Collection, storage and transport recommendations for first-void urine samples

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INTRODUCTION

Urine, in particular, the first-20ml known as first-void urine (FVU)/ - first catch can be used to detect human papillomavirus virus (HPV)[1], sexually transmitted infections (STIs)[2] and prostate cancer biomarkers[3]. Novosanis' Colli-Pee® is suited for standardized and volumetric urine collection .

In addition to urine collection, storage, transport and handling are critical to gain accurate results. The Colli-Pee® device can be prefilled with the nonlytic and non-toxic Novosanis proprietary Urine Conservation Medium (UCM), which allows the preservation of urine during storage and transport.

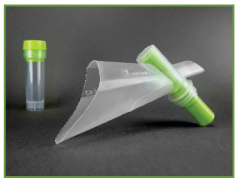
1. COLLECTION

A properly collected first-void urine sample is vital for accurate detection. Colli-Pee® is easy-to-use and allows for more accurate collection of first-void urine (20 mL or 10 mL) compared to a standard urine cup.

The volume of sample collected with Colli-Pee® was consistently around the targeted volume of the collector tube[4]:

- 20 mL variant - Average volume collected: 19.66 mL (σ=1.83)
- 10 mL variant - Average volume collected: 10.0 mL (σ=0.89ml)

The volume collected with a standard urine cup was consistently above the targeted 20 mL volume - Average volume collected: 23.03 mL (σ=13.48 mL)


Colli-Pee® (20 mL)


Colli-Pee® (10 mL)


Regular urine cup

2. STORAGE

Storage conditions suggested for first-void urine (FVU) collected with UCM:

- Short-term storage at room temperature (21-25°C): 7 days after sample collection[5]
- Mid-term storage at -20°C: 7 to 90 days[1].
- Long-term storage at -80°C: Aliquoted into cryovials for up to 12 months[6].

	Room Temp	-20°C	-80°C
FVU with UCM	7 days	upto 90 days	*
FVU without UCM	<72 hours	-	-
FVU UCM in cryovials	-	-	upto 12 months

Table 1: *Storage recommendations for FVU. Room temperature is between 21°C to 25°C*

3. TRANSPORT

Self-collection devices are often subject to leakage or evaporation from improperly capped tubes, especially if stored for a long period, transported through low pressure such as air flight or alongside liquids with low surface tension. In addition, the plastic creep can weaken the tube-cap tension over time, causing spillage[7].

Colli-Pee®'s unique internal thread concept with inlying closure ring allows prefilled tubes with UCM to be stored without leakage[7]. The shelf-life of the Colli-Pee® 20 mL variant with UCM is 24 months[8].

FVU urine collected in the Colli-Pee® device prefilled with UCM can be transported by postal mail at ambient temperature[9] following the below guidelines for exempt specimen samples:
Air transportation of diagnostic specimens is governed under authority of the International Civil Aviation Organization (ICAO) and its regulations are published by the International Air Transport Association (IATA). Since courier services designated as “ground” may involve an air transport segment, the IATA publications are broadly applicable to both air and ground shipment.

The IATA Dangerous Goods Manual was revised on January 1, 2005, and most recently amended accordingto Addendum III, issued on July 5, 2005. This addendum introduces the following guidance:

In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt under this paragraph. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions.

Examples of specimens which may be transported under this paragraph include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antigens (PSA); tests required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or therapeutic drug monitoring; tests conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy tests; biopsies to detect cancer and antibody detection in humans or animals.
For those collecting samples which may not fit the definition above, more stringent requirements for transportation apply. These include the use of a rigid outer container, application of UN2814 (Category A pathogens) or UN3373 (Category B pathogens) labels and demonstration of compliance with pressure tests.

3.6.2.2.3.6 Patient specimens for which there is minimal likelihood that pathogens are present are not subject to these regulations if the specimen is transported in a packaging which will prevent any leakage and which is marked with the words “EXEMPT HUMAN SPECIMEN”or “EXEMPT ANIMAL SPECIMEN”, as appropriate.

The packaging must meet the following conditions:
(a) The packaging must consist of three components:

- a leak-proof primary receptacle(s),
- a leak-proof secondary packaging, and
- an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm × 100 mm.

(b) For liquids, absorbent material in sufficient quantity to absorb the entire contents mustbe placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material.
(c) When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

*Colli-Pee® collector tubes may become brittle upon storage at -80°C hence should be handled with care.

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