



## FOR IMMEDIATE RELEASE

### **RPS announces FDA 510(k) clearance for RPS Adeno Detector Plus™**

*Ten-minute test allows clinicians to accurately diagnose viral conjunctivitis*

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SARASOTA, FL (May 23, 2011) – On May 18, the U.S. Food and Drug Administration (FDA) granted Rapid Pathogen Screening, Inc. (RPS) 510(k) clearance of the RPS Adeno Detector Plus™. The RPS Adeno Detector Plus – an improved version of the company’s first FDA-cleared product – is the latest rapid point-of-care diagnostic test produced by RPS. The FDA 510(k) clearance permits RPS to begin marketing the RPS Adeno Detector Plus in the United States, following the product’s recent release in countries outside of the United States. RPS expects this new test to be categorized as a CLIA-waived test similar to its predecessor, the RPS Adeno Detector™.

Adenoviral conjunctivitis represents the most common external ocular infection and is the most frequent virus isolated from the conjunctiva. Due to the significant overlap of signs and symptoms of bacterial and viral conjunctivitis (pink eye), clinicians cannot accurately diagnose the disease based upon a clinical exam. This often leads to an unnecessary prescription of antibiotics, which are an ineffective treatment for the viral form of this disease. Antibiotics are prescribed in up to 95 percent of conjunctivitis cases leading many patients to return to school, work or day care while still contagious.

The RPS Adeno Detector Plus requires only a small sample of human tears to detect all known serotypes of Adenoviral conjunctivitis in just 10 minutes. By using the RPS Adeno Detector Plus, the clinician can make an accurate diagnosis and provide appropriate treatment before the patient leaves the office, reducing the spread of disease.

“The FDA’s clearance of this new product is further validation of the series of revolutionary diagnostic tests being brought to market by RPS,” says Thomas Orsini, president and chief executive officer of RPS. “Receiving FDA 510(k) clearance signifies a critical step in bringing affordable, easy-to-use diagnostics to market that will not only improve patient care, but will help reduce both the spread of disease and healthcare costs.”

Much like a rapid Strep test used currently by healthcare providers to diagnose infections in patients with a sore throat, the first generation FDA-cleared RPS Adeno Detector was the first rapid, in-office test available to provide an accurate diagnosis to aid in effective patient management and treatment decisions.

Similar to the first generation test, the presence of a single control line indicates a negative test result and the appearance of both a control line and a result line indicate a positive result. Now with added features to improve the contrast and visualization of test results, the RPS Adeno Detector Plus displays a blue control line and a red positive result line to clearly illustrate a positive or negative test result.

The RPS Adeno Detector Plus has ten times greater analytical sensitivity than the first generation test and demonstrates a clinical sensitivity of 90 percent and a specificity of 96 percent when compared against cell culture – the gold standard – as the reference method. This level of accuracy allows for the initiation of appropriate patient management at the office visit and reduces future superfluous medical office visits, the cost of unnecessary prescriptions, and the need for additional laboratory testing, resulting in healthcare cost savings of hundreds of millions of dollars per year. To learn more about the RPS Adeno Detector Plus or other RPS diagnostics, visit [www.rpsdetectors.com](http://www.rpsdetectors.com).

#### **About RPS**

Founded in 2004, Rapid Pathogen Screening, Inc. (RPS) is a leading developer, manufacturer and marketer of rapid, easy-to-use, point-of-care diagnostic tests. The company's revolutionary, patented Direct Sampling Micro-Filtration (DSMF) technology and patent-pending Direct Multi-Planar Chromafiltography (DMC) technology allow for the current and future development of tests to confirm patients with infectious diseases and agents, inflammatory conditions, and asymptomatic exposure to chemical warfare and bio-terrorism agents. RPS tests have superior sensitivity and specificity and can be easily performed by a clinician's staff without extensive training or additional equipment.

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#### **For additional information, contact:**

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