DIAZYME LABORATORIES

CANCER MARKER

HUMAN KAPPA (κ) AND LAMBDA (λ) FREE LIGHT CHAIN ASSAYS

Dual Vial Liquid Stable

Diazyme's Human Kappa (ƙ) and Lambda (ƛ) Free Light Chain assays provide accurate and reliable testing across the full analytical range and correlates well with current methods. Diazyme's Free Light Chain Assays utilize a cost effective latex particle enhanced immunoturbidimetric methodology for use on a wide range of clinical chemistry systems. Both assays display excellent precision on the low end while its liquid stable format requires no reagent preparation saving time and reducing sample handling.

DIAZYME HUMAN KAPPA (κ) AND LAMBDA (λ) FREE LIGHT CHAIN ASSAYS ADVANTAGES

- Fast test results (10 minutes) for a rapid turnaround time
- Wide range of instrument parameters available for facilitating and simplifying implementation
- Liquid stable format requires no reagent preparation saving time and reducing sample handling

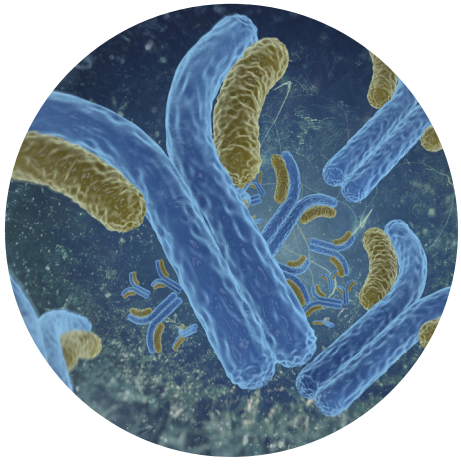
REGULATORY STATUS

510(k) Cleared Health Canada Registered EU: CE IVD

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Roche**

  - Hitachi



HUMAN KAPPA (κ) AND LAMBDA (λ) FREE LIGHT CHAIN ASSAYS

Dual Vial Liquid Stable Assays

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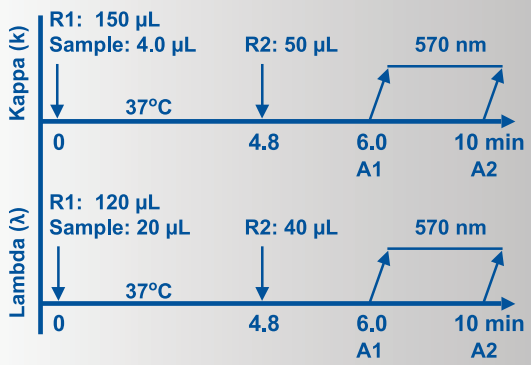
ASSAY SPECIFICATIONS

Assay	Kappa (κ)	Lambda (λ)
Method	Latex Enhanced Imunoturbidimetric Assay	Latex Enhanced Imunoturbidimetric Assay
Sample Type & Volume	• Serum Sample Volume 4.0 µL	• Serum Sample Volume 20 µL
Method Correlation	Linear Regression N = 126 y-intercept = -2.536 Slope = 0.958 R^2 = 0.977 *Samples range from 4.63 - 2975.8 mg/L*	Linear Regression N = 126 y-intercept = 0.636 Slope = 1.054 R^2 = 0.972 *Samples range from 6.19 to 3917.80 mg/L*
Linearity	4.5 - 3000 mg/L	6.1 - 4000 mg/L
LOB LOD LOQ	1.2 mg/L 2.0 mg/L 4.5 mg/L	1.7 mg/L 2.9 mg/L 6.1 mg/L

*Diazyme Human Kappa (κ) And Lambda (λ) Free Light Chain Assay Procedures**



***Analyzer Dependent**

For a list of validated parameters please contact Diazyme technical support at 858-455-4768 or email support@diazyme.com

KAPPA (κ) PRECISION

The precision of the Assay was evaluated according to CLSI EP5-A guideline. In the study, eight levels of serum specimens containing kappa FLC spanning AMR and two levels of serum based kappa FLC controls were tested with 2 runs per day with duplicates over 20 working days using multiple lots of the reagents on multiple analyzers. The precision data was analyzed according to three-way nested ANOVA and the results of mean (mg/L) and CV% are summarized below:

One lot of the reagent on three analyzers

ID	Mean n=240	Within-Run	Between Run	Between Day	Between Instrument	Total
S1	9.38	7.6%	4.9%	3.5%	5.1%	11.0%
S2	35.30	2.1%	1.5%	1.3%	2.0%	3.5%
S3	122.37	2.4%	0.9%	1.8%	0.8%	3.2%
S4	5.95	7.5%	3.0%	8.5%	N/A	11.7%
S5	15.76	2.9%	1.6%	2.1%	0.2%	3.9%
S6	25.92	1.7%	1.3%	0.5%	0.4%	2.2%
S7	139.23	1.5%	1.5%	0.7%	1.1%	2.5%
S8	2588.59	1.4%	0.6%	2.6%	1.5%	3.3%

Three lots of the reagent on one analyzer

ID	Mean n=240	Within-Run	Between Run	Between Day	Between Instrument	Total
S1	9.49	7.9%	5.7%	5.7%	2.6%	11.6%
S2	35.14	2.9%	0.8%	1.5%	0.8%	3.5%
S3	121.53	2.6%	1.5%	2.3%	N/A	3.8%
S4	5.81	6.3%	2.6%	2.7%	0.7%	7.4%
S5	15.40	2.4%	0.9%	0.6%	2.2%	3.5%
S6	25.66	1.1%	0.3%	0.6%	1.0%	1.7%
S7	138.28	1.1%	N/A	1.0%	1.0%	1.8%
S8	2588.45	1.3%	1.0%	2.5%	1.5%	3.3%

LAMBDA (λ) PRECISION

One lot of the reagent on three analyzers

ID	Mean n=240	Within-Run	Between Run	Between Day	Between Instrument	Total
S1	11.89	6.3%	4.5%	6.1%	N/A	9.9%
S2	48.65	2.1%	0.7%	1.3%	0.8%	2.7%
S3	144.55	1.6%	1.0%	1.3%	0.6%	2.4%
S4	8.31	6.5%	0.4%	3.1%	0.8%	7.3%
S5	22.27	3.0%	1.4%	2.6%	1.1%	4.3%
S6	35.09	2.1%	1.2%	1.4%	1.0%	2.9%
S7	181.13	0.8%	0.7%	1.3%	1.1%	2.0%
S8	3472.59	3.6%	N/A	2.1%	0.6%	4.2%

Three lots of the reagent on one analyzer

ID	Mean n=240	Within-Run	Between Run	Between Day	Between Instrument	Total
S1	11.78	5.9%	4.0%	7.4%	4.9%	11.4%
S2	48.95	1.3%	N/A	1.7%	0.3%	2.2%
S3	142.63	1.1%	0.8%	0.5%	0.8%	1.6%
S4	8.16	6.3%	2.3%	N/A	3.1%	7.4%
S5	21.90	2.9%	1.3%	N/A	0.6%	3.2%
S6	34.79	2.0%	0.4%	0.3%	N/A	2.1%
S7	183.02	0.6%	0.3%	0.8%	0.3%	1.1%
S8	3442.60	3.2%	N/A	2.0%	N/A	3.8%

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