K961799

510(k) SUMMARY

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1. 510(k)
Light Diagnostics
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2. Device:
Light Diagnostics
Varicella-zoster Virus Direct Immunofluorescence Assay
A direct immunofluorescence assay for the identification of Varicella-zoster virus

3. Substantial Equivalence to:

Meridian Diagnostics, Inc.
Merifluor VZV
Varicella-zoster virus direct fluorescence antibody stain for VZV identification.

4. Device Description:

Light Diagnostics Varicella-zoster virus direct Immunofluorescence Assay (VZV DFA) uses the standard laboratory direct immunofluorescence technique for the culture confirmation and direct specimen detection of Varicella-zoster virus. The DFA is based on the principle of antigen identification using a detector monoclonal antibody conjugated to fluorescein isothiocyanate. The substrate consists of a slide prepared from a direct specimen vesicular smear or the tissue cultured cells from a clinical specimen inoculum. Anti VZV FITC labeled antibody is applied to the substrate. The antibody will bind to specific antigen, if present, in the substrate. The fluorescein conjugated monoclonal antibody allows for visualization of the antigen / antibody complex by fluorescence microscopy.

A blend of mouse monoclonal antibodies are used as detector antibodies in ***Light Diagnostics*** Varicella-zoster virus direct Immunofluorescence Assay. The monoclonal antibodies are specific for the glycoprotein gp I or the immediate early antigen of VZV. The use of monoclonal antibodies ensures increased specificity and reduced non-specific interference.

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5. Intended Use:

Light Diagnostics Varicella-zoster virus Direct Immunofluorescence Assay is intended for in vitro diagnostic use in the qualitative detection of VZV from vesicular smears and in cell culture viral isolation and confirmation.

6. Technological Characteristics Comparison of ***Light Diagnostics*** Varicella-zoster virus Direct Immunofluorescence Assay and the Merifluor VZV kit:

   a. Principle: Both kits use standard immunofluorescence assay technique using substrate slides prepared from vesicular smears or the cells from tissue culture isolation.

   b. Materials: Both kits incorporate monoclonal antibodies specific for VZV as the detector antibodies.

Performance Data for Light Diagnostics Varicella-zoster virus Direct Immunofluorescence Assay Kit

1. Nonclinical evaluation:

The conjugated monoclonal antibodies used in the kit were characterized for their ability to detect Varicella-zoster virus. The anti VZV antibodies reacted concordantly when tested with reference virus strains and clinical isolates.

The conjugated monoclonal antibodies were evaluated for cross reactivity to a variety of viral pathogens and host cell controls. No discordant results were obtained.

2. Clinical Evaluation:

Light Diagnostics Varicella-zoster virus Direct Immunofluorescence Assay was compared in clinical evaluation to the Meridian Diagnostics, Inc. Merifluor kit for direct specimen detection and cell culture isolation / confirmation.
Two hundred and five specimens were evaluated with results for 95% confidence interval sensitivity of 91.3% to 100% and specificity of 96.2% to 100%.

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3. Conclusions Drawn from Evaluations:

Light Diagnostics Varicella-zoster virus Direct Immunofluorescence Assay Kit uses the standard laboratory DFA in the culture confirmation and direct detection of Varicella-zoster virus. The monoclonal antibodies used in the kit have been characterized to ensure maximum specificity and reliability. In clinical evaluations, the kit performed consistent with results obtained using the Meridian Diagnostics, Inc. Merifluor VZV in vitro diagnostic kit.

The characterization and clinical evaluation of ***Light Diagnostics*** Varicella-zoster Direct Immunofluorescence Assay verifies its safety and effectiveness when used as intended.