SDRN: Scottish Diabetes Research Network

Collection of a Urine Sample for Research Studies

Clinical S.O.P. No.: 33
Version 1

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CHIEF SCIENTIST OFFICE

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DOCUMENT HISTORY

Version number	Detail of purpose / change	Author / edited by	Date edited
1.0	New SOP	Louise Greig	

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1. Introduction

Urine sampling for biochemical analysis is a necessary procedure in most studies, and may be required in research studies for research-proteomics and metabolomics.

2. Objectives

To describe the procedure for collecting a urine sample for biochemical analysis, and to promote uniformity in accordance with ICH GCP guidelines.

3. Responsibilities

Only nurses who have been trained in this procedure and in the process of sample handling, and patient identification, should be dealing with the samples as per ICH GCP guidelines. All bodily fluids should be considered as potentially infectious material and should be handled accordingly.

4. General Points

- The research personnel will greet the research subject and identify themselves.
- The researcher will explain the urine collection procedure to the research subject.
- The researcher will gain the consent of the research participant prior to collection of the urine sample.
- The research subject will be correctly identified prior to urine collection.
- Ensure all sample containers and equipment needed to competently and efficiently carry out the urine collection will be assembled prior to the procedure.
- Bar-coded labels will be applied to all urine specimens immediately after urine collection.
- The research personnel will arrange for the urine specimens to be transported to the research laboratory as applicable.
- Urine specimen containers will not be labelled in advance of urine collection.
- Bar-coded labels will be applied to all urine specimens immediately after urine collection.
- The research personnel will ensure that the lids of the urine specimen containers are securely replaced so that leakage does not occur during transport.

5. Method

- Give the patient a clean container. Ask him or her to go to bathroom and pass urine into the container. A randomly voided sample is suitable for most routine urinalysis.

- If local testing is required then test the urine sample as soon as possible, but if urine cannot be tested within 1 hour then refrigerate the specimen immediately. Let the specimen return to room temperature and invert container in order to mix urine before testing.

- Test urine by dipping/completely immersing the strip into the urine sample. Hold strip in a horizontal position, to avoid the mixing of chemicals form the adjacent reagent areas then and then place it onto a clean paper towel.

- The proper read time is important for optimal results so wait the appropriate length of time for each test (use stop watch) and the hold strip close to the colour blocks on the strip and match carefully. Read off result from urine chart on side of bottle. Colour changes after 2 minutes are of no diagnostic value.

- Record results in CRF (case report form).

- If urine sample is positive for leucocytes, nitrites, blood or protein, send a dipstick to local lab for culture and sensitivity and inform patient that they may have a urinary tract infection.

- To ensure that the urine sample is suitable for retention into a research tissue bank, it must be subject to a urinalysis test and be negative for blood, leucocytes and nitrites. If urine sample is positive for leucocytes, nitrites, blood or protein, send a dipstick to local lab for culture and sensitivity and inform patient that they may have a urinary tract infection.