eSensor® Respiratory Viral Panel (RVP) Background and Principle

BACKGROUND

The eSensor Respiratory viral panel (RVP) is a multiplex nucleic acid test used for qualitative detection and identification of multiple respiratory viruses obtained from patients suspected of having viral respiratory disease (Table 1). Respiratory pathogens are a major source of illness, including the common cold, influenza, pneumonia, and croup. Children average approximately six respiratory tract infections each year, with the majority occurring between November and March. Bronchiolitis is the leading cause of hospitalization of infants typically caused by respiratory syncytial virus (RSV) followed by human rhinovirus (HRV)[3]. Respiratory disease severity can be especially high and even fatal in susceptible infants, the immunocompromised, the elderly, and those with underlying cardiopulmonary disease[4]. When assessing a patient with a respiratory illness, the challenge to the physician is determining the underlying cause so that an effective treatment plan can be determined.

Table 1: Targets detected by eSensor® RVP

Analyte	Abbreviation	Classification	Season of highest incidence	Most commonly infected, age demographics
Influenza A	Flu A	Orthomyxovirus (RNA)	Winter	All ages, 5 – 20% of US population
Influenza A H1	Flu A H1			
Influenza A H3	Flu A H3			
Influenza A H1N1	Flu A H1N1			
Influenza B	Flu B			
Respiratory Syncytial virus	RSV A	Paramyxovirus (RNA)	Winter	Infants, children, older adults
Respiratory Syncytial virus	RSV B			
Human metapneumovirus	hMPV	Paramyxovirus (RNA)	Late winter, early spring	Infants, children
Human rhinovirus	HRV	Picornavirus (RNA)	Fall, spring	All ages
Adenovirus sp. B/E	ADV B/E	Adenovirus (DNA)	Late winter to early summer	All ages, immunocompromised
Adenovirus sp. C	ADV C			
Parainfluenza virus 1	PIV 1	Paramyxovirus (RNA)	Fall	Infants, children
Parainfluenza virus 2	PIV 2		Fall, early winter	Infants, children
Parainfluenza virus 3	PIV 3		Spring, summer	Infants, children, immunocompromised
Parainfluenza virus 4	PIV 4		Fall	Children, immunocompromised
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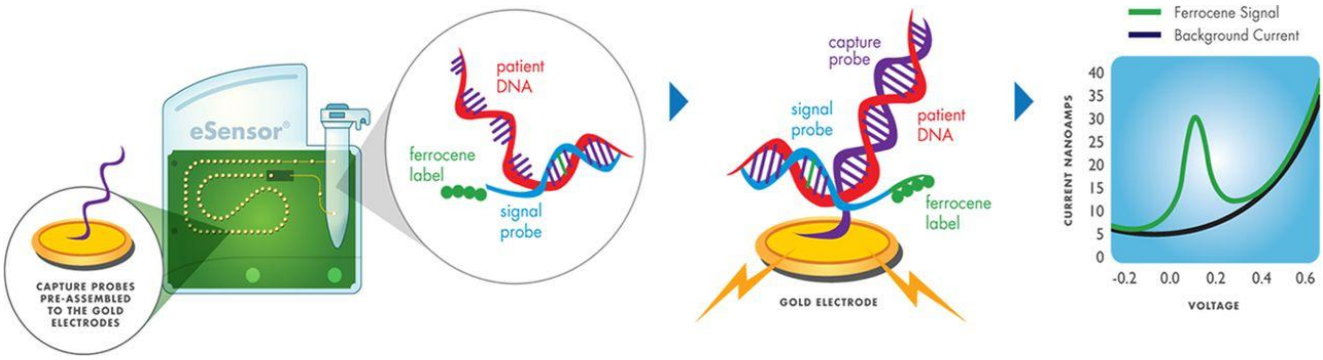
PRINCIPLE

eSensor technology is based on the principles of competitive DNA hybridization and electrochemical detection of the viral target sequences. The presence of each target is determined by voltammetry, which generates specific electrical signals from a ferrocene-labeled signal probe (fig. 1).

- Conventional PCR is performed. Amplification conditions consist of a reverse transcription step followed by denaturation, annealing and extension of the viral nucleic acid in a multiplex mastermix.
- After PCR, an exonuclease reaction is performed to create single-stranded target DNA
- Target DNA is mixed with the single-stranded signal probes labeled with ferrocene. If target DNA is present, hybridization occurs to the signal probe immediately
- The mixture of amplified sample and signal hybridization buffer is loaded into a detection cartridge containing single-stranded oligonucleotide capture probes bound to gold-plated electrodes. The capture probe and signal probe are complementary to a different segment of the target DNA (or biomarker)
- The unbound segment of the target DNA binds to the electrode-bound capture probe, creating a target DNA, signal probe, capture probe complex
- The complex produces an electrochemical signal detected by the XT-8 system

Figure 1: **eSensor RVP cartridge and detection technology**



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Historical Record

Version	Written/Revised by:	Effective Date:	Summary of Revisions
1	P. Ackerman	08.12.15	Initial Version
2	P. Ackerman	08.27.2016	Reformatted for CMS upload; changed logo