

For *in vitro* Diagnostic use only

For Professional use only

**10.0mL, Vacuum blood collection tube**  
**AMPULAB<sup>®</sup> Cell-Free DNA CTS Tube**  
**Collection, Transportation and Storage Tube**

**1. INTENDED USE**

AMPULAB<sup>®</sup> Cell-Free DNA CTS Tube is directly used to collect a whole blood for stabilization, transportation, and preservation of cfDNA (cell-free plasma DNA). This product is "For *in vitro* Diagnostic Use Only."

**2. PRINCIPLES**

The state of analysis sample; hemolysis, release of cellular gDNA (genomic DNA) and degradation of cfDNA, is an important factor to get the accurate analysis result of cfDNA.

AMPULAB<sup>®</sup> Cell-Free DNA CTS Tube contains preservative reagents to stabilize and preserve the cellular genomic DNA in nucleated blood cells and the circulating epithelial cells (tumor cells) found in whole blood. This preservative reagent stabilizes nucleated blood cells and prevents the release of cellular gDNA and the degradation of cfDNA. Moreover, the anticoagulant K<sub>3</sub> EDTA in the preservative reagent, prevents blood coagulation.

**3. COMPONENTS**

AMPULAB<sup>®</sup> Cell-Free DNA CTS Tube contains cell preservatives with the anticoagulant K<sub>3</sub> EDTA in a liquid form.

**4. ADDITIONAL MATERIALS REQUIRED BUT NOT SUPPLIED**

Product	Use for
Blood collection needles and multi-tube collection devices for vacuum blood collection tube	Collect blood by venipuncture
Personal protective equipment • Disposable gloves • Alcohol swab • Tourniquet • Bandage • Gauze • Sharp disposal container for disposal of used materials	

**5. STORAGE AND SHELF LIFE**

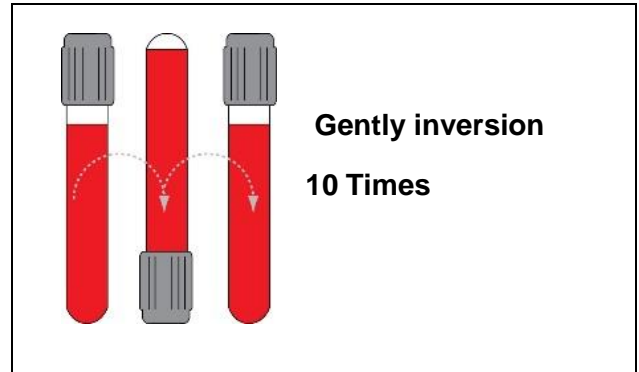
1. Unused product is stable at 18–25°C until the product's expiration date. The expiry date is specified on primary label.
2. Blood samples collected in AMPULAB<sup>®</sup> Cell-Free DNA CTS Tube is stable at 15–25°C for 10 days.

**6. WARNINGS AND PRECAUTIONS**

1. This product is used for *in vitro* diagnostic use only.
2. Do not use this product after expiration date.
3. Do not use this product for collection of materials to be injected into patients.
4. Do not freeze this product.
5. Do not re-use this product.
6. Do not de-cap of tube, until collect blood and mix with preservative.
7. Do not dilute or add other components to the preservative reagent in this product
8. Recommend to use by only be well-trained personnel about blood collection by venipuncture.
9. Avoid contact the preservative reagent with skin and mucous membranes.
10. This product should be disposed with infectious medical waste.
11. When remove and reinsert the tube cap, gently grasp the tube cap and tube glass with a simultaneous twisting and pulling to avoid a tube breakage and injury.
12. The preservative with liquid form of unused product could be transformed to gel or solid, but there is nothing wrong with performance until the product's expiration date.

**7. INSTRUCTIONS FOR USE**

1. Recommend to follow CLSI H3-A6 for detailed method to collect blood specimens by venipuncture.
2. Collect blood by venipuncture. To prevent backflow from the tube, keep patients arm in the downward position during the collection and hold the tube with the stopper in the uppermost position.
3. Fill tube and confirm that the fill volume is between the minimum fill line and the nominal fill line. The expected blood collection volume is 10mL.
4. Fill tube and remove tube from stopper.
5. Immediately mix by gently inversion 10 times to avoid hemolysis. DO NOT SHAKE.



6. After collection, should keep in the recommended temperature range (10–25 °C) to transport and store the tube.
7. When extracting DNA, please follow a method using commercially available kits. Pay attention to do not exceed 1600 x g relative centrifugal force for 10–15 minutes.

**8. LIMITATIONS**

1. AMPULAB<sup>®</sup> Cell-Free DNA CTS Tube is a disposable product. For single use only.
2. The use of butterfly collection needle for venipuncture is not recommended.

**9. STERILIZATION**

AMPULAB<sup>®</sup> Cell-Free DNA CTS Tube has been gamma irradiation and dosimetrically released using a certified facility based upon EN / ISO 11137-1:2006 recommended practices.

**10. DISPOSAL**


AMPULAB<sup>®</sup> Cell-Free DNA CTS Tube is a disposable product. Discard according to the local regulation or guideline for waste treatment of good laboratory practices.


**11. LITERATURE REFERENCES**


1. Preparation and Testing of reagent water in the clinical laboratory, CLSI C3-P4
2. Protection of laboratory workers from occupationally acquired infection, CLSI M29-A3
3. Procedures for the Collection for Diagnostic Blood Specimens by Venipuncture, CLSI H3-A6
4. Gielis E.M., Ledeganck K.J., De Winter B.Y., Del Favero J., Bosmans J.L., Claas F.H.J., et al. Cell-free DNA: an upcoming biomarker in transplantation. American Journal of Transplantation 2015
5. Sheila E. Norton, Kristin K. Luna, Joel M. Lechner, Jianbing Qin, and M. Rohan Fernando. A New Blood Collection Device Minimizes Cellular DNA Release During Sample Storage and Shipping When Compared to a Standard Device. Journal of Clinical Laboratory Analysis 27:305-311 (2013)
6. Kausik Das, M. Rohan Fernando, Sara Basiaga, Stephanie M. Wigginton, Tom Williams. Effects of a novel cell stabilizing reagent on DNA amplification by PCR as compared to traditional stabilizing reagents. Acta histochemical 116 (2014) 55-60


## 12. GLOSSARY OF HARMONIZED SYMBOLS


 Catalog Number

 Do not Re-use


 Batch Code (Lot Number)


 Use By (Expiration Date)


 Manufacturer

 Temperature limitation (Storage Temp.)


 In Vitro Diagnostic Medical Device

 This product fulfills the requirement of the European Directive 98/79/EC for *in vitro* diagnostic medical devices

 Authorized representative in the European community

 Consult Instructions for use (IFU)

 Sterilized using irradiation

 Contains sufficient for tests

## LIST OF CHANGES MADE IN THE INSTRUCTION MANUAL

VER	Location of changes	Essence of changes
SGT-003-01-00	Subsection 2 of 5. Storage and shelf life	For "10~25°C" there substituted "15~25°C"

## 13. CUSTOMER AND TECHNICAL SUPPORT

To place an order or for technical support, please contact SOYAGREENTEC CO.,LTD., Monday through Friday, from 09:00 to 18:00 (UTC+09:00). Fax at +82-2-6925-7407 may also place orders.

For orders outside of Republic of Korea, please contact your local distributor. Additional information about SOYAGREENTEC can be found on our website; [www.soyagreentec.co.kr](http://www.soyagreentec.co.kr).

## 14. CONTACT INFORMATION


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