All about our products in Nephelometry and Turbidimetry

— κλοneus Free Light Chains

Presentation

Alternative approach for the determination of BJP based on the IFCC guidelines

Non dedicated reagent line

Clinical Chemistry automatic analyzers

Dedicated reagent lines

- *BN*[™] *Series* and Atellica® NEPH 630 from *Siemens Healthcare*
- **IMMAGE® 800** from Beckman Coulter
- Optilite® from The Binding Site



For further information contact support@3diag.com www.3diag.com (+34) 932 448 679



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.



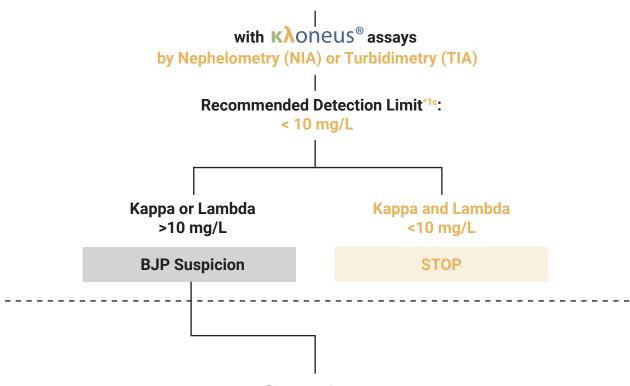
Alternative Approach for the determination of Bence Jones Proteinuria (BJP), based on the IFCC Guidelines*1a

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



Confirmation Test

to determine the electrophoretic, mono, oligo or polyclonal distribution of the quantified ur-FLC by κλοneus® assays

by Immunofixation (IF)
of concentrated urine
Recommended Sensitivity*1e: < 10 mg/L

the quantitative result obtained by κλοneus®

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 quantication 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 quanfication of the protein. However, since the indicated amount for polyclonal LC excretion is approximately 10 mg/l (10, 11), a method with a sensivity 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."







Kits for Turbidimetry (TIA)

This catalogue lists the Kits (consisting of reagents, calibrators and controls) intended for testing Specific Proteins, by turbidimetric method, on general **Clinical Chemistry automatic analyzers.**

◆ 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.Blochem 1989;27:519-23)..



κλοneus® - S-FLC-K TIA KIT

REF TD-42510-K

▼ 100 test

Contains Free Kappa Reagents,
Calibrators, and Controls - Serum

kλoneus® - S-FLC-L TIA KIT

REF TD-42510-L

▼ 100 test

Contains Free Lambda Reagents,
Calibrators, and Controls - Serum

KNoneus® - U-FLC - TIA KIT

REF TD-42510-U ▼100+100 test Contains Free Kappa and Lambda Reagents, Calibrators, and Controls -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).

3diag - U-B2m - TIA KIT

3diag - B2m - TIA KIT

REF TD-42535-U

₹100 test

Contains Reagents, Calibrator and Controls

Contains Reagents, Calibrator and Controls

→ C1q Complement

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

3diag - C1q - TIA KIT

REF TD-42555

₹100 test

Contains Reagents, Calibrators and Controls.

C5 Complement

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

3diag - C5 - TIA KIT

REF TD-42575

₹100 test

Contains Reagents, Calibrators and Controls.





→ C1 (Esterase) Inhibitor

Turbidimetric Immunoassay (TIA).

3diag - C1In - TIA KIT

REF **TD-42595**

▼ 100 test

Contains Reagents, Calibrators and Controls.

→ 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).*

3diag - U-CysC - TIA KIT

3diag - CysC - TIA KIT

REF TD-42615-U

₹100 test

REF TD-42615

₹100 test

Contains Reagents, Calibrators and Controls Contains Reagents, C

Contains Reagents, Calibrators and Controls

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).

3diag - HPX - TIA KIT

Contains Reagents, Calibrators and Controls.

→ 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).

3diag - IgD - TIA KIT

REF TD-42655

▼100 test

Contains Reagents, Calibrators and Controls

→ Retinol Binding Protein - serum and urine

Particle-enhanced Turbidimetric Immunoassay (PETIA).

3diag - RBP - TIA KIT

3diag - U-RBP - TIA KIT

 REF TD-42675-U ▼100 test

Contains Reagents, Calibrators and Controls

Contains Reagents, Calibrators and Controls





→ Soluble Transferrin Receptor (sTfR)

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

3diag - sTfR - TIA KIT

Contains Reagents, Calibrators and Controls.

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).

3diag - KAP - TIA KIT

REF TD-42775

▼100 test

Contains Reagents, Calibrators and Controls.

3diag - U-LAM - TIA KIT

REF TD-42795-U ₹ 100 test

Contains Reagents, Calibrators and Controls.

3diag - U-KAP - TIA KIT

REF **TD-42775-U** ₹ 100 test

Contains Reagents, Calibrators and Controls.

3diag - LAM - TIA KIT

REF **TD-42795**

▼ 100 test

Contains Reagents, Calibrators and Controls.

→ Factor B (C3 Proactivator)

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

3diag - FB - TIA KIT

Contains Reagents, Calibrators and Controls.

→ Alpha-1 Microglobulin - urine

Particle-enhanced Turbidimetric Immunoassay (PETIA).

3diag - U-A1m - TIA KIT

Contains Reagents, Calibrators and Controls.

→ Serum Amyloid A (SAA)

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

3diag - SAA - TIA KIT

Contains Reagents, Calibrators and Controls.







Kits for *BN™ Series* and *Atellica® NEPH 630* Nephelometers

This catalogue lists the Kits (consisting of reagents, calibrators and controls) intended for testing Specific Proteins on *Siemens Healthcare's* **BNTM Series** and **Atellica® NEPH 630** Nephelometers (BNTM and Atellica® are registered trademarks of *Siemens Healthcare Diagnostics Products GmbH*, Marburg, Deutschland).

→ Free Light Chains (FLC) - Urine

Particle-enhanced Nephelometric Immunoassays (PENIA), traced to the *European Reference Material* (code: ERM® - DA470k/IFCC) to the *Institute for Reference Materials and Measurements (IRMM)*, using the formula of M.M. Lievens.



κλoneus® - U-FLC - BNs Kit

REF TD-42505 ▼ 100+100 test GTIN/UDI-DI: 8434477 20106 6 Siemens Health. SMN: 11309431

Contains Free Kappa Reagents, Free Lambda reagents, Calibrator and Controls (3 levels)

→ C1q Complement

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

N Latex C1q Kit

Contains Reagents, Calibrator and Controls (2 levels)

→ C5 Complement

Nephelometric Immunoassay (NIA), standardized to the WHO's International Ref. Preparation for human serum complement Factors (NIBSC's code: W1032).

N C5 Kit

Contains Reagents, prediluted Calibrators (2 levels)





→ IgD Immunoglobulins

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

N Latex IgD Kit

Contains Reagents, Calibrator and Controls (2 levels)

→ Factor B (C3 Proactivator)

Nephelometric Immunoassay (NIA), standardized to the WHO's International Ref. Preparation for human serum complement Factors (NIBSC's code: W1032).

N C3Pa Kit

REF TD-42720 ▼100 test GTIN/UDI-DI: 8434477 21208 6 Siemens Health. SMN: **10873732**

Contains Reagents, Calibrator and Controls (2 levels)







Kits for IMMAGE® 800 Immunochemical Systems

This catalogue lists the Kits (consisting of reagents, calibrators and controls) intended for testing Specific Proteins on *Beckman Coulter's IMMAGE®* 800 Immunochemical Systems (*IMMAGE®* is a registered trademark of *Beckman Coulter, Inc.*, Fullerton, CA, USA).

→ Free Light Chains (FLC) - serum and urine

Particle-enhanced **Non-competitive Nephelometric** Assays, traced to the *European Reference Material* (code: ERM®-DA470k/IFCC) of the *Institute for Reference Materials and Measurements (IRMM)*.



κλoneus® - S-FLC-K - 800 KIT

REF TD-42500-K ▼ 100 test P/N Beckman Coulter: B28093 Contains Free Kappa Reagents, prediluted Calibrators (6+4 levels), and Controls (3 levels), for SERUM

κλoneus® - S-FLC-L - 800 KIT

P/N Beckman Coulter: B28105
Contains Free Lambda Reagents, prediluted Calibrators (6+4 levels), and Controls (3 levels), for SERUM

κλoneus® - U-FLC - 800 KIT

REF TD-42500 ▼ 100+100 test P/N Beckman Coulter: B28035 Contains Free Kappa and Lambda Reagents, prediluted Calibrators (6+4 levels), and Controls (3 levels), for URINE

→ Beta-2 Microglobulin - serum and urine

Non-competitive NIPIA Assay, standardized to the *WHO's* **1st International Standard for Beta2 Microglobulin** (code: B2M).

3diag - B2m - 800 KIT

P/N *Beckman Coulter:* **B28030 B28030**

Contains Reagents, prediluted Calibrators (6 levels) and

Controls (3 levels) for serum and urine

→ C1q Complement

Non-competitive NIPIA Assay, standardized to the *WHO's International Ref. Preparation for human serum complement Factors.* (code: W1032).

3diag - C1q - 800 KIT

Contains Reagents, prediluted Calibrators (6 levels) and Controls (2 levels)





→ C5 Complement

Non-competitive Nephelometric Assay, standardized to the *WHO's International Ref. Preparation for human serum complement Factors* (code: W1032).

3diag - C5 - 800 KIT

P/N *Beckman Coulter*: **B28032**

Contains Reagents, prediluted Calibrators (6 levels) and Controls (2 levels)

→ C1 (Esterase) Inhibitor

Non-competitive Nephelometric Assay.

3diag - C1In - 800 KIT

REF **TD-42580**

▼100 test P/N Beckman Coulter: B28033

Contains Reagents, prediluted Calibrators (6 levels) and Controls (2 levels)

Cystatin C - serum and urine

Non-competitive NIPIA Assay, standardized to the *European Reference Material for the Cystatin C* (code: ERM®-DA471/IFCC), of the *Institute for Reference Materials and Measurements (IRMM)*.

3diag - CysC - 800 KIT

Contains Reagents, prediluted Calibrators (6 levels) and Controls (2 levels) for serum and urine

→ Hemopexin

Non-competitive Nephelometric Assay, standardized to the 1st British Standard for Human Serum Proteins (other than Inmunoglobulins) (code: 74/520) (NIBSC - a WHO Laboratory for Biological Standards).

3diag - HPX - 800 KIT

Contains Reagents, prediluted Calibrators (6 levels) and Controls (2 levels)

IgD Immunoglobulins

Non-competitive NIPIA Assay, standardized to the *British Research Standard for IgD* (code: 67/037) (NIBSC - a WHO Laboratory for Biological Standards).

3diag - IgD - 800 KIT

Contains Reagents, prediluted Calibrators (6 levels) and Controls (2 levels)





→ Retinol Binding Protein - serum and urine

Non-competitive NIPIA Assay.

3diag - RBP - 800 KIT

Contains Reagents, prediluted Calibrators (6 levels) and Controls (2 levels) for serum and urine

→ Soluble Transferrin Receptor (sTfR)

Non-competitive NIPIA Assay, standardized to the WHO's **Reference Reagent Recombinant Soluble Transferrin Receptor (rsTfR)** (code: 07/202).

3diag - sTfR - 800 KIT

Contains Reagents, prediluted Calibrators (6 levels) and Controls (2 levels)

→ Serum Amyloid A (SAA)

Non-competitive NIPIA Assay, standardized to WHO's Serum Amyloid A (SAA) 1st International Standard (code: 92/680).

3diag - SAA - 800 KIT

P/N Beckman Coulter:

Contains Reagents, prediluted Calibrators (6 levels) and Controls (2 levels)







Kits for *Optilite*® analyzer

This catalogue lists the Kits (consisting of reagents, calibrators and controls) intended for testing Specific Proteins, by turbidimetric method, on *Optilite®* analyzers.

OR codes for loading analytical parameters into the analyzer. Application version control.

→ C1q Complement

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

3diag - C1q - Opt Kit

REF TD-42547 ₹100 test Contains Reagents, Calibrator and Controls.

→ C5 Complement

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

3diag - C5 - Opt Kit

REF TD-42567 ₹100 test Contains Reagents, Calibrator and Controls.

→ Factor B (C3 Proactivator)

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

3diag - FB - Opt Kit

REF TD-42717 ₹100 test

Contains Reagents, Calibrator and Controls.

→ 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).

3diag - KAP - Opt Kit

REF TD-42777 ₹100 test Contains Reagents, Calibrator and Controls.

REF TD-42787

₹100 test

REF TD-42778

₹100 test

Contains Reagents, Calibrator and Controls.

3diag - U-KAP - Opt Kit

Contains Reagents, Calibrator and Controls.

3diag - LAM - Opt Kit

3diag - U-LAM - Opt Kit

REF TD-42788

₹100 test

Contains Reagents, Calibrator and Controls.





→ Retinol Binding Protein - serum and urine

Particle-enhanced Turbidimetric Immunoassay (PETIA).

3diag - RBP - Opt Kit

3diag - U-RBP - Opt KIT

REF TD-42667

▼100 test REF TD-42677

Contains Reagents, Calibrator and Controls

Contains Reagents, Calibrator and Controls

₹100 test

Serum Amyloid A (SAA)

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

3diag - SAA - Opt KIT

REF TD-42887

₹100 test

Contains Reagents, Calibrator and Controls.

→ Soluble Transferrin Receptor (sTfR)

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

3diag - sTfR - TIA KIT

REF TD-42687

₹100 test

Contains Reagents, Calibrator and Controls.