1. COMPANY IDENTIFICATION

ORCHID BIOMEDICAL SYSTEMS
A DIVISION OF TULIP DIAGNOSTICS (P) LTD
Plot No.88, 89 & 93 Phase II C
Verna Industrial Estate
Verna Goa, India - 403722

2. PRODUCT NAME

Clue hCG Dipstick (One Step Pregnancy test)

3. INTENDED USE

Immunochromatographic test for the determination of human chorionic gonadotropin (hCG), a marker for pregnancy in urine specimens.

4. PHYSICAL AND CHEMICAL PROPERTIES

Nitrocellulose membrane pre-dispensed with anti hCG antiserum- colloidal gold conjugate, rabbit IgG colloidal gold conjugate, anti-hCG antiserum and anti-rabbit antiserum at the respective regions, laminated on a plastic backing and enclosed in a plastic casing.

5. HAZARDS TO HEALTH

When used in accordance with the Principles of Good Laboratory Practice, Good Standards of Occupational Hygiene and the instructions stated in the product insert, these products are not considered to present a hazard to health.

6. FIRST AID

In all cases call physician or poison control centre
**Eye / Skin contact:** Immediately flush eyes or skin with copious amounts of water for at least 15 minutes while removing contaminated clothing and shoes. Assure adequate flushing of the eyes by separating the eyelids with fingers.
If inhaled: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

If swallowed: Wash out mouth with water provided person is conscious. Wash contaminated clothing before reuse. Discard contaminated shoes.

7. PRECAUTIONS

The storage must be between 4°C and 30°C.

For IN VITRO diagnostic use only.

The raw materials used in this kit are of non-human origin and hence free from the presence of the antibodies to HIV and HCV as well as for HBsAg.

WARNING

Because no test method can offer complete assurance that HIV, HCV, HBsAg or other infectious agents are absent the kit contents should be handled carefully.

8. EMERGENCY ACTION

If the material comes in contact with the skin or is splashed into the eyes, rinse immediately with plenty of water.

9. FIRE HAZARDS

Extinguishing media: Carbon dioxide, dry chemical powder or polymer foam.

Special fire fighting procedures: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

10. DISPOSAL REQUIREMENTS

Remains of samples and reagents should be autoclaved for 15 minutes at 121 °C.
Observe all Federal, State and local laws.
11. TOXICOLOGICAL INFORMATION
None known.

12. ECOLOGICAL INFORMATION
None known.

13. STABILITY AND REACTIVITY
Stable, avoid heat, moisture and direct sunlight.

14. TRANSPORT PRECAUTIONS
Special requirements: NONE.

15. REGULATORY REQUIREMENTS
Not applicable.

16. OTHER INFORMATION
Not applicable.

THE ABOVE INFORMATION IS BELIEVED TO BE CORRECT, BUT DOES NOT INTEND TO BE ALL INCLUSIVE, AND SHOULD BE USED ONLY AS A GUIDE. Orchid Biomedical Systems SHALL NOT BE HELD RESPONSIBLE FOR ANY DAMAGE RESULTING FROM HANDLING OR USE OF THE PRODUCT.