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CÔNG TY TRÁCH NHIỆM HỮU HẠN ROCHE VIỆT NAM

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

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SPECIFICATION

for

Anti-Tg

0636 8697 190

Part 1 (M)	
Appearance:	red-brown sediment with clear supernatant
Streptavidine coated micro particles	648 - 792 µg/ml
Part 2 (R1)	
Appearance	clear solution
pH value (TRIS buffer)	6.8 – 7.2
Biotinylated TG	proved by performance test
Part 3 (R2)	
Appearance	clear solution
pH value (TRIS buffer)	6.8 – 7.2
Monoclonal anti-TG antibodies~ruthenium complex	proved by performance test
Performance test	
Recovery of anti-TG in (based on assigned value)	
PreciControl Thyro AB 1	80 – 120 %
PreciControl Thyro AB 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.