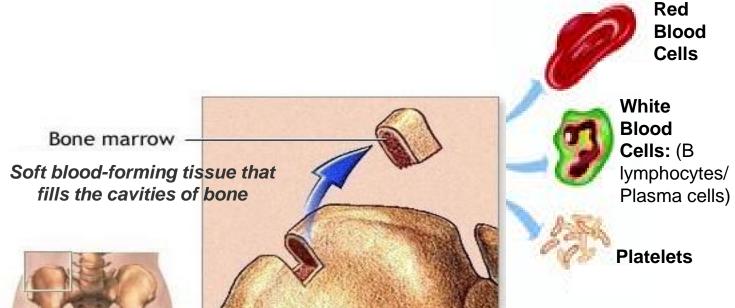


# Understanding Freelite<sup>®</sup>, the lab test for serum free light chains

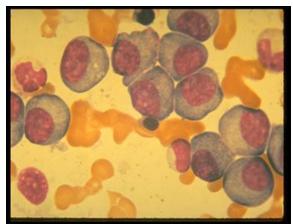
Anne L Sherwood, PhD Director of Scientific Affairs The Binding Site, Inc.



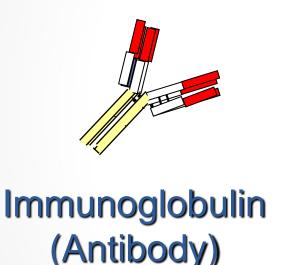
## AL Amyloidosis: abnormality of proteins from Plasma Cells in the Bone Marrow



Plasma cells make antibodies (<u>immunoglobulins</u>) to block bacteria and viruses



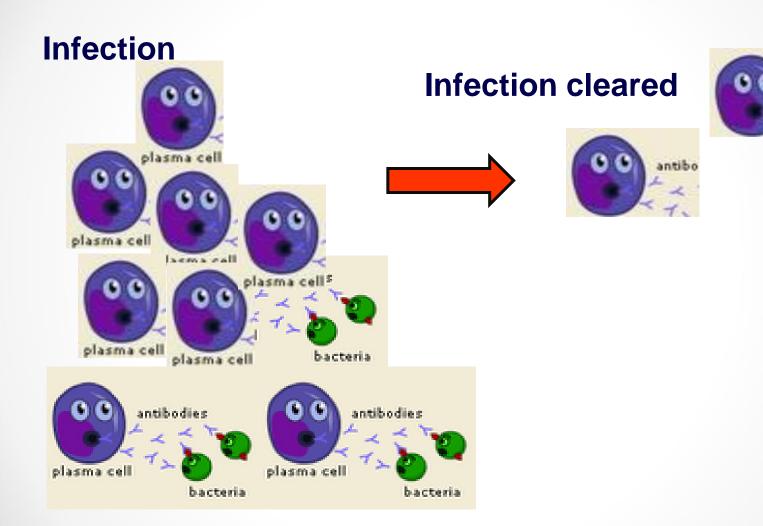
## Antibodies Are Made Up Of Heavy Chains And Light Chains



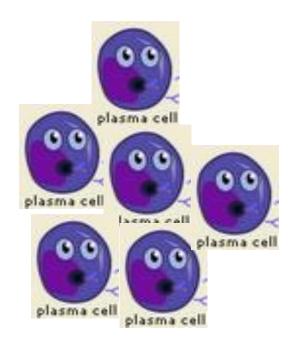
**Light Chains** 

**Heavy Chains** 

### Plasma cells increase in response to infection



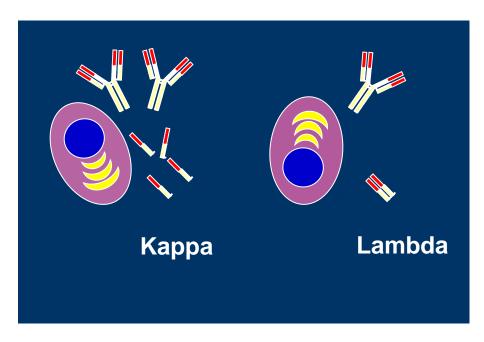
### In AL (or primary) amyloidosis, there is an abnormal expansion of plasma cells

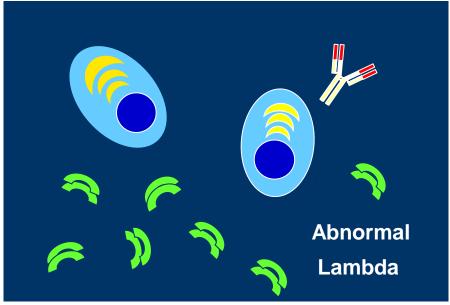


- AL = increase of one specific (clone) of defective plasma cells
- These plasma cells produce and secrete abnormal free light chains (FLCs) into the blood
- Levels of FLCs are associated with the number of defective plasma cells in a patient with AL amyloidosis

### What makes these FLCs Abnormal??

## Primary [AL] Amyloidosis is a plasma cell disorder

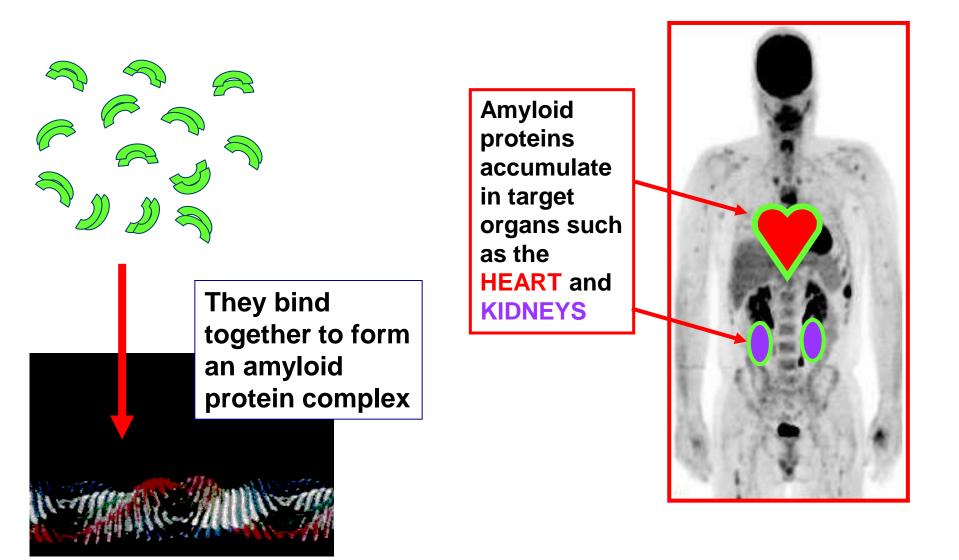




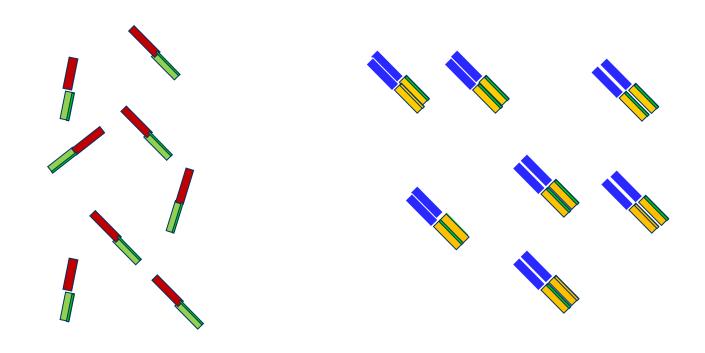
**Normal Healthy Plasma cells** 

Mutated (diseased) Plasma cells

## These abnormal light chains have mutations which make them "sticky"



## The FreeLite Test Measures both types of Free Light Chains - Kappa And Lambda



Kappa Free Light Chains (Leonhard Korngold "Kappa")

Lambda Free Light Chains (Rose Lipari "Lambda")

### Normal Ranges for Serum Free Light Chains

Units (mg/dL)

Kappa: 3.3–19.4 mg/L

Lambda: 5.7-26.3 mg/L

 $\kappa/\lambda$  ratio: 0.26–1.65

Kappa: 0.33-1.94 mg/dL

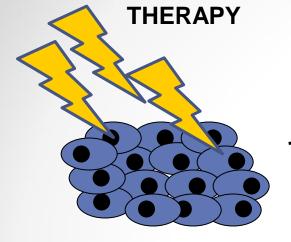
Lambda: 0.57-2.63 mg/dL

 $\kappa/\lambda$  ratio: 0.26–1.65

## Examples

May

Description	Flag	Flag Result		Normal Range
KAPPA LAMBDA FREE LIGHT CH	MAN			
KAPPA FREE LIGHT CHAIN	н	38.50 MG/DL		0.33 - 1.94
LAMBDA FREE LIGHT CHAIN	ı L	0.31 M	G/DL	0.57 - 2.63
KAPPA LAMBOA RATIO	н	124.19	%	0.26 - 1.65
July			= 385	mg/L
Free K+L Lt Chains, Qn, S Free Kappa Lt Chains, S	303.00	Righ	mg/L	3.30 - 19.40
**Results verified by rep	0.56	TOM	mg/L	5.71 - 26.30
**Results verified by rep Kappa/Lambda Ratio,S	peat testin 541.08	ng** High		0.26 - 1.65



## AL amyloidosis Therapy





KILLS ABNORMAL PLASMA CELLS



LESS ABNORMAL
PLASMA CELLS =
FEWER LIGHT
CHAINS + LESS
AMYLOID

# Why do doctors watch difference rather than ratio for involved light chain?

## Involved FLC (iFLC) & Difference in FLC (dFLC)

- If your abnormally elevated light chain is lambda then:
  - Involved FLC (iFLC) is lambda
  - Uninvolved FLC is kappa
  - o dFLC is lambda-kappa
  - dFLC is used more for monitoring
  - FLC ratio still very important
    - Diagnosis
    - Assessing Complete Response (CR)

# ISA Consensus Panel 2010 Updated Hematologic response criteria

Response Criteria (following treatment)

Complete Response (CR): negative serum and urine IFE and normal FLC ratio

Very Good Partial Response (VGPR): dFLC <40 mg/L

Partial Response (PR): dFLC decrease >50%

No Response (NR): none of the above

### **Examples of Response Criteria Calculations**

 Partial Response: difference between the involved and uninvolved LC decrease by greater than 50% (compare two test results)

```
Example: k = 1 \text{ mg/dL}, \lambda = 25 \text{ mg/dL}, dFLC = 24 k = 0.8 \text{ mg/dL}, \lambda = 10 \text{ mg/dL}, dFLC = 9.2 [50% of 24 = 12, 12 > 9.2]
```

- Very Good Partial Response: Difference between involved and uninvolved LC is less than 4 mg/dL (only one test result required)
   Example: k = 1 mg/dL, λ = 4.2 mg/dL, dFLC = 3.2 mg/dL
- Complete Response: normal FLC ratio; serum and urine IFE (-) (one test result)

```
Example: k = 0.8 \text{ mg/dL}, \lambda = 2 \text{ mg/dL}, ratio 0.8/2 = 0.4 (FLC ratio nr = 0.26-1.65)
```

### Additional Resources

- www.wikilite.com (web version of our "black 6<sup>th</sup> edition book")
- Google "Binding Site"
- Email us info@thebindingsite.com
- Call The Binding site 800-633-4484
  - Experts are on hand to assist you
- Understanding Serum Free Light Chain Assays (IMF booklet)

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Video Now Available: Freelite® - The Standard of Care for Myeloma

February 20th 2014

Dr. Rafael Fonseca Discusses Multiple Myeloma: Monitoring and Treatment

February 12th 2014

Binding Site's Hevylite® assays are now available in the USA!

January 10th 2014



## Questions?



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For more information Or to keep up-to-date!!

<u>VISIT</u>



