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(54) Title: METHODS AND PRODUCTS FOR EVALUATING AN IMMUNE RESPONSE TO A THERAPEUTIC PROTEIN

(57) Abstract: The invention relates to methods and products for the identification of a clinically significant immune response in subjects treated with a therapeutic protein. A first aspect of the invention relates to methods and compositions for identifying a clinically significant immune response in patients treated with therapeutic amounts of a VLA4 binding antibody (e.g., natalizumab) . A second aspect of the invention concerns the chronological details of sample collection for determining the titre of antibodies against the therapeutic protein, e.g. the collection of at least two samples at two different time points . A third aspect of the invention relates to the selection of the critical threshold level, which corresponds to the antibody titre of untreated patients increased by the double of the standard deviation of this control antibody titre.

WO 2006/107962 A3