Pel-Freez BIOLOGICALS
205 North Arkansas Street
Rogers, AR 72756

tificate of Analysis

PRODUCT: [redacted] Level 2 Modified Rabbit Plasma I.N.R. 3.2 - 3.4

CODE NO: 31172 **LOT NO:** 18346

DATE OF MANUFACTURE: July 1, 2024 **ORIGIN:** U.S.A.

STORAGE: -10 ˚C to -20 ˚C for 15 days from DOM; -70 ˚C or below for 12 months from DOM.

HEALTHY ANIMAL STATEMENT: This product is made from raw materials that were collected from animals and found free from obvious signs of infectious and contagious disease.

EU REQUIREMENTS: Product meets EU requirements for production of technical blood products. **EC 1069/2011:** AR-TEC-0007

PROCEDURE: Modified rabbit plasma is produced from custom rabbit plasma (Pel-Freez Part # 91162) and adsorbed rabbit plasma (Pel-Freez Part # 81162), using Pel-Freez SMP 31172.

Rabbit blood was collected and processed from New Zealand white rabbits (mixed gender, 8-12 weeks, US grown) at USDA plant P-202 and were found to be free of obvious signs of contagious diseases.

APPEARANCE: Clear, amber fluid

ASSAYS:

Required Assays	Specification	Result
INR	3.2 – 3.4	3.4

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP01656560	**3.3**	**3.3**	**3.4**	**3.3**
UP01570790	**3.4**	**3.4**	**3.4**	**3.4**
UP1229542	**3.3**	**3.3**	**3.4**	**3.4**
UP1046206	**3.3**	**3.3**	**3.4**	**3.4**
UP01670440	**3.3**	**3.3**	**3.4**	**3.4**

INR obtained using [redacted] meter. Key code: S-486-XSPT
Test strips: 560993

QUALITY ASSURANCE
Quality Control Release Date: July 2, 2024

Avery Donson
Quality Systems Tech/ Clerk
Meets or exceeds specifications ☑
Does not meet specifications ☐

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES