

# Standard operating procedure (SOP)

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## Urine sampling

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### Ambulatory Care Setting

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**Version 1.0**

## Aim

This SOP is intended to provide a minimum set of services in the context of recruiting the ambulatory care settings in Bangladesh, Norway, Pakistan, Poland and the United Kingdom of Great Britain (UK) (England and Northern Ireland). In addition, the regional management teams should take the specific cultural and local circumstances in the individual study regions into account.

## Scope of the SOP

The scope refers to all regional managements and ambulatory care facilities involved in the EUthyroid2 ambulatory care setting.

## Abbreviations

|     |  |
|-----|--|
| IMR | Institute of Marine Research, Norway                     |
| SOP | Standard operating procedure                             |
| UK  | The United Kingdom of Great Britain and Northern Ireland |

## Background

The participating study regions Bangladesh University of Health Sciences (BUHS), Institute of Marine Research (IMR), Norway, Islamia College Peshawar, Pakistan (ICP), Jagiellonian University, Poland (JU), University of Surrey, UK (Surrey) and Queen's University Belfast, UK (QUB) are supposed to collect urine samples among the participants at three times (T1, T2, T3) during the study period in the ambulatory care setting. This SOP serves as a standard for all settings. Documents are provided in English and could be translated by the regional management of the participating study regions. Any changes beyond this basic SOP must be reported to the steering committee.

## Information about urine sampling to regional management

To assess iodine status, participants will provide spot urine samples for analysis of urinary iodine concentration (UIC). This helps us understand the impact of the intervention on iodine status. The participants in both the intervention group and the control group will provide urine samples at three specific time-points during the study:

- T1: At baseline, before the intervention
- T2: 1<sup>st</sup> follow-up: 2-4 weeks after the intervention
- T3: 2<sup>nd</sup> follow-up: 6-8 months after the intervention

Before starting the study, the IMR in Norway will send all the equipment needed for urine sampling among the participants. All urine samples from your country should be shipped to the IMR (Bergen, Norway) when the data collection is completed.

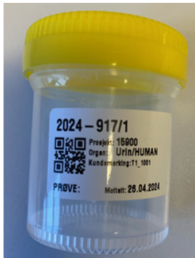



The equipment needed for urine sampling are (**Picture 1**):


- **Urine cup collectors:** One for each participant at each time-point.

- **Analytical tubes:** Two analytical tubes for each time-point for each participant that will be sent to the IMR in Norway.
- **Disposable pipettes:** For transfer of urine aliquot from the urine collectors to the analytical tubes.
- **Cryobox:** For storage of the analytical tubes in freezer that will be sent to the IMR in Norway.
- **Gloves:** To use when transfer the urine aliquot
- **List of ID numbers:** Match the urine ID number from the QR-code with the pseudonym ID number from Greifswald, Germany.

You will receive bags with the urine cup collectors and analytical tubes for each time point (T1, T2, T3). Each small plastic bag contains one urine cup collector and two analytical tubes for one participant at each time-point (see more information below).

## Equipment needed for urine sampling

|  |   |
|--|---|
|  <p><b>Urine cup collectors</b></p> <ul style="list-style-type: none"> <li>• For collection of urine samples (n= 1 for each participant at each time-point)</li> </ul> |  <p><b>Analytical tubes</b></p> <ul style="list-style-type: none"> <li>• Transfer of urine from urine collectors to analytical tubes (n= 2 for each participant at each time-point)</li> </ul> |
|  <p><b>Disposable pipettes</b></p> <ul style="list-style-type: none"> <li>• Transfer of urine aliquot from urine collectors to analytical tubes</li> </ul>            |  <p><b>Cryoboxes</b></p> <ul style="list-style-type: none"> <li>• Storage of analytical tubes in freezer</li> </ul>   |



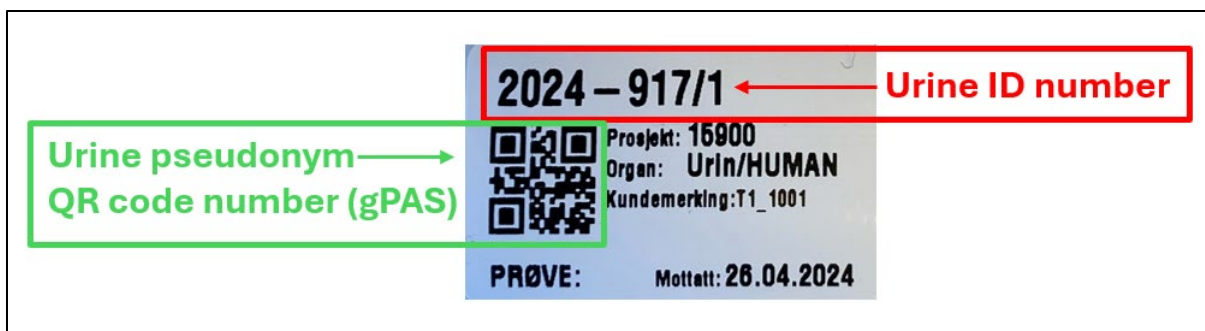
**Picture 1.** Equipment needed for urine sampling among participants in EUthyroid2

### Labelling of urine cup collectors and analytical tubes

All the urine cup collectors and analytical tubes will be labelled in advance (by the IMR in Norway).

The label on the urine cup collector several lines with text and number. The only information you need to care about on the label is:

- Urine ID number (at the top row)
- Urine pseudonym QR code number (to be inserted in gPAS)



**Picture 2.** Example of labelling of urine cup collectors

### **Urine ID-number**

The urine sample ID-number on the urine cup collectors differs according to country, time-point and participant:

2024-xxxx/xxx

- The first number is similar for all countries and gives the year 2024.
- The next number consists of three or four digits and varies from time-point and country. E.g. Norway has the number 917 for T1, 918 for T2 and 919 for T3 (see **Picture 3** below).
- The last number varies from 1-300 and gives the unique number for each participant at each time-point.

**Table 1.** Urine sample ID-number for each country at the different time-points

| <b>Country</b>        | <b>T1:</b> Urine sample ID-number (white label) | <b>T2:</b> Urine sample ID-number (white label with a purple dot) | <b>T3:</b> Urine sample ID-number (white label with a green dot) |
|-----------------------|---|---|--|
| Norway                | 2024-917/xxx                                    | 2024-918/xxx  | 2024-919/xxx   |
| UK – England          | 2024-1459/xxx                                   | 2024-1460/xxx   | 2024-1461/xxx  |
| UK – Northern Ireland | 2024-1462/xxx                                   | 2024-1463/xxx   | 2024-1464/xxx  |
| Poland                | 2024-1456/xxx                                   | 2024-1457/xxx   | 2024-1458/xxx  |
| Bangladesh            | 2024-1465/xxx                                   | 2024-1466/xxx   | 2024-1467/xxx  |
| Pakistan              | 2024-1468/xxx                                   | 2024-1469/xxx   | 2024-1470/xxx  |

**Table 1** gives the urine sample ID-number for each country indicating each of the three time points. An example for how the label is in Norway at the different time-points is given in **Picture 3**:

- T1: The number 917 in the urine sample ID-number indicates that this is T1 for Norway.
- T2: The number 918 in the urine sample ID-number indicates that this is T2 for Norway and it is marked with a purple dot.

- T3: The number 919 in the urine sample ID-number indicates that this is T3 for Norway and it is marked with a **green dot**.



**Picture 3.** Examples of labelling of urine cup collectors from Norway at the three different time-points

### Urine pseudonym QR-code number for urine sample

When scanning the QR-code from the urine cup collector a number consisting of seven digits (e.g. S738942) will show up.

This is the number that will be inserted into gPAS for connection to the pseudonym from each participant (see instructions below).

This number is connected to the urine sample ID-number and the list of associated numbers (both urine sample ID-number and QR-code pseudonym number) can be found in the Excel-sheet “EUthyroid2\_urine\_samples\_ID\_number\_pseudonyms\_gPAS”.

### Registration of urine samples into gPAS

**Picture 4.** Registration of urine sample into gPAS

1. Insert the **pseudonym** of the participant into gPAS (the pseudonym given from Greifswald), see picture above.

2. Insert the **pseudonym QR-code** from the urine cup collector into gPAS (see picture above).  
NOTE: It is very important that you use the QR-code on the urine cup collector and NOT the analytical tubes. It is only the pseudonym QR-code number from the urine cup collectors that works in gPAS. This can be inserted with three different options:
  - a) **Barcode scanner:** Scan the QR-code on the urine cup collector with a barcode scanner and insert the number into gPAS. If you don't have a barcode scanner you have two options:
  - b) **Scan the QR-code with your mobile phone camera:** Scan the QR-code on the urine cup collector with your camera on your mobile phone and the number will show up (see Picture 5 where the number S738942 is given from scanning the QR-code). Insert this number (seven digits) into gPAS.



Picture 5. Example of scanning the QR-code on the urine cup collectors

- c) **Excel-sheet:** In the Excel-file "EUthyroid2\_urine\_samples\_ID\_number\_pseudonyms\_gPAS" find the corresponding pseudonym QR-code number with the urine sample ID-number at the top of the urine cup collector. An example is given in Picture 6 where the urine sample ID-number of 2024-917/1 gives the pseudonym QR-code S738942.

|   | A   | B                                |
|---|---|----------------------------------|
| 1 | T1_Norway_Pseudonym_QR_code_urine_sample_gPAS | T1_Norway_ID_number_urine_sample |
| 2 | S738942                                       | 2024-917/1                       |

Picture 6. Example of corresponding urine sample ID-number and pseudonym QR-code to gPAS

## Transfer of urine aliquot from the urine cup collector to the analytical test tubes and storage

When the participant has delivered the urine sample in the urine cup collector at the study site, the urine sample should be stored in a refrigerator until transfer of urine to the analytical tubes.

At each of the three time-points, participants will collect urine in one urine cup collector, and a urine aliquot will be transferred to the two analytical tubes. One tube is for iodine analysis, and the other is for creatinine analysis. Depending on the study site, the transfer of urine to the analytical tubes may be performed by the health care personnels or other regional management. To ensure accurate analysis, follow these steps when transferring urine aliquots from the urine collector to the analytical test tubes:

1. Make sure to register the urine cup collector with the participant pseudonym in gPAS (see instruction in the section above).
2. Put on gloves to maintain hygiene.
3. Confirm that the urine ID number on the urine sample at the urine cup collector matches the ID number on the two analytical tubes (this is very important). The corresponding analytical tubes is in the same plastic bag as the urine cup collector. The urine ID number is given at the top on the label (e.g. the number 2024-xxxx/xx).
4. Gently mix the urine sample in the urine cup collector without shaking it.
5. Use a disposable pipette to transfer urine from the urine cup collector into each of the two analytical tubes.
6. Place the analytical tubes into a cryobox and store them in a freezer set to a temperature of minus 20°C or colder. If an immediate freezer access isn't available, you can temporarily store the tubes in a refrigerator for a few days until they are transferred to a freezer.
7. Store the remaining volume of urine in the urine cup collector from the participants in your freezer as a backup.

Important: Avoid using any type of stick or dipstick in the participant's urine sample to prevent contamination.

## Shipment of the urine samples to Norway

At the end of the study, the cryoboxes with all the urine samples collected from the participants in the ambulatory care setting, must be shipped to the IMR in Bergen, Norway.

Contact with us at e-mail address [kunnskap@hi.no](mailto:kunnskap@hi.no) when you are ready to send us the urine samples. After you have finished urine sampling from the participants at T1 and T2 you should send us the samples. This means that urine samples from T3 should be send later when the study ends. We will further arrange the sending details and order pick up of samples at your site. Remember to give us address details for pick up and a contact person (name and phone number).

## Practical information about urine sampling to the participant

Depending on regional management, the participants may:

1. **Collection of urine samples at home:** The participant receive the urine cup collector before their appointment at the study site and collect the sample at home. They should be instructed not to use the first void after waking up (no morning urine). Participants must store the sample in a refrigerator until delivering it to the study site.

*or*

2. **Collection of urine samples at the study site:** If the participant has not received the urine cup collector beforehand or forgot to collect the sample at home, they should provide the spot urine sample during the appointment at the study site.

Instructions on how to collect the urine samples is given below. This information should be given to the participant by the health care personnel or other regional management.

### Steps to collect a urine sample: Instructions to the participant

1. Use the urine cup collector you have received from the study personnel to collect the urine sample. Collect the urine sample at home the day before the study appointment. The urine sample should not be the first void after a night sleep (no morning urine). If you have not received the urine collector before the study appointment or have forgotten to collect the urine sample at home, you should collect the spot urine sample during the appointment at the study site.
2. Wash your hands thoroughly with soap and warm water before collecting the urine sample.
3. Position yourself comfortably over a toilet, bathtub, or any other suitable place for collecting urine.
4. Start urinating as normal and collect the midstream urine with the urine cup collector to avoid contaminating it with initial or final urine into the urine container. A volume of 30 to 60 ml is ideal. Once you have collected the required amount, remove the urine collector carefully to avoid spillage.
5. Make sure the urine collector it is tightly sealed to prevent leakage or contamination.
6. After completing the process, wash your hands thoroughly with soap and warm water.
7. If collecting the urine sample at home, store the urine sample in a refrigerator until you bring it to the appointment at the study site and give it to the health care personnel.