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510(K) SUMMARY
Abbott CMV Total AB Diagnostic EIA

I. SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING A
SUBSTANTIALLY EQUIVALENT DETERMINATION

The Abbott CMV Total AB Diagnostic EIA enzyme immunoassay is substantially equivalent to the CETUS Cytomegalovirus Indirect Hemagglutination Assay (IHA) which is based on the IHA of Yeager, and originally used for CMV antibody detection by Bernstein and Stewart prior to May 28, 1976. The Abbott CMV Total AB Diagnostic EIA and the CETUS CMV IHA are substantially equivalent in that:

- a. Both are intended for use in the detection of antibody to CMV.
- b. Both are in vitro immunological test systems.
- c. Both are used to determine serologic status on a single specimen.
- d. Both are based on the formation of complexes between CMV antigens and CMV antibody.

The assays differ in that:

The Abbott CMV Total AB Diagnostic EIA is designed to be used with a spectrophotometer to give an absorbance value which is interpreted objectively. The IHA result, on the other hand, is determined by a subjective interpretation of the erythrocyte settling pattern.

Five facilities evaluated a total of 2312 specimens from random healthy adults by CMV Total AB Diagnostic EIA and IHA. Twenty-three specimens were uninterpretable with IHA. Of the remaining 2289 specimens, 51.07% (1169/2289) were positive for antibody to CMV as determined with the CMV Total AB Diagnostic EIA and 49.37% (1130/2289) were positive for antibody to CMV as determined by IHA. The overall agreement between CMV Total AB Diagnostic EIA and IHA was 95.50% (2186/2289). Relative specificity was calculated to be 93.87% $[(1159-71)/1159]$ with a

95% confidence interval of 92.34 to 95.18%. Relative sensitivity was calculated to be 97.17% $[(1130-32)/1130]$ with a 95% confidence interval of 96.03 to 98.06%.

In addition, a total of 11 serum specimens from CMV infected pediatric patients was tested and all specimens were positive for anti-CMV with the Abbott CMV Total AB Diagnostic EIA.

In conclusion, these data demonstrate that Abbott CMV Total AB Diagnostic EIA is as safe and effective and is substantially equivalent to CETUS CMV IHA.

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