

K965116

510(k) Summary FEB 20 1997

**Summary of Safety and Effectiveness Information Supporting a
Substantially Equivalent Determination**

The following information as presented in the Premarket Notification [510(k) for ABBOTT TestPack® Plus™ hCG COMBO with OBC®] constitutes data supporting a substantially equivalent determination. ABBOTT TestPack Plus hCG COMBO with OBC (List No. 7B34) is substantially equivalent to ABBOTT TestPack® Plus™ hCG COMBO (List No. 3A60).

Substantial equivalence has been demonstrated between the ABBOTT TestPack Plus hCG COMBO with OBC assay and the ABBOTT TestPack Plus hCG COMBO assay. The intended use of both assays is the qualitative determination of human chorionic gonadotropin in serum or urine. A concordance analysis between the two assays, using 1085 serum specimens and 934 urine specimens, yielded a concordance of 100% for serum specimens and a concordance of 100% for urine specimens.

Both the ABBOTT TestPack Plus hCG COMBO with OBC assay and the ABBOTT TestPack Plus hCG COMBO assay measure hCG levels of 25 mIU/mL or greater.

While both assays utilize a plus/minus indicator, the ABBOTT TestPack Plus hCG COMBO with OBC assay incorporates additional On Board Controls: POS CTL (√) and NEG CTL (X).

In conclusion, these data demonstrate that ABBOTT TestPack Plus hCG COMBO with OBC (List No. 7B34) is safe and effective and is substantially equivalent to ABBOTT TestPack Plus hCG COMBO (List No. 3A60).

Prepared and Submitted December 19, 1996 by:

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