

immune deficiency (SCID) mouse). Such models maintain the genetic characteristics of the patient as well as tumor heterogeneity. Presently, the major difficulty of using PDX model for individualized precision medical treatment is the lengthy time period spent on modelling and sensitivity test, and the low success rate for modelling. For example, primary cell transplantation takes 2~3 months, and the drug sensitivity test takes 3~4 months. In addition, PDX modelling requires a high level of technical skills. Surgeons, histologists and researchers need to cooperate closely after the tumor sample is obtained from the patient. Therefore, how to improve the method for determining the sensitivity of tumor cells to an anti-tumor drug by using a PDX model becomes an urgent issue.

## Summary

To overcome the above mentioned technical problems, the present inventor has developed a method for screening anti-tumor drugs by determining the sensitivity of a tumor cell to one or more candidate drugs in a time-efficient and accurate manner.

Disclosed is a method for determining the sensitivity of a primary tumor cell to an anti-tumor drug, including the following steps:

- (1) transferring a primary tumor cell into an implant device;
- (2) implanting the implant device comprising the primary tumor cell into an animal;
- (3) administering a candidate drug to the animal;
- (4) determining the sensitivity of the tumor cell to the candidate drug.

In one aspect, the present disclosure refers to a method for screening anti-tumor drugs by determining the sensitivity of a primary tumor cell to one or more candidate drugs, comprising the following steps:

- (1) isolating the primary tumor cell by digestion and sorting;
- (2) transferring the primary tumor cell into an implant device, wherein the implant device is a modified polyvinylidene fluoride (PVDF) tube with an inner diameter of 1-2mm;
- (3) implanting the implant device comprising the primary tumor cell into an animal;
- (4) administering the candidate drugs to the animal; and
- (5) determining the sensitivity of the primary tumor cell to the candidate drugs.

In examples, the primary tumor cell is obtained from an ex vivo tumor tissue sample. The ex vivo tumor sample can be obtained from a patient, or a PDX model established by using a tumor cell of the patient.

In examples, the animal is a mouse, preferably a nude mouse.

In examples, the sensitivity of the tumor cell to the candidate drug is determined in vitro.

In examples, the candidate drug is administered to an animal orally or

parenterally.

In examples, the primary tumor cell is an isolated tumor cell that has been digested and sorted.

In examples, the sensitivity of the tumor cell to the candidate drug is determined 5 5-14 days after administering the candidate drug to the animal, preferably 5-7 days after administering the candidate drug to the animal.

In examples, the implant device is a tubular device having a molecular weight cut-off value of about 500,000 Dalton, preferably a modified polyvinylidene fluoride (PVDF) tube having a molecular weight cut-off value of about 500,000 Dalton, more 10 preferably a modified PVDF tube with an inner diameter of about 1-2mm having a molecular weight cut-off value of about 500,000 Dalton. In examples, the tubular device having a molecular weight cut-off value of about 500,000 Dalton is a sealed device.

Disclosed is a kit for determining the sensitivity of a primary tumor cell to an 15 anti-tumor drug, comprising an implant device, said implant device is a tubular device with a molecular weight cut-off value of about 500,000 Dalton, preferably a modified polyvinylidene fluoride (PVDF) tube having a molecular weight cut-off value of about 500,000 Dalton, more preferably a modified PVDF tube with an inner diameter of about 1-2mm having a molecular weight cut-off value of about 500,000 20 Dalton.

In another aspect, the present disclosure refers to a kit for screening anti-tumor drugs by determining the sensitivity of a primary tumor cell to one or more candidate drugs, which is used for carrying out the method as disclosed herein.

Disclosed is the use of the kit of the present invention for determining the 25 sensitivity of a primary tumor cell to an anti-tumor drug and for screening anti-tumor drugs in a time-efficient manner.

In another aspect, the present disclosure refers to use of the kit as described herein for screening anti-tumor drugs by determining the sensitivity of a primary tumor cell to one or more anti-tumor drugs.

## 30 **Figures**

Figure 1 is a schematic diagram of the method of the present invention.

Figure 2 is a growth curve of primary gastric cancer cells obtained from a patient after administration of anti-tumor drug Tegafur in a traditional mouse PDX model GAPF155.

Figure 3 shows the pharmacodynamic data according to the method of the 35 present invention of anti-tumor drug Tegafur (S-1) for gastric cancer cells from an *ex*

## Claims

- 1、 A method for screening anti-tumor drugs by determining the sensitivity of a primary tumor cell to one or more candidate drugs, comprising the following steps:
- 5 (1) isolating the primary tumor cell by digestion and sorting;  
(2) transferring the primary tumor cell into an implant device, wherein the implant device is a modified polyvinylidene fluoride (PVDF) tube with an inner diameter of 1-2mm;  
(3) implanting the implant device comprising the primary tumor cell into an  
10 animal;  
(4) administering the candidate drugs to the animal; and  
(5) determining the sensitivity of the primary tumor cell to the candidate drugs.
- 2、 The method of claim 1, wherein the primary tumor cell is obtained from an ex  
15 vivo tumor tissue sample.
- 3、 The method of claim 2, wherein the ex vivo tumor tissue sample is obtained from a patient, or obtained from a patient-derived xenograft (PDX) model established using a tumor cell of a patient.  
20
- 4、 The method of any one of claims 1-3, wherein the animal is a mouse, preferably a nude mouse.
- 5、 The method of any one of claims 1-4, wherein the sensitivity of the tumor cell  
25 to the candidate drugs is determined in vitro.
- 6、 The method of any one of claims 1-5, wherein the candidate drugs are administered to the animal orally or parenterally.
- 7、 The method of any one of claims 1-6, wherein the sensitivity of the tumor cell  
30 to the candidate drugs is determined 5-14 days after administering the candidate drug to the animal, preferably the sensitivity of the tumor cell to the candidate drug is

determined 5-7 days after administering the candidate drug to the animal.

8、 The method of any one of claims 1-7, wherein the implant device has a molecular weight cut-off value of 500,000 Dalton.

5

9、 The method of any one of claims 1-8, wherein the implant device is implanted into the animal subcutaneously.

10、 A kit for screening anti-tumor drugs by determining the sensitivity of a primary tumor cell to one or more candidate drugs, which is used for carrying out the method according to any one of claims 1-9.

10

11. The kit of claim 10, wherein the implant device is a sealed device.

12、 Use of the kit of any one of claims 10-11 for screening anti-tumor drugs by determining the sensitivity of a primary tumor cell to one or more anti-tumor drugs.

15