Human Chorionic Gonadotropin Rapid Test Device (Urine)

INTENDED USE
The Clarity hCG Rapid Test Device (Urine) is a rapid visual immunoassay for the qualitative presumptive detection of human chorionic gonadotropin (hCG) in the urine of women in order to detect pregnancy. This kit is intended for use as an aid in the early detection of pregnancy.

PROCEDURE
The Clarity hCG Rapid Test Device (Urine) detects human chorionic gonadotropin through visual interpretation of color development. The urine specimen is used to determine if hCG is present in the urine sample.

1. Bring the test to room temperature (15-30°C) before use. Do not use if the foil pouch is torn, punctured, or damaged.
2. Add 3 drops of specimen (approximately 120 µL) directly into the specimen well (S) and start the timer.
3. Avoid trapping air bubbles in the specimen well (S) and do not add any solution to the result area.
4. Wait for the colored band(s) to appear. The result should be read at 3 minutes. Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS
Positive: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

Negative: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

Invalid: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test.

QUALITY CONTROL
Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.

LIMITATIONS OF THE TEST
1. The Clarity hCG Rapid Test Device (Urine) is for professional use in vitro diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
3. This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
4. Avoid cross-contamination of specimens by using a new specimen container for each specimen obtained.
5. Read the entire procedure carefully prior to testing.
6. Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against micro-biological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Using testing materials should be discarded according to local regulations.

STORAGE AND STABILITY
The Clarity hCG Rapid Test Device (Urine) is stable under the following conditions: 2°C to 30°C when stored in the foil pouch. The test must remain in the sealed pouch until use. Do not freeze. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE
The Clarity hCG Rapid Test Device (Urine) is intended for use with human urine specimens only. Although urines from females of any age can be used, first morning urine specimens are preferable as they contain the highest concentration of hCG.

Collected urine specimens must be put in clean, dry containers.

PHYSICAL SPECIFICATIONS
Relative Sensitivity: >99.9% (99.8%-100.0%)*
Relative Specificity: >99.9% (99.8%-100.0%)*
Relative Agreement: >99.9% (99.8%-100.0%)*
Confidence Interval: >99.9% (99.8%-100.0%)*

INTERFERING SUBSTANCES
The following substances were added to hCG and urine samples spiked with 20 µIU/mL hCG:

- None of the substances interfered with the assay at the listed concentrations.
- Acetaminophen: 20 µg/dl
- Acetylsalicylic Acid: 20 µg/dl
- Ascorbic Acid: 20 µg/dl
- Atropine: 20 µg/dl
- Caffeine: 20 µg/dl
- Glucose: 2 g/dl
- Hemoglobin: 1 mg/dl

PERFORMANCE CHARACTERISTICS
Table: Clarity hCG Rapid Test vs. EIA

<table>
<thead>
<tr>
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<tbody>
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SPECIFICITY
The specificity of the Clarity hCG Rapid Test Device (Urine) was determined in cross-reactivity studies with known amounts of Luteinizing Hormone (LH), Follicle Stimulating Hormone (FSH) and Thyroid Stimulating Hormone (TSH). 300 µIU/mL LH, 1000 µIU/mL FSH and 1000 µIU/mL TSH all gave negative results.

LITERATURE REFERENCES

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