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SPECIFICATION

for

Elecsys Anti-Tg

0702 6919 190

0900 5021 190

0702 6897 190

0636 8697 190

0900 4998 190

Part 1 (M)

Appearance

sediment with clear supernatant

Streptavidin-coated microparticles

648 - 792 µg/mL

Part 2 (R1)

Appearance

clear solution

Biotinylated Tg

proved by performance test

pH value

6.8 - 7.2

Part 3 (R2)

Appearance

clear solution

Monoclonal anti-Tg antibodies

labeled with ruthenium complex

proved by performance test

pH value

6.8 - 7.2

Performance test

Recovery of Anti-Tg in

(based on assigned value)

PreciControl Thyro AB Level 1

80 - 120 %

PreciControl Thyro AB Level 2

85 - 115 %

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 initial thyroid glandular tissue extract containing the human thyroglobulin has shown to be free from HBsAg and antibodies to HCV and HIV.

The testing methods used assays approved by the FDA or cleared in compliance with the European Directive 98/79/EC, Annex II, List A (0702 6919 190, 0702 6897 190, 0636 8697 190)

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