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RAPID DETERMINATION OF **SMALL DENSE LDL CHOLESTEROL** IN **SERUM OR PLASMA WITHOUT SAMPLE PRE-TREATMENT**

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Introduction

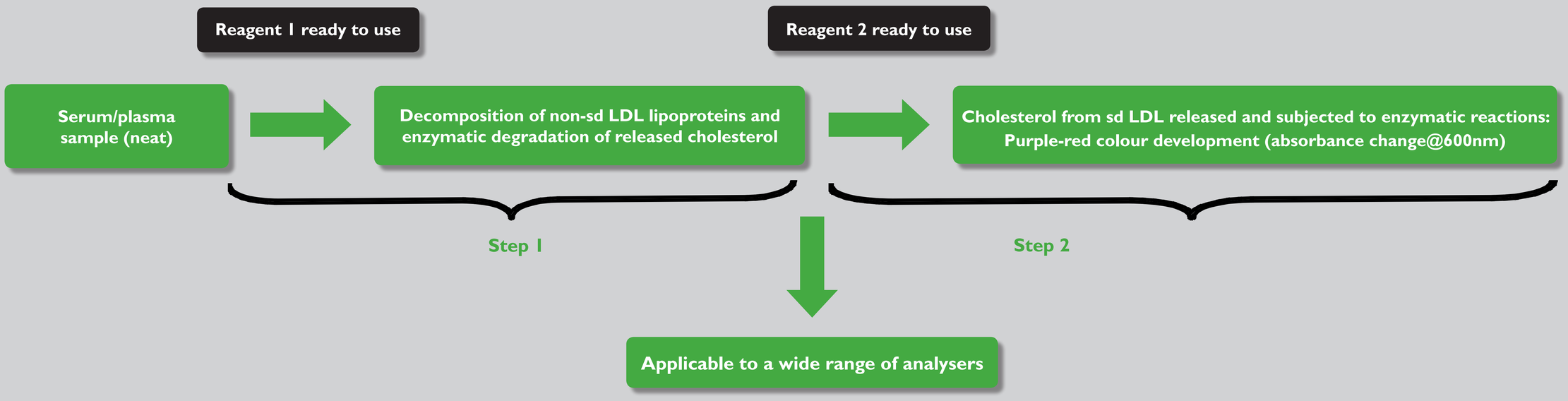
Low-density lipoprotein cholesterol (LDL-C) is considered a critical risk factor for developing coronary heart disease(CHD) and cardiovascular heart disease(CVD). LDL particles are heterogeneous with respect to size and density of lipid composition. The small dense LDL (sd LDL)s are atherogenic with higher levels in patients with CAD/CHD than in controls with a clear relationship between sd LDL levels and disease severity.[1,2] The predominance of sd LDL-C as a strong and independent predictor of CAD/CHD has been reported.[3] Current methods for the measurement of LDL particle size are too laborious for general clinical use.

We report the analytical evaluation of a rapid direct method for the measurement of sd LDL in serum/plasma without sample pre-treatment, this is of value for applications in clinical settings.

Methodology

Assay Principle

2 STEP ASSAY: completion within 10 minutes



Samples

Typically between 3µl -6µl of neat serum/plasma sample (EDTA-2K, EDTA-3K, Heparin-Lithium) required.

sLDL assay kit (cat no.562616), calibrators (cat no.CH5050), controls (cat no.LE5013, LE5014, LE5015) were used (Randox Laboratories, Crumlin, Northern Ireland). The assay was performed following the manufacturer's instructions.

Results

The evaluation of the analytical performance is reported.

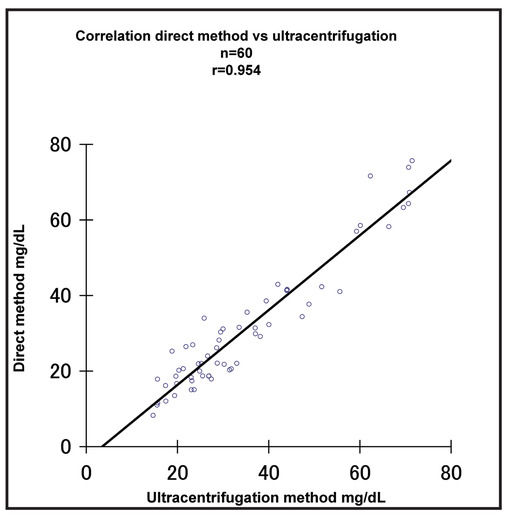
Sensitivity, linearity

Sample Type	Detection Limit mg/dL	Linearity mg/dL
Serum/Plasma	1.0	100

Precision

Within-run precision (n=10):
%CV <3% for different concentration levels

Correlation



Linear regression equation: y=0.990x - 3.40
r=0.954
n=60

Interferences:

No interferences were observed for the following analytes up to the levels indicated.

Analyte	Ascorbic Acid	Haemoglobin	Bilirubin (conjugated)	Bilirubin (unconjugated)	Triglycerides
Level	50 mg/dL	500 mg/dL	30 mg/dL	30 mg/dL	1800 mg/dL

Conclusion

- **Data indicate optimal analytical performance of the enzymatic assay for in vitro determination of small dense LDL in serum/ plasma samples on RX series analysers.**
- **Detection limit: 1.0 mg/dL, Linearity: 100mg/dL, reproducibility: within-run precision %CV<3% for different concentration levels.**
- **No requirement for any off-line sample pre-treatment steps: quicker and more user friendly method.**
- **Excellent agreement with other commercially available system.**
- **Liquid assay reagents ready to use.**

This is of value as analytical tool for clinical settings.

References

1. Hirano, T *et al.* Clinical significance of small, dense low-density lipoprotein cholesterol levels determined by the simple precipitation method. *Arterioscler. Thromb. Vasc. Biol.* 2004, 24: 558.

2. Koba, S., *et al.* Significance of small dense low-density lipoprotein cholesterol concentrations in relation to the severity of coronary heart diseases. *Atherosclerosis*, 2006, 189: 206.

3. St-Pierre, A.C., *et al.* Low-density lipoprotein subfractions and the long-term risk of ischemic heart disease in men, 13-year follow-up data from the Quebec cardiovascular study. *Arterioscler. Thromb. Vasc. Biol.*, 2005, 25: 553.

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