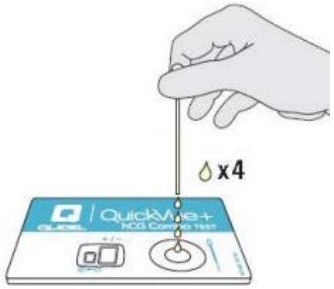
Quidel QuickVue+ One-Step hCG Combo Test

Manual Urine Pregnancy Self-Study Packet

- **Reagent Requirements**

	Quantimetrix Controls	QuickVue+ hCG Combo Test Kit
Storage Temperature	2° - 25°C	15° - 30°C
Stability	1 Month at Room Temp; Manufacturer's expiration at 2-8°C	Manufacturer's expiration date
Handling Requirements	- Record *"Open Date"* and *"Expiration Date"* on each QC vial once opened. - Bring to room temp before use. - *Do not* use beyond manufacturer's expiration date or more than 30 days after opening.	- Record *"Open Date"* on each box once opened. - *Do not* use beyond manufacturer's expiration date.
Handling Precautions	- *Use caution to avoid contamination of QC vials.*	- *Keep out of direct sunlight and do not freeze.*

- **Testing Procedural Notes**
  - First morning sample is preferred, but a freshly collected specimen may be taken and tested at any time of day.
  - Urine collection containers must be labeled with at least two patient identifiers in the presence of the patient, on the cup itself, not the lid.
  - All Reaction Units must be labeled with two patient identifiers if testing a patient, or at least one identifier if testing Quality Control.
  - Internal Procedural Controls, positive and negative, must be assessed and documented with each test – quality control and patient.
  - To perform testing, four drops of sample are added to the Reaction Unit and results interpreted after 3 minutes.



  - The sensitivity of the QuickVue+ One-Step hCG Combo test is 20 mIU/mL for urine.
  - Negative test results in patients suspected to be pregnant should be retested with a sample obtained 48-72 hours later, or by sending a blood sample to the Core Laboratory for quantitative analysis.
  - If a computer is not available in the same room where patient testing is performed, a Urine hCG Patient Result Log must be filled out for each patient at the time of testing, then referenced when resulting the Manual Urine hCG on the patient's chart, using "POCT hCG, Urine, Qualitative [POC99]".
  - Biotin supplements in concentrations greater than 1,000 µg may interfere with this test and cause invalid test results. If this is suspected, a sample must be sent to the core laboratory for testing.

- **Results Interpretation**
  - *Positive:* Indicated by the presence of a pink and blue plus sign (+) in the large square Read Result Window, along with a vertical blue line in the small square Control Window. Any shade of pink on the vertical line should be interpreted as a positive result.
  - *Negative:* Indicated by the presence of a blue minus sign (-) in the large square Read Result Window, along with a vertical blue line in the small square Control Window.
  - *Invalid*: If no vertical blue line appears in the small square Control Window or the background color in the large square Read Result Window interferes with test interpretation, the result is considered Invalid. If observed during QC, no patient testing can be reported until the issue has been resolved. If observed during patient testing, run QC to confirm no issues with supplies; if both levels pass as expected, send a specimen to the Core Lab for testing.

  - Results recorded on the Manual Urine hCG Quality Control and/or Patient Result Logs must be written as either “Pos/Positive” or “Neg/Negative”. The use of (-) and (+) signs is not permitted.

- **Troubleshooting**
  - If either level of QC fails, verify that both the QC and Reaction Units are within their expiration date(s) and have been properly stored, then repeat testing with the same materials, ensuring use of proper technique.
  - If QC fails a second time, open new bottle(s) of QC solution and repeat testing.
  - If QC fails a third time, open a new box of Reaction Units and repeat testing.
  - If QC fails with the new QC solution(s) and Reaction Units, DO NOT perform any patient testing. Contact the POCT Office (5-2645) or by sending a CORUS message to “POCT Consult”.

- **Operator Competency**
  - Review POCTW009 at initial training, in tandem with the completion of the Initial Operator Training and Competency form with a POCC, Nurse Educator, or designated unit trainer.
    - Complete review with any additional assigned revision campaigns from HPO or the POCT Office.
  - Complete the applicable MyLearning module with at least an 80% on the Post-Test at initial training and annually thereafter.
  - Both levels of QC must be performed and documented successfully and correctly at initial training and at least once annually thereafter.