5. SUMMARY OF SAFETY AND EFFECTIVENESS

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The IMAGEN™ Respiratory Screen is a qualitative indirect immunofluorescence test for the detection of Respiratory Syncytial Virus, Influenza A virus, Parainfluenza virus type 3 and Adenovirus directly in respiratory specimens and Respiratory Syncytial Virus, Influenza A and B virus, Parainfluenza virus types 1, 2 and 3 and Adenovirus in cell culture monolayers. The test consists of the following reagents,

i) a Screening reagent; a pool of purified mouse monoclonal antibodies each of which has individual specificity for either Respiratory Synctial virus, Influenza A and B virus, Parainfluenza types 1,2 and 3 and Adenovirus.

ii) a Negative control reagent; pooled mouse monoclonal antibodies with no anti-viral activity .

iii) a Fluorescein Isothiocyanate (FITC) Conjugate reagent; FITC conjugated $F(ab')_2$ fragment of rabbit anti-mouse immunoglobulins

iv) Mounting fluid; containing a photobleaching inhibitor in glycerol

v) Positive and Negative Control slides; fourteen well combined positive and negative control slides. Each slide consists of seven wells containing acetone-fixed cells infected with either RSV, Influenza A or B virus, Parainfluenza virus type 1, 2 or 3 or Adenovirus (one well specific for each virus) and seven wells containing acetone fixed uninfected cells (negative control wells).

IMAGEN™ Respiratory Screen is a two-step direct immunofluorescence staining method. The Screening reagent utilises a pool of mouse monoclonal antibodies to bind specifically to either Respiratory Syncytial Virus, Influenza A or B virus, Parainfluenza virus types 1, 2 or 3 or Adenovirus. The FITC conjugate reagent is used to detect any Screening reagent antibody which has bound to virus present in the respiratory specimen or cell culture monolayer. The Negative control reagent contains mouse monoclonal antibodies with no reactivity with any viral antigen or any antigen likely to be present in a respiratory specimen and is used to monitor the specificity of the stain. The respiratory virus present can be specifically identified using individual IMAGEN™ reagents.

Performance characteristics have been established by external clinical evaluation against the Bartels Viral Respiratory Screening and Identification Kit and standard viral isolation reference methods used for screening for the presence of respiratory viruses. (Exhibit F) and by evaluation of cross-reactivity (Exhibit G). Currently sufficient data has only been collected to establish claims for the identification of Respiratory Syncytial virus, Influenza A virus, Parainfluenza virus type 3 and Adenovirus directly in respiratory specimens. Trials are ongoing to collect adequate data to establish the outstanding claims for Influenza B virus and Parainfluenza virus types 1 and 2 for direct specimen testing. Data is submitted to support claims for the identification of all seven viruses (Respiratory Synctial virus, Influenza A and B virus, Parainfluenza virus types 1, 2 and 3 and Adenovirus) in cell culture isolates.

IMAGEN™ Respiratory Screen is intended for use in laboratories where qualified technicians are familiar with routine indirect immunofluorescence testing for microbiological diagnosis. However specific quality control information regarding the validity of test results is included in the Product Insert, to facilitate reliable and reproducible results and minimise the occurrence of false positive or false negative results. Procedures include the use of positive and negative control slides, a negative control reagent and specifications for acceptable results. Technical references and a Technical Services phone number are provided to aid the user in further trouble-shooting.

The IMAGEN™ Respiratory Screen is similar in use and technology to Bartel's Viral Respiratory Screening and Identification Kit, which is already in commercial distribution in the U.S.

The product insert contains a list of safety and technical precautions which should be followed to ensure safe and effective use of the IMAGEN™ Respiratory Screen diagnostic test. This includes advice on handling and disposal of clinical specimens as though potentially infectious. Suggested precautions include the wearing of disposable gloves when handling clinical specimens and infected cells and washing of hands immediately after completion of the test. In addition the test should be carried out in a designated work area where eating, drinking, smoking, preparation and storage of food and application of cosmetics are not carried out. Materials should not be pipetted by mouth.

The following safety information about reagents is given in the Directions for Use:-

The IMAGEN™ Respiratory Screen reagents contain 15mmol/L sodium azide which is a POISON. Sodium azide may react with copper and lead plumbing systems to form explosive metal azides. Always dispose of azide-containing materials by washing with large quantities of water.

Evans blue dye is present in the FITC reagent. This may be carcinogenic and contact with the skin should be avoided

Care should be taken when using the mounting fluid as it may cause skin irritation. Skin should be flushed with water if contact occurs.

Further information regarding the safety and effectiveness of IMAGEN™ Respiratory Screen will be made available within 30 days of request by any person. This information excludes confidential patient information and proprietary manufacturing procedures pertinent to this device. Please contact:

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