

Status hCG Control Kit Positive and Negative Urine Controls (Human)

P-51010-A

For In Vitro Diagnostic Use

Intended Use

Status hCG Positive and Negative Urine Controls are intended for use as unassayed control materials for in vitro tests that detect hCG in urine. The use of these controls enables the laboratorian to monitor the efficacy and to ensure proper kit performance of commercially available tests used to detect elevated levels of hCG in urine. These are not intended to replace any controls furnished with a commercial kit or to be used as a standard.

Summary And Principle

Emphasis for many years on quality control procedures in serology has resulted in a high uniformity of test performance within and among laboratories. One of the most important quality control procedures for assurance of reliable and reproducible tests results is the use of stable control samples that have a predetermined reactivity potency and pattern. Routine use of controls enables laboratories to monitor day-to-day testing, operator and lot-to-lot performance of test kits variation, as well as identifying systematic test errors.

Status hCG Positive and Negative Urine Controls are developed for use as control material to monitor the test systems performance during day to day use.

Each lot of **Status hCG** Positive and Negative Urine Controls are tested in several different methodologies and assay systems including LifeSign hCG tests to insure proper reactivity.

Reagents

FOR IN VITRO DIAGNOSTIC USE. STORE AT 2-8°C WHEN NOT IN USE.

1. Positive Urine Control (Human)
Urine control containing hCG with 0.1% sodium azide as preservative.
2. Negative Urine Control (Human)
Urine control negative for hCG with 0.1% sodium azide as preservative.

Storage

Store at 2-8°C. Do not freeze

Procedural Precautions

- Add 3 drops of control into the sample well of the test device.
- Discard if gross contamination or turbidity is observed.
- This product contains human urine. In accordance with Good Laboratory Practice, all human source material should be considered potentially infectious.

This control set contains sodium azide as a preservative. Sodium Azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal flush with a large amount of water to prevent potentially explosive azide build up.

Preparation For Use

Status hCG Positive and Negative Urine Controls come ready to use. Allow material to equilibrate to room temperature.

Procedure

CONSULT PACKAGE INSERT OF THE ASSAY PROCEDURE BEING USED FOR SPECIFIC DIRECTIONS FOR USE IN A PARTICULAR KIT OR TEST METHODOLOGY.

Use **Status hCG** Positive and Negative Urine Controls in the same manner as patient samples according to directions of the test kit being employed.

Performance Characteristics And Expected Values

The **Status hCG** Positive Urine Controls should test positive as outlined in the insert of the test being employed. For interpretation of end point / results refer to the "PERFORMANCE CHARACTERISTICS" of the kit being employed. The **Status hCG** Negative Urine Control should test negative. Each laboratory must establish complete quality control testing in accordance with the requirements of regulatory and/or accrediting organizations and a laboratory's quality control goals. A trend log should be maintained for batch to batch consistency of the test. Result variations may indicate manufacturers modifications to the test system or improper technique.



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