



TSH Receptor Autoantibody Specificity Test – Instructions for use

FOR RESEARCH USE ONLY

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INTENDED USE

RSR's TRAb SPEC™ is intended for use by professional persons only in order to check the specificity of TRAb measurements.

TEST PRINCIPLE

Plastic tubes coated with a purified, concentrated stable TSHR fragment (TSHR260, Miller-Gallacher et al 2019 Crystal structure of a ligand-free stable TSH receptor leucine-rich repeat domain, Journal of Molecular Endocrinology 62 117-128) are provided. Addition of test sera to the tubes followed by a 60 minute incubation with shaking results in binding of TRAb in the test sera to TSHR260 coated on the tubes.

STORAGE AND HANDLING OF TSHR260 COATED TUBES

Store the coated tubes sealed in their foil pouches (10 tubes per pouch) at 2 – 8°C. Allow pouches of tubes to stand at room temperature (20 – 25°C) for 30 minutes before opening. After opening, remove the required number of tubes. Unused tubes from opened pouches should be stored in the pouches at 2 – 8°C with the pouch tops re-sealed with appropriate tape.

TEST PROCEDURE

Sera which need to be tested by TRAb SPEC™ will usually have been assayed for TRAb previously. A positive result would have been obtained but there may be concern about the result being a true positive.

Test sera should have TRAb levels of less than 40 IU/L in the initial assay. Samples with higher levels should be diluted in TRAb assay negative control sera.

Table with 2 columns: Step number and description. Step 1: Add the test serum sample (100 – 250 µL depending on the volume required for the TRAb assay to be performed) to a TRAb SPEC™ tube. Step 2: Cover the tubes and incubate for 60 minutes at room temperature (20 – 25°C) with continuous shaking (200 shakes per min.).

Table with 2 columns: Step number and description. Step 3: After this 60 minute incubation remove the test serum sample and assay for TRAb according to the IFU of the assay being performed.

Include a sample of the test serum which has not been incubated in the TRAb SPEC™ tube in the assay for comparison.

TYPICAL RESULTS OBTAINED USING THE ElisaRSR™ TRAb Fast™

Table with 3 columns: Test Sample, TRAb level (IU/L) before incubation in TRAb SPEC™, and TRAb level (IU/L) after incubation in TRAb SPEC™. Rows A-E show decreasing TRAb levels after incubation.

ElisaRSR™ TRAb Fast™ measuring range 1 – 40 IU/L. Incubation in TRAb SPEC™ tubes reduced TRAb in samples A, B, C, D and E to undetectable levels.

SAFETY CONSIDERATIONS

Follow the instructions carefully. Observe expiry dates stated on the label. Wash hands thoroughly if contamination has occurred and before leaving the laboratory. Sterilise all potentially contaminated waste, including test specimens before disposal. Avoid ingestion, inhalation, injection and contact with skin, eyes and clothing.