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VIII. Safety and Effectiveness Summary

The STA[®]-Liatest[®] vWF test kit is intended for use with the STA[®] analyzer to perform quantitative assays of von Willebrand Factor (vWF) antigen in citrated plasma by the immuno-turbidimetric method based on the measurement of light absorbance produced by a suspension of microlatex particles coated with specific anti-vWF antibodies.

Each STA[®]-Liatest[®] vWF test kit provides: 4 x 5-ml vials of ready-for-use glycine buffer; 4 x 2-ml vials of a suspension of microlatex particles coated with rabbit anti-human vWF antibodies; 4 x 4-ml vials of diluent solution containing glycine for dilution of the latex reagent before use.

Reagents in intact vials remain stable for 18 months after the date of manufacture, when stored at 2°-8°C. After opening of the vials or after dilution, kit reagents are stable for 15 days on board the STA[®] analyzer.

The proposed STA[®]-Liatest[®] vWF test kit has demonstrated substantial equivalence to the commercially available ASSERA[®]-PLATE vWF kit (Diagnostica Stago, France; K861417) which is an electro-immunodiffusion procedure for the quantitative determination of vWF antigen levels in citrated plasma.