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CYSTATIN C REAGENT CHANGE TO IFCC STANDARDIZED REFERENCE MATERIAL

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Effective March 25, 2019, **Cystatin C** assay (test code: **CYC**) reagent kit standardized to the ERM-DA471/IFCC reference material will replace the non-IFCC standardized kit. Only the value assignment has been adjusted to reflect traceability to the ERM-DA471/IFCC reference material. There is no modification made compared to the current non-IFCC standardized reagent kit.

Cystatin C (CysC) is an additional biomarker for the estimation of renal function (estimated glomerular filtration rate - eGFR)¹ and also for prediction of cardiovascular risk. The calibration and standardization of assays are key factors for developing eGFR equations based on CysC alone or in combination with creatinine. The IFCC traceable reagent is made available by our current method manufacturer, Siemens, Inc., for use on the BN II nephelometry system².

A comparison study of the new IFCC reagent and the current reagent performed with in-house patients showed a slope of 1.19 for the IFCC reagent, which is in close agreement with the manufacturer's claim of 1.174. The reference interval was calculated non-parametrically and was determined to be 0.49 to 1.19 mg/L as compared to the reference interval of 0.53 to 0.95 mg/L by the current non-IFCC reagent. The ~20% up bias of the upper reference is consistent with the internal and manufacturer's comparison study. Please note the changes in the reference ranges based on these studies.

The updated reference ranges are:

- 0 - 3 months: 0.81 - 2.76 mg/L
- 4 - 11 months: 0.65 - 1.77 mg/L
- 1 - 17 years: 0.50 - 1.51 mg/L
- Adults: 0.49 - 1.19 mg/L

QUESTIONS

- Test information is available in [Marshfield Labs Test Reference Manual](#) or from Marshfield Labs Customer Service Department.



- Clinical and technical questions may be directed to Joyce Flanagan, PhD, Clinical Chemist.
- Phone number: 800-222-5835.

REFERENCES

1. Kidney Disease: Improving Global Outcomes (KDIGO) CKD work group. KDIGO 2012 clinical practice guideline for the evaluation and management of chronic kidney disease. *Kidney Intl Suppl.* 2013; 3:1-150.
2. Bargnoux A. et. al. Multicenter evaluation of cystatin C measurement after assay standardization. *Clin Chem.* 2017; 63:833-841. 