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AMERICAN BIOPRODUCTS COMPANY
Premarket 510(k) Notification
STA[®]-vWF Control [N]+[P] Kit

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VII. SAFETY AND EFFECTIVENESS SUMMARY

The STA[®]-vWF Control [N]+[P] kit provides two citrated human plasmas intended for use as a normal and an abnormal controls for von Willebrand Factor (vWF) antigen assays by the immuno-turbidimetric method performed on the STA[®] analyzer (Diagnostica Stago, France; K942117).

Each manufactured lot of STA[®]-vWF Control [N]+[P] is assigned vWF values (normal and abnormal levels) which are determined with an internal vWF reference that has been assayed against the third International Standard 91/666 for Factor VIII and von Willebrand Factor established in 1992.

Each STA[®]-vWF Control [N]+[P] kit provides 12 x 1-ml vials of freeze-dried human plasma containing vWF at the normal level (STA[®]-vWF Control [N]) and 12 x 1-ml vials of freeze-dried human plasma containing vWF at the abnormal level (STA[®]-vWF Control [P]). Both the normal and abnormal plasmas in the freeze-dried state are stable for 24 months after the date of manufacture, when stored at 2°-8°C; after reconstitution with water, both plasmas are stable for 8 hours on board the STA[®] analyzer.