# SCOPE:

This document applies to UPMC Hanover Laboratory.

# PURPOSE:

# This procedure provides instructions for performing qualitative detection of hCG in serum or urine for early detection of pregnancy.

**PRINCIPLE:**

The Fisher SURE-VUE Serum/Urine hCG-STAT test is a lateral flow test using monoclonal antibody specific to the beta subunit of hCG to detect hCG as early as 2 to 3 days before the expected menses..

**REAGENTS:**

The SURE-VUE Serum/Urine hCG-STAT test kit is distributed by Fisher Healthcare. Catalog Number: 23900529.

**Materials Supplied**

* Reaction cassette
* Disposable dropper

**Materials Required but not Provided**

* Timer or watch that measures minutes or seconds
* Specimen collection containers
* QC Material [Negative: random male serum and urine]

[Positive: Biorad Urine Control, Level 2 and Biorad Immunoassay Control, Level 2]

**Storage and Stability**

* Store kit at room temperature 15-30° C. The test cassette is stable through the expiration date printed on the sealed pouch.

**WARNING AND PRECAUTIONS:**

* For *in vitro* diagnostic use
* Do not use contents of kit after expiration date printed on the outside of the box.
* The Reaction unit must remain sealed in the foil pouch just prior to use.
* To obtain accurate results, package insert instructions must be followed.

**SPECIMEN COLLECTION AND STORAGE:**

**Urine**

* Collect urine in a clean container. First morning specimens are optimal, because it contains the greatest concentration of hCG.
* Samples can be stored 8 hours at 15-30°C or up to 72 hours at 2-8°C.
* Do not freeze urine sample.
* EPIC order test code is **Pregnancy, Urine [LAB437]**.

**Serum**

* No special patient preparation is necessary. Obtain whole blood, allow to clot and use the separated serum for testing.
* Serum specimens may be stored at 2-8°C. for up to 48 hours.
* If testing is delayed for more than 48 hours, the sample may be frozen once at -20°C. If frozen, mix after thawing. Do not refreeze.
* EPIC order test code is **Pregnancy,Qualitative [LAB4033 or LAB4034]**.
* As of December 1, 2018, the Serum Qualitative HCG with reflex to Quantitative HCG is no longer available.

**QUALITY CONTROL:**

**External Quality Control**

* Run positive and negative controls for urine and serum HCG with each new shipment and once every 30 days.
* Process controls as for patient samples. See procedure below.
* Refer to the test Risk Assessment as documented in the IQCP for additional information.

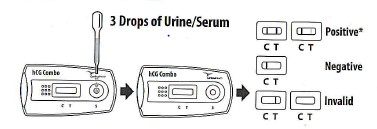
**Internal Control Features**

* A red line in the Control Window is considered an internal positive procedural control.
* A clear background in the Read Result Window is considered an internal negative procedural control.
* If internal controls do not perform as expected, repeat with a new test device. If still invalid, **do not** report patient results. Contact technical support, if indicated. If a result is still needed recommend a quantitative hCG test to the doctor.

**TEST PROCEDURE:**

|  |  |
| --- | --- |
| Step | Action |
| 1 | Remove the Reaction cassette from the foil pouch. |
| 2 | Draw serum or urine into the disposable dropper and dispense **3 drops** into the **Add Sample** well. **NOTE:** After the sample is added, a pink to purple color will be seen moving across the Reaction Unit’s windows. The **Read Result Window** contains a preprinted horizontal blue line on the membrane |
| 3 | **Read result at 3 minutes for urine and 5 minutes for serum.**  **Note:** Some positive results may appear sooner. |

**INTERPRETATION OF RESULTS**



**Positive Result:**

Positive results are indicated by **two distinct red lines.** One line should be in the Control region [C] and the other in the Test region [T].

**Negative Results:**

One red line appears in the Control region [C]. No apparent red or pink line appears in the Test region [T].

**Invalid Result:**

No red line in the Control Window.

Background color in the Read Result Window interferes with test interpretation.

**Notes**:

* In case of an invalid result, a repeat the testing with a fresh cartridge. If still invalid, a fresh specimen should be tested or contact Technical Support at the phone number noted in the Package Insert.
* If a negative result is obtained, but pregnancy is suspected, another sample should be collected after 48-72 hours and tested.

**REPORTING OF RESULTS IN EPIC:**

* Manually record external control results on the “HCG Quality Control Log.”
* The internal control will be recorded with each patient result. When entering the patient result in EPIC, enter “S”- Satisfactory or “U” – Unsatisfactory in the space provided. Use the “Test Comment” function to append the test kit lot number to the Internal Control result.
* All negative urine results will automatically include the interpretive statement “False negative results may occur with dilute urine samples. If pregnancy is still suspected, a first-morning sample should be obtained and tested”.
* **POSITIVE** SERUM OR URINE HCG QUALITATIVE RESULTS ON SAME DAY SURGERY OR OPERATING ROOM PATIENTS WILL BE CALLED TO THE APPROPRIATE UNIT STAT. Document the name of the individual notified and the time called in Specimen Comments.

**LIMITATIONS:**

* Kit is for the **qualitative** detection of hCG in serum or urine.
* Test results must always be evaluated with other data available to the physician.
* A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG values alone.
* Very low levels of hCG are present in serum and urine shortly after implantation. Positive test results from a very early pregnancy may later be negative due to natural termination of pregnancy. This is estimated to occur in 50% of conceptions. If a very low, faint positive serum results is obtained, another sample should be obtained in 48 hours and retested. If waiting 48 hours is not medically advisable, the test result should be confirmed with a quantitative hCG test.
* Patients with trophoblastic and nontrophoblastic disease may have elevated hCG levels, therefore, the possibility of hCG secreting neoplasms should be eliminated prior to diagnosis of pregnancy.
* If a urine sample is too dilute, it may not contain a representative hCG concentration.

**EXPECTED VALUES:**

* The sensitivity of the SURE-VUE hCG-STAT test is 10 mlU/ml for serum or 20 mlU/ml for urine.
* In normal pregnancy, hCG levels in urine can reach 25 mlU/ml as early as 7 to 10 days post conception, and continue to increase exponentially to reach a maximum concentration in excess of 200,000 mlU/ml at the end of the first trimester.

**REFERENCES:**

SURE-VUE Serum/Urine hCG-STAT package insert, Fisher Healthcare, 01/15/2018.

Fisher Sure-Vue Risk Assessment / Individualized Quality Control Plan (IQCP), UPMC Hanover

**Document History**

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| --- | --- | --- |
| Date of Origination and Document Control Number | CHEM 6003.2  May 26, 2017 | Method implementation.  Replaces CHEM 6001.1 and CHEM 6003.1 |
| Prepared by: John R Samuel, MT(ASCP) |
| Revision History/ Biennial Review: | CHEM 6003.3  May 16, 2019 | Reviewed and updated for format and LIS change.  John R Samuel, MT(ASCP) |
| Revision History/ Biennial Review: | CHEM 6003  August 8, 2019 | Switched from the Cardinal-branded version of this test to the identical Fisher-branded version  John R Samuel, MT(ASCP) |
| Revision History/ Biennial Review: | August 16, 2021 | Biennial review – no changes.  John R Samuel, MT(ASCP) |
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