Cell-Free DNA Urine Preserve

INSTRUCTIONS FOR USE

INTENDED USE

Cell-Free DNA Urine Preserve is a general purpose preservative reagent intended to stabilize cell-free DNA (cfDNA) in urine samples during storage and transportation for up to 7 days at 6 °C to 37 °C. This reagent also stabilizes blood cells found in urine.

Each single use vial (5 mL) is intended to stabilize one urine sample. The preservative is capable of stabilizing 25 mL to 100 mL of urine.

SUMMARY AND PRINCIPLES

Accurate analysis of cellular and non-cellular components of urine can be compromised by sample handling, shipping and processing. Stabilization of all cellular components of urine including red blood cells, white blood cells, and cfDNA at the time of collection ensures integrity for downstream applications.

Cell-Free DNA Urine Preserve stabilizes nucleated cells, preventing the release of genomic DNA, and inhibits nuclease mediated degradation of cfDNA, contributing to the overall stabilization of cfDNA. Treated urine samples are stable for up to 7 days at temperatures when stored between 6 °C to 37 °C, allowing convenient transportation and storage.

REAGENTS

Cell-Free DNA Urine Preserve is a general purpose reagent that contains urine enzyme inhibitors and a cell preservative in a ready to use format.

Cell-Free DNA Urine preserve also contains a PCR compatible blue dye to provide visual reassurance the sample was treated.

PRECAUTIONS

1. To the best of our knowledge, unused product does not require any special disposal. However, each facility must determine proper disposal methods to comply with federal, state and local regulations.
2. Avoid contact with skin and mucous membranes.
3. Do not ingest.
4. Do not use reagents after the expiration date.
5. Product is intended for use as supplied. Do not dilute or add other components to Cell-Free DNA Urine Preserve.
6. All biological specimens and materials coming in contact with them are considered biohazards and should be treated as if capable of transmitting infection. Dispose of in accordance with federal, state and local regulations. Avoid contact with skin and mucous membranes.
7. SDS can be obtained at streck.com, by calling 800-843-0912, or by calling your local supplier.

STORAGE AND STABILITY

1. Store unused Cell-Free DNA Urine Preserve plastic ampoules out of direct light to prevent fading of the blue additive dye.
2. When stored at 2 °C to 30 °C, unused Cell-Free DNA Urine Preserve is stable through expiration date.
3. Short-term storage from 2 °C to 40 °C is acceptable for unused plastic ampoules of Cell-Free DNA Urine Preserve for up to 14 days.
4. Proper insulation may be required for shipment during extreme temperature conditions.
5. Urine samples with the addition of Cell-Free DNA Urine Preserve are stable for up to 7 days when stored between 6 °C to 37 °C.

INDICATIONS OF PRODUCT DETERIORATION

1. Cloudiness or precipitate visible in reagent of unused vials.
2. If indications of product deterioration occur, contact Streck Technical Services at 800-843-0912 or technicalservice@streck.com.

INSTRUCTIONS FOR USE

1. Collect urine sample according to your institutional best practices.
   Note: Collection must occur in an untreated urine collection device. Introduction of other reagents may interfere with the stabilization activity of Cell-Free DNA Urine Preserve.
2. Remove the Cell-Free DNA Urine Preserve vial from the strip.
3. Twist the cap off the vial away from you and squeeze the entire contents into the urine sample. Each preservative vial contains 5ml of reagent. This volume is sufficient to preserve individual urine sample volumes from 25ml to 100ml.
   Note: It is recommended that the reagent is added to specimens within 2 hours of collection.
4. Mix by gentle inversion 3 to 5 times.
5. After collection, transport and store preserved urine samples within the recommended temperature range (6 °C to 37 °C).

URINE CELL-FREE DNA AND CELLULAR GENOMIC DNA EXTRACTION

1. Extraction of cell-free DNA or genomic DNA from urine can be accomplished with commercially available kits. Optimal results must include a Proteinase K treatment step (≥ 30 mAU/ml digest) at 60 °C in the presence of chaotropic salts for 1 hour when extracting cell-free DNA and for 2 hours when extracting cellular genomic DNA.
2. For isolation of cell-free DNA, centrifuge specimens at room temperature at 4000 rpm (≈ 2680 x g) for 10 minutes, or follow extraction kit manufacturer's instructions.
3. Carefully remove supernatant without disturbing the pellet and transfer to a new tube using a pipette followed by cell-free DNA extraction.
4. For optimal results, include a Proteinase K treatment step (≥ 30 mAU/ml digest) at 60 °C in the presence of chaotropic salts for 1 hour when extracting cell-free DNA and for 2 hours when extracting cellular genomic DNA.

REFERENCES

1. Clinical and Laboratory Standards Institute. GP16-A3, Urinalysis: Approved Guideline - Third Edition. 2009.
2. Clinical and Laboratory Standards Institute. MM13-A, Collection, transport, preparation, and storage of specimens for molecular methods; Approved Guideline. 2005.

ORDERING INFORMATION

Please call our Customer Service Department at 800-228-6090 for assistance. Additional information can be found online at streck.com.

GLOSSARY OF SYMBOLS

See the Instructions (IFU) tab under Resources on the product page at streck.com.

See streck.com/patents for patents that may be applicable to this product.

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