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SPECIFICATION

for

Anti-Tg CalSet

0636 8603 190

0900 5030 190

Part 1 (Anti-TG Cal1)

Appearance

lyophilized substance

Anti-TG-antibodies (human) in human serum matrix

approx. 40 IU/mL

Part 2 (Anti-TG Cal2)

Appearance

lyophilized substance

Anti-TG- antibodies (sheep) in human serum matrix

approx. 3250 IU/mL

Cobas e 402 and 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 applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A (0636 8603 190)

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 (0900 5030 190)