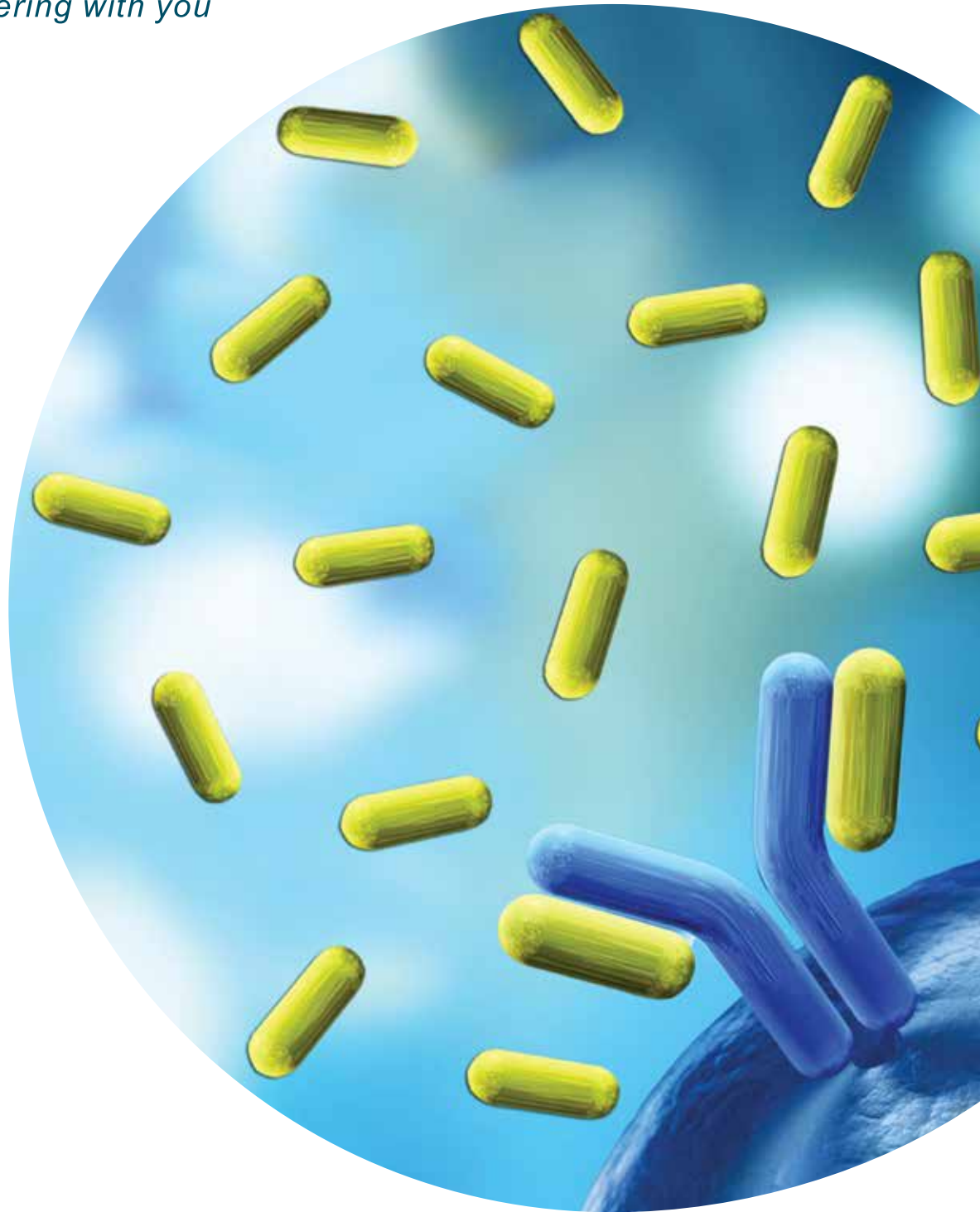




ADVY

Partnering with you



PURIFIED HUMAN KAPPA FREE LIGHT CHAINS

PURIFIED HUMAN KAPPA FREE LIGHT CHAINS

Product code: 00-AGN-TM-BJK-001

SALIENT FEATURES

- Bence Jones Proteins (Human Kappa Free Light Chains), manufactured from human renal failure patient pooled urine (protein type: native protein).
- Highly purified protein (>98% by SDS-PAGE).
- Negligible cross contaminants in finished product (<1 % Lambda FLC, IgG, IgA, IgM, Cystatin-C and microalbumin).
- Kappa Free Light Chains concentration can be customized as per customer specification.
- Extensively tested for absence of HBsAg, Anti-HCV and Anti-HIV I +II by enzyme-linked immunosorbent assay (ELISA) and for viral DNA/RNA (HBV, HIV and HCV) by Polymerase chain reaction (PCR).
- Shelf life: 1.5 year at 2-8°C.
- Processed at EHS compliant facility under ISO 13485 QMS.
- Advy is a primary manufacturer able to produce large lots for the IVD industry.
- Shipment can be made in preferred aliquots (Nalgene pre-sterilized bottles used).
- Labeling compliant with global regulatory requirements.
- Secondary and Tertiary packaging validated for cold-chain shipment.

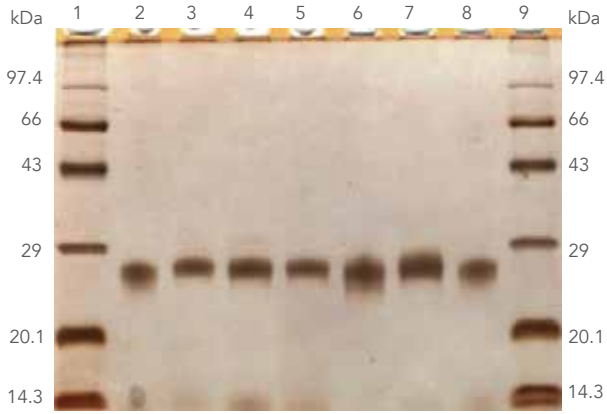
SUITABILITY

- As Controls and Calibrators in qualitative and quantitative turbidimetric, ELISA, CLIA, ECLIA and CMIA assays.
- For use in Radial Immunodiffusion, Immunoelectrophoresis, Western Blotting, Dot Blot and other similar assays.
- For development of target-specific assay reagents.
- In cancer research and development processes.
- As an immunogen to raise antibodies in animals.
- As a ligand for immunoaffinity purification.

SPECIFICATIONS

Test Parameters	Acceptance Criteria
Physical Appearance	Colorless to pale yellow solution
Formulation	Liquid
Shelf life	1.5 years
Concentration	≥ 1.0 mg/ml (Nephelometry method)
Buffer details	50mM Phosphate buffer, 150mM Sodium chloride pH7.4 ± 0.2
Preservative	0.1% Sodium azide
Purity	≥ 98% (SDS-PAGE)
Cross Contaminants	≤ 1%: Lambda free light chain, IgG, IgM, IgA, Cystatin-C and Microalbumin
HBsAg, Anti-HCV and Anti-HIV I +II	Negative (ELISA Assay)
HBV DNA	Not Detected (PCR Analysis)
HIV DNA	Not Detected (PCR Analysis)
HCV RNA	Not Detected (PCR Analysis)
Syphilis	Non Reactive
Storage conditions	2 to 8°C

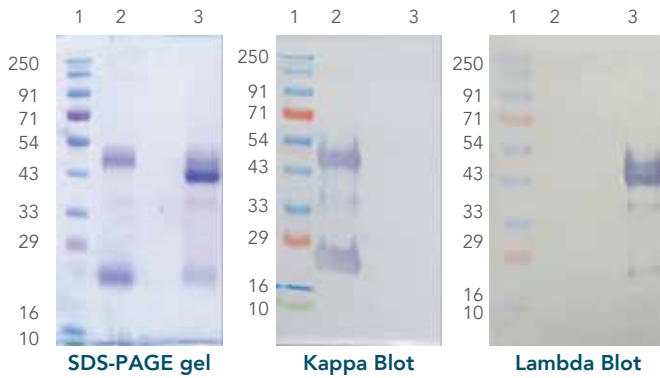
**COMPARISON WITH
COMMERCIALLY AVAILABLE
KAPPA FREE LIGHT CHAINS**



12% SDS-PAGE Reducing gel

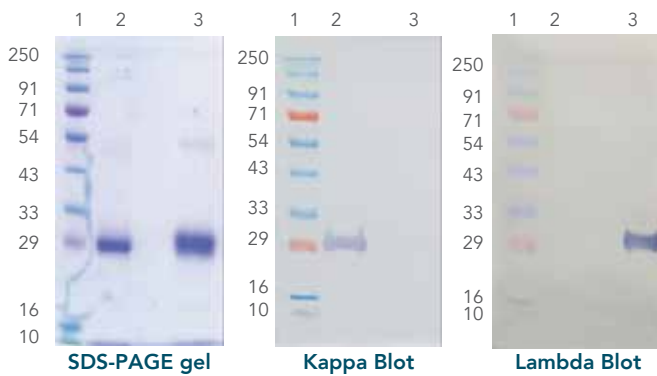
Lane -1	Marker protein
Lane - 2	Commercial sample
Lane - 3	BJK T-001/0118
Lane - 4	BJK T-002/0318
Lane - 5	BJK T-003/0418
Lane - 6	BJK T-004/0918
Lane - 7	BJK T-005/0919
Lane - 8	Commercial sample
Lane - 9	Marker protein

**IDENTIFICATION AND PURITY PROFILE
OF ADVY'S KAPPA FREE LIGHT CHAINS**



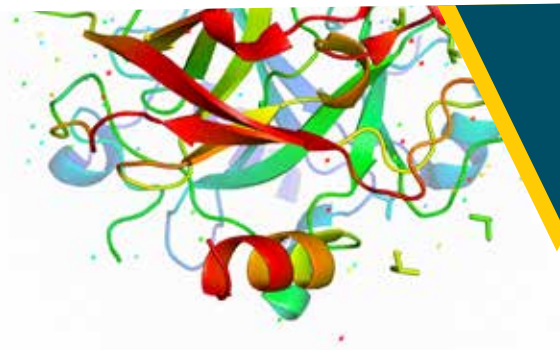
Non reducing conditions

Lane-1	Marker Protein
Lane-2	Advy purified Kappa FLC
Lane-3	Lambda FLC control

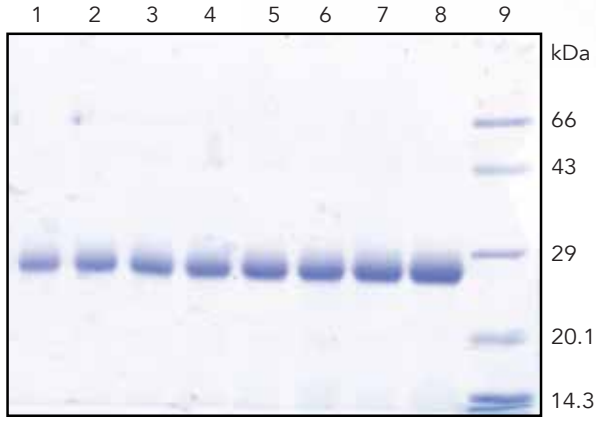


Reducing conditions

Lane-1	Marker Protein
Lane-2	Advy purified Kappa FLC
Lane-3	Lambda FLC control



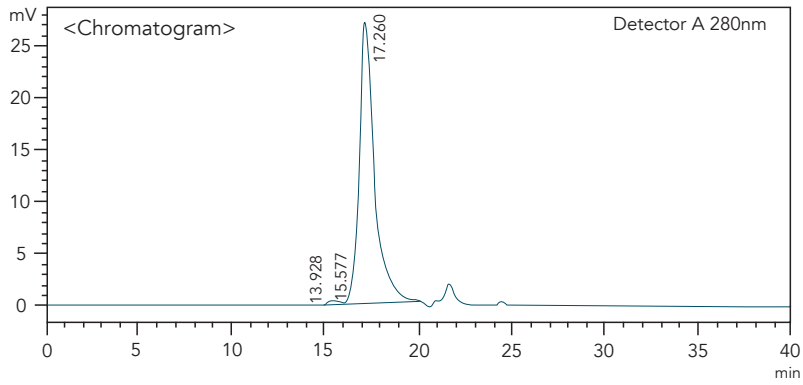
HIGHLY PURITY ILLUSTRATED BY SDS-PAGE ANALYSIS



12% SDS-PAGE Reducing gel (CBB stain)

Lane - 1	5.0 µg Kappa FLCs
Lane - 2	6.0 µg Kappa FLCs
Lane - 3	7.0 µg Kappa FLCs
Lane - 4	8.0 µg Kappa FLCs
Lane - 5	9.0 µg Kappa FLCs
Lane - 6	10.0 µg Kappa FLCs
Lane - 7	12.0 µg Kappa FLCs
Lane - 8	15.0 µg Kappa FLCs
Lane - 9	Marker protein

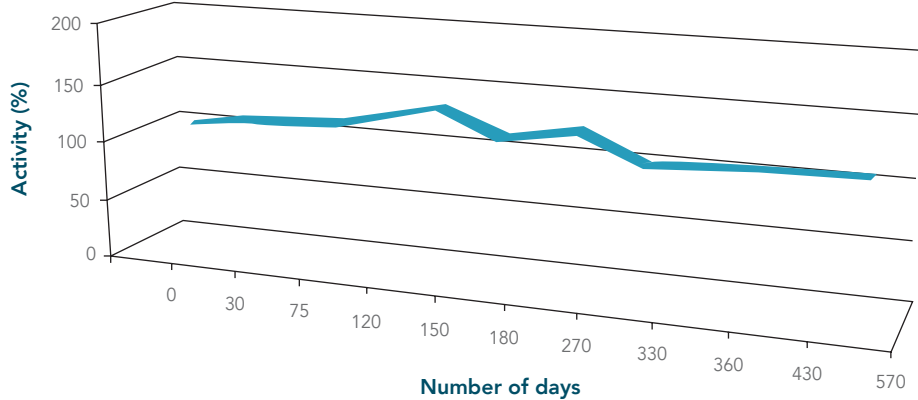
HIGH PURITY AS CONFIRMED BY SEC-HPLC



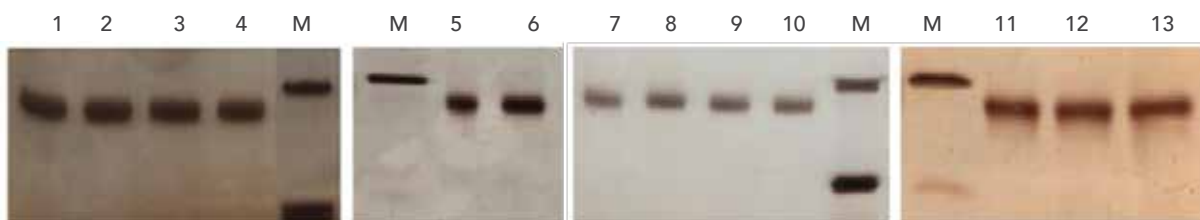
Detector A 280 nm			
Peak#	Ret. Time	Area	Area %
1	13.928	1009	0.067
2	15.577	15582	1.041
3	17.260	1480830	98.892
Total		1497421	100.000



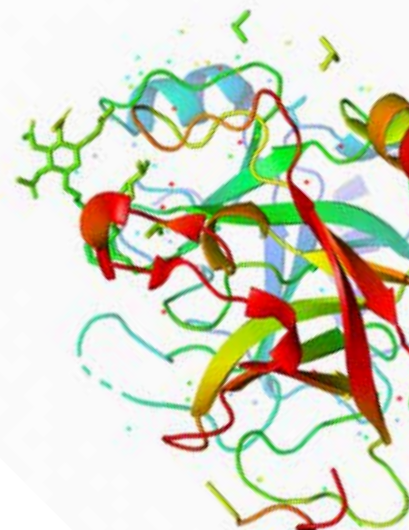
SHELF LIFE (REAL TIME STABILITY STUDIES)



Stability profile of Kappa free light chains (2-8°C), exhibits better activity up to 570 days by using Binding Site Freelite human kappa free kit (Siemens BN Prospec Nephelometer).



SDS PAGE Profile for Real Time Stability Studies. Lane M: Marker Protein; Lane 1 to 13: Purified kappa free light chains sample of 0, 15, 30, 45, 120, 150, 245, 270, 300, 330, 360, 430, and 570 days respectively





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