



# Urine Pregnancy Test

- **Background**
- Participants of the 035 study will be screened for pregnancy every month or if suspected.
- It is essential that none of the women participating in HPTN 035 are pregnant while using the products.
- FDA has strict guidelines concerning research on pregnant women.
- There was a concern that if a woman had a small amount of gel in the urine would it interfere with the pregnancy test.



# Background

- Validation tests were performed on 9 FDA approved kits with 1%, 5%, and 10% BufferGel, PRO2000, and placebo gels.
- 4 of 9 kits gave false negative results with 5% BufferGel and 7 of 8 with 5% placebo.
- All 9 kits performed accurately with 1% of all of the gels.
- The kits were then evaluated on the availability at all sites, FDA approved, ease of use, and price.
- Quidel QuickVue One-Step hCG Urine test was chosen to be the only urine pregnancy test used for the 035 study.



# QUICKVUE<sup>®</sup>

QUIDEL<sup>®</sup>

● *One-Step hCG Urine test*

2004/08/2





# Storage of Kits

- Store at room temperature (15°-30°C) out of direct sunlight.
- The kits come with long expiration dates therefore ordering a few months in advance is possible.



# Specimen Collection

- First morning specimens contain the highest concentration of hCG. However, any specimen is acceptable.
- If the participant is being tested for pregnancy only the specimen does not need to be refrigerated immediately.
- If the participant is also being tested for CT/GC or urinalysis, the specimen must be refrigerated immediately. For ProbeTec CT/GC testing, refrigerate and transport 15ml on ice to the testing laboratory.



# Test Procedure

- Remove the test cassette from the foil pouch just before use and place on clean dry surface.
- Using the disposable pink pipette, dispense 3 drops of urine into the Round Sample Well.
- Do not move the test cassette.
- Wait 3 minutes.



# Test Procedure

- Record the results on the lab log sheet for the specimen
- Specimens that are invalid should be retested. If on repeat testing the QC fails, test with external controls. If the external controls pass, request another specimen. If external controls fail use a different lot of the kit.





# Quality Control

- **Internal QC**
- Each test panel has a built in positive and negative control.
- A blue line developing within 3 minutes on the C line indicates sufficient sample was added.
- No blue line is considered an invalid test.
- A white or light pink background that does not interfere with the reading of the test on the T line is a negative control.

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One-Step hCG Urine test

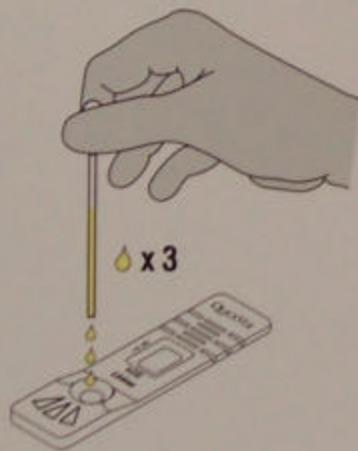
## PROCEDURE CARD

Anleitungskarte  
Scheda di procedura  
Fiche de procédure  
Tarjeta de procedimientos  
Cartão para procedimento

1



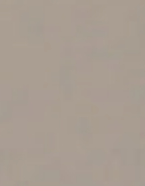
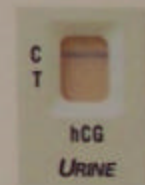
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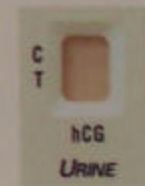
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# Interpretation of Results

- **Positive**
  - Pink to red test line (T) along with a blue control line(C)
- **Negative**
  - Blue control line (C) and no pink test line (T)
- **Invalid Results**
  - NO blue control line (C) at 3 minutes
  - Confirming results can be done with a serum test. Not required for 035.
  - Do not confirm with a different urine kit. Not validated for this study.
- Record the test and control results in the lab report log.



# External QC

- CLIA requires testing each lot number and each shipment with a commercial external control. In addition I recommend testing at least monthly the lot being used.
- Do not use urine from a known pregnant woman. During the pregnancy the levels of hCG decrease and may give a false negative results.
- Quidel QC kits are available and are recommended for this test by the manufacturer.
- Record the QC on a urine pregnancy QC report log. (See handout example)



# Limitations

- If the test is negative, but the woman is suspected of being pregnant, the levels of hCG may be too low to detect. Request a second sample after 48-72 hours.
- hCG may remain detectable for a few days to several days after delivery, abortion, or natural termination.