NORTHERN NEVADA ADULT MENTAL HEALTH POLICY AND PROCEDURE

SUBJECT: POINT OF CARE (POCT) PREGNANCY TEST PROCEDURE

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APPROVAL:	Rosalyne Reynolds {s}	, Agency Director

I. PURPOSE

The purpose of this policy is to establish the procedure by which Northern Nevada Adult Mental Health Services (NNAMHS) performs point of care testing on consumers for pregnancy. A consumer's pregnancy status has serious implications related to psychiatric treatment. There for it is vital that those providing psychiatric treatment have timely, accurate information about the consumer's pregnancy status.

II. POLICY

It is the policy of NNAMHS to use SureView Urine hCG Tests to establish pregnancy information on the Psychiatric Observation Unit and outpatient services. **III. REFERENCES**

1. Sure-Vue Urine hCG Package Insert

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IV. PROCEDURES

Point of care pregnancy testing is available on the observation unit by following the Sure-Vue[®] Urine hCG Test Laboratory Procedure listed below

I. Test Principle

The Sure-Vue[®] Urine hCG Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding a urine specimen to the specimen well of the test device and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

II. Specimen Collection/Treatment

- A. Specimen: Urine Specimen.
- B. Collection Container: Clean and dry container.

- C. Specimen Storage: Urine may be stored refrigerated at 2-8° C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20° C.
- D. Handling Precautions: Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.

III. Reagents and Equipment

A. Storage and Stability

Store as packaged in the sealed pouch at 15°-30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

B. Quality Control

External Quality Control Testing

It is required that a positive hCG control and a negative hCG control be evaluated to verify proper test performance.

External Quality Control Testing

Remedial Actions

When correct control results are not obtained, do not report patient results. Contact Technical Services at 800-637-3717.

E. Precautions

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test device should be discarded in a proper biohazard container after

testing.

IV. Test Procedure

Specimen Collection and Handling:

- A urine specimen must be collected in a clean and dry container.
- A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used.
- Urine specimens exhibiting visible precipitates should be allowed to settle to obtain a clear specimen for testing.
- Urine specimens may be stored at 2 8°C for up to 48 hours prior to testing.

Test Procedure:

Allow the test device, urine, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- 1. Remove the test device from the sealed pouch and use it as soon as possible.
- 2. Label each devise with the patient's name or positive or negative control.
- 3. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100µl) to the specimen well of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well.
- 4. Wait for the red line(s) to appear. The result should be read at 3 minutes. It is important that the background is clear before the result is read.
- A positive and negative control will be run each time a patient test is performed. 3 drops of each control will be placed in the test well of a labeled cassette.
- 6. All patient and control results will be recorded on the appropriate forms. The date and time completed will be written on the patient report form.
- 7. The doctor will be contacted with the results. The date and time he was contacted will be recorded on the report form.

V. Interpretation of Test Results

POSITIVE*: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact Technical Support at (800) 637-3717.

VI. Limitations

- Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
- False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
- 3. Very low levels of hCG (less than 50 mIU/mL) are present in urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons,⁵ a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
- 4. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasm's including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG.^{6,7}

Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.

5. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

VII. Expected Values

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals.

The Sure-Vue Urine hCG has a sensitivity of 25 mIU/mL, and is <u>capable of detecting</u> pregnancy as early as 1 day after the first missed menses.

Sensitivity and Specificity

The Sure-Vue Urine hCG detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 μ IU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to hCG negative and positive specimens.

Acetaminophen	20 mg/mL	Caffeine	20 mg/mL
Acetylsalicylic Acid	20 mg/mL	Gentisic Acid	20 mg/mL
Ascorbic Acid	20 mg/mL	Glucose	2 g/dL
Atropine	20 mg/mL	Hemoglobin	1 mg/dL
Bilirubin (urine)	2 mg/dL		

None of the substances at the concentration tested interfered in the assay.