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South East Wales Trials Unit Standard Operating Procedure

Capturing Images of FLEXICULT Plates in the POETIC Study

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1. Acronyms and definitions

AF	Auto Focus (on camera)
Authorised approver	A member of SEWTU who has been authorised to sign off and approve SOPs
CRF	Case Report Form
DL	Development Lead (SOP); anyone with previous experience of the procedure / completing the procedure being described, who will take the lead in drafting the SOP or delegating specific section of the SOP to the appropriate person.
DG	Development Group (SOP); A group of approximately 2-4 personnel who are responsible for helping develop, maintain and improve the SOP system, consists of other suitably experienced members
Generic SOP	SOP where the procedure can be applied to all studies
ICH GCP	International Conference on Harmonisation – Good Clinical Practice
POCT	Point Of Care Test
RCT	Randomised Controlled Trial
SEWTU	South East Wales Trials Unit
SEWTU Group Lead	The SEWTU Group Leads are the leads for the Qualitative, Data Management, Information Services, Study Managers, Statistics, Admin and Finance groups.
SOP	Standard Operating Procedure; Specifies what should be done, when, where and by whom
SSI	Statens Serum Institut
Study Specific SOP	SOP, where the procedure is to be applied to a specific study
UK	United Kingdom
UTI	Urinary Tract Infection

2. Background

POETIC is an evaluation of a novel Point Of Care Test (POCT) guided urinary tract infection (UTI) management strategy for use in adult women presenting in primary care with suspected uncomplicated UTI. The POCT being evaluated is the FLEXICULT SSI Urinary Kit (agar plate) which enables the culture and quantification of bacteria and the resistance profiles to selected antibiotics.

3. Purpose

The purpose of this procedure is to capture adequate images of FLEXICULT urinary agar plates after incubation of plates inoculated with urine from patients with suspected

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urinary tract infection (see FLEXICULT SSI Urinary Kit Manual specific to UK, The Netherlands and Spain). These images will be used for quality control purposes during the POETIC pilot and RCT phases of the study.

4. Scope

This procedure applies to all primary care practices/study sites involved in the pilot and RCT phases of the POETIC study.

This SOP is specific to the use of Olympus SP-620UZ camera and FLEXICULT SSI Urinary Kit.

5. Responsible personnel

Any personnel using the FLEXICULT urinary agar plates during the POETIC study must be familiar with this SOP and the processes herein.

6. Procedure

Images of the FLEXICULT agar plates should only be taken after urine inoculation and overnight incubation as described in the FLEXICULT SSI Urinary Kit Manual. Images should be taken as soon as possible after reading and recording the plate profiles, ideally within 24 hours.

Step 1: Plate Set-Up

- a) Plates should be placed in an area of natural daylight (i.e. by a window), if this is not possible in a well lit room avoiding direct light above the plate. Individual plates should be placed on the POETIC Photo Template with the lids removed. The plate should be placed on the circle in the middle of the template with the large quantification section at the bottom.
- b) The POETIC patient ID number corresponding to that plate should be stuck on the paper below the plate, along with the date and time of image capture.


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Step 2: Camera Operation and Image Capture (the camera has been pre-programmed; do not alter the settings on the camera)

- a) Remove the lens cap and press the ON/OFF button.
- b) Press the left side of the wheel controller.



- c) Scroll the wheel controller until the **P** on the screen is high-lighted yellow, press OK.
- d) This program has been pre-programmed with the required settings for this study; there is no need to alter this. If for any reason the camera needs to be re-programmed refer to Appendix 2.
- e) Position the camera directly over the plate with the thick grey rectangle on the template approximately in line with the outer edge of the camera screen frame (you may have to turn the camera 90° to do this). Do not use the zoom; physically move the camera up/down to get it in position. The only parts of the template visible in the camera screen frame should be the outer edge of the rectangle, the plate, the study label and date/time.
- f) To focus press the shutter button halfway (the AF target mark lights green and the shutter speed and aperture value are displayed when the focus and exposure are locked).
- g) Press the shutter button completely to capture the image.
- h) To view the image, press the play button  (use the wheel controller to scroll through the images).
- i) Make sure the images are clear (without blur), repeat if necessary.
- j) To turn off the camera, set the power switch to OFF and replace the lens cap.
- k) Camera memory cards should be retained within the camera until requested by a member of the POETIC Study Management Team.

Step 3: Record on CRF

Indicate on the FLEXICULT plate (POCT) CRF 004 that an image has been captured for each plate.

Examples of images:

GOOD Image ✓

BAD Image ✗

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7. References

- POETIC Protocol V 1.0 04.12.12
- FLEXICULT SSI Urinary Kit Manuals (specific to each country UK, The Netherlands and Spain)
- POETIC Photo Template V 4.0
- OLYMPUS SP-620UZ Manual (on the CD supplied with the camera, select Manual: ENU)

8. Appendices

- Appendix I: Process flow chart