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Document Author:	Schwaiger, Nicole {DOMS~Penzberg}
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Signed By:	schwaign (Nicole Schwaiger {DOMSTO})
Role:	Author
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Signed By:	wickerts (Sabine Wickert {DOMSW})
Role:	Reviewer
Signed Date:	31-May-2022 08:53:28 (UTC)
Signed By:	tassonir (Richard Tassoni {DOMS})
Role:	Approver
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SPECIFICATION

for

Testosterone II CalSet II

0520 2230 190

Bottle 1 (TESTO Cal1)	
Appearance	lyophilized substance
Testosterone	approx. 0.4 ng/mL or 1.4 nmol/L
Bottle 2 (TESTO Cal2)	
Appearance	lyophilized substance
Testosterone	approx. 11.5 ng/mL or 40 nmol/L

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cobas e 801 analyzer: The exact lot-specific calibrator values are encoded in the electronic barcode and available via the cobas link.
All other analyzers: The exact lot-specific calibrator values are encoded in the barcode as well as printed on the enclosed (or electronically available) calibrator barcode sheet.

All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV.
The testing methods use assays that have been approved by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.

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Trương Thị Tố Hoa
Trưởng phòng Đăng ký,
Đối ngoại và Quản lý Chất lượng