

# Technical Note



## Latex Microparticle–Enhanced Immunoturbidimetric Assays for the Quantitation of the Proteins Kappa ( $\mu$ -KLC) and Lambda ( $\mu$ -LLC) Chains, Albumin (mALB), Immunoglobulin G ( $\mu$ -IgG) and Beta-2-Microglobulin ( $\mu$ - $\beta$ 2M)

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A panel of kits based on latex microparticle–enhanced immunoturbidimetric assays for the quantitation of the proteins Kappa ( $\mu$ -KLC) and Lambda ( $\mu$ -LLC) chains, Albumin (mALB), Immunoglobulin G ( $\mu$ -IgG) and Beta-2-microglobulin ( $\mu$ - $\beta$ 2M) in urine was developed by Sclavo Diagnostics International S.p.A., R. & D. Department., Siena, Italy (1). All the tests, due to their good analytical performances (Table 1) can be used manually and with semi- and fully-automated clinical chemistry analyzers to screen urine samples with clinically suitable sensitivity.

### Kit performances

Kit	$\mu$ -KLC	$\mu$ -LLC	mALB	$\mu$ -IgG	$\mu$ -B2M
Specificity	100%	100%	100%	100%	100%
Working range (mg/L)	1 - 200	1 - 100	1 - 100	1 - 300	0.01 - 2
Linearity (mg/L)	0 - 250	0 - 200	0 - 200	0 - 500	0 - 2
Recovery (%)	99,8 - 100,9	99,1 - 106,2	102,1 - 106,2	98,2 - 101,3	93,2 - 107,3
Prozone (g/L)	> 14	> 10	> 8	> 30	> 70
Stability 2-8°C (months)	18	18	18	18	18
Within-run precision	$\leq$ 5%	$\leq$ 5%	$\leq$ 5%	$\leq$ 5%	$\leq$ 5%
Between-run precision	$\leq$ 5%	$\leq$ 5%	$\leq$ 5%	$\leq$ 5%	$\leq$ 5%

The development of these diagnostic methods was made feasible by the achievement of the following technical objects:

- A solid phase with a high density of covalently linked ligand and an elevated immunocapturing capacity was set up by using immunoaffinity purified antibodies, properly functionalized micro-particles (product reference K3-025 [# 23 698 084] NH<sub>2</sub>-modified Estapor® Microspheres-Merck Chimie SAS, France) and a space arm of suitable length to preserve the functional conformation of bound antibodies and to reduce steric hindrance.
- Hook (prozone)- effect was not detected up to relatively high concentrations of analytes and consequently the risk of false negative results was removed.
- The interferences related to the frequent alterations of the urine chemical and physical profiles were significantly reduced by sample dilution.
- Microparticle auto-agglutination and sedimentation were prevented by a specific formulation of the diluent buffer.

### Conclusion

For this specific immunoturbidimetric assay development, the NH<sub>2</sub>-modified estapor microparticles were found the most useful, most reproducible and easy to optimise and to handle. New tests are still under development with the same microspheres and also with new surfaces.

Presentini, R., Di Dio, M., Viciani, G., and Fabrizi, P. (2000) Highly sensitive particle – enhanced immunoturbidimetric assays for quantitative determination of proteins in urine. *Eur. Clin. Lab.* 19 (6), 8. Full text on – line : [www.iscpubs.com](http://www.iscpubs.com)

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