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510(k) SUMMARY

1. 510(k)
Light Diagnostics
28835 Single Oak Drive
Temecula, California 92590

Contact Person: Dale Dembrow
(909) 676-8080
Extension 230

2. Device:
Light Diagnostics
Cytomegalovirus Direct Immunofluorescence Assay
A direct immunofluorescence assay for the identification of Cytomegalovirus

3. Substantial Equivalence to:

Light Diagnostics
Cytomegalovirus Immunofluorescence Assay
Cytomegalovirus Pre-CPE Culture Identification Test

Syva *MicroTrak*
CMV Culture Identification Test
For pre-CPE and CPE applications

4. Device Description:

Light Diagnostics Cytomegalovirus Direct Immunofluorescence Assay (CMV DFA) uses the standard laboratory direct immunofluorescence technique for the culture confirmation of cytomegalovirus. 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 the tissue cultured cells from a clinical specimen inoculum. Anti CMV 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.

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Mouse monoclonal antibody is used as the detector antibody in ***Light Diagnostics*** Cytomegalovirus Direct Immunofluorescence Assay. The use of monoclonal antibody ensures increased specificity and reduced non-specific interference.

The monoclonal antibody is specific for a 68-72 kDa non-structural protein designated as immediate early (IE) antigen of human CMV.

5. Intended Use:

The ***Light Diagnostics*** Cytomegalovirus Direct Immunofluorescence Assay is intended for use in centrifugation enhanced shell vials in the qualitative detection and identification of immediate early antigen- of human CMV.

6. Technological Characteristics Comparison of ***Light Diagnostics*** Cytomegalovirus Direct Immunofluorescence Assay and other legally marketed *in vitro diagnostic* kits for detection and identification of CMV.

   a. Principle: All kits use standard immunofluorescence assay techniques on cell substrate slides obtained after processing specimens for viral isolation in tissue culture.

   b. Materials: All kits incorporate monoclonal antibody specific for CMV as the detector antibody.

Performance Data for Light Diagnostics Cytomegalovirus Direct Immunofluorescence Assay Kit

1. Nonclinical evaluation:

The conjugated monoclonal antibody used in the kit was characterized for its ability to detect Cytomegalovirus. The anti CMV antibody reacted appropriately when tested with reference virus strains and clinical isolates.

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

The monoclonal antibody was evaluated for cross reactivity to a variety of microorganisms. No cross reactions were observed.

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2. Clinical Evaluation:

Light Diagnostics Cytomegalovirus Direct Immunofluorescence Assay was compared in clinical evaluation to indirect immunofluorescence tests for detection and identification of CMV. Five hundred and sixteen specimens were evaluated with results for 95% confidence interval sensitivity of 82.5% to 98.7% and specificity of 97.2% to 99.5%.

3. Conclusions Drawn from Evaluations:

Light Diagnostics Cytomegalovirus Direct Immunofluorescence Assay Kit uses the standard laboratory DFA in the culture confirmation of cytomegalovirus. The monoclonal antibody used in the kit has been extensively characterized to ensure maximum specificity and reliability. In clinical evaluations, the kit performed comparably with results obtained by indirect immunofluorescence.

Extensive characterization and clinical evaluation of ***Light Diagnostics*** Cytomegalovirus Direct Immunofluorescence Assay verifies its safety and effectiveness when used as intended.