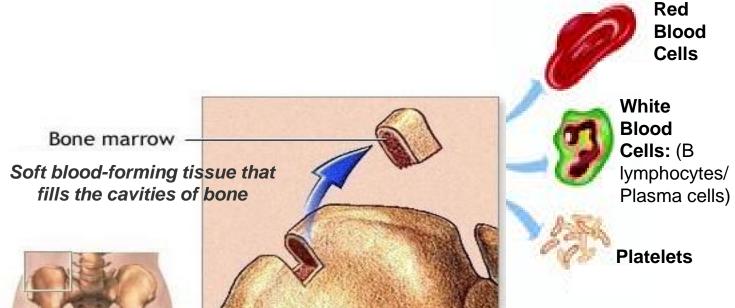


Understanding Freelite[®], the lab test for serum free light chains

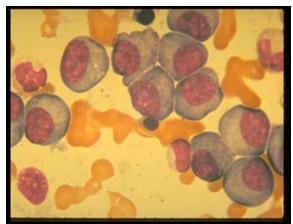
Anne L Sherwood, PhD Director of Scientific Affairs The Binding Site, Inc.



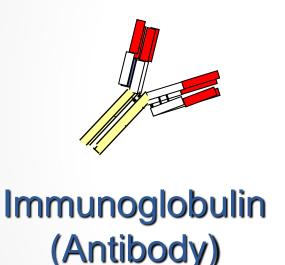
AL Amyloidosis: abnormality of proteins from Plasma Cells in the Bone Marrow



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



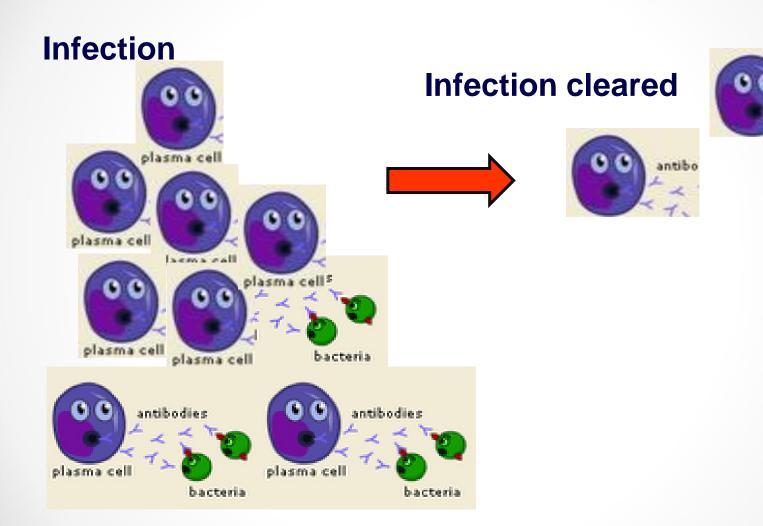
Antibodies Are Made Up Of Heavy Chains And Light Chains



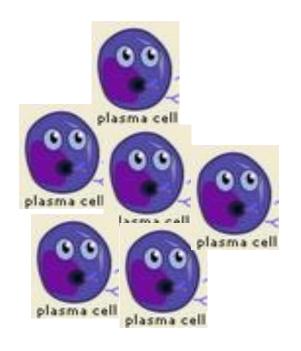
Light Chains

Heavy Chains

Plasma cells increase in response to infection



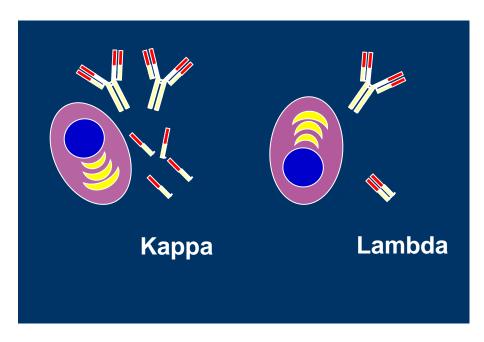
In AL (or primary) amyloidosis, there is an abnormal expansion of plasma cells

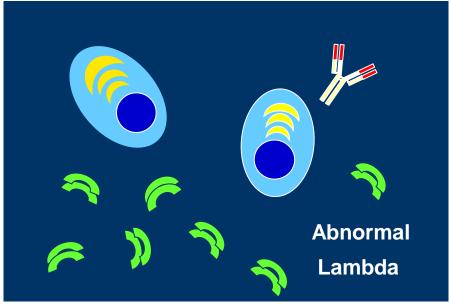


- AL = increase of one specific (clone) of defective plasma cells
- These plasma cells produce and secrete abnormal free light chains (FLCs) into the blood
- Levels of FLCs are associated with the number of defective plasma cells in a patient with AL amyloidosis

What makes these FLCs Abnormal??

Primary [AL] Amyloidosis is a plasma cell disorder

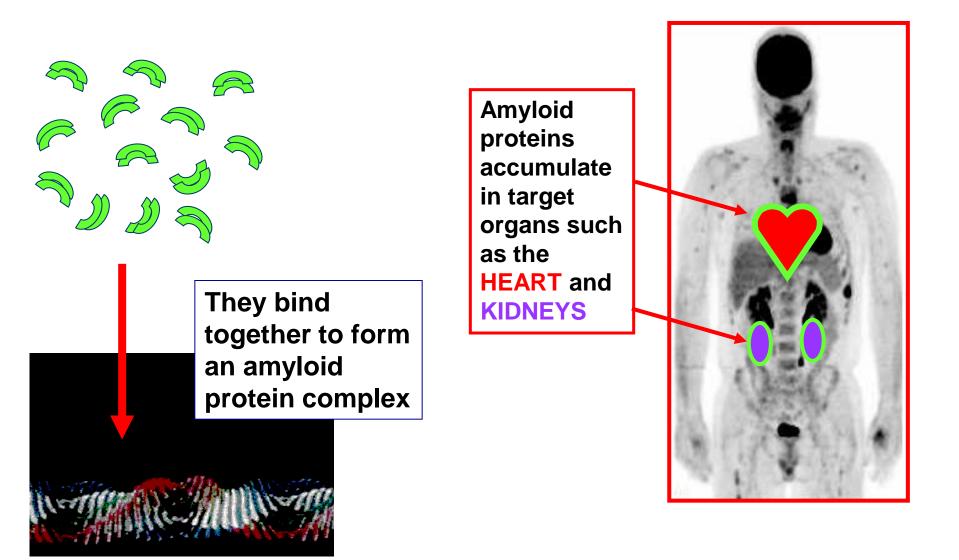




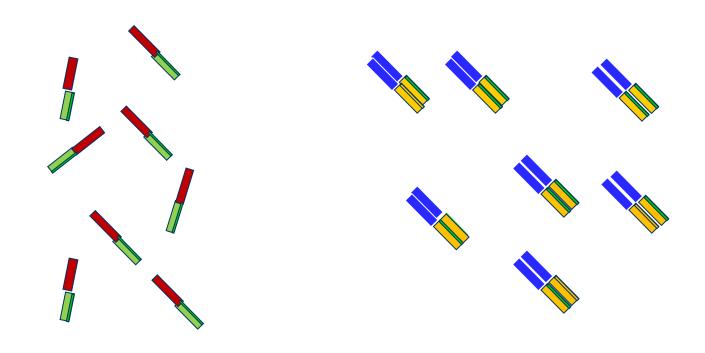
Normal Healthy Plasma cells

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

 κ/λ ratio: 0.26–1.65

Kappa: 0.33-1.94 mg/dL

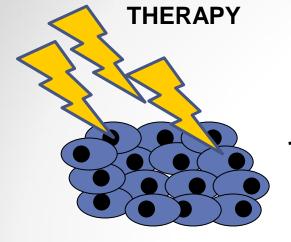
Lambda: 0.57-2.63 mg/dL

 κ/λ 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 6th 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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Recognizing the Signs and Symptoms of Multiple Myeloma in the Primary Care Setting

Educational Webinar Resource for Clinicians

Drs. Edward Stadtmauer and Craig Wynne address Multiple Myeloma in the primary care setting, including common symptoms, current standard of care in the assessment process, and which diagnostic tools are available to aid in the diagnosis. Click here to view: www.managingmyeloma.com.

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>



