RAPID ONE STEP IMMUNOCROMATOGRAFIC TESTS

RESPIRATORY LINE
Novamed's novel approach allows for fast and reliable detection of group A Streptococcal antigen directly from a patient throat swab with no reagent manipulation.

StrepAID is a true "No Step" LFIA Test Device.

No-hassle Streptococcus A antigen detection!

Just put your swab in and turn the cap!

Test & Detect with unmatched ease!

Result in 5 minutes or less!

Excellent Performance
- 100% sensitivity
- 100% specificity
- 97.7% overall agreement with Streptococcus Blood Agar culture.

*In-house study conducted at Novamed (refer to Insert for additional performance claims).

Easy to Use
- Unique patent pending all-in-one device allows effortless test conduction and interpretation.
- Truly straightforward single step procedure: just put your swab in and turn the cap!
- Failsafe! Absolutely no operator involvement with test reagents.
- Anyone can do it!

Convenient Packaging
- All required reagents are integrated in the unique platform.
- Individually packaged for convenient single-use testing and disposal.

KIT CONTENTS (1 determination)
1 StrepAID Throat Swab Test Device
1 Sterile swab
1 Instruction for Use

ORDERING INFORMATION
R-5001 StrepAID Throat Swab Test Device (single test)
GROUP A STREPTOCOCCUS “SINGLE REAGENT”

INTENDED USE
Single Reagent StrepA Throat Swab Test Device is a rapid immunochromatographic in-vitro diagnostic assay. This assay is intended for direct determination of Group A Streptococcus in throat swab specimens to aid in the diagnosis of streptococcal pharyngitis. The test utilizes a Novamed proprietary technology which facilitates minimal user’s involvement in the testing process.

SUMMARY AND EXPLANATION
Group A streptococci are of focus of interest not only because of their causal role in acute streptococcal pharyngitis and other pyogenic infections but also because of their association with post streptococcal sequelae, specifically acute rheumatic fever and acute glomerulonephritis. In order to properly treat the disease using antibiotic therapy, it is important to use an accurate diagnostic method to identify the pathologic agent. The Single Reagent StrepA Throat Swab Test Device is a rapid test to qualitatively detect the presence of GAS antigen in specimens, providing results within 5-10 minutes. The test utilizes antibodies specific for whole cell Lancefield GAS to selectively detect Strep A antigen in a specimen.

KIT CONTENTS (20 determinations)
20 StrepASTick (Throat Swab) One Step Assay Devices
20 Sterile throat swabs
20 dropper vials containing 0.4 ml of Extraction Reagent (active component: 0.4M Acetic Acid) and placed into a plastic stand
1 Instruction for Use

ORDERING INFORMATION
R-6057 StrepASTick (Throat Swab) One Step Assay (20 determinations)

GROUP A STREPTOCOCCUS “DOUBLE REAGENT”

INTENDED USE
StrepASTick (Throat Swab) One Step Assay is a rapid test to qualitatively detect the presence of Strep A antigen in throat swab specimens, providing results within 5-10 minutes.

SUMMARY AND EXPLANATION
Group A streptococci are of focus of interest not only because of their causal role in acute streptococcal pharyngitis and other pyogenic infections but also because of their association with post streptococcal sequelae, specifically acute rheumatic fever and acute glomerulonephritis. In order to properly treat the disease using antibiotic therapy, it is important to use an accurate diagnostic method to identify the pathologic agent.

KIT CONTENTS (25 determinations)
25 StrepASTick (Throat Swab) One Step Assay dipsticks
25 Sterile throat swabs
25 Empty test vials placed into a plastic stand
1 Dropper bottle with Extraction Reagent A (2M Sodium Nitrite)
1 Dropper bottle with Extraction Reagent B (0.16M Acetic Acid)
1 Instruction for Use

ORDERING INFORMATION
R-6010 StrepASTick (Throat Swab) One Step Assay (25 determinations)

ADENOVIRUS

INTENDED USE
AdenoStick (Respiratory Antigens) One-Step Assay is a rapid immunochromatographic assay for the qualitative detection of Adenovirus antigens in human nasopharyngeal specimens (swab, nasopharyngeal wash and aspirate) to aid in the diagnosis of Adenovirus respiratory infection.

SUMMARY AND EXPLANATION
Most infections with adenovirus result in infections of the upper respiratory tract, which often show up as conjunctivitis, tonsillitis (which may look exactly like strep throat and cannot be distinguished from strep except by throat culture), an ear infection, or croup. Adenoviruses serotypes in humans are responsible for 5–10% of upper respiratory infections in children, and many infections in adults as well.

KIT CONTENTS (25 determinations)
25 AdenoStick (Respiratory Antigens) One-Step Assay dipsticks
25 sample dilution vials placed into a plastic stand
1 dropper bottle containing 15 ml of sample diluent B
1 Instruction for Use

ORDERING INFORMATION
R-5188 RotaStick One Step Assay (25 determinations)
RESPIRATORY SYNCYTIAL VIRUS (RSV)

INTENDED USE
RSVStick One Step Assay is a rapid qualitative immunochromatographic assay for the detection of respiratory syncytial virus (RSV) antigens in human nasopharyngeal specimens to aid in the diagnosis of RSV infection.

SUMMARY AND EXPLANATION
Respiratory syncytial virus (RSV) is the most important cause of pneumonia and bronchiolitis in infants and small children. Because of its high infectivity and because hospital staff as well as patients are susceptible, RSV has emerged as the most frequent cause of nosocomial infections on pediatric wards. RSV is an antigenically heterogeneous species, available reagents, including monoclonal antibodies, react equally with all clinical isolates.

KIT CONTENTS (25 determinations)
25 RSVStick One-Step Assay dipsticks
25 sample dilution vials placed into a plastic stand
1 dropper bottle containing 15 ml of sample diluent B
1 Instruction for Use

ORDERING INFORMATION
R-5198 RSVStick One Step Assay (25 determinations)

TUBERCULOSIS

INTENDED USE
Tuberculosis One-Step Assay is a rapid qualitative screening test for the detection of human antibodies to Koch's bacillus in serum, plasma, or whole blood. The test is able to specifically detect antibodies from patient in active phase of the disease. Samples from vaccinated people will not react with Novamed’s Tuberculosis One-Step Assay.

SUMMARY AND EXPLANATION
Tuberculosis remains an important socio-economical and medical problem throughout the world. According to the Centre for Disease Control, the incidence of TB is expected to increase from 7.5 million cases per year in 1995 to 11.9 million in 2005. The case fatality rate is estimated at 55% for untreated people and 15% for the treated patients.

KIT CONTENTS (25 determinations)
20 Tuberculosis One-Step Assay devices
1 dropper bottle containing 5 ml of saline buffer, detergent and sodium azide (NaN₃ < 0.1%)
20 Disposable plastic pipettes
1 Instruction for Use

ORDERING INFORMATION
R-6017 Tuberculosis One-Step Assay (20 determinations)

INFLUENZA TYPE A and TYPE B

INTENDED USE
Influenza A+B One Step Assay is a rapid chromatographic immunoassay for the qualitative detection of Influenza type A (including subtype A(H1N1) and A(H3N2)) and type B antigens in human nasopharyngeal specimens to aid in the diagnosis of Influenza infection.

SUMMARY AND EXPLANATION
Influenza is caused by a virus that attacks mainly the upper respiratory tract – the nose, throat and bronchi and rarely also the lungs. In some people, the infection may lead to severe complications of underlying diseases, pneumonia and death. The currently circulating influenza viruses that cause human disease are divided into group A and B. Influenza A has 2 subtypes which are important for humans: A (H3N2) and A (H1N1), of which the former is currently associated with most deaths

KIT CONTENTS (20 determinations)
20 Influenza A+B One Step Assay devices
20 Specimen collection vials
1 dropper bottle containing of sample diluent B
20 Sterile swabs
1 Influenza positive control
1 Instruction for Use

ORDERING INFORMATION
R-6036 Influenza A+B One Step Assay (20 determinations)

EPSTEIN-BARR VIRUS

INTENDED USE
EBV M One Step Assay is a rapid immunofiltration assay which uses ZEBRA and VCA p18 antigens for the qualitative detection of anti EBV IgM in serum.

SUMMARY AND EXPLANATION
Epstein-Barr virus is one of the most widespread viruses in human. It belongs to the Herpesvirinae family which includes other human pathogenic viruses (Herpes simplex 1 and 2, Varicella zona virus (VZV), cytomegalovirus (CMV), HHV6, HHV7 and HHV8).

KIT CONTENTS (25 determinations)
25 EBV M One Step Assay devices
2 vials containing 21 ml of sample diluent buffer, Reagent 1
2 vials containing 21 ml of anti-IgM conjugate coupled to blue polystyrene beads, Reagent 2
2 vials containing 21 ml of washing buffer, Reagent 3.
1 Instruction for Use

ORDERING INFORMATION
R-6038 EBV M One Step Assay (25 determinations)