

CLIAwaived,™ Inc. PREGNANCY TESTS

The CLIAwaived,™ Inc. pregnancy tests are qualitative immunoassays for the detection of human chorionic gonadotropin (hCG) in human urine for the early detection of pregnancy. HCG is a hormone produced by the placenta, which, in normal subjects, provides an early indication of pregnancy. Early testing and detection of hCG is vital for the health of the mother and child, and to deliver reliable diagnostic information on which health care professionals can base optimal patient management strategies.

- Simple, accurate, one-step testing
- Built-in procedural control
- Results in 5 minutes or less

The CLIAwaived,™ Inc. pregnancy tests are available in urine (dip-strip), combo (dip-strip or cassette) or pregnancy urine (cassette) testing formats.

Product Description	Type	FDA	CLIA	CE	Packaging	Catalog #
CLIAwaived,™ Inc. Pregnancy Urine Test	Dip-strip	■	■	■	50 tests	CLIA-02-2471
CLIAwaived,™ Inc. Pregnancy Combo Test*	Dip-strip	■		■	50 tests	CLIA-02-2427
CLIAwaived,™ Inc. Pregnancy Combo Test*	Cassette	■		■	25 tests	CLIA-02-2423
CLIAwaived,™ Inc.. Pregnancy Urine Test	Cassette	■	■	■	25 tests	CLIA-02-2478
CLIAwaived,™ Inc. Pregnancy Urine Test	Cassette	■	■	■	50 tests	CLIA-02-2479
Reimbursement Information: CPT Code # 81025QW – Urine pregnancy test by visual color comparisons. National Limit Amount: \$8.90.						

*Note: The CLIAwaived,™ Inc. Pregnancy Combo Test (Dip-Strip) and the CLIAwaived,™ Inc. Pregnancy Combo Test (Cassette) are not CLIA-waived when using serum samples.

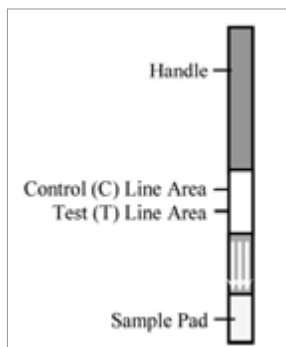


PREGNANCY TESTS

The **CLIAwaived,™ Inc. Pregnancy Urine Test (Dip-Strip)** is a qualitative immunoassay for the detection of human chorionic gonadotropin (hCG) in human urine for the early detection of pregnancy.

The **CLIAwaived,™ Inc. Pregnancy Combo Test (Dip-Strip)** is a qualitative immunoassay for the hCG in human urine or serum for the early detection of pregnancy.

Both tests are for health-care professional use only and not for self-testing.

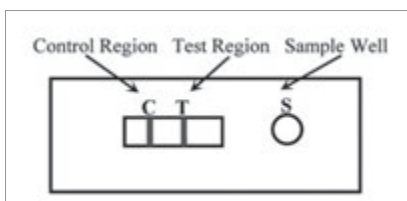


1. Refrigerated specimens and other test materials including device, must be equilibrated to room temperature before testing.
2. Remove the test device from the container or pouch, whichever applies. Label the test and sample container (not provided), accordingly.
3. Holding the test device vertically from the handle end, dip the sample pad in the specimen for about 10 seconds. Keep the sample surface at the level indicated by the arrow sign on the test.
4. Remove the test from specimen, place it on a flat, dry surface.
5. Strong positive results may be observed in 2-3 minutes. Weak positive results may take a longer time, up to 5 minutes, to develop.

The **CLIAwaived,™ Inc. Pregnancy Urine Test (Cassette)** is a qualitative immunoassay for the detection of human chorionic gonadotropin (hCG) in human urine for the early detection of pregnancy.

The **CLIAwaived,™ Inc. Pregnancy Combo Test (Cassette)** is a qualitative immunoassay for the hCG in human urine or serum for the early detection of pregnancy.

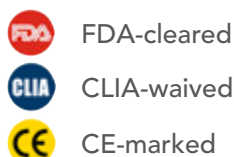
Both tests are for health-care professional use only and not for self-testing.



1. Refrigerated specimens and other test materials including devices, must be equilibrated to room temperature before testing.
2. Remove the test device from its pouch and place it on a flat surface.
3. Holding the dropper vertically, add four drops of the specimen to the sample well.
4. Strong positive results may be observed in 2-3 minutes. Weak positive results may take longer time, up to 5 minutes to develop.

⚠ Please refer to package inserts for detailed instructions and technical information.

DISCLAIMER – The CPT information contained in this document is provided as representative examples of reimbursement in this category. It is intended to assist providers in accurately obtaining reimbursement for health care services. It is not intended to increase or maximize reimbursement by any payor. Providers should consult their payor organizations with regard to local reimbursement policies. The information provided in this document is for information purposes only and represents no statement, promise or guarantee by CLIAwaived™ Inc. All CPT codes are supplied for information purposes only and represent no statement, promise or guarantee by CLIAwaived™ Inc. that these codes will be appropriate or that reimbursement will be made. CPT codes and descriptions are copyrights of the American Medical Association. CPT does not include fee schedules, relative values or related ratings. The source for this information is the Center for Medicare and Medicaid Services. The content provided by the Center for Medicare and Medicaid Services is updated frequently. It is the responsibility of the service provider to confirm the appropriate coding required by their local Medicare carriers, fiscal intermediaries and commercials. All product information and prices are subject to change without notice at any time. Please call our office before ordering to verify current prices.



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