

Pel-Freez®

Analysis Certificate

PRODUCT: Level 4 Modified Rabbit Plasma INR 6.6**CODE NO:** 60015**LOT:** 27336**STORAGE:** -10 °C to -20 °C for 15 days from DOM; -70 °C or below for 12 months from DOM.**DATE OF
MANUFACTURE:** September 30, 2014**EU
REQUIREMENTS:** Product meets European Union requirements for production of technical blood products.**PROCEDURE:** Rabbit blood was collected at USDA plant P-202 from New Zealand White rabbits (mixed gender, 8-12 weeks, US grown) that were found to be free of contagious diseases. Custom Rabbit Plasma was produced by mixing blood with custom anticoagulant solution according to Pel-Freez SMP 91162, chilled for 2 hours on wet ice and frozen at -70 °C. Adsorbed Rabbit Plasma was produced by mixing Custom Rabbit Plasma with barium sulfate, centrifuged, chilled and frozen at -70°C in the same manner.

Custom Rabbit Plasma and Adsorbed Rabbit Plasma were thawed, mixed with 9.972 g/L HEPES hemisodium salt, and blended together in proportions to yield an INR of 6.6. After mixing thoroughly, the product was chilled for 2 hours on wet ice and frozen at -70°C.

The Data Tables below illustrate the INR values of the final bulk and final QC testing.

EC 1069/2009: EU # AR-TEC-0007**EU 142/2011:****APPEARANCE:** Slightly clouded, reddish-colored liquid**ASSAYS:** INR obtained using [REDACTED] meter.
Test strips: code 0**Final Bulk INR Testing Data Table**

Meter	Final Bulk INR
UP0734328	6.6
UP0610760	6.7
UP0690781	6.5
UP0751548	6.7
UP1014649	6.6

Target INR: **6.6**INR Range: **6.4 – 6.7** INRFinal Bulk Average INR: **6.6**

Final QC INR Testing Data Table

Meter	Replicate 1	Replicate 2	Average
UP0734328	6.8	6.5	6.7
UP0610760	6.7	6.5	6.6
UP0690781	6.8	6.4	6.6
UP0751548	6.9	6.4	6.5
UP1014649	6.9	6.6	6.8

Target INR: **6.6**INR Range: **6.4 – 6.7** INRFinal QC Average INR: **6.7****QUALITY ASSURANCE****Quality Control Release Date: October 13, 2014**Chris Lyle
Quality Systems Manager

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSE