CLAIMS

1. A method for identification of a causative drug of a severe cutaneous adverse drug reaction, comprising the steps of:

   step1: incubating the lymphocytes from a biological specimen with a suspected drug or its metabolite *in vitro* to form a reactant, said reactant is the supernatant of the lymphocytes and said biological specimen is from a subject with severe cutaneous adverse drug reaction;

   step 2: quantifying the expression level of a granulysin protein, polypeptides or mRNA in the reactant and comparing to that of a control, said control is the expression level of a granulysin protein, polypeptide or mRNA in the supernatant of a lymphocyte incubated in a culture medium with or without a solvent,

   wherein the expression level of the granulysin protein, polypeptides or mRNA in the reactant is ≥ 1.2-fold higher compared to that of the control indicates the suspected drug or its metabolite is the causative drug for the severe cutaneous adverse drug reaction, said causative drug induces T cell activation.

2. The method of claim 1, wherein the expression level of granulysin level in step 2 is quantified by a specific capture antibody and a detection antibody to detect the granulysin protein or polypeptide in the reactant.

3. The method of claim 1, wherein the expression level of granulysin level in step 2 is quantified by hybridizing the granulysin mRNA in the reactant with specific oligonucleotide primers or probes.

4. The method of claim 1, wherein the lymphocytes are cells from peripheral blood or a biological fluid isolated from the subject, preferably from peripheral blood.

5. The method of claim 2, wherein the method of detection the expression level of granulysin in the reactant by a capture antibody and a detection antibody is enzyme-linked immunosorbent assay or enzyme-linked immunospot.

6. The method of claim 1, wherein the severe cutaneous adverse drug reaction comprises Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), erythema multiforme majus (EMM), and fixed drug eruption (FDE).

7. The method of claim 1, wherein the causative drug is allopurinol or oxypurinol.