

# CONSGen Cell-Free DNA Blood Collection Tube

## I. Introduction

CONSGen Blood Free DNA Preservation Tube is a new type of vacuum blood collection tube that combines the three processes of “sampling, stabilization, and preservation”. It can directly collect whole blood for isolation of cell-free DNA in plasma, and the proprietary preservative can stably store cell-free plasma DNA during transportation.

The blood stored in the CONSGen Cell-Free DNA Blood Collection Tube can be subjected to cell-free DNA extraction according to most commercially available kits, and the extracted cell-free DNA can be used for downstream detection and analysis. CONSGen Cell-Free DNA Blood Collection Tube can also stably store nuclear cell genomic DNA. (This product can only be used for scientific research, not for medical diagnosis).

## II. Principle

Nucleic acid detection in the blood is an extremely convenient and reliable way in disease diagnosis. In addition to the analysis of nuclear cells (including free tumor cells), the detection and analysis of cell-free DNA in plasma is a newly developed field. Although there is only a small amount of cell-free DNA in healthy human plasma, the increase or decrease of this free DNA content is associated with many clinical diseases and can be used as a basis for fetal genetic disease detection in prenatal diagnosis. In the process of cell-free DNA analysis, the collection, transportation, and storage of the sample can easily lead to the decomposition of nuclear blood cells, further release the cellular genomic DNA that affect the content of cell-free DNA. Improper storage environment can lead to ineffective inhibition of nuclease activity which might cause cell-free DNA degradation and further affect downstream clinical detection. Studies have shown that cell-free DNA preservation tube can be used as a non-invasive, rapid and sensitive diagnostic tool. It can effectively protect the quality and content of cell-free DNA, and can be used for molecular diagnosis and detection of clinical acute diseases, and prenatal diagnosis of fetal genetic diseases.

CONSGen Cell-Free DNA Blood Collection Tube contains  $K_3EDTA$  anticoagulant and a proprietary liquid preservative that stabilizes nucleated blood cells, prevents the release of genomic DNA, inhibits nuclease activity, and contributes to the overall stability of cell-free DNA.

CONSGen Cell-Free DNA Blood Collection Tube protects cell surface antigens, maintains cell morphology, and enhances cell-free DNA extraction, detection, and analysis. Blood samples collected in the CONSGen blood safety tube can be stored stably for 14 days at 6-37°C to facilitate sample collection, transportation and storage. CONSGen Cell-Free DNA Blood Collection Tube can be used for clinical research, drug development and enhanced diagnostic testing.

## III. Features

### • Easy storage

CONSGen Cell-Free DNA Blood Collection Tube can be stored directly at room temperature for up to 14 days without the need for cryogenic storage, which is more convenient for sample transport and storage.

### • Widely used

CONSGen Cell-Free DNA Blood Collection Tube can be extracted with most commercially available kits, resulting in high quality cell-free DNA for a variety of clinical medical research, drug discovery, and diagnostic tests

- Accurate results

CONSgen Cell-Free DNA Blood Collection Tube requires minimal processing of the sample to enhance sample stability and cell-free plasma DNA extraction without affecting the cell-free DNA concentration in the sample.

#### IV. CONSgen Cell-Free DNA Blood Collection Tube Test Data

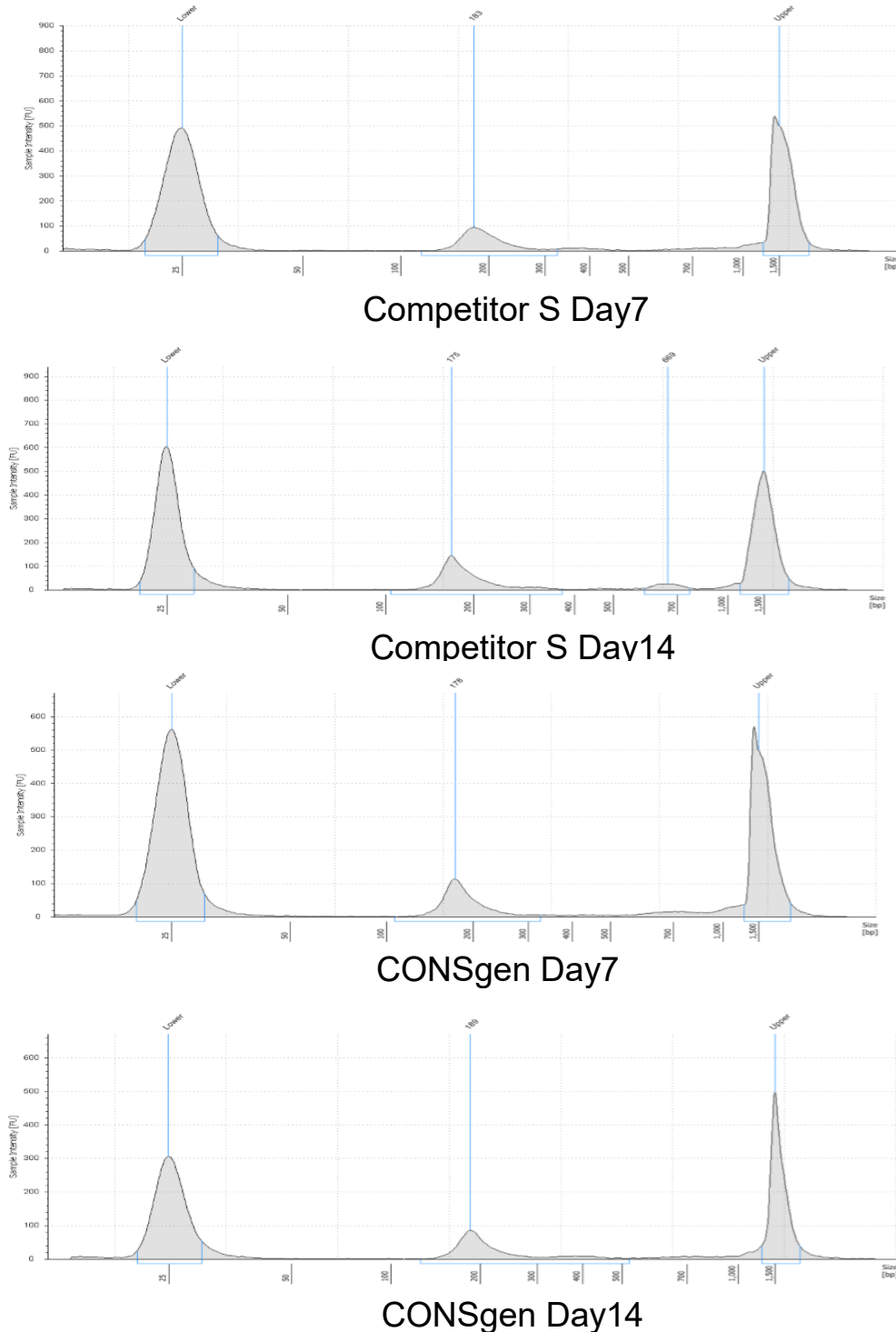


Fig. 1. Effect of different collection tube on plasma DNA concentration after RT storage. Blood samples were drawn into Competitor S and CONSgen tube and stored at RT. Aliquots of blood were transfer at indicated times and the plasma was separated. After cfDNA isolation from plasma, cfDNA was analyzed by Bioanalyzer 2200 with High Sensitivity D1K ScreenTape.

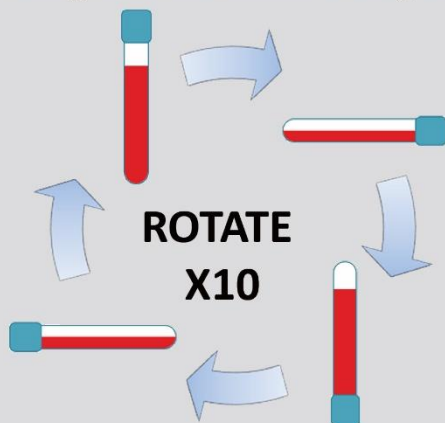
## V. Using Protocol

- Required Blood Collection Accessories (not included with CONSGen Cell-Free DNA Blood Collection Tube).

1. Blood collection devices .
2. Tube Holder .
3. Labels for specimen identification, if required.
4. Alcohol swab for cleansing site.
5. Dry sterile gauze.
6. Tourniquet.
7. Biohazard container for used needle or needle/holder combination.

- Specimen Collection

- A. Take a blood sample with a venous puncture according to the description in Vacuum Blood Collection Tube Blood Collection.
- B. Since the CONSGen Cell-Free DNA Blood Collection Tube contains chemical additives, prevent backflow of the liquid. Please observe the following precautions:
  1. Keep the patient's arm up during the acquisition.
  2. Keep tube cover up when holding tube.
  3. Unfasten the tourniquet within two minutes after the blood begins to collect.
  4. During the collection process, avoid contact with the tube cap or needle in the tube.
- C. Perform blood draw according to the sequence of operations outlined in Vacuum Blood Collection Sampling.
- D. Make sure the blood is completely filled with test tubes
- E. Remove the blood collection tube connected to the test tube and invert it 8 to 10 times as shown in the following figure to fully mix the liquid in the tube with the blood. Inadequate mixing or no immediate mixing may weaken the preservation effect and affect the test results.



- F. After the collection of blood samples is completed, please transport and store within the specified temperature range.
- G. Perform cell-free DNA extraction according to the extraction kit manufacturer's instructions

- Cell-Free Plasma DNA and Cell Genomic DNA Extraction

- A. CONSGen Cell-Free DNA Blood Collection Tube can be used with most commercially available kits for the extraction of cell-free plasma DNA and cellular genomic DNA.
- B. To obtain the best extraction efficiency, in the chaotropic salt lysate, add Proteinase K ( $\geq 30$  mAU/ml) and perform  $60^{\circ}\text{C}$  treatment to extract the cell-free DNA for 1 hour, and extract the genomic DNA of the cell for 2 hour.

• Freezing and Thawing Plasma from Whole Blood Collected in the CONSGen Cell-Free DNA Blood Collection Tube

- A. For long-term storage, freezing plasma at  $-20^{\circ}\text{C}$  or  $-70^{\circ}\text{C}$  /  $-80^{\circ}\text{C}$  in cryogenic tubes is recommended.
- B. Thaw the tubes at room temperature ( $15\text{--}25^{\circ}\text{C}$ ). Note: Do not thaw at lower temperatures (e.g.,  $4^{\circ}\text{C}$ ).
- C. If cryoprecipitates form in the plasma, vortex the tube for 30 seconds after thawing and continue according to the instructions provided with the ImaBeads® Circulating Nucleic Acid Kit.

Note: Do not centrifuge the plasma to remove cryoprecipitates because they may contain cfDNA.

Note: To avoid the formation of cryoprecipitates, tubes can be thawed for 30 minutes at  $30^{\circ}\text{C}$  instead of at room temperature.

## VI. Storage and transportation

- CONSGen Cell-Free DNA Blood Collection Tube can be stored stably during the shelf life at  $18\text{--}30^{\circ}\text{C}$ . Do not refrigerate the empty CONSGen Cell-Free DNA Blood Collection Tube. Proper isolation measures must be taken when transporting under extreme temperature conditions.

- After collecting samples from the CONSGen Cell-Free DNA Blood Collection Tube, blood samples for cell-free DNA analysis can be stably stored for 14 days at  $6\text{--}37^{\circ}\text{C}$ .

## VII. Other considerations

A. This product can only be used for scientific research and cannot be used for medical diagnosis.

B. Contents of this tube may cause irritation to the eyes and skin.

- After skin contact, wash skin with soap and water. Get medical attention if irritation persists after washing.
- After eye contact, flush eyes with water as a precaution. If irritation occurs, get medical assistance.
- After swallowing, rinse mouth. Get medical attention if any discomfort occurs.

C. Discard all blood collection tubes and accessories in biohazard containers approved for their disposal.

D. Do not re-use CONSGen Cell-Free DNA Blood Collection Tubes.

E. Do not use CONSGen Cell-Free DNA Blood Collection Tubes after expiration date printed on tube label.

F. Excessive or low blood collection can cause imbalances in the ratio of blood and additives, which may lead to incorrect analytical results or reduced product performance. Do not dilute or add other ingredients.

G. After blood collection with other anticoagulants or preservatives, transfer to CONSGen Blood Free DNA Preservation Tube may cause clotting of the blood sample.

H. The volume of the storage solution in the CONSGen Cell-Free DNA Blood Collection Tubes are sparse and do not cause hemodilution, so dilution correction is not required.