BETATEX DIRECT PLUS® Ref OD072/OD062/OD072/E

Sensitive direct latex agglutination test for detection of Pregnancy
Store at 2°C to 8°C. DO NOT FREEZE.
For in vitro diagnostic use only.

INTRODUCTION

The immunological detection of human chorionic gonadotrophin (hCG) is now universally accepted as the presumptive diagnostic test for pregnancy. The hCG is secreted by the developing placenta and its appearance in urine can be detected as early as 7 days after conception, doubling in concentration about every 1.5 days, thereafter reaching peak of 100-350 IU/ml by the end of the first trimester.

INTENDED USE

The **BETATEX DIRECT PLUS** kit has been designed as an **in-vitro** diagnostic test for the detection of hCG in urine.
For professional use only.

PRINCIPLE OF TEST

The **BETATEX DIRECT PLUS** kit is a direct latex agglutination test. Polystyrene latex particles have been optimally coated with purified anti-hCG antibodies. The antibodies are beta chain specific, significantly reducing the likelihood of false positive results due to LH, FSH and TSH at physiological levels. In the presence of urine containing hCG an agglutination reaction occurs. Agglutination is considered a positive result.

The sensitivity of **BETATEX DIRECT PLUS** is 0.2IU/ml, a level achieved 3 to 4 days after the first missed menstral period.

This test has been calibrated to WHO 4th International Std for Chorionic Gonadotropin 75/589.
No cross reactions have been detected with LH (2nd International Standard 80/552) at levels below 5 IU/ml – Normal level below 0.12 IU/ml.
No cross reactions have been detected with FSH (1st International Standard 83/575) at levels below 10 IU/ml – Normal level below 0.012 IU/ml.

CONTENTS

	Ref OD072	Ref OD062	Ref OD072/E
			
Latex	Suspension of polystyrene particles (1%) coated with purified anti-hCG. Working Strength.		
Control +	Positive Control. Phosphate Buffer solution containing hCG. Working Strength.	**0.5ml**	**0.5ml** **N/A**
Control –	Negative Control. Phosphate Buffer solution free of hCG. Working Strength.	**0.5ml**	**0.5ml** **N/A**
STIRRERS		**50**	**100** **N/A**
PLASTIC RE-USABLE TEST SLIDE		**1**	**1** **N/A**
INSTRUCTION LEAFLET		**1**	**1** **1**

MATERIAL REQUIRED BUT NOT PROVIDED

Micropipettes capable of dispensing 50µl.

PRECAUTIONS

BETATEX DIRECT PLUS Positive Control contains hCG of human origin which has been tested and confirmed negative for HCV, HIV I and HIV II antibodies, and HBsAg by approved procedures at single donor level. Because no test can offer complete assurance that products derived from human source will not transmit infectious agents it is recommended that the reagents within this kit be handled with due care and attention during use and disposal. All reagents should, however, be treated as potential biohazards in use and for disposal. Do not ingest.

BETATEX DIRECT PLUS reagents do not contain dangerous substances as defined by current UK Chemicals (Hazardous Information and Packaging for Supply) regulations. All reagents should, however, be treated as potential biohazards in use and disposal. Final disposal must be in accordance with local legislation.

BETATEX DIRECT PLUS reagents contain 0.095% sodium azide as a preservative which may be toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.

STORAGE

Reagents must be stored at temperatures between 2°C to 8°C.

The kit will perform within specification until the stated expiry date as determined from date of product manufacture and stated on kit and components. Expiry date is the last day of the month on the bottle and the kit label. Do not use reagents after the expiry date.

Exposure of reagents to excessive temperatures should be avoided. Do not expose to direct sunlight.

DO NOT FREEZE ANY OF THE REAGENTS as this will cause irreversible damage.

SPECIMEN COLLECTION AND PREPARATION

Urine samples collected at any time may be used, however, it is recommended that to maximise hCG concentration, the first voided morning specimen should be used. The urine should be collected in a clean dry container (plastic or glass) which must be free from detergent. Urine specimens should be as fresh as possible and it is preferable to test within 24 hours of collection. The sample may be stored for longer periods (72 hours) prior to use, if stored, store at 2°C to 8°C.

Filtration or centrifugation is generally not necessary for urine used in the **BETATEX DIRECT PLUS** test, however, if a sample is very turbid, centrifugation or filtration may be necessary. (The use of supernatant from turbid samples allowed to sediment naturally prior to use may negate the need for sample preparation – this does not affect the hCG concentration.)

REAGENT PREPARATION

All reagents should be brought to room temperature (20°C to 25°C) and mixed gently prior to use. Do not induce foaming.

The test slide should be thoroughly cleaned before use as traces of detergent or prior specimen may affect the result.
Recommended Cleaning procedure:

1. Used cards must be immediately immersed in a disinfectant solution. Follow disinfectant manufactures guidelines.
2. The reaction circles must be physically rubbed with non-abrasive material to ensure removal of possible adhering particles.
3. Thoroughly rinse in purified water.
4. Allow reaction card to dry.
5. Spray cards with a 70% alcohol solution.
6. Allow the alcohol to evaporate prior to re-use.

LIMITATIONS OF USE

The use of samples other than urine have not been validated in this test.

There is no reuse protocol for this product.

A low or suspected positive result should be re-assessed. Diagnosis should not be made solely on the findings of one clinical assay. When making an interpretation of the test it is strongly advised to take all clinical data into consideration.

False positive and false negative pregnancy tests have been reported in tests of specimens from individuals taking a variety of drugs. The false reaction may be related to the donor and/or the drug. Whenever possible, it is best to test the specimen from donors who are not taking drugs.

Although pregnancy is by far the most common reason for the appearance of hCG in urine, elevated hCG levels may also be associated with trophoblastic or non-trophoblastic neoplasms, e.g. chorionic epithelioma or hydatidiform mole.

ASSAY PROCEDURE

1. Allow kit reagents and patients sample to come to room temperature
2. Place one drop of urine sample (50µl) on to the reaction area of the slide using a clean disposable pipette./stirrer.
3. Shake the latex reagent, then one drop of latex reagent and mix using the plastic stirrer, used in step 1.
4. Gently and evenly rock and rotate the test slide for 2 minutes whilst examining the test slide for agglutination. Read the test at 2 minutes.

RESULTS AND INTERPRETATION

Examine the test slide under a strong light source after 2 minutes.

Kit controls or known level value samples should be tested with each test run. The kit negative control should give a negative result after 2 minutes. The kit positive control should give a positive result at a titre of 1/16 +/- one double dilution after 2 minutes. If levels of controls or users known samples do not give expected results, test results must be considered invalid. Occasionally samples may give an intermediate pattern (very weak agglutination). In this event a fresh sample should be tested 3-5 days later.

A positive result is indicated by the obvious agglutination pattern of the latex, in a clear solution. A negative result is indicated by no change in the latex suspension on the test slide.

Positive results will be obtained at a hCG concentration of 0.2 IU/ml or more and negative results will be obtained at a hCG concentration below 0.2 IU/ml.
Titres of 5000 IU/ml have been detected with Betatex Direct Plus with no prozone (hook) effect.

TROUBLESHOOTING

Use a separate disposable tip for each sample to prevent cross contamination.

Replace caps on all reagents immediately after use.

Prior to the start of the assay bring all reagents to room temperature (20^{o}C to 25^{o}C). Gently mix all reagents by gentle inversion or swirling.

For use by operatives with at least a minimum of basic laboratory training.

Do not use damaged or contaminated kit components.

EVALUATION DATA

Reproducability of **BETATEX DIRECT PLUS** is 100% (+/- one double dilution).

	Betatex Direct Plus		Totals
	+	-	
hCG +	16	0	16
hCG -	0	84	84
	16	84	100

Sensitivity 16/16 = 100%
Specificity 84/84 = 100%

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OMEGA DIAGNOSTICS LTD.
Omega House, Hillfoots Business Village
Alva FK12 5DQ, Scotland, United Kingdom
odl@omegadiagnostics.co.uk
www.omegadiagnostics.co.uk
AN ISO 9001:2000 CERTIFIED COMPANY