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INTENDED USE

Intended as a replacement component for the Bartels Viral Respiratory Screening and Identification Kit (Catalogue Number B1029-86). Bartels Viral Respiratory Screening and Identification Kit is intended for use in cell culture confirmation and direct specimen detection. The screening reagents and the individual antibodies directed against adenovirus, influenza A, influenza B, parainfluenza type 1, 2, and 3, and respiratory syncytial virus (RSV) can be used for cell culture confirmation. The influenza A, influenza B, parainfluenza type 1, parainfluenza type 3, and respiratory syncytial virus (RSV) individual antibodies can be used for direct specimen detection. Specimens found to be negative on direct specimen examination should be confirmed by cell culture confirmation. Monoclonal antibodies directed against influenza and parainfluenza viruses are type specific, while monoclonal antibodies directed against adenovirus and RSV will detect all identified serotypes of the respective virus. The Bartels Viral Respiratory Screening and Identification Kit uses indirect fluorescent antibody technology.

Note: To be used as a replacement component for Bartels Viral Respiratory Screening and Identification Kit, catalogue number B1029-86. This package insert provides summary information only. For more detailed information refer to package insert (catalogue number B1029-86), or contact Technical services in the U.S. at 1-800-325-3424, or outside the U.S. at (353) 1 276 9800.

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Anti-Mouse IgG F(ab')₂ FITC Conjugate-1 vial, 10 mL. Affinity purified goat or sheep anti-mouse IgG F(ab')₂ antibodies conjugated to fluorescein isothiocyanate (FITC) are diluted in phosphate buffered saline (0.15 M sodium chloride and 0.01 M sodium phosphate) with 0.75% protein stabilizer. Sodium azide and ProClin[®] 950 are added at concentrations of 0.1% as preservatives. Evan's blue is the included counterstain at a concentration of 0.008%. Store at 2-8°C in the dark.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.

- Any reagent containing sodium azide or ProClin® 950 should be evaluated for proper 2. disposal. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. If products containing sodium azide are discarded into a drain, flush with a large volume of water to prevent azide build-up. Check with regulatory agencies to determine at what concentration sodium azide may cause a product to be regulated as a hazardous waste. MSDS for sodium azide and ProClin® 950 are available by phoning a Technical Service Representative in the U.S. at 1-800-325-3424, or outside the U.S at (353) 1 276 9800.
- Reagent is supplied at working strength. Dilution of the reagent will decrease sensitivity. 3
- 4. Reagent should not be used beyond its expiration date.
- 5. Microbial contamination of reagent may cause a decrease in sensitivity.
- 6. All specimens and materials should be considered potentially infectious and handled in a manner which prevents infection of laboratory personnel. Decontamination is most effectively accomplished with a 0.5% solution of sodium hypochlorite (1:10 dilution of household bleach).
- Never pipette reagents or clinical samples by mouth. Avoid splashing, generation of aerosols, and contact with broken skin when processing 8
- clinical specimens or virus stocks.
- Do not substitute reagents from other manufacturers.
- 10. Incubation times or temperatures other than specified in the test instructions may give erroneous results.
- Cross-contamination of reagents could cause false results. If staining multiple patients on the same slide, keep each specimen within the perimeter of its well to insure that reagents 11. will not be drawn out of the well when stained.
- 12. Do not allow wells to dry once assay has begun.
- 13 Reusable glassware must be washed and thoroughly rinsed free of all detergents.
- Evan's blue dye is a potential carcinogen. If skin contact occurs with the conjugate, flush 14. with water immediately
- Due to the affinity of adenovirus for the occular area, hand to eye contact should be 15 avoided during processing of respiratory specimens and when performing diagnostic tests. Use aseptic technique and sterile equipment and materials for all tissue culture procedures.
- 16. STORAGE AND STABILITY

Store at 2-8°C in the dark.

Reagent component will retain its full potency until the expiration date shown on the label of each vial when stored at recommended temperatures. The fluorescent antibody conjugate should not be left out in the light for prolonged periods.

TECHNICAL INFORMATION

For further information or assistance, contact: Technical Services in the U.S at 1-800-325 3424, or outside the U.S. at (353) 1 276 9800

