

Cell-Free DNA Urine Preserve



INSTRUCTIONS FOR USE

INTENDED USE

Cell-Free DNA Urine Preserve is a general purpose preservative reagent intended to stabilize circulating 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 and preserves blood cells found in urine. Each 5 mL vial of preservative is intended for one-time use per individual urine sample (25 mL to 100 mL volume).

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, cfDNA, and proteins at the time of collection ensures integrity of sample elements for numerous downstream applications. The inability to effectively stabilize urine samples can lead to lysis of nucleated blood cells and subsequent release of cellular genomic DNA. Additionally, degradation of cfDNA due to nuclease activity can be problematic.

The formaldehyde-free preservative reagent contained in Cell-Free DNA Urine Preserve stabilizes nucleated cells, preventing the release of cellular genomic DNA, and inhibits nuclease mediated degradation of cfDNA, contributing to the overall stabilization of cfDNA. Urine samples with the addition of Cell-Free DNA Urine Preserve are stable for up to 7 days at temperatures between 6 °C to 37 °C, allowing convenient transportation and storage.

The cellular components in stabilized urine samples can be identified on urine analyzers such as the Sysmex® UF-1000i™.

REAGENTS

Cell-Free DNA Urine Preserve is a general purpose reagent that contains urine enzyme inhibitors and a cell preservative in a liquid medium.

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. SDS can be obtained at www.streck.com, by calling 800-843-0912, or by calling your local supplier.

STORAGE AND STABILITY

1. When stored at 2 °C to 30 °C, unused Cell-Free DNA Urine Preserve is stable through expiration date.
2. Short-term storage from 2 °C to 40 °C is acceptable for unused ampules of Cell-Free DNA Urine Preserve for up to 14 days.
3. Proper insulation may be required for shipment during extreme temperature conditions.
4. 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. Wash hands with soap and water prior to sample collection.
2. Collect urine in a specimen collection cup.
3. Remove the Cell-Free DNA Urine Preserve vial from the strip.
4. Twist the cap off the vial away from you and squeeze the entire contents into the urine sample collected in the cup. 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.
5. Cap the cup tightly and mix by gentle inversion 3 to 5 times.
6. Wash hands with soap and water after sample collection.
7. 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 and cellular genomic DNA from urine can be accomplished using most commercially available kits.
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.

Note: Urine samples preserved with Cell-Free DNA Urine Preserve are generally compatible with urine analyzers such as Sysmex® UF-1000i and CLINITEK Atlas®. Only slight changes in pH, specific gravity and conductivity are observed.








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 www.streck.com.

GLOSSARY OF HARMONIZED SYMBOLS

 Batch Code	 Biological Risk	 Catalog Number	 Use By
 Manufacturer	 Consult Instructions For Use	 Temperature Limitation	
Glossary of symbols may contain symbols not used in the labeling of this product.			

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



Streck
7002 S. 109 Street, La Vista, NE 68128 USA

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