

CLAIMS

1. A method for ~~testing presence or absence of~~ detecting a mycoplasma in a specimen, the method comprising:

(a) a step of culturing a specimen;

(b) a step of removing ~~impurities~~ mycoplasma nucleic acid fragments by collecting the specimen with a filter using centrifugal separation, wherein the mycoplasma nucleic acid fragments are removed by passing through the filter, and the filter having has a molecular cutoff of 1000kDa or less or a pore size of 0.22µm or less;

(c) a step of recovering solution containing mycoplasma trapped with the filter;

(d) a step of extracting a nucleic acid from the recovered solution and performing amplification of the nucleic acid using a primer capable of amplifying a nucleic acid sequence derived from a mycoplasma; and

(e) a step of performing electrophoresis of an amplified product obtained from the step (d) and checking the presence or absence of a DNA band against a positive control and a negative control,

wherein the specimen is ~~a biotechnology-related product~~ a cell subjected to processing, a cell to be provided to processing, a reagent to be used in processing or testing, a culture medium for culturing a cell, a cell washing solution for washing a cell, or a preservation

liquid for preserving a regenerative medicine product.

~~2. The method according to claim 1, wherein the specimen is a regenerative medicine-related product.~~

~~3~~2. The method according to claim 1 ~~or 2~~, wherein the step of performing amplification of the nucleic acid is performed by a polymerase chain reaction (PCR) method.

~~4~~3. The method according to ~~any one of claims 1 to 3~~or 2, wherein the method includes performing anaerobic cultivation in the step (a).

~~5~~4. The method according to ~~any one of claims 1 to 3~~or 2, wherein in the step (a), two or more specimens are each cultured in an aerobic or anaerobic condition.

~~6~~5. The method according to any one of claims 1 to ~~4~~3, wherein an amount of the specimen cultured in the step (a) is 10 μ L to 10 mL.

~~7~~6. The method according to any one of claims 1 to ~~6~~5, wherein in the step (a), cultivation is performed for 3 to 14 days.

~~8. The method according to any one of claims 1 to 7, wherein the regenerative medicine-related product includes at least one selected from a cell subjected to processing, a cell to be provided to processing, a reagent to be used in processing or testing, a culture medium for culturing a cell, a cell washing solution for washing a cell, and a preservation liquid for preserving a regenerative medicine~~

~~product.~~

~~9. A method of managing quality of a biotechnology-related product, the method comprising:~~

~~— a step of testing presence or absence of a mycoplasma~~

5 ~~in a specimen by the method according to any one of claims 1 to 8.~~

~~10~~7. A kit for use in the method according to any one of claims 1 to ~~8~~6, the kit comprising: a culture medium for

culturing a mycoplasma; and a primer capable of amplifying

10 a nucleic acid sequence derived from mycoplasma;i

~~wherein the kit further comprises a filter for removing mycoplasma nucleic acid fragments.~~

~~11. The kit according to claim 10, further comprising a filter for removing impurities.~~