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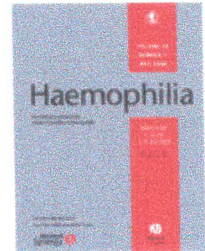


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Production of recombinant human coagulation Factor IX in the milk of genetically modified mice

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Transgenic animals present attractive applications in biomedicine and to improve livestock production traits. Expression of biopharmaceutical proteins in transgenic animals is an attractive alternative due to the possibility of reducing production costs and to overcoming the limitations from the others expression systems. The aim of this work was to express the human coagulation Factor IX in transgenic mice. The human coagulation Factor IX gene was cloned into the vector pBC1 under control of beta-casein promoter that directed the expression of the gene almost exclusively to the lactating mammary gland. For the production of transgenic mice, the transgene was inserted into the host genome by microinjection. Studies were carried out to evaluate the presence of the foreign gene inserted into mice founders (F₀), F₁ and F₂ generations, utilizing PCR and Southern blot analysis. The human coagulation Factor IX was detected in the milk of transgenic animals by western blot and ELISA assays. Transgenic mice were capable of producing recombinant proteins secreted at levels as high as 20–35 µg/mL in the milk. Hemoagglutination bioassays were carried to confirm protein activity demonstrating its functionality. This work will be the foundation for the future application of the DNA recombinant technology for production of pharmaceuticals recombinant proteins in a large-scale basis in other animals such as cow and goat.