CLAIMS

[Claim 1] An antibody analysis method, comprising:

digesting a biological protein and a target antibody with a protease;

performing mass spectrometry of peptide fragments of the biological protein and the target antibody obtained by the digesting; and

quantifying the target antibody based on a ratio between a detected intensity of the biological protein and a detected intensity of the target antibody obtained by the mass spectrometry,

the digesting with a protease including:

immobilizing the biological protein and the target antibody inside pores of a support; and

bringing a microparticle close to the support, the microparticle having a diameter larger than a diameter of the pores and having a surface to which a protease is immobilized,

wherein the biological protein has a domain capable of being immobilized inside the pores

wherein the target antibody includes at least two antibodies.

[Claim 2] The antibody analysis method according to claim 1, further comprising:

performing mass spectrometry of the biological protein at a predetermined concentration and the target antibody at a predetermined concentration; and

determining in advance the ratio between a detected intensity of the biological protein and a detected intensity of the target antibody, based on results of the mass spectrometry.

[Claim 3] The antibody analysis method according to claim 1 or 2, wherein the biological protein includes a reference antibody or an Fc fusion protein.

[Claim 4] The antibody analysis method according to claim 3, wherein the reference antibody is a monoclonal antibody.

[Claim 5] The antibody analysis method according to claim 3, wherein the reference antibody is selected from the group consisting of trastuzumab, bevacizumab, cetuximab, rituximab, nivolumab, brentuximab, pembrolizumab, ipilimumab, mogamulizumab, ramucirumab, atezolizumab, durvalumab, avelumab, infliximab, tocilizumab, adalimumab, golimumab, mepolizumab, ustekinumab, and eculizumab.

[Claim 6] The antibody analysis method according to claim 3, wherein the Fc fusion protein is selected from the group consisting of abatacept, aflibercept, and etanercept.

[Claim 7] The antibody analysis method according to claim 1 or 2, wherein the target antibody is an antibody contained in a biological sample.

[Claim 8] The antibody analysis method according to claim 1 or 2, wherein the target antibody includes an antibody produced in a living body.

[Claim 9] An antibody analysis method, comprising:

digesting a biological protein and a sample containing at least two target antibodies, with a protease;

performing mass spectrometry of peptide fragments of the biological protein and the target antibodies obtained by the digesting; and

quantifying each of the target antibodies based on a ratio between a detected intensity of the biological protein and a detected intensity of the each of the target antibodies obtained by the mass spectrometry,

wherein the biological protein is a monoclonal antibody.

[Claim 10] A kit for use in the antibody analysis method according to claim 1 or 2, the kit comprising:

the biological protein;

the microparticle having a surface to which a protease is immobilized; and

the support provided with a pore.

[Claim 11] A program for use in the antibody analysis method according to claim 1 or 2, the program causing a processor to execute processes of:

receiving a mass spectrum output from a mass spectrometer;

retrieving a ratio between a detected intensity of the biological protein and a detected intensity of the target antibody, from a storage member;

correcting a detected amount of the biological protein calculated from the mass spectrum; and

calculating an amount of the target antibody.