
To: To whom it may concern Copies:

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Independent product lines and sources for Calibrators or Controls

Relating to the rules of NCCLS C24-A(2)

„7.3 Relation to calibrators

Control materials need to be different from the calibrator materials to ensure that the QC procedure provides an independent assessment of system performance."

We state in this document, that the following calibrator and control products

Calibrator	Controls
Cfas	PNU / PPU / PNU plus / PPU plus / Precibil
Cfas Protein	PNP / PPP / CRP T Control N
Cfas CK-MB	PN CK-MB / PP CK-MB (outphasing started – depending on end of shelf life of last lot)
Cfas Lipids	PNL / PPL / PP HDL/LDL (outphasing started – depending on end of shelf life of last lot)
Cfas PUC	PN PUC / PP PUC
Cfas PAC	Controlset PC (outphasing started – depending on end of shelf life of last lot)
PM Fruct	PN Fruct / PP Fruct
Iron Standard	PNU / PNU plus / PPU plus
Cfas Cfas P Cfas CK-MB Cfas Lipids Cfas PAC Cfas IgAM CSF Iron Standard	PC CC 1 / PC CC 2

are manufactured at Operation Centralized Diagnostics, Penzberg under the following conditions:

- Separate production events
- Separate manufacturing master protocols
- Different material no. and/ or lot no. of raw materials and intermediates

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Dr. J. Hoch
Global Regulatory Affairs

A blue ink signature of Dr. S. Scheib, written in a cursive style.

Dr. S. Scheib
Global Regulatory Affairs