

**SEASONAL EFFECT ON ACCURACY OF IN-HOME URINARY PREGNANCY TEST FOR DETECTION OF EARLY PREGNANCY**D.P. Gupta<sup>1</sup>, D.K. Saxena<sup>2</sup>, Hem Prabha Gupta<sup>3</sup>, R.P. Gupta<sup>4</sup>**HOW TO CITE THIS ARTICLE:**

D.P. Gupta, D.K. Saxena, Hem Prabha Gupta, R.P. Gupta. "Seasonal Effect on Accuracy of In-Home Urinary Pregnancy Test for Detection of Early Pregnancy". Journal of Evolution of Medical and Dental Sciences 2014; Vol. 3, Issue 02, January 13; Page: 342-346, DOI:10.14260/jemds/2014/1831

**ABSTRACT: OBJECTIVE:** A study was planned to find out the cause of false positive urinary pregnancy test in early pregnancy as some times when ultrasonography is done on these women with positive pregnancy test, they are found to be non-pregnant. Such reports on false positive urinary pregnancy test, confirmed by ultrasonography are few and therefore the study was planned. **METHOD:** A total number of 218 women who came to the Deptt. of Radiology Era's Lucknow Medical College Lucknow, for routine first trimester ultrasonographies from April 2012 to Dec 2012 were analyzed. All these women had their urinary pregnancy test positive tested by commonly available test kits. Some of them were found to be non- pregnant on ultrasonography. The study was conducted for nine months. **RESULT:** Out of the 218 women who came with positive urinary pregnancy test were examined by ultrasonography. Out of these 18(8.2%) cases were found to be non-pregnant and the test was false positive. These women had performed the urinary pregnancy test by themselves and out of these 4 cases were confirmed by hospital/ lab. These women had performed the urinary pregnancy test in the months from April 2012 to September 2012, when atmospheric temperature is high and weather is dry. **CONCLUSION:** Care should be taken to avoid drying of the test membrane in the pregnancy card test kit by replacing it in its packet soon after adding the urine sample. The result should be noted within the time mentioned on the pack. Such instructions should be followed strictly while testing the urine for pregnancy.

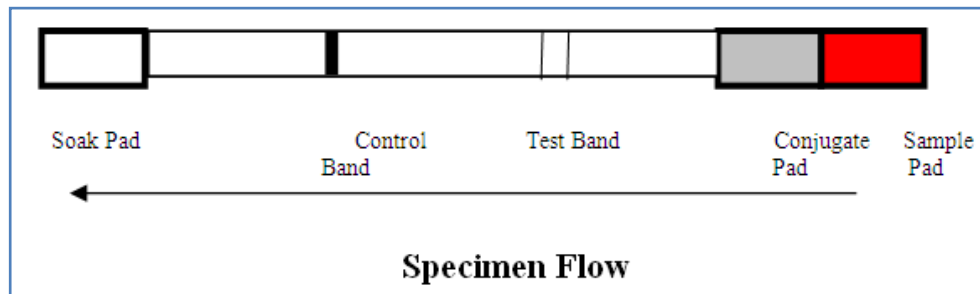
**KEYWORDS:** False positive, pregnancy, seasonal.

**INTRODUCTION:** An ideal pregnancy test is one which can detect the lowest levels of hCG in the patient's urine/ serum. On an average, level of 25-100 mIU/ml is reached on the first day of missed period. Pregnancy test is ideal when it can detect levels greater than 10mIU/ml (20 mIU/ ml-100 mIU/ml).<sup>1</sup> It has been observed that hCG levels less than 10mIU/ml may be found in healthy non-pregnant women and even normal healthy men. Since the  $\alpha$ - subunit of hCG is similar to that of LH, FSH and TSH, test for pregnancy should be specific to the  $\beta$ - subunit of hCG only, ensuring no false positive reaction due to cross reactivity with other hormones. False positive results however have devastating psychological trauma on the women, who want to be pregnant, she thinks she is, and in reality she is not, therefore proper UPT is necessary. They may lead to a purposeless abortion procedure also.<sup>2</sup>

Concentration of hCG in urine depends on the time of urine collection, volume of urine passed and fluid intake. hCG is a very stable molecule if preserved properly. It dissociates at much faster rate when left in urine. Urine facilitates bacterial growth, it may drastically alter the pH, ionic concentration and it may increase the turbidity of the specimen, which may affect the hCG concentration and give a wrong interpretation.

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**Principle of membrane based rapid diagnostic test:** All pregnancy kits available are membrane based immunoassay that allow visual detection of hCG in a liquid specimen. Test comprises of a base membrane such as nitrocellulose. A detector reagent (antigen/ antibody indicator complex) specific to the hCG, is impregnated at one end of the membrane. A capture reagent is coated on the membrane at the test region. When a specimen is added to the sample pad, it rapidly flows through the membrane or conjugate pad. hCG if present in the specimen passes over the test band to which the captive reagent is coated; the hCG detector reagent complex is immobilized. A colored band proportional to the amount of hCG present in the sample develops. The excess unbound detector reagent moves further up the membrane and is immobilized at the control band. (Diagram 1)



**Diagram 1- showing Components of membrane -based rapid diagnostic test**

**Factors affecting the results:** The results of rapid diagnostic kit are affected by pH, viscosity and turbidity. Warm ambient temperatures speed up evaporation from the result window. Due to evaporation, the excess sample along with unreacted/ unbound conjugate from the soak pad flows back, and gets deposited on the band resulting in appearance of a faint ghost band after some time. This is the band that is misinterpreted as positive reaction

**MATERIAL AND METHOD:** A total number of 218 women who came for the first time for ultrasonography in the department of Radiology, Era's Lucknow Medical College Lucknow, in the early weeks after missed period, were examined and the women in the 1-10 weeks amenorrhea were included in the study. The following questions were asked from each woman who came for the ultrasonography.

1. Age
2. Parity
3. Date of last menstrual period (LMP)
4. Pregnancy test performed on the urine sample by a) herself b) hospital/ pathology clinics.
5. Educational status a) literate b) illiterate.
6. Kit used if performed by self.
7. Container used for collection of urine sample
8. Time of collection of urine a) morning b) later sample
9. After how many minutes test was read.
10. Any medication for infertility and liver diseases.<sup>3</sup>

Only those women who had come after they had got the rapid pregnancy test done either in the hospital or by themselves were included in the study. The study was done for a period of 9

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months that is from April 2012 to December 2012, so that summer, rainy and winter season could be included. Ultrasonography was performed on those selected cases by a single sonologist on one ultrasound machine; a Elpro GE logic 200 & a 3.5 MHz sector transducer was used. They were examined by transabdominal sonography for the presence of gestational sac, embryo or fetus.

### Observation:

1. Total number of cases 218
2. Total number of false positive cases- 18 (8.2%)
3. Duration of missed period was between 1 week to 10 weeks, (a) less than 1 week 50 cases, (b) 1-2 weeks- 105 cases (c) more than 2 weeks – 63 cases.
4. Literacy
 

(a) Literate-	117	53.6%
(b) Illiterate -	101	46.4%
5. Clean washed and dried container used in 41% cases
6. Any container 59%
7. Time taken for reading the results 4-5 mts 33% cases  
Waited for a longer time for line to appear 67%
8. Morning sample used by 100% cases.
9. Kit used was from a well-advertised company, A card test kit was used.
10. Parity in whom False positive cases were detected
 

Primipara	10 cases	4.58%
Multipara	8 cases	3.66%

Out of 18 false positive cases 10 were performed by literate women and 8 were performed by illiterate women. In the 18 false positive cases, 4 were confirmed by the hospital lab, as the women had brought the urine sample for confirmation to the hospital also.

The table 1- clearly shows that the number of false positive tests is more during summers and no such case was seen during winters.

Month	No.of cases	False positive	%
April	16	3	18.7
May	20	7	35%
June	14	1	7.1
July	31	3	9.6
August	43	2	9.6
September	33	2	4.6
October	23	-	-
November	21	-	-
December	17	-	-

Table 1- Monthwise Pregnancy test performed with false positive results.

**RESULT:** A total of 218 cases who came for ultrasonography in the Department of Radiology, Era's Lucknow Medical College Lucknow for confirmation of pregnancy after they had found that their

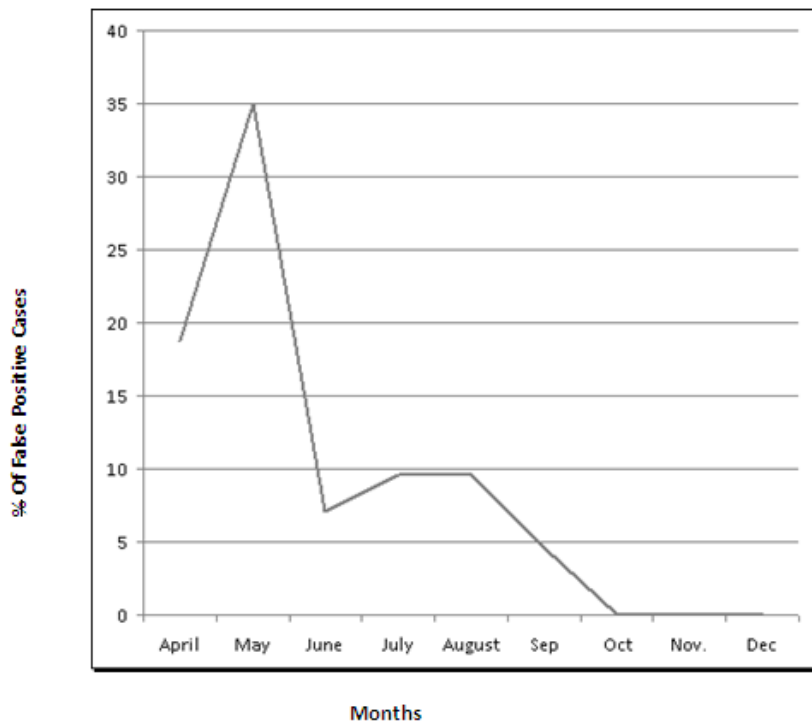
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urine examination for UPT was positive. 18 (8.2%) cases out of the 218 cases were found to be non-pregnant on ultrasonography. Table no. 1 shows the number of women who came for ultrasound from April 2012 to December 2012, and the number of cases that were declared to be non-pregnant. From the table no.1, it becomes evident that higher number of cases was diagnosed as false positive in months when the atmospheric temperature was high and weather was dry. As rainy season started (July to September) the temperatures became low and the humidity increased, false positive cases were reported in less numbers. (Graph-1)

A temperature fell further in winters, no false positive case was reported. (Graph-1)

Out of 218 cases, 53.6% of women were literate and they understood the instruction given on the pack of kit, while 46.4% of women were illiterate.

41% of women were sure that they had used a cleaned washed and dried container to collect the urine sample and 59% cases were not very-very sure if the container was clean or not. Only 33% women had used a watch for timing to see the result. 67% women had waited for a longer time to see the result.<sup>2</sup> All the women had used the morning sample.



**Graph 1- Seasonal Variation in the frequency of false positive pregnancy tests**

**DISCUSSION:** 218 cases were examined for confirmation of pregnancy. 18 (8.2%) were found to be non-pregnant on ultrasound, the test was false positive. In 10 cases who reported false positive UTP were literate and in 8 cases the women were illiterate. Among the false positive cases 10 (4.58%) were primipara and had performed the test for the first time and 8 (3.66%) women were multipara who had used the UPT on earlier occasions also. So the parity has not much effect on the outcome of the test result.

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From our study we observed that during summer months when temperature was high and weather was dry false positive pregnancy test were reported more. This was because the urine sample dried faster and a “ghost” line appeared at the test band. While during rainy season and in winters evaporation was negligible and “ghost” line appeared very late and less false positive cases were reported. It appeared that though literate women were 53.6% false positive tests were reported by 10 women (8.5%), and illiterate women were 46.4% false positive tests were reported by 8 women (4.7%).

So literacy is not an issue in false positive reporting. The time taken for watching the pink line to appear in the test band was more in the women whose report was false positive test, as they had waited for a longer time in the hope that the pink line would take longer time to appear. They had taken more time than stipulated 5 minutes time instructed on the kit, a ghost line appeared and this they interpreted as positive.

All kits available in the market give instruction as to time (3-5 mts.) that should be taken to look for the pink line in the test band but there is no instruction about avoiding the drying of the strip in the kit, thus preventing interpretation of the ghost line as positive.

**CONCLUSION:** Care should be taken to avoid drying of the test membrane in the pregnancy card test kit by replacing it in its packet soon after adding the urine sample. The result should be noted within the time mentioned on the pack. As all test kits mention the time required for interpretation of the test, similarly they should also give instructions to avoid the drying of the strip to avoid the false reports, which should be made mandatory. Such instructions should be followed strictly while testing the urine for pregnancy.

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