

24h urine container with integrated transfer device For in vitro diagnostic use Instructions for Use

Intended use

VACUETTE® URI-PLUS is to be used for collection of urine over a 24-hour period and subsequent transfer of a urine sample into urine tubes. The device is to be used by appropriately trained healthcare professionals in accordance with the instructions.

Product description

VACUETTE® URI-PLUS is a non-sterile, graduated, amber plastic container with an integrated transfer device in the lid including a long straw for sample collection into vacuum collection tubes.

Handling

The laboratory should give information on appropriate storage of urine during the 24-hour period.

Collection

1. After the patient has emptied his/her bladder into the toilet for the first time in the morning, the 24-hour collection begins. The time and date is noted on the container label and on any documentation provided as instructed by the laboratory.
2. During the following 24 hours, every drop of urine from the patient should be collected in the container. It is recommended that a separate clean cup or beaker be used to collect urine while voiding and the contents emptied into the 24h urine container each time.
3. Exactly 24 hours after beginning, the collection ends with a final emptying of the bladder into a cup or beaker to be added to the 24h urine container. Again, time and date should be documented on the label and on any associated paperwork.
4. The volume of urine collected should be determined by checking the fill against the scale on the container.

Transfer

5. Mix the contents of the 24h urine container prior to transferring a sample into the urine tube.
6. Lift up the label on the lid of the 24h urine container and firmly push the urine tube into the transfer device opening. Hold the tube in position until the tube has filled completely.
7. For safety reasons, replace the label over the opening after specimen transfer.

Precautions/Cautions

- Do not touch the inside of the transfer device.
- Keep the label over the integrated transfer device during 24-hour collection to avoid accidental needlestick injury.
- Keep the container upright at all times to prevent any leakage of the contents.

Only applicable for member states of the European Union: Should any serious incidents occur in relation to the product, these must be reported to the manufacturer and the competent authority in the member state, in which the user/patient is established.











Storage of the VACUETTE® URI-PLUS urine container

Keep away from direct sunlight.


Disposal

The general hygiene guidelines and legal regulations for the proper disposal of infectious material should be considered and followed. The lid contains a needle and should therefore be disposed of in an appropriate sharps container.

Labelling on packaging

	Catalogue number		Do not re-use
	Batch code		<i>In vitro</i> diagnostic medical device
	Use-by date		This way up
	Manufacturer		Keep away from sunlight
	Date of manufacture		Consult instructions for use

Production location:
ENFA Envases Farmacéuticos, S.A., C/Paralela, 15. Paracuellos de Jarama, 28860 Madrid, Spain
Distributed by Greiner Bio-One GmbH, Austria



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Appendix - Log of changes since last revision

Location in the document	Change description
Precautions/Cautions	Addition of a note regarding reporting of serious incidences in the European Union.
Storage	Adaption of the header from "Storage prior to collection" to "Storage of the VACUETTE® URI-PLUS urine container"
Label Information	Addition of the symbols <i>Keep away from sunlight</i> , <i>date of manufacture</i> , and <i>consult instructions for use</i> .