Potency Determination of Anti-Inhibitor Coagulant Complex – Autoplex

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A three-point reference standard is employed in the quantitative determination of Autoplex activity. The principle upon which this reference standard is based is the definition of a factor VIII correctional unit. One unit of factor VIII correctional activity is that quantity of Autoplex which, upon appropriate dilution and addition to an equal volume of severely deficient factor VIII, or inhibitor plasma, will correct the clotting time of that plasma to 35 s (normal) when using an activated partial thromboplastin reagent. Components of this assay system are as follows: ellagic acid activated partial thromboplastin, factor VIII-deficient plasma or

DILUTION UNITS OF F-VIII CORRECTION ACTIVITY

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217

inhibitor plasma, calcium chloride and the reference standard or test material.

The test is performed in the following manner using a fibrometer as the end-point detector. 0.1 ml actin (Dade's ellagic acid-activated partial thromboplastin) is prewarmed in a reaction cup, Fibro Tube, for 3 min. To the actin, 0.1 ml factor VIII-deficient or inhibitor plasma and 0.1 ml of diluted Autoplex or reference standard are added. The mixture is incubated for 3 min following which 0.1 ml of prewarmed 0.02 M CaCl₂ is added to initiate the clotting reaction. The test is performed in duplicate with precision of the assay being comparable to other coagulation factor assays.