

PRODUCT GUIDE

Radio and Enzyme Immunoassays



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THYROID

TSH receptor autoantibodies

TSH-REZAK[®]

Radio receptor assay for the determination of TSH receptor autoantibodies (TRAb) in serum (1. generation)

Assay principle: Radio receptor assay (comp.)	Reaction type: homogeneous phase
Tracer: ¹²⁵ I-TSH porcine	Total incubation time: 150 min
Bound/free Separation: PEG and centrifugation	Sample volume: 50 µl
Standard range: 5 - 405 U/l	Cut off: 14 U/l
	Functional assay sensitivity: 8 U/l

Available formats: Code **1000** (100 determinations)

SELco[®] TRAb

Radio receptor assay for the determination of TSH receptor autoantibodies (TRAb) in serum - coated tube technique (2. generation)

Assay principle: Radio receptor assay (comp.)	Reaction type: solid phase (coated tubes)
Tracer: ¹²⁵ I-TSH porcine	Total incubation time: 180 min
Standard range: 1-40 IU/l (WHO 90/672)	Sample volume: 100 µl
	Cut off: 1.5 IU/l
	Functional assay sensitivity: 1.0 IU/l

Available formats: Code **1040** (100 determinations)

Medizym[®] T.R.A.

Enzyme immunoassay (EIA) for the quantitative determination of autoantibodies to TSH receptor in human serum (2. generation)

Assay principle: Enzyme immunoassay (comp.)	Format: microtiter plate coated with monoclonal antibodies (mouse) / TSH receptor (porcine)
Total incubation time: 180 min	
Conjugate: TSH (porcine) - SA-POD	Sample volume: 100 µl
Standard range: conc. see leaflet enclosed (WHO 90/672)	Substrate: TMB
	Cut-off: 1.5 IU/l
	Functional assay sensitivity: 0.8 IU/l

Available format: Code **4003** (96 determinations)

Medizym[®] TRAb clone

Enzyme immunoassay (EIA) for the quantitative determination of autoantibodies to TSH receptor in human serum (3. generation)

Assay principle: Enzyme immunoassay (comp.)	Format: microtiter plate coated with monoclonal antibodies (mouse) / TSH receptor (porcine)
Total incubation time: 180 min	
Conjugate: M22 (stimulating human AB) - SA-POD	Sample volume: 75 µl
Standard range: conc. see leaflet enclosed (WHO 90/672)	Substrate: TMB
	Cut-off: 0.4 IU/l
	Functional assay sensitivity: 0.22 IU/l

Available format: Code **3805** (96 determinations)

THYROID

Tg autoantibodies

anti-Tg magnum

Radio ligand assay for the determination of autoantibodies to Thyroglobulin (Tg Ab) in serum

Assay principle: Radio ligand assay
Tracer: ¹²⁵I-Tg human
Bound/free Separation: magnetic particle and device
Standard range: 20 - 4000 IU/ml

Reaction type: homogeneous phase
Total incubation time: 30 min
Sample volume: 25 µl diluted serum, 1 + 50 (v + v)
Cut off: 50 U/ml
Functional assay sensitivity: 35 IU/ml

Available formats: Code **2010** (100 determinations)

CentAK[®] anti-Tg

Radio ligand assay for the determination of autoantibodies to Thyroglobulin (Tg Ab) in serum

Assay principle: Radio ligand assay
Tracer: ¹²⁵I-Tg human
Bound/free Separation: Protein A and centrifugation
Standard range: 6 - 2000 IU/ml

Reaction type: homogeneous phase
Total incubation time: 60 min
Sample volume: 50 / 25 µl diluted serum 1 + 20 (v + v)
Cut off: 50 U/ml
Functional assay sensitivity: 22 IU/ml

Available formats: Code **1200** (100 determinations)

SELco[®] anti-Tg

Radioimmuno assay for the determination of autoantibodies to Thyroglobulin (Tg Ab) in neat serum, no predilution required

Assay principle: RIA (competitive)
Tracer: ¹²⁵I-Tg human
Standard range: 20 - 4000 IU/ml

Reaction type: solid phase (coated tubes)
Total incubation time: 120 min one step
Sample volume: 20 µl
Cut off: 100 U/ml
Functional assay sensitivity: 40 IU/ml

Available formats: Code **1540** (100 determinations)

Medizym[®] anti-Tg

Enzyme-linked immunosorbent assay (ELISA) for the quantitative determination of autoantibodies to Thyroglobulin (Tg Ab) in human serum

Assay principle: Enzyme immunoassay
Total incubation time: 60 min
Conjugate: anti-human-IgG-HRP
Substrate: TMB
Standard range: 25 - 5.000 IU/ml

Format: microtiter plate coated with highly purified human Tg
Sample volume: 50 µl diluted serum, 1 + 100 (v + v)
Cut-off: 50 U/ml
Functional assay sensitivity: 25 IU/ml

Available format: Code **3103** (96 determinations)

THYROID

TPO autoantibodies

anti-TPO magnum

Radio ligand assay for the determination of autoantibodies to Thyroid Peroxidase (TPO Ab) in serum

Assay principle: Radio ligand assay
Tracer: ¹²⁵I-TPO human recombinant
Bound/free Separation: magnetic particle and device
Standard Range: 20 - 8000 U/ml

Reaction type: homogeneous phase
Total incubation time: 15 min
Sample volume: 25 µl diluted serum, 1 + 50 (v + v)
Cut off: 50 U/ml
Functional assay sensitivity: 35 IU/ml

Available formats: Code **1910** (100 determinations) **1900** (200 determinations)

CentAK[®] anti-TPO

Radio ligand assay for the determination of autoantibodies to Thyroid Peroxidase (TPO Ab) in serum

Assay principle: Radio ligand assay
Tracer: ¹²⁵I-TPO human recombinant
Bound/free Separation: Protein A and centrifugation
Standard range: 12 - 4000 U/ml

Reaction type: homogeneous phase
Total incubation time: 30 min
Sample volume: 50 / 25 µl diluted serum, 1 + 20 (v + v)
Cut off: 50 U/ml
Functional assay sensitivity: 15 IU/ml

Available formats: Code **1100** (100 determinations)

SELco[®] anti-TPO

Radioimmuno assay for the determination of autoantibodies to Thyroid Peroxidase (TPO Ab) in neat serum, no predilution required

Assay principle: RIA (competitive)
Tracer: ¹²⁵I-TPO human recombinant
Standard range: 8 - 7500 U/ml

Reaction type: solid phase (coated tubes)
Total incubation time: 90 min one step
Sample volume: 20 µl
Cut off: 50 U/ml
Functional assay sensitivity: 30 IU/ml

Available formats: Code **1500** (100 determinations)

SELco[®] anti-TPO Ref

Radioimmuno assay (human-homologue) for the determination of autoantibodies to Thyroid Peroxidase (TPO Ab) in neat serum, no predilution required

Assay principle: RIA (competitive)
Tracer: ¹²⁵I-TPO human
Standard range: 0 - 1900 IU/ml (human)
(WHO standard: NIBSC 66/387)

Reaction type: solid phase (coated tubes)
Total incubation time: 120 min one step
Sample volume: 20 µl
Cut off: 50 IU/ml
Functional assay sensitivity: 10 IU/ml

Available formats: Code **1501** (100 determinations)

THYROID

TPO autoantibodies

Medizym[®] anti-TPO

Enzyme-linked immunosorbent assay (ELISA) for the quantitative determination of autoantibodies to Thyroid Peroxidase (TPO Ab) in human serum

Assay principle: Enzyme immunoassay
Total incubation time: 60 min
Conjugate: anti-human-IgG-HRP
Substrate: TMB
Standard range: 15 - 3.000 IU/ml

Format: microtiter plate coated with recombinant human TPO
Sample volume: 50 µl diluted serum, 1 + 100 (v + v)
Cut-off: 30 IU/ml
Functional assay sensitivity: 8 IU/ml

Available format: Code **3003** (96 determinations)

TSH

TSH Magnum rapid

Immunoradiometric assay for the determination of Thyrotropin (TSH) in serum

Assay principle: IRMA
Tracer: ¹²⁵I-anti-hTSH mAb (mouse)
Bound/free Separation: magnetic particle and device
Standard range: 0.06 - 100 mIU/l (IRP 80/558)

Reaction type: homogeneous phase
Total incubation time: 60 min
Sample volume: 200 µl
Reference range: 0.3 – 3.5 mIU/l
Functional assay sensitivity: 0.05 mIU/l

Available formats: Code **1470** (200 determinations)

SELco[®] TSH rapid

Immunoradiometric assay for the determination of Thyrotropin (TSH) in serum

Assay principle: IRMA
Tracer: ¹²⁵I-anti hTSH mAb (mouse)
Standard range: 0.06 - 100 mIU/l (IRP 80/558)

Reaction type: solid phase (coated tubes)
Total incubation time: 60 min
Sample volume: 200 µl
Reference range: 0.3 – 3.5 mIU/l
Functional assay sensitivity: 0.03 mIU/l

Available formats: Code **1450** (100 determinations)

Medizym[®] TSH hs

Enzyme-linked immunosorbent assay for the high sensitive determination of Thyrotropin (TSH) in human serum (3. generation)

Assay principle: Enzyme immunoassay
Total incubation time: 75 min
Conjugate: anti-human-TSH-HRP,
Substrate: TMB
Standard range: 0.0 - 15 mIU/l

Reaction type: microtiter plate coated with anti-TSH antibodies
Sample volume: 50 µl serum
Reference range: 0.3 – 3.5 mIU/l
Functional assay sensitivity: 0.015 mIU/l

Available format: Code **3808** (96 determinations)

THYROID

FT3 / FT4 / TT3 / TT4

SELco® FT4

Radioimmuno assay for the determination of free Thyroxine (FT4) in serum

Assay principle: RIA (one step)	Reaction type: solid phase (coated tubes)
Tracer: ¹²⁵ I-anti-T4 (monoclonal)	Total incubation time: 120 min
Standard range: 0 - 100 pmol/l	Sample volume: 50 µl
Analytical assay sensitivity: 0.7 pmol/l	Reference range: 11 - 23 pmol/l

Available formats: Code **1881** (100 determinations)

SELco® FT3

Radioimmuno assay for the determination of free Triiodothyronine (FT3) in serum

Assay principle: RIA (one step)	Reaction type: solid phase (coated tubes)
Tracer: ¹²⁵ I-anti-T3 (monoclonal)	Total incubation time: 120 min
Standard range: 0 - 40 pmol/l	Sample volume: 100 µl
Analytical assay sensitivity: 0.6 pmol/l	Reference range: 2.5 – 6.2 pmol/l

Available formats: Code **1652** (100 determinations)

SELco® T3

Radioimmuno assay for the determination of total Triiodothyronine (TT3) in serum

Assay principle: RIA (competitive)	Reaction type: solid phase (coated tubes)
Tracer: ¹²⁵ I-T3	Total incubation time: 120 min
Standard range: 0 - 12 nmol/l	Sample volume: 100 µl
Analytical assay sensitivity: 0.3 nmol/l	Reference range: 1.0 - 3.3 nmol/l

Available formats: Code **2200** (100 determinations) production after request

SELco® T4

Radioimmuno assay for the determination of total Thyroxine (TT4) in serum

Assay principle: RIA (competitive)	Reaction type: solid phase (coated tubes)
Tracer: ¹²⁵ I-T4	Total incubation time: 120 min
Standard range: 0 - 320 nmol/l	Sample volume: 25 µl
Analytical assay sensitivity: 7 nmol/l	Reference range: 55 - 170 nmol/l

Available formats: Code **2100** (100 determinations) production after request

TUMOR MARKER

Thyroglobulin

SELco[®] Tg

Immunoradiometric assay for the determination of Thyroglobulin (Tg) in serum

Assay principle: IRMA (1 step)

Tracer: ¹²⁵I-anti Tg mAb (mouse)

Standard range: 0.3 - 250 ng/ml

Reaction type: solid phase (coated tubes)

Total incubation time: over night

Sample volume: 100 µl

Functional assay sensitivity: 0.4 ng/ml
(≈ 0.9 ng/ml CRM)

Available formats: Code **1300** (100 determinations)

Medizym[®] Tg Rem

Enzyme-linked immunosorbent assay (ELISA) for the quantitative determination of Thyroglobulin in human serum

Assay principle: Enzyme immunoassay (two-site type)

Total incubation time: over night + 2 hours

Conjugate: anti-hTg-HRP

Substrate: TMB

Standard range: 0 - 3 ng/ml (CRM 457)

Format: microtiter plate coated with antibodies to thyroglobulin (mouse, monoclonal)

Sample volume: 25 µl

Functional assay sensitivity: 0.03 ng/ml

Available format: Code **4018** (96 determinations)

Medizym[®] Tg

Enzyme-linked Immunosorbent Assay for quantitative determination of Thyroglobulin (Tg) in human serum

Assay principle: Enzyme immunoassay (sandwich)

Total incubation time: 75 min

Conjugate: anti-hTg-HRP

Substrate: TMB

Standard range: 0 - 200 ng/ml (CRM 457)

Format: microtiter plate coated with antibody to thyroglobulin (mouse, monoclonal)

Sample volume: 50 µl

Functional assay sensitivity: 1.9 ng/ml

Available format: Code **3807** (96 determinations)

Calcitonin

Calcitonin-IRMA magnum

Immunoradiometric assay for the determination of human Calcitonin (hCT) in serum

Assay principle: IRMA

Tracer: ¹²⁵I-anti-hCT mAb (mouse)

Bound/free separation: magnetic particle and device

Standard range: 0 - 2000 pg/ml

Reaction type: homogeneous phase

Total incubation time: overnight + 2 hours

Sample volume: 200 µl

Functional assay sensitivity: 3 pg/ml

Available formats: Code **1620** (50 determinations)

TUMOR MARKER

Calcitonin

SELco[®] Calcitonin

Immunoradiometric assay (coated tube) for the quantitative determination of human Calcitonin (hCT) in serum or plasma

Assay principle: IRMA

Tracer: ¹²⁵I-anti-hCT mAb (mouse)

Standard range: 1 - 1800 pg/ml

Reaction type: solid phase (coated tube)

Total incubation time: 18 - 24 (5) hours

Sample volume: 100 µl

Functional assay sensitivity: 3 pg/ml

Available formats: Code **1630** (100 determinations) **1631** (50 determinations)

TYPE 1 DIABETES

GAD₆₅ autoantibodies

CentAK[®] anti-GAD₆₅

Radio ligand assay for the determination of autoantibodies to Glutamic Acid Decarboxylase (GAD₆₅ Ab) in serum

Assay principle: Radio ligand assay

Tracer: ¹²⁵I-GAD₆₅ human recombinant

Bound/free Separation: Protein A and centrifugation

Standard range: 0.1 - 300 U/ml

Reaction type: homogeneous phase

Total incubation time: 180 min

Sample volume: 20 µl

Cut-off: 0.9 U/ml

Functional assay sensitivity: 0.6 U/ml

Available formats: Code **1700** (100 determinations) **1720** (50 determinations)

Medizym[®] anti-GAD

Enzyme-linked immunosorbent assay (ELISA) for the quantitative determination of autoantibodies to Glutamic Acid Decarboxylase (GAD₆₅ Ab) in serum

Assay principle: Enzyme immunoassay

Total incubation time: 160 min

Conjugate: Streptavidin-POD

Standard range: 5 - 2000 IU/ml
(WHO standard: NIBSC 97/550)

Format: microtiter plate coated with GAD₆₅
(human recombinant)

Sample volume: 25 µl serum

Substrate: TMB

Cut-off: 5 IU/ml

Functional assay sensitivity: 4 IU/ml

Available format: Code **3802** (96 determinations)

TYPE 1 DIABETES

Protein Tyrosine Phosphatase IA₂ autoantibodies

CentAK[®] anti-IA₂

Radio ligand assay for the determination of autoantibodies to Protein Tyrosine Phosphatase IA₂ (IA₂ Ab) in serum

Assay principle: Radio ligand assay
Tracer: ¹²⁵I-IA₂ human recombinant
Bound/free Separation: Protein A and centrifugation
Standard range: 0.1 - 50 U/ml

Reaction type: homogeneous phase
Total incubation time: over night + 30 min
Sample volume: 20 µl
Cut-off: 0.75 U/ml
Functional assay sensitivity: 0.7 U/ml

Available formats: Code **1750** (50 determinations)

Medizym[®] anti-IA₂

Enzyme-linked immunosorbent assay (ELISA) for the quantitative determination of autoantibodies to Protein Tyrosine Phosphatase IA₂ (IA₂ Ab) in serum

Assay principle: Enzyme immunoassay
Total incubation time: overnight + 100 min
Conjugate: Streptavidin-POD
Standard range: 1 - 400 IU/ml
(WHO standard: NIBSC 97/550)

Format: microtiter plate coated with Protein Tyrosine Phosphatase (human recombinant)
Sample volume: 50 µl serum
Substrate: TMB
Cut-off: 10 IU/ml
Functional assay sensitivity: 0.8 IU/ml

Available format: Code **3803** (96 determinations)

Insulin autoantibodies and antibodies

CentAK[®] - IAA

Radio ligand assay for the determination of autoantibodies to Insulin (IAA) in serum

Assay principle: Radio ligand assay
Tracer: ¹²⁵I-Insulin human
Bound/free Separation: anti-human IgG and centrifugation
Standard range: 1 - 100 U/ml

Reaction type: homogeneous phase
Total incubation time: over night + 120 min
Sample volume: 20 µl
Cut-off: 1 U/ml
Functional assay sensitivity: 0.6 U/ml

Available formats: Code **1730** (100 determinations)

Medizym[®] IAA

Enzyme immunoassay for the determination of auto- (IAA) and antibodies (IA) to Insulin in human serum

Assay principle: Enzyme immunoassay
Total incubation time: 90 min
Conjugate: anti-IgG HRP
Substrate: TMB
Standard range: 0.1 - 20 U/ml

Format: microtiter plate coated with human recombinant Insulin
Sample volume: 100 µl diluted serum (1+100 v+v)
Cut-off: 2.4 U/ml
Functional assay sensitivity: 0.9 U/ml

Available format: Code **3806** (96 determinations)

TYPE 1 DIABETES

Islet cell antibodies

Medizym[®] ICAscreen

Enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative determination of autoantibodies to islet cell antigens in human serum

Assay principle: Enzyme immunoassay

Total incubation time: over night + 100 min

Conjugate: anti-ICA-biotin, streptavidin-POD

Substrate: TMB

Format: microtiter plate coated with IC antigens

Sample volume: 50 µl serum

Cut-off: Binding index= 1.0

Conversion to WHO NIBSC 97/550 and JDF units possible

Functional assay sensitivity: BI < 0.5

Available format: Code **3804** (96 determinations)