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Quantification of the ADCC activity of Rituxan using novel engineered effector cells and target cells over expressing CD20 and homologous CD20 negative control cells

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The activity of a number of monoclonal antibodies is mediated in part by antibody-dependent cell-mediated cytotoxicity (ADCC). Traditional methods for quantifying ADCC activity are labor intensive and have a high level of inherent variability. This is due in part to the use of primary human NK-cells from different donors as the effector cells and the use of a complex endpoint that is difficult to standardize, namely cytotoxicity. These limitations have been overcome by the use of an engineered effector cell line expressing the low affinity Fc receptor, FcγRIIIa (CD16) that responds to ligation of the Fc moiety of antibody bound to the specific antigen expressed on target cells by activation of a reporter gene. The use of novel engineered effector cells together with engineered target cells that over-express a constant high level of a specific antigen and the homologous control cells in which the gene encoding the specific antigen has been invalidated by genomic editing, provide the basis for the establishment of a precise and highly sensitive assay for the quantification of ADCC activity. Novel effector cells and engineered target B-cells that have been engineered to over-express a constant level of CD20,together with homologous control B-cells that do not express CD20, have been used to quantify the ADCC activity of Rituxan with a high degree of precision and sensitivity and with minimal interference from human serum.

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