

Appendix H: ICCTG – Urine Specimen (Banking) Protocol

1. Urine should be collected at the visit immediately preceding treatment and at the last visit (following treatment) by the clean catch method in which each female patient wipes the labial area, and each male patient wipes the head of the penis, with 10% povidone iodine/titratable iodine 1% solution, and then collects a midstream urine into a standard sterile container. Specimens should then be labeled with the patient's identifier number and date, and kept at 4° C or on ice until transported to a laboratory (within one hour of collection is desirable).
2. Urine specimens should then be put into 15ml sterile centrifuge tubes (VWR #21008-216) and cellular debris removed by low speed centrifugation (1900 x g for 10 minutes at room temperature).
3. Urine supernatants should be removed, aliquotted into 10 (2ml) aliquots in polypropylene freezer tubes (Continental Lab products, San Diego, CA #3472), and the remainder transferred to clean 15ml tubes. All specimens should then be frozen as quickly as possible at –70 to –80 C. (Label each tube with patient's identifier number and date of collection).
4. Once every six months, all banked urine from patient's who have completed the study should be shipped in styrofoam lined boxes on dry ice by an overnight carrier (e.g., Federal Express or other), to the University of Pennsylvania. The boxes will be provided to each center at the start of the study.