

TPS[®] ELISA

REF 10-212



INSTRUCTIONS FOR USE
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NOTICE D'UTILISATION
INSTRUCCIONES DE USO
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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**

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TPS[®] ELISA

INSTRUCTIONS FOR USE

INTENDED USE

TPS[®] ELISA is an assay intended for determination of cytokeratin 18 in serum. This assay is for research use only, not for use in diagnostic procedures.

PRINCIPLE OF THE ASSAY

TPS[®] ELISA is a one step enzyme linked sandwich immunoassay. Standards, controls and samples react during incubation simultaneously with a solid phase monoclonal catcher antibody and the HRP-conjugated monoclonal detector antibody (M3). After washing, the TMB substrate is added and after an incubation time the reaction is stopped and the absorbance at 450 nm is measured. The developed colour is directly proportional to the concentration of the analyte.

ASSAY SPECIFICITY

TPS[®] ELISA measures the M3-epitope on soluble 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 50 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 or contaminated. Avoid hemolyzed samples, they may cause false positive results.

PRECAUTIONS

1. TPS[®] ELISA 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. The accuracy of the test is related to adherence to the assay procedure and accurate volume pipetting.
5. Standards, controls and samples in duplicates are recommended.
6. All patient specimens should be regarded as contagious, handled and disposed of according to appropriate regulations.
7. Wear protective gloves and eyewear.
8. Avoid microbiological contamination of reagents.
9. Do not eat, drink or smoke within the designated work area.
10. Material Safety Data Sheet is available on request.

MATERIALS REQUIRED BUT NOT PROVIDED

Microplate reader (wavelength 450 nm)
Shaker for incubation with a recommended oscillation ~450 rpm.
Wash equipment for microplates.
Routine laboratory equipment, e.g. precision pipettes and vortex.
Deionized or distilled water.

COMPONENTS IN TPS[®] ELISA

Materials supplied for 96 determinations.

TPS[®] ELISA Microstrips

1 plate, 96 dry wells (12 strips), coated with monoclonal anti-cytokeratin 18 antibody. Packed in aluminium bag with desiccating device. Ready for use.

TPS[®] ELISA HRP Conjugate

1 vial, 11 ml, M3 antibodies conjugated with HRP, protein stabilized buffer, pH 7.5. Blue colored. Preservative added. Ready for use.

TPS[®] ELISA 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[®] ELISA Standard (30, 150, 500, 1200 U/l)

4 vials standard, 1 ml/vial, TPS[®] ELISA standard material in protein stabilized buffer, pH 7.5. Concentrations as stated on vials. Yellow colored. Preservative added. Ready for use.

TPS[®] ELISA Control (Low, High)

2 vials, 1 ml/vial, TPS[®] ELISA standard material in protein stabilized buffer, pH 7.5. Yellow colored. Preservative added. Ready for use.

Wash tablet

One blisterpacked tablet, the tablet should be dissolved in 500 ml of fresh deionized water.

TMB Substrate: 1 vial, 22 ml. Protect from light and keep lid tightly closed. Do not sample more than what is needed for the analysis. Ready for use.

Stop Solution: 1 vial, 12 ml, 0.5 M sulfuric acid. Ready for use.

Sealing Tape: 1 sheet Sealing Tape for Microstrips.

TPS[®] ELISA Certificate

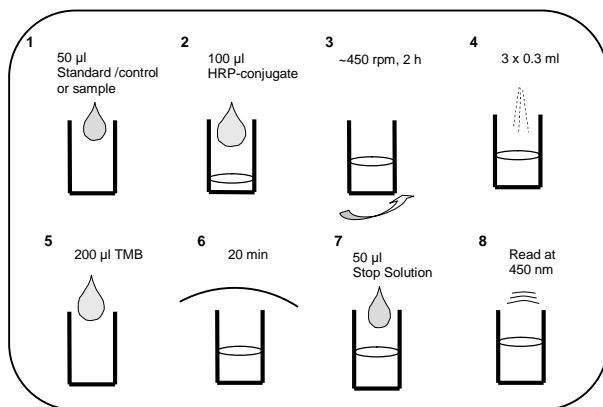
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ASSAY PROCEDURE

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 50 µl standards, controls or samples per well. Leave two empty wells for background absorbance measurement (blank).
2. Add 100 µl TPS[®] ELISA HRP Conjugate per well except the blank wells. *Nb! Steps 1 and 2 should be performed sequentially without interruption.*
3. Incubate for 2 h ± 10 min on a shaker at ~450 rpm. Correct setting of the shaker is important for correct results.
4. Prepare the wash solution by dissolving one wash tablet in 500 ml of deionized water.
5. Aspirate and wash the wells 3 times with 0.3 ml wash solution.
6. Add 200 µl TMB substrate per well, including the blank wells. Incubate in darkness for 20±1 min.
7. Add 50 µl Stop Solution per well. Agitate on a shaker for 1 min.
8. Read the absorbance at 450 nm within 30 min after addition of the Stop Solution
9. Calculate the cytokeratin 18 concentration (U/l) of the samples. Samples showing concentrations > 1200 U/l should be suitably diluted with TPS[®] ELISA Diluent (Standard 0 U/l) before repeated analysis.



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 OD-value (optical density) by subtracting the blank OD. Calculate the mean OD-value for each duplicate. Construct a standard curve by plotting the mean OD-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. The reagents should be stored in their original containers. Be sure to store TPS® ELISA micro well strips in the aluminium bag with the desiccant device, if not all strips are used at once. The wash solution is stable for 4 weeks when stored at 2-8°C.

LIMITATIONS OF THE ASSAY

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 - 1200 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® ELISA is < 6 U/l, defined as the concentration of TPS® antigen that corresponds to the OD-value being two standard deviations from the OD-value 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 1 – 8 % CV. The average within and between assays CV was 5 % and 4 % respectively.

Recovery: Determined recovery was 95 - 102 % after adding specified quantities of TPS® antigen to human serum specimens.

Dilution: Determined recovery was 95 – 113 % after diluting high concentration samples with TPS® ELISA Diluent.

Interference: Interference from added hemoglobin caused up to three times higher values than expected, 300 % recovery. There was no detectable interference from bilirubin and lipids, recovery ranges from 97 – 105 % and 97 – 107 % respectively.

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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