

# Quality Control Certificate

PrecisionBioLogic

## CRYOcheck™ Pooled Normal Plasma

### Product Identification

Catalog Number: **CCN-10**  
Lot Number: **A1358**  
Expiry: **2026-05-31**

### Test System Information

Instrument: **Diagnostica Stago STA-R®**  
PT Reagent: **HemosIL RecombiPlasTin 2G®**  
APTT Reagent: **HemosIL APTT-SP®**

All plasmas used in the manufacture of CRYOcheck Pooled Normal Plasma are tested and found:

- negative when screened for Lupus Anticoagulants
- negative when screened for HIV 1 & 2, HCV, and HBsAg
- acceptable when screened for CJD/nvCJD risk

Each lot of CRYOcheck Pooled Normal Plasma has been assayed and confirmed to contain normal levels of coagulation factors II through XII, and fibrinogen.

The plasma collection process is validated to confirm that all plasmas used are platelet-poor prior to freezing.

For controls to work effectively, control ranges must be established in each laboratory. Optimally, control data should be collected from at least 20 runs on different days before control ranges are calculated<sup>1</sup>.

The results presented below are calculated from data specific to the reagent/instrument combination used for internal quality control testing at Precision BioLogic. Results may vary depending on instrument, method, and technique used.

PT	APTT
12.6 sec	32.2 sec

<sup>1</sup>Cembrowski GS, Carey RN. Laboratory quality management. Chicago: ASCP Press; 1989.