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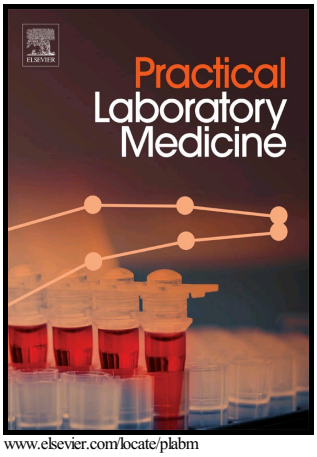

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Validated low-volume aldosterone immunoassay tailored to GCLP-compliant investigations in small sample volumes

Schaefer, J.; Burckhardt, B. B.[*]; Tins, J.; Bartel, A.; Laeer, S.

[1]Institute of Clinical Pharmacy and Pharmacotherapy, Heinrich-Heine-University Duesseldorf, Universitaetsstrasse 1, 40225 Duesseldorf, Germany

[*]Corresponding author. Bjoern B. Burckhardt, PhD; Institute of Clinical Pharmacy and Pharmacotherapy, Heinrich-Heine-University Duesseldorf, Universitaetsstrasse 1, 40225 Duesseldorf, Germany; . bjoern.burckhardt@uni-duesseldorf.de

Abstract

Introduction

Heart failure is well investigated in adults, but data in children are lacking. To overcome this shortage of reliable data, appropriate bioanalytical assays are required.

Objectives

Development and validation of a bioanalytical assay for the determination of aldosterone concentrations in small sample volumes applicable to clinical studies under Good Clinical Laboratory Practice.

Methods

An immunoassay was developed based on a commercially available enzyme-linked immunosorbent assay and validated according to current bioanalytical guidelines of the EMA and FDA.

Results

The assay (range 31.3 pg/mL - 1000 pg/mL [86.9 pmol/L - 2775 pmol/L]) is characterized by a between-run accuracy from -3.8 % to -0.8 % and a between-run imprecision ranging from 4.9 % to 8.9 % (coefficient of variation). For within-run accuracy, the relative error was between -11.1 % and +9.0 %, while within-run imprecision ranged from 1.2 % to 11.8 %