, OC43), human metapneumovirus, human rhinovirus/enterovirus, influenza A virus, influenza B virus, parainfluenza viruses 1, 2, 3, and 4, respiratory syncytial virus (RSV), and SARS-CoV-2
Sample type	nasopharyngeal swab samples collected in Copan Universal Transport Medium System (UTM-RT®) or BD™ Universal Viral Transport System (UVT) or equivalent
Minimum amount of sample	0.4 mL
Technology	First assay using Roche's proprietary TAGS technology (temperature activated generation of signal) to enable higher multiplex within existing hardware and system software.
Size and open kit stability	192 tests; 90 days with 40 re-uses

Test performance[6]

Target virus	PPA	NPA
Influenza A	100.0%	99.1%
Influenza B	100.0%	99.8%
RSV	96.0%	99.8%
SARS-CoV-2	98.4%	98.2%
Adenovirus	100.0%	98.4%
Human Metapneumovirus	96.3%	99.8%
Enterovirus and Rhinovirus	83.9%	98.4%
Common Human Coronaviruses (229E, HKU1, NL63, OC43)	96.4%	97.3%
Parainfluenza virus 1	100.0%	99.3%
Parainfluenza virus 2	100.0%	99.6%
Parainfluenza virus 3	95.8%	99.9%
Parainfluenza virus 4	97.4%	99.5%

Ordering information

cobas® Respiratory flex	P/N: 09623701190
cobas® Respiratory flex Control Kit	P/N: 09623728190
cobas® Respiratory flex Buffer Negative Control Kit	P/N: 09051953190 (or P/N: 07002238190 for 68/8800 only)
cobas® Microbial Inactivation Solution (sold separately)	P/N: 08185476001

References

1. Ferkol T, Schraufnagel D. The global burden of respiratory disease. Ann Am Thorac Soc. 2014;11:404-6.
2. Ghebrehewet S, MacPherson P, Ho A. Influenza. BMJ. 2016;355:i6258.
3. World Health Organization. The global burden of disease: 2004 update. Published: 2 Mar 2004; Accessed 29 Jan 2024. https://iris.who.int/bitstream/handle/10665/43942/9789241563710_eng.pdf?sequence=1.
4. Shi T, McAllister DA, O'Brien KL, et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in young children in 2015: A systematic review and modelling study. Lancet. 2017;390:946-58.
5. Mokdad AH, Marks JS, Stroup DF, Gerberding JL. Actual causes of death in the United States, 2000. JAMA. 2004;291:1238-45.
6. **cobas®** Respiratory flex assay for use on the cobas® 5800/6800/8800 systems for in vitro diagnostic use. Instructions for use. Pleasanton, CA. Roche Molecular Systems, 2024.

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