FÖRSTA SIDA 80 X 130 mm

TPS® RIA

For accurate tumor status

TPS® RIA

REF 10-311

CE

INSTRUCTIONS FOR USE / GEBRAUCHSANWEISUNG / NOTICE D'UTILISATION INSTRUCCIONES DE USO / ISTRUZIONI PER L'USO / NÁVOD K POUŽITÍ NÁVOD NA POUŽITIE / ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

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EXPLANATION OF SYMBOLS, ERKLÄRUNG VON SYMBOLEN, LISTE DES SYMBOLES, EXPLICACIÓN DE LOS SÍMBOLOS SPIEGAZIONE DEI SIMBOLI, VYSVĚTLENÍ SYMBOL, VYSVETLIVKY K SYMBOLOM, ΕΠΕΞΗΓΗΣΗ ΣΥΜΒΟΛΩΝ

REF	Catalogue number Bestellnummer Référence du catalogue Número de catálogo Numero di catalogo Katalogové číslo Katalógové číslo Αριθμός καταλόγου		Temperature limitation Obere Temperaturbegrenzung Limite supérieure de température Límite superior de temperatura Limite superiore di temperatura Nejvyšší přípustná teplota Najvyššia prípustná teplota Ανώτερο όριο θερμοκρασίας
LOT	Lot number Chargenbezeichnung Code du lot Código de lote Codice del lotto Číslo šarže Číslo šarže Αριθμός Παρτίδας	Σ n	Contains sufficient for < n > tests Inhalt ausreichend für <n> Prüfungen Contenu suffisant pour "n"tests Contenido suficiente para <n> ensayos Contenuto sufficiente per "n" saggi Lze použít pro <n> testů Obsah postačuje na <n> stanovení Περιεχόμενο επαρκές για «ν» εξετάσεις
IVD	In Vitro Diagnostic Medical Device In-Vitro-Diagnostikum Dispositif médical de diagnostic in vitro Producto sanitario para diagnóstico in vitro Dispositivo medico-diagnostico in vitro In Vitro diagnostický zdravotnický prostředek Zdravotnícka pomocka in vitro In Vitro Διαγνωστικό Ιατροτεχνολογικό προϊόν		Consult instructions for use Gebrauchsanweisung beachten Consulter les instructions d'utilisation Consulte las instrucciones de uso Consultare le istruzioni per l'uso Viz návod k použití Viď návod na použitie Συμβουλευτείτε τις οδηγίες χρήσης
	Manufacturer Hersteller Fabricant Fabricante Fabbricante Výrobce Výrobca Κατασκευαστής		For IVD Performance evaluation only Nur zur IVD Leistungsbewertung Réactifs IVD reservés à l'évaluation des performances Sólo para evaluación del funcionamiento Soltanto per valutazione delle prestazioni Pouze pro ověření funkční způsobilosti IVD Iba na preoverenie funkčnej sposobilosti IVD Μόνο για αξιολόγηση απόδοσης IVD
	Use by Verwendbar bis Utiliser jusque Fecha de caducidad Utilizzare entro Použitelné do Použiteľné do Ημερομηνία λήξης		Radioactive material Radioaktives Material Matériau radioactif Material radiactivo Materiale radioattivo Radioaktivní materiál Rádioaktívny materiál Ραδιενεργό υλικό

ENGLISH

INSTRUCTIONS FOR USE

INTENDED USE
TPS® RIA is an assay intended for the determination of cytokeratin 18 in serum. This assay is for research use only, not for use in diagnostic procedures.

PRINCIPLE OF THE ASSAY
TPS® RIA is a one step solid phase radiometric sandwich assay based on immunochemical technique. Standards, controls and samples react during incubation simultaneously with a solid phase monoclonal catcher antibody and the ^{125}I-labeled detector antibody (M3). After washing, the radioactivity is assessed in a gamma counter. The radioactivity is directly proportional to the concentration of the analyte.

ASSAY SPECIFICITY
TPS® RIA measures the M3-epitope on cytokeratin 18 fragments. There is no detectable cross reactivity to cytokeratin 8 and 19.

SAMPLES
Serum samples or heparinized plasma samples are recommended. Enough blood should be collected to be sufficient for 2 x 100 µl sample (duplicates) at each analysis. If the analysis will be performed within 24 h, the samples should be refrigerated (2 - 8 °C). If delayed analysis, serum should be frozen (≤-18 °C). Avoid repeated thawing and freezing. Do not use serum samples that are grossly lipemic, hemolysed or contaminated.

PRECAUTIONS

General
1. TPS® RIA is for research use only, not for use in diagnostic procedures.
2. Do not use the kit after expiry date.
3. Do not mix reagents from different lots.
4. All patient sampless should be regarded as contagious and handled and disposed of according to appropriate regulations.
5. Wear protective gloves and eyewear.
6. Avoid microbiological contamination of reagents.
7. The accuracy of the test is related to adherence to the assay procedure and accurate volume pipetting.
8. Standards, controls and samples in duplicates are recommended.
9. Do not eat, drink or smoke within the designated work area.
10. Material Safety Data Sheet is available on request.

Radioactive material
1. Radioactive material must be handled according to local regulations and may be received, acquired, possessed and used only by possessors of appropriate permissions.
2. Radioactive material should be stored and handled in designated areas. Immediately decontaminate spilled material. Wash all contaminated areas with a suitable detergent.
3. All material used should be considered as radioactive and disposed of in designated containers.

MATERIALS REQUIRED BUT NOT PROVIDED
Gamma counter for ^{125}I (efficiency > 40%).
Shaker for incubation with a recommended oscillation ~450 rpm.
Wash equipment for beads.
Tubes with a recommended diameter of 12 mm.
Bead dispenser.
Routine laboratory equipment, *e.g.* precision pipette(s) and vortex.
Deionized or distilled water.

COMPONENTS IN TPS® RIA
Materials supplied for 100 determinations.

TPS® RIA Coated Beads
1 bottle, 100 dry beads, coated with monoclonal anti-cytokeratin 18 antibody. Packed with desiccating device. Ready for use.

TPS® RIA ^{125}I Tracer
2 vials, 11 ml/vial, M3 antibodies labeled with ^{125}I, radioactivity
≤ 0.24 MBq/vial (≤ 0.48 MBq/kit), emitting ionizing radiation, γ (35 keV) and X (28 keV), half-life 59.4 days. Protein stabilized buffer, pH 7.5.
Blue colored. Preservative added. Ready for use.

TPS® RIA Diluent (Standard 0 U/l)
1 vial, 5 ml, sample diluent and standard 0 U/l, protein stabilized buffer, pH 7.5. Yellow colored. Preservative added. Ready for use.

TPS® RIA Standard (50, 150, 500, 3000 U/l)
4 vials standard, 1 ml/vial, TPS® RIA standard material in protein stabilized buffer, pH 7.5. Concentrations as stated on vials.
Yellow colored. Preservative added. Ready for use.

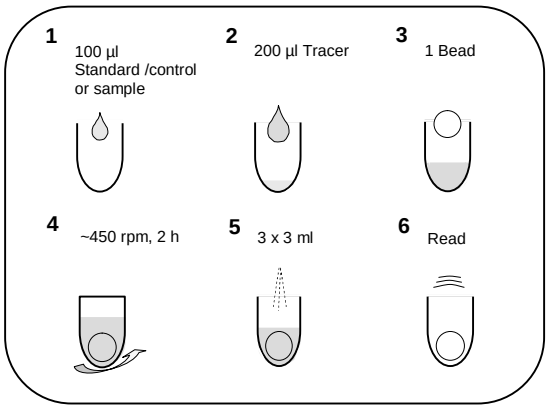
TPS® RIA Control (Low, High)
2 vials, 1 ml/vial, TPS® RIA standard material in protein stabilized buffer, pH 7.5. Yellow colored. Preservative added. Ready for use.

TPS® RIA Certificate
Certificate of lot content.

ASSAY PROCEDURE
The assay should be performed at room temperature, 22 ± 6 °C.
Allow all reagents and samples to adjust to room temperature. Vortex all reagents prior to use.

1. Pipette 100 µl standards, controls or samples per tube.
2. Add 200 µl TPS® RIA ^{125}I Tracer to each tube.
3. Add 1 bead per tube. Cover the tubes with plastic film.
   NB! Steps 2 and 3 should be performed sequentially without interruption.
4. Incubate for 2 h ± 10 min on shaker at ~450 rpm.
   Correct setting of the shaker is vital for correct results.
5. Aspirate and wash the beads 3 times with 3 ml fresh deionized or distilled water.
6. Assess the radioactivity in a gamma counter. Add two empty tubes for background cpm measurement.
7. Calculate the cytokeratin 18 concentration (U/l) of the samples. Samples showing concentrations > 3000 U/l should be suitably diluted with TPS® RIA Diluent (Standard 0 U/l) before repeated analysis.

Schematic assay procedure



PROCESSING OF RESULTS
Use computer software for handling the raw data. Use Spline smoothed as a curve fitting algorithm. For generation of valid data, ensure that included controls are within range.
Manual processing of results: Correct each cpm (counts per minute) value by subtracting the background radioactivity (cpm). Estimate the mean value for each duplicate. Construct a standard curve by plotting the mean cpm value for each standard (y-axis) against the corresponding concentration (x-axis). Determine the concentrations of the samples against the standard curve.

REAGENT STORAGE
The kit should be stored at 2 - 8 °C. Do not freeze. Store reagents in their original containers if not used at once. Reseal the bottle with TPS® RIA Coated Beads, including the desiccating device, if not all beads are used at once.

LIMITATIONS OF THE PROCEDURE
The assay values should be interpreted in conjunction with all available information. Increased values can also be found *e.g.* in cases of pregnancy, liver disease, renal failure and general infections. If a temporary infection is suspected, it may be necessary to repeat the test at a later occasion. The test is for research use only, not for use in diagnostic procedures.

ASSAY CHARACTERISTICS
Measuring range: The measuring range is 10 - 3000 U/l. The assay does not show any high-dose hook effect up to 20 000 U/l.
Analytical sensitivity: The minimal detectable concentration in TPS® RIA is < 10 U/l, defined as the concentration of TPS® antigen that corresponds to the cpm being two standard deviations from the cpm of standard 0 U/l.
Normal range: The 95th percentile for apparently healthy Swedish blood donors has been determined to 80 U/l. It is recommended that each laboratory establishes its own normal range.
Reproducibility: The intra- and inter-assay precision of the assay, defined according to NCCLS guidelines, ranges from 2 – 7 % CV. The average within and between assays CV is 4 % and 3 % respectively.
Recovery: Determined recovery was 98 - 119 % after adding specified quantities of TPS® antigen to human serum samples.
Dilution: Determined recovery was 100 – 117 % after diluting high concentration samples with TPS® RIA Diluent.

WARRANTY
The performance data presented here were obtained using the procedure indicated. Any change or modification in the procedure, not recommended by IDL Biotech AB, may affect the results. In such event IDL Biotech AB disclaims all warranties expressed, implied or statutory, including the implied warranty of merchantability and the fitness for use.

TRADEMARKS
TPS® is a registered trademark of IDL Biotech AB.

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