

DEVELOPMENT AND EVALUATION OF I-TRACKER BELATACEPT AND I-TRACKER ANTI-BELATACEPT KITS: FAST AND INNOVATIVE CHEMILUMINESCENT ASSAYS FOR THE MONITORING OF PATIENTS TREATED WITH BELATACEPT

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Background

Belatacept is a fusion protein combining a modified cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) extracellular domain with the constant region fragment of human IgG1. Belatacept binds to CD80 and CD86 receptors on the antigen-presenting cell surface. Belatacept prevents T cell activation and proliferation and inhibits subsequent alloimmune responses following organ transplantation, especially in kidney transplant recipients. Theradiag has just developed innovative assays for the quantification of Belatacept and Anti-Belatacept antibodies on the fully automated random access i-Track10 chemiluminescent analyzer.

Methods

Analytical performances were assessed with spiked and clinical human serum samples. Belatacept from serum samples was captured by magnetic microparticles coupled with a neutralizing anti-Belatacept antibody and detected with polyclonal antibodies directed against Belatacept conjugated to acridinium ester. Anti-Belatacept antibodies were captured in using Belatacept coupled magnetic microparticles and detected with the use of Belatacept conjugated to acridinium ester. Light emission was linked to the quantity of Belatacept, or anti-Belatacept antibodies, present in the sample.

Results

The dynamic ranges of the assays were 1 to 50 µg/mL for Belatacept and 10 to 1000 ng/mL for anti-Belatacept antibodies. Belatacept measurement showed high accuracy (recovery was between 80% and 120%). High precision was reached for both assays (CV were <20%) and no interference was seen with biologic agents.

Conclusion

i-Tracker kits are innovative assays which exhibit fast (time to results < 40min), accurate and reproducible results. i-Tracker kits are valuable tools for the monitoring of patients treated with Belatacept.