

TITLE: EVALUATION OF A RAPID IMMUNOCHROMATOGRAPHIC POINT OF CARE TEST THAT DETECTS THE RESPIRATORY SYNCYTIAL VIRUS IN HUMAN RESPIRATORY SAMPLES**Authors:** Murillo R¹, Mercadal L¹, Martín T.², Montes M.² and Cilla G.².**Affiliation:** ¹OPERON Immunodiagnostics S.A., Cuarte de Huerva, Saragossa, Spain²Microbiology Department, Hospital Universitario Donostia-Biodonostia Health Research Institute, San Sebastián, Gipuzkoa, Spain

The Respiratory Syncytial Virus (RSV) is the leading cause of emergency rooms visits and hospitalizations for acute lower respiratory tract infections in infants and young children worldwide¹during winter. RSV can also become a serious problem in the elderly, adults with heart and lung diseases, or anyone with a very weak immune system (immunocompromised)². RSV is one of the main causes of nosocomial infection³ due to its high infectivity, the virus potential to be spread over extensive periods, and its ability to survive for hours on environmental surfaces. Outbreaks due to RSV infection occur each year during the autumn and winter months, it is a very seasonal infection⁴. The rapid identification of this virus⁵ is very important since it allows to reduce the number of hospitalised patients and the number of prescribed antibiotics which, as a result, reduces healthcare costs

The Simple/Stick RSV (OPERON S.A., Spain) is a one-step lateral flow assay which allows the qualitative and rapid detection of the RSV in about 20 minutes, from sample collection till the end of the lateral flow run. The test shows a mean analytical sensitivity of 62.5 ng/ml using a pure preparation of the RSV obtained from the Long culture strain in Hep-2 cells, though 31.2 ng/ml is often detected. The test can be easily performed without any specialized equipment, which makes it a real option for point of care testing.

The objective of this study is to demonstrate that the RSV test from OPERON, S.A is suitable for the rapid detection of the RSV in clinical environments. Data presented here were obtained in the evaluation of the RSV assay at Donostia University Hospital (San Sebastian, Spain). The evaluation included 123 respiratory samples (108 nasopharyngeal aspirates from children under 14 years old and 15 pharyngeal swabs in viral transport medium from adult population) received at hospital from November 2017 to January 2018, with a request for the determination of RSV. All samples were tested both with the lateral flow assay RSV from OPERON S.A. and with the immunoassay RSV Directigen from Becton and Dickinson (B&D) using the molecular test Seegene RT-PCR panel I as the reference method.

The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) (in %) of the two rapid tests that detect RSV in relation to the molecular PCR technique appear in the following table:

	Sensitivity	Specificity	PPV	NPV
OPERON	73.4%	97.7%	98.3%	67.2%
B&D	75.9%	97.7%	98.4%	69.4%

Conclusion: the RSV test from OPERON, S.A is a new rapid test, ease to use and interpret that can be used as a point of care for RSV detection.

REFERENCES:

- 1. Trends in respiratory syncytial virus bronchiolitis hospitalizations in children less than 1 year: 2004-2012.** Sanchez Luna M. et al, 2016. *Curr Med Res Opin* Feb 3: 1-7.
- 2. Respiratory syncytial virus infection in adults.** Falsey, AR. and Walsh, EE. 2000. *Clin. Microbiol. Rev.* 13: 371-384.
- 3. Respiratory syncytial virus. Manual of clinical microbiology, Ed. 8.** Tristram D. In: Murray PR et al. ASM Press, 2003:1378-1388.
- 4. Evaluation of the Activity of Influenza and Influenza-Like Viruses in the Epidemic Season 2013/2014.** Bednarska K, Hallmann-Szelinska E, Kondratiuk K, Brydak LB. *Adv Exp Med Biol* 2015; 857:1-7.
- 5. Respiratory Syncytial Virus Diagnostics Market Analysis By Product (Direct Fluorescent Antibody (DFA), Rapid Antigen Diagnostic Tests (RADTs), Molecular Diagnostics, Chromatographic Immunoassay, Diagnostic Imaging, Gel Microdroplets, Flow Cytometry), By End-use (Hospitals, Laboratory, Clinics, Homecare) And Segment Forecasts To 2022.** Published: January 2016 | ISBN Code: 978-1-68038-680-6.