



- (51) **International Patent Classification:**
G01N 33/564 (2006.01) *G01N 33/94* (2006.01)
- (21) **International Application Number:**
PCT/US2012/025437
- (22) **International Filing Date:**
16 February 2012 (16.02.2012)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
61/444,097 17 February 2011 (17.02.2011) US
61/484,594 10 May 2011 (10.05.2011) US
61/496,501 13 June 2011 (13.06.2011) US
- (71) **Applicant (for all designated States except US):** **PRO-METHEUS LABORATORIES INC.** [US/US]; 9410 Carroll Park Drive, San Diego, CA 92121-5201 (US).
- (72) **Inventors; and**
- (75) **Inventors/Applicants (for US only):** **SINGH, Sharat** [US/US]; 8171 Top of the Morning Way, Rancho Santa Fe, California 92127 (US). **WANG, Shui Long** [US/US]; 4555 Saddle Mountain Court, San Diego, California 92130 (US). **OHRMUND, Linda** [US/US]; 3519 Tennyson Street, San Diego, California 92106 (US). **HAUENSTEIN, Scott** [US/US]; 3565 Caminito El Rincon #211, San Diego, California 92130 (US).
- (74) **Agents:** **HAO, Joe C.** et al.; Kilpatrick Townsend & Stockton LLP, Two Embarcadero Center, Eighth Floor, San Francisco, California 94111-3834 (US).
- (81) **Designated States (unless otherwise indicated, for every kind of national protection available):** AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) **Designated States (unless otherwise indicated, for every kind of regional protection available):** ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:**
— with international search report (Art. 21(3))

(54) **Title:** ASSAYS FOR DETECTING AUTOANTIBODIES TO ANTI-TNF α DRUGS

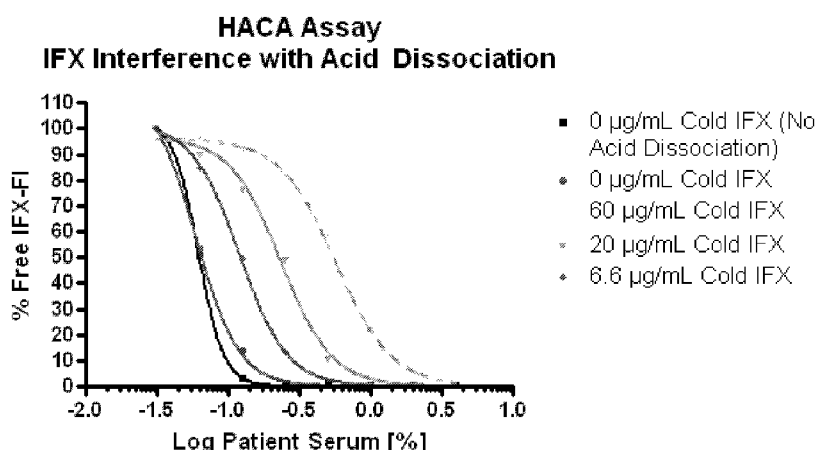


FIG. 28

(57) **Abstract:** The present invention provides assays for detecting and measuring the presence or level of autoantibodies to anti-TNF α drug therapeutics in a sample. The present invention is useful for optimizing therapy and monitoring patients receiving anti-TNF α drug therapeutics to detect the presence or level of autoantibodies against the drug. The present invention also provides methods for selecting therapy, optimizing therapy, and/or reducing toxicity in subjects receiving anti-TNF α drugs for the treatment of TNF α -mediated disease or disorders.