Urine Pregnancy Screening for Research Staff: Overview

Objectives

Urine Pregnancy Screening Competency Training Overview

- What test kits are used?
- Who can perform urine pregnancy screening test?
- Who trains research staff? Who do I contact?
- Which urine test kits are used?
- Where is information about competency training located?
- How do research staff obtain test kits and supplies?
- Who performs quality control?

STUDY DESIGN: Purpose of Urine Pregnancy Screening

- The investigator has determined that the study intervention(s) pose a potential risk to a fetus or that inclusion of pregnant women would affect the integrity of the study data.
- Urine pregnancy screening is a method for ruling out pregnancy prior to the onset of study interventions.
- This test is a screen to exclude women who may not be known to be pregnant.
**DOCR COMPETENCY TRAINING QUIDEL**

- The urine pregnancy test used must be the commercially available test kit(s) specified by DOCR
- Currently approved urine test for pregnancy screening using the Quidel QuickVue+ One Step Test
- CLIA Waived Procedure

**DOCR COMPETENCY TRAINING Urine Test Procedures**

- Following demonstration of clinical competency, research staff may perform the QuickVue+ One-Step hCG Test.
- Competency must include the performance of a known negative and a known positive sample documented annually from the Duke Office of Clinical Research (DOCR).

**Approved DOCR Trainers**

- Ana Garcia-Turner, RPM Ophthalmology
- Barbara Kurth, RPM Radiology
- Bonnie Thiele, RPM, OB/GYN
- Catee Mullen, RPM Heart Center
- Deborah Hannah, RPM Dermatology
- Eang King, RPM CFM
- Holly Tiemann, DOCR
- Sharon Minda, RPM Psychiatry
- Terry Ainsworth, DOCR
Registering for DOCR Training

Training information can be obtained from

• DOCR at docr.help@dm.duke.edu
• or (919) 681-6665

Department OBGYN Urine Pregnancy Trained Research Staff 2012

• Department OBGYN Competency Training Completion List sent to DOCR
• Competency training modified

DEMONSTRATION OF CLINICAL COMPETENCY

• Specimen Collection
• Patient Testing
• Documentation
• Interpretation of Results
DOCR MATERIALS SUPPLIED

Each QuickVue One-Step hCG Urine Test Kit contains:
• Disposable Droppers
• Biohazard Bags
• Specimen Collection Container

STUDY TEAM MATERIALS

Material needed, but not included in the DOCR Urine Kit
• Clock or timer
• Gloves

Quality Control

External Quality Control:
• DOCR will perform commercial quality control initially
• Approved Trainer will perform commercial quality control at each location during monthly maintenance.

These results are documented on the QUICKVUE + ONE-STEP hCG QC LOG SHEET
Quality Control

Internal Quality Control:
- The appearance of the control band in the small result window is an internal positive procedural control.
- The white to light pink background of the patient test window is an internal negative procedure control.

These two internal controls validate the test system is working properly and the operator has performed the test correctly.

References and Tools

- DOCR Urine Testing for Pregnancy Screening using the Quidel QuickVue+ One Step Test V 01/xx/2013
  http://docr.som.duke.edu

- DUHS HRPP Program Policy Statement Regarding Pregnancy Testing V 01/13/2013
  http://irb.duhs.duke.edu

Questions?