

κλoneus®

Free Light Chains

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by  **TRIMERO**
DIAGNOSTICS

Free Light Chains urine and serum.

Reagents based on polyclonal antibodies and immunogens.

Particle-enhanced assays for serum and urine.

Values referred to the European Reference Material ERM-DA470k/IFCC to ensure lot-to-lot traceability.

Nephelometric assays for BN™ series and IMMAGE® systems.

Turbidimetric assays for ADVIA™, AU® and other systems.

Good correlation with the densitometric estimation of Bence-Jones proteinuria.



Compatible with



**BECKMAN
COULTER**

**SIEMENS
Healthineers**

systems

Alternative Approach for the determination of Bence Jones Proteinuria (BJP), based on the IFCC Guidelines^{*1a}

Screening Test

Quantification of Free Light Chains in non-concentrated urine (ur-FLC)

Recommended Sample^{*1b}:

2nd morning void and expressing the results relative to creatinine

with **κλoneus[®]** assays

by Nephelometry (NIA) or Turbidimetry (TIA)

Recommended Detection Limit^{*1c}:

< 10 mg/L

Kappa or Lambda
>10 mg/L

Kappa and Lambda
<10 mg/L

BJP Suspicion

STOP

Confirmation Test

to determine the electrophoretic, mono, oligo or polyclonal distribution of the quantified ur-FLC by **κλoneus[®]** assays

by Immunofixation (IF)
of concentrated urine

Recommended Sensitivity^{*1e}: < 10 mg/L

the quantitative result obtained by **κλoneus[®]** is an objective guide to establish the urine concentration factor and it can also be useful in monitoring and quantitative estimation of the urinary monoclonal component ^{*1f} which is more precise and sensitive than densitometrically dosed

1. "Guidelines for the Analysis of Bence Jones Protein"

M. Graziani et al. for the IFCC Committee on Plasma Proteins
and the SIBioC Study Group on Proteins
Clin Chem Lab Med 2003; 41(3):338-346

1a. page 339:

"Alternative approaches

Immunochemical methods (nephelometry, turbidimetry) for the quantification of FLCs in urine can be used for BJP detection as an initial screening to exclude BJP, thus reducing the number of samples to process further."

1b. page 339:

"Sample

...

... we recommend the use of the second morning void (5) and expressing the concentration of BJP relative to urinary creatinine."

1c. page 340:

"Alternative approaches

...

... it is mandatory to control and avoid antigen excess and to document a detection limit below 10 mg/l."

1d. page 340:

"Alternative approaches

...

... A positive test should be followed by immunofixation (IF) for the following reasons: ..."

1e. page 339:

"Sensitivity

The indication of a detection limit for BJP can only be approximate since there is no way of obtaining an accurate quantification of the protein. However, since the indicated amount for polyclonal LC excretion is approximately 10 mg/l (10, 11), a method with a sensitivity down to this limit is suggested."

1f.

page 340:

"Quantification

...

Despite all these drawbacks, the immunochemical estimation of BJP may be of clinical value to monitor the clone during treatment, but it is necessary to utilize the same antisera and calibrators throughout the follow-up and to keep in mind all the caveats listed above."



This catalogue lists Reagents, Calibrators and Controls intended for testing Specific Proteins, by turbidimetric method, on general **Clinical Chemistry automatic analyzers.**

Products are also available
for other analytical platforms

For further information, please contact the
Customer Support Service at support@3diag.com

Free Light Chains (FLC) - serum and urine



Particle-enhanced Turbidimetric Immunoassays (PETIA), traced to the **European Reference Material** (code: ERM[®]-DA470k/IFCC) of the *Institute for Reference Materials and Measurements (IRMM)*, using the formula of M.M. Lievens (J.Clin.Chem.Clin.Biochem 1989;27:519-23)..

- | | | |
|------------|--|--|
| REF | TD-42511-SK | kloneus[®] - S-FLC-K - TIA |
| | Contents: Free Kappa Reagents - Serum | ▽ 100 test |
| REF | TD-42511-SL | kloneus[®] - S-FLC-L - TIA |
| | Contents: Free Lambda Reagents - Serum | ▽ 100 test |
| REF | TD-42511-UK | kloneus[®] - U-FLC-K - TIA |
| | Contents: Free Kappa Reagents - Urine | ▽ 100 test |
| REF | TD-42511-UL | kloneus[®] - U-FLC-L - TIA |
| | Contents: Free Lambda Reagents - Urine | ▽ 100 test |
| REF | TD-42512-SK | kloneus[®] - S-FLC-K - CAL-L SET |
| | Contents: Free Kappa Prediluted Calibrators (6 levels) - Serum | |
| REF | TD-42512-SL | kloneus[®] - S-FLC-L - CAL-L SET |
| | Contents: Free Lambda Prediluted Calibrators (6 levels) - Serum | |
| REF | TD-42501-U | kloneus[®] - U-FLC - CAL SET |
| | Contents: Free Light Chain Prediluted Calibrators (6 levels) - Urine | |
| REF | TD-42502-SK | kloneus[®] - S-FLC-K - CONTROL |
| | Contents: Free Kappa Controls (3 levels) - Serum | |
| REF | TD-42502-SL | kloneus[®] - S-FLC-L - CONTROL |
| | Contents: Free Lambda Controls (3 levels) - Serum | |
| REF | TD-42502-U | kloneus[®] - U-FLC - CONTROL |
| | Contents: Free Light Chain Controls (3 levels) - Urine | |

Beta-2 Microglobulin - serum and urine

Particle-enhanced Turbidimetric Immunoassay (PETIA), standardized to the **WHO's 1st International Standard for Beta2 Microglobulin** (code: B2M).

- | | | |
|------------|---|-----------------------------------|
| REF | TD-42531 | 3diag - B2m - TIA |
| | Contents: Reagents | ▽ 100 test |
| REF | TD-42531-U | 3diag - U-B2m - TIA |
| | Contents: Reagents - Urine
Beckman Coulter P/N: C33726 | ▽ 100 test |
| REF | TD-42522 | 3diag - B2m - CAL SET |
| | Contents: Prediluted Calibrators (6 levels) | |
| REF | TD-42532 | 3diag - U-B2m - CAL SET |
| | Contents: Prediluted Calibrators (6 levels) - Urine
Beckman Coulter P/N: C33725 | |
| REF | TD-42523 | 3diag - B2m - CONTROL (x3) |
| | Contents: Controls (3 levels) (3 units) - Serum and Urine
Beckman Coulter P/N: B28051 | |
| REF | TD-42533 | 3diag - B2m - CONTROL |
| | Contents: Controls (3 levels) - Serum and Urine
Beckman Coulter P/N: B28107 | |

C1q Complement

Particle-enhanced Turbidimetric Immunoassay (PETIA), standardized to the **WHO's International Ref. Preparation for human serum complement Factors** (code: W1032).

- | | | |
|------------|---|------------------------------|
| REF | TD-42551 | 3diag - C1q - TIA |
| | Contents: Reagents
Beckman Coulter P/N: B28110 | ▽ 100 test |
| REF | TD-42542 | 3diag - C1q - CAL SET |
| | Contents: Prediluted Calibrators (6 levels)
Beckman Coulter P/N: B28100 | |
| REF | TD-42552 | 3diag - C1q - CAL |
| | Contents: Calibrator | |
| REF | TD-42543 | 3diag - C1q - CONTROL |
| | Contents: Controls (2 levels)
Beckman Coulter P/N: B28101 | |

C5 Complement

Turbidimetric Immunoassay (TIA), standardized to the **WHO's International Ref. Preparation for human serum complement Factors** (code: W1032).

- | | | |
|------------|---|-----------------------------|
| REF | TD-42571 | 3diag - C5 - TIA |
| | Contents: Reagents | ▽ 100 test |
| REF | TD-42562 | 3diag - C5 - CAL SET |
| | Contents: Prediluted Calibrators (6 levels) | |

- REF TD-42578** **3diag - C5 - CAL-L**
Contents: Calibrator
- REF TD-42563** **3diag - C5 - CONTROL (x3)**
Contents: Controls (2 levels) (3 units)
- REF TD-42573** **3diag - C5 - CONTROL**
Contents: Controls (2 levels)

→ C1 (Esterase) Inhibitor

Turbidimetric Immunoassay (TIA).

- REF TD-42591** **3diag - C1In - TIA**
Contents: Reagents ▽ 100 test
Beckman Coulter P/N: **B28111**
- REF TD-42582** **3diag - C1In - CAL SET**
Contents: Prediluted Calibrators (6 levels)
Beckman Coulter P/N: **B28102**
- REF TD-42583** **3diag - C1In - CONTROL**
Contents: Controls (2 levels)
Beckman Coulter P/N: **B28103**

→ Cystatin C - serum and urine

Particle-enhanced Turbidimetric Immunoassay (PETIA), standardized to the **European Reference Material for the Cystatin C** (code: ERM®-DA471/IFCC), of the *Institute for Reference Materials and Measurements (IRMM)*.

- REF TD-42611** **3diag - CysC - TIA**
Contents: Reagents ▽ 100 test
Beckman Coulter P/N: **B28114**
- REF TD-42602** **3diag - CysC - CAL SET**
Contents: Prediluted Calibrators (6 levels)
Beckman Coulter P/N: **B28046**
- REF TD-42603** **3diag - CysC - CONTROL (x3)**
Contents: Controls (2 levels) (3 units) - Serum and Urine
Beckman Coulter P/N: **B28052**
- REF TD-42613** **3diag - CysC - CONTROL**
Contents: Controls (2 levels) - Serum and Urine

→ Hemopexin

Turbidimetric Immunoassay (TIA), standardized to the **1st British Standard for Human Serum Proteins (other than Immunoglobulins)** (code: 74/520) (*NIBSC - a WHO Laboratory for Biological Standards*).

- REF TD-42631** **3diag - HPX - TIA**
Contents: Reagents ▽ 100 test
- REF TD-42622** **3diag - HPX - CAL SET**
Contents: Prediluted Calibrators (6 levels)
- REF TD-42623** **3diag - HPX - CONTROL (x3)**
Contents: Controls (2 levels) (3 units)
- REF TD-42633** **3diag - HPX - CONTROL**
Contents: Controls (2 levels)

→ IgD Immunoglobulins

Particle-enhanced Turbidimetric Immunoassay (PETIA), standardized to the **British Research Standard for IgD** (code: 67/037) (*NIBSC - a WHO Laboratory for Biological Standards*).

- REF TD-42651** **3diag - IgD - TIA**
Contents: Reagents ▽ 100 test
- REF TD-42642** **3diag - IgD - CAL SET**
Contents: Prediluted Calibrators (6 levels)
- REF TD-42643** **3diag - IgD - CONTROL**
Contents: Controls (2 levels)

→ Retinol Binding Protein - serum and urine

Particle-enhanced Turbidimetric Immunoassay (PETIA).

- REF TD-42671** **3diag - RBP - TIA**
Contents: Reagents ▽ 100 test
- REF TD-42662** **3diag - RBP - CAL SET**
Contents: Prediluted Calibrators (6 levels)
- REF TD-42672** **3diag - RBP - CAL**
Contents: Calibrator
- REF TD-42663** **3diag - RBP - CONTROL**
Contents: Controls (2 levels) - Serum and Urine

→ Soluble Transferrin Receptor (sTfR)

Particle-enhanced Turbidimetric Immunoassay (PETIA), standardized to the **WHO's Reference Reagent Recombinant Soluble Transferrin Receptor (rsTfR)** (code: 07/202).

- REF TD-42695** **3diag - sTfR - ADV**
Contents: Reagents - for **ADVIA®** ▽ 100 test
Siemens Healthcare REF: **11415031**
ADVIA® and their associated brands are registered trademarks of Siemens Healthcare
- REF TD-42696** **3diag - sTfR - ADV (5)**
Contents: Reagents - for **ADVIA®** ▽ 500 test
Siemens Healthcare REF: **11415057**
- REF TD-42691** **3diag - sTfR - TIA**
Contents: Reagents ▽ 100 test
Beckman Coulter P/N: **B28115**
- REF TD-42682** **3diag - sTfR - CAL SET**
Contents: Prediluted Calibrators (6 levels)
Beckman Coulter P/N: **B28076**
Siemens Healthcare REF: **11415032**
- REF TD-42692** **3diag - sTfR - CAL**
Contents: Calibrator
- REF TD-42683** **3diag - sTfR - CONTROL**
Contents: Controls (2 levels)
Beckman Coulter P/N: **B28080**
Siemens Healthcare REF: **11415033**

→ Light Chains (B&F) - serum and urine

Turbidimetric Immunoassays (TIA), traced to the **European Reference Material** (code: ERM®-DA470k/IFCC) of the *Institute for Reference Materials and Measurements (IRMM)*, using the formula of M.M. Lievens (J.Clin.Chem.Clin.Biochem 1989;27:519-23).

REF TD-42771 **3diag - KAP - TIA**
 Contents: Reagents ▽ 100 test
 Beckman Coulter P/N: **B28065**

REF TD-42791 **3diag - LAM - TIA**
 Contents: Reagents ▽ 100 test
 Beckman Coulter P/N: **B28066**

REF TD-42772 **3diag - KL - CAL SET**
 Contents: Prediluted Calibrators (5 levels)
 Beckman Coulter P/N: **B28108**

REF TD-42792 **3diag - KL - CAL**
 Contents: Calibrators (2 levels)
 Beckman Coulter P/N: **B28067**

REF TD-42773 **3diag - KL - CONTROL (x3)**
 Contents: Controls (2 levels) (3 units)
 Beckman Coulter P/N: **B28109**

REF TD-42774 **3diag - KL - CONTROL**
 Contents: Controls (2 levels)
 Beckman Coulter P/N: **B28068**

TD-42793 **3diag - U-KL - CONTROL**
 Contents: Controls (2 levels) - Urine

→ Factor B (C3 Proactivator)

Turbidimetric (TIA) Immunoassay, standardized to the *WHO's International Ref. Preparation for human serum complement Factors* (code: W1032).

REF TD-42726 **3diag - FB - TIA**
 Contents: Reagents ▽ 100 test

REF TD-42727-H **3diag - FB - CAL-H**
 Contents: Calibrator (High)

REF TD-42727-L **3diag - FB - CAL-L**
 Contents: Calibrator (Low)

REF TD-42728-H **3diag - FB - CONTROL-H**
 Contents: Control (High)

REF TD-42728-L **3diag - FB - CONTROL-L**
 Contents: Control (Low)

→ IgE Immunoglobulins

Particle-enhanced Turbidimetric Immunoassay (PETIA), standardized to the *WHO's 2nd WHO International Reference Preparation of Human Serum Immunoglobulin E (IgE)* (code: 75/502).

REF TD-42811 **3diag - IgE - TIA**
 Contents: Reagents ▽ 100 test

REF TD-42822 **3diag - IgE - CAL SET**
 Contents: Prediluted Calibrators (5 levels)

REF TD-42823 **3diag - IgE - CONTROL**
 Contents: Controls (2 levels)

→ Alpha-1 Microglobulin - urine

Particle-enhanced Turbidimetric Immunoassay (PETIA).

REF TD-42831 **3diag - U-A1m - TIA**
 Contents: Reagents ▽ 100 test
 Beckman Coulter P/N: **C40494**

REF TD-42832 **3diag - U-A1m - CAL SET**
 Contents: Prediluted Calibrators (6 levels)
 Beckman Coulter P/N: **C40493**

REF TD-42833 **3diag - U-A1m - CONTROL**
 Contents: Controls (2 levels)
 Beckman Coulter P/N: **C40492**

→ Serum Amyloid A (SAA)

Particle-enhanced Turbidimetric Immunoassay (PETIA), standardized to the *WHO's Serum Amyloid A (SAA) 1st International Standard* (code: 92/680).

REF TD-42891 **3diag - SAA - TIA**
 Contents: Reagents ▽ 100 test

REF TD-42882 **3diag - SAA - CAL SET**
 Contents: Prediluted Calibrators (6 levels)

REF TD-42892 **3diag - SAA - CAL**
 Contents: Calibrator

REF TD-42883 **3diag - SAA - CONTROL**
 Contents: Controls (2 levels)