Application Note
Guideline for Determination of Cystatin C in Serum/Plasma on ADVIA 1650

General information

Intended use
The Application Note is intended for the quantitative determination of cystatin C in human sample material by turbidimetry on ADVIA 1650 (1, 2).

Measuring range
Approximately 0.4-6.3 mg/L depending on the specific lot of the calibrator. In case of post-concentration or -dilution the range can be expanded.

Reference interval
For individuals 1-50 years: 0.55-1.15 mg/L.
For individuals >50 years: 0.63-1.44 mg/L.
It is recommended to determine the reference interval for the local population.

Instrument settings
Instrument programming is performed according to the “Instrument Settings” on page 3.

Code No.   Name
Reagents
Antibody LX 002 DakoCytomation Cystatin C Immunoparticles
Reaction buffer S 2361 DakoCytomation Reaction Buffer 9
Calibrator X 0974 DakoCytomation Cystatin C Calibrator
Controls X 0973 DakoCytomation Cystatin C Control Set
Diluent NaCl solution 154 mmol/L (0.9% w/v)

Samples
Human serum, heparin-plasma or EDTA-plasma.
Stable for 2 days at 2-8 °C.
Stable for at least 3 months at –20 °C.
Frozen samples should preferable be thawed at 37 °C and mixed well before analysis.

Calibrator
Dilution of standards is performed automatically by the instrument.

Reaction buffer
The reaction buffer is ready for use. On board stability is estimated to 8 weeks based on results obtained on an equivalent instrument.

Antibody
The immunoparticle solution is ready for use.
Stability at 2-8°C: See specification sheet and expiry on the label.
On board stability is estimated to 8 weeks based on results obtained on an equivalent instrument.
Capacity: 1 mL immunoparticle solution is equivalent to approximately 36 cuvette readings of standards or samples.
The dead volume of the reagent bottle should be added when calculating the required amount of reagent.

Calibration stability
It is recommended to recalibrate every 4 weeks, when reagent lots change or quality control results fall outside the range as established by the individual laboratory.

Trouble shooting
If performance is unacceptable, try to recalibrate. Check reagents and procedure. If the problem persists, please contact instrument supplier or DakoCytomation Technical Service.
Performance Data

Sensitivity
An OD value of approximately 0.16 on ADVIA 1650 corresponds to a concentration around 6.3 mg/L cystatin C.

Precision
The within-run precision was estimated to be 1.1% at a concentration of 4.96 mg/L cystatin C and 1.0% at a concentration of 1.20 mg/L cystatin C.

Accuracy
A recovery of cystatin C of 85–115% can be expected for DakoCytomation Cystatin C Control 1, code No. X 0973, and DakoCytomation Cystatin C Control 2, code No. X 0973.

Linearity
The assay is linear in the range 0.4-6.6 mg/L.

Security range
No antigen excess is found for cystatin C concentrations below 25 mg/L (the highest concentration tested).

Interference
No interference is found at concentrations up to 10 g/L of hemoglobin, 600 mg/L of bilirubin, 15 g/L of triglyceride, 10 g/L intralipid, and 1200 IU/mL of rheumatoid factor.

Method comparison
Determination of cystatin C according to this Application Note was compared with a commercially available nephelometric assay. Data are available on request.

References
2. ADVIA 1650 manual(s).