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## Changes in the results of the multi reagents strips in a single lot: A comparative study

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### Abstract

**Topic:** Changes in the results of the multi reagents strips in a single lot.

**AIM:** To verify whether the multi reagent strips show changes in results of pH and specific gravity.

**Introduction:** Urine chemical reagent Strips are square measure firm plastic strips onto that many separate reagent areas are affixed. The test is for the detection of one or more lot of the subsequent analytes in urine: Leukocytes, Glucose, organic compound ketone (Acetoacetic acid), Bilirubin, Blood, specific gravity, Protein, Nitrite, Urobilinogen and pH. Urine undergoes several changes throughout states of malady or body pathology before blood composition is altered to a major extent. Urinalysis may be a helpful procedure as an indicator of health or malady as such may be a part of routine health screening.

**Materials and Methods:** Sample size: 100 multi reagent strips were taken from a single lot. The test is for the detection of one or more lot of the subsequent analytes in urine: Leukocytes, Glucose, organic compound ketone (Acetoacetic acid), Bilirubin, Blood, specific gravity, Protein, Nitrite, Urobilinogen and pH.

The strips were verified for any changes by dipping it in an artificially prepared single urine sample, analyzed as per the user's manual and results were analyzed.

**Result:** The average pH value is 7.0, in this slot of 100 strips had variations ranging between 6.19 and 7.82. Whereas specific gravity the average value is 1.01, in this slot of 100 strips had variations ranging between 1.006 and 1.016.

**Conclusion:** When manually analyzed it shows difference and variations in each strip in a single lot for pH and specific gravity of 5.8% and 2.6% respectively. Therefore, it is applicable for manual urine analysis method.

**Keywords:** Urina analysis, Multi-Reagent strips, pH, Specific gravity, single lot

### Introduction

Urine analyzing chemical reagent Strips are square measure firm plastic strips onto that many separate reagent areas are affixed. The test is for the detection of one or more lot of the subsequent analytes in urine: Leukocytes, Glucose, organic compound ketone (Acetoacetic acid), Bilirubin, Blood, relative density, Protein, stercobilinogen, Nitrite, and pH. Urine undergoes several changes throughout states of malady or body pathology before blood composition is altered to a major extent. Urinalysis may be a helpful procedure as an indicator of health or malady as such may be a part of routine health screening. Piddle (liquid excretory product) chemical agent Strips may be employed in general analysis of health, and aids within the diagnosing and observation of metabolic or general diseases that have an effect on urinary organ perform, endocrine disorders and diseases or disorders of the tract.

These tests may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and urinary tract infection. The dipsticks ought to be unbroken in the slightest degree times within the sealed instrumentation. Heat, cold, wet and lightweight can spoil the sticks. Don't touch the colored squares, not because they are toxic, however as a result of moisture on your fingers might spoil the testing strips. A full pot of twenty-five sticks are often unbroken for up to twelve months, however check the "use by" date. Because microalbuminuria is generally regarded as an excellent marker for assessing early renal damage in common conditions such as diabetes and hypertension [1, 2, 3, 4]. The symptomatic reagent strip, with at least 1 reagent cushions clung to a plastic handle, is a standout amongst the most well-known testing innovations in routine clinical use. The key explanation behind its acknowledgment is convenience.

One of the main reagent strips contained a reagent cushion for glucose <sup>[5]</sup>. That could be dunked into sample, was permitted to respond for a moment, and read. This indicative strategy killed the need of getting ready fluid reagents and was less demanding to use than tablet reagents. Amid the following 40 years numerous items were created that offered a similar usability and effortlessness, benefits still esteemed today. After the sample glucose strips, a progression of reagents was produced, at first with diabetes mellitus as the ailment center. As dry reagent cushion tests for more analytes ended up accessible, testing boards were characterized to help conclusion in the territories of kidney work, liver capacity, urinary tract diseases, and sugar metabolism <sup>[6]</sup>. standard urinalysis board utilized today tests for glucose (1956), protein (1957), ketone (1957), pH (1959), mysterious blood (1961), bilirubin (1969), urobilinogen (1969), nitrite (1972), specific gravity (1981), leucocytes (1984) Multistix 10 SG was an early numerous board with 10 reagents included on 1 reagent strip. Beside urinalysis, strip innovation was additionally connected to blood examination with a progression of glucose-checking items, beginning with Dextrostix <sup>[7]</sup> and prompting the present glucose techniques. Furthermore, strip innovation was utilized for examination of other blood analytes, for example, lipids, hemoglobin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, and uric corrosive, and for therapeutic sedate checking. Instrumentation for these utilizations incorporated the Reflotron framework (Boehringer Mannheim, Indianapolis, IN; 1985) and the Seralyzer framework. Early dipsticks depended entirely on colorimetric reagents (qualitative analysis), and even today most items are colorimetric. The reagents change shading, with the force of the shading relative to the concentration of the analyte estimated in the clinical example. For visual understanding, the shade of the reagent is coordinated against at least two hinders on a cautiously created shading graph. Each square speaks to an allocated analyte fixation extend. Assignments depend on understanding of reagent strip results with reference techniques. The reagent is perused at a predetermined time after utilization of the example.

During the 1980s, reagent strip configuration started to incorporate numerous reagent layers to quantify one analyte. This enabled synthetic reagent frameworks to be put in particular reagent layers and accommodated response partition steps, for example, chromatography and filtration. Immuno chromatography strips are constructed with the goal that compound responses happen in particular regions of reagent. The chromatography response happens in the third region, called the test or catch zone, regularly a nitrocellulose film. In the first and second regions, an analyte-explicit counter acting agent responds with the analyte in the example and is chromatographically exchanged to the nitrocellulose film. The immune response will undoubtedly shaded latex particles as a label <sup>[8]</sup>. If the example contains the analyte, it responds with the named counter acting agent. In the catch zone per second neutralizer is immobilized in a band and catches particles when analyte is available. A colored test line is framed. A second band of reagent is additionally immobilized in the catch zone to permit a control line to respond with particles, framing shading. Shading at the control line is constantly shaped when the test framework is working legitimately,

even without hCG in the patient. Entire blood glucose strips frequently utilize numerous reagents to trap flawless RBCs that meddle with the shading age zone. For instance, the Encore glucometer (Bayer) utilizes a catching zone put straightforwardly over the shading producing territory. The shading is perused from the base of the strip through a straightforward window.

Different plans permit the sample to relocate to a shading producing zone beside the catching zone, and shading is perused from the highest point of the strip. Entire blood test strips regularly make utilization of plastic tapes to hold the response zones set up. Different layers of reagent have additionally been connected to film slides, for example, the reagent framework utilized with the Ektachem analyzer (Vitros) developed by Eastman Kodak in 1980. Slides empowered numerous isolating, spreading, and shading shaping territories to improve hues. Common substance responses happening in dry reagent strips can be gathered as color official, enzymatic, immunologic, and redox catalysis <sup>[9]</sup>. Dye authoritative to analytes, for example, egg whites prompts shading changes at micromolar levels. Marker colors can be covalently bound to the analyte (diazonium mixes restricting bilirubin) or firmly connected with the analyte (sodium-detecting pointers). Enzymatic responses can be utilized to recognize catalysts at micromolar levels through responses with shading framing substrates. Enzymatic responses can likewise be utilized to identify molecules, for example, glucose, through responses with chemicals to yield hued finished results. Molecule named antibodies are the essential reagents that accommodate the discernible response of immuno-rationale strips dependent on chromatography. Redox catalysis utilizes metal chelates to oxidize or diminish markers within the sight of explicit analytes, for example, hemoglobin, and can identify atoms down to the nanomolar level. Microalbumin Reagent Strip (Bayer) is a case of a progressively delicate and explicit innovation that shows clinically critical analyte levels through new science tests <sup>[10]</sup>.

### Principle and expected values

#### Leukocytes:

Normal urine specimens generally yield negative results. An increase in leukocytes is an indication of pyuria, it may often be present in non-infective conditions. A strip result of small or greater is a useful indicator of infection.

**Sensitivity:** 5-15 WBC's/hpf in clinical urine.

#### Nitrite

Normally no nitrite is detectable in urine. Many enteric gram-negative organisms give positive results when their number is greater.

**Sensitivity:** 0.06-0.1 mg/dl nitrite ion.

#### Urobilinogen

Urobilinogen is normally present in urine at concentration upto 1.0 mg/dl. A result of 2.0 mg/dl represents the transition from normal to abnormal, and the patient and/or urine specimen should be evaluated further for hemolytic and hepatic disease. Evaluation of both the bilirubin and Urobilinogen results helps in the differential diagnosis of jaundice, As well as other liver and biliary disorders.

**Protein**

Protein in urine can be the result of urological and nephrological disorders. In normal urine, less than 150 mg of total protein is excreted per day. Clinical proteinuria is indicated at greater than 500 mg of protein per day (strip result of >30 mg/dL). Positive results may also indicate tubular or overflow proteinuria in the absence of any glomerular abnormality or proteins of renal origin that may be excreted during infection. Urinary protein excretions can be temporarily elevated in the absence of renal abnormality by strenuous exercise, orthostatic proteinuria, dehydration, urinary tract infection and acute illness with fever<sup>[11, 12]</sup>.

**Sensitivity:** 15-30 mg/dL albumin.

**pH**

The normal pH of urine can range from 4.6 to 8.0. Certain dietary conditions can produce acid or alkaline urines, which can be useful in the treatment of some calculi<sup>[6]</sup>.

**Blood**

This test is based on the peroxidase-like activity of hemoglobin which catalyzes the reaction of cumene-hydroperoxide and 3, 3', 5, 5'-tetramethylbenzidine. The resulting color ranges from orange to green to dark blue. Any green spots or green color development on the reagent area within 60 seconds is significant and the urine specimen should be examined further. Blood is often, but not invariably, found in the urine of menstruating females. Normally no hemoglobin is detectable in urine.

**Sensitivity:** 0.015-0.062 mg/dL hemoglobin.

**Specific gravity**

This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration to green and yellow-green in urine of increasing ionic concentration. Randomly collected urine may vary in specific gravity from 1.003-1.040. Twenty-four-hour urine from healthy adults with normal diets and fluid intake will have a specific gravity of 1.001-1.035. In cases of severe renal damage, the specific gravity is fixed at 1.010, the value of the glomerular filtrate.

**Ketone bodies**

This test is based on ketones reacting with nitroprusside and acetoacetic acid to produce a colour change ranging from light pink for negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise.

**Sensitivity:** 5-10 mg/dL acetoacetic acid.

**Bilirubin**

This test is based on azo-coupling reaction of bilirubin with diazotized dichloroaniline in a strongly acidic medium. Varying bilirubin levels will produce a pinkish-tan color proportional to its concentration in urine. In normal urine, no bilirubin is detectable by even the most sensitive

methods. Even trace amounts of bilirubin require further investigation. Atypical results (colors different from the negative or positive color blocks shown on the color chart) may indicate that bilirubin-derived bile pigments are present in the urine specimen, and are possibly masking the bilirubin reaction. When very small amounts of bilirubin in urine are sought, ICOTEST reagent tablets should be the method of choice.

**Sensitivity:** 0.4-0.8 mg/dL bilirubin.

**Glucose:**

This test is based on the enzymatic reaction that occurs between glucose oxidase, peroxidase and chromogen. Glucose is first oxidized to produce gluconic acid and hydrogen peroxide in the presence of glucose oxidase. The hydrogen peroxide reacts with potassium iodide chromogen in the presence of peroxidase. The extent to which the chromogen is oxidized determines the color which is produced, ranging from green to brown. Low amounts of glucose are normally excreted in urine. Glucose concentrations as low as 100 mg/dL, read at either 10 or 30 second, may be considered abnormal if results are consistent.

**Sensitivity:** 75-125 mg/dL glucose.

**Materials and methods**

Sample size: 100 multi reagent strips were taken from a single lot. The test is for the detection of one or more subsequent analytes in urine: Leukocytes, Glucose, organic compound ketone (Acetoacetic acid), Bilirubin, Blood, specific gravity, Protein, Nitrite, Urobilinogen and pH.

A strip consists of a ID band and test pads and the bottle has colour block. Dip all the test pads of the strip and compare each test pad to the corresponding colour blocks on the bottle label. Later, read each pad at the time shown on the label, starting with the shortest time.

**Results**

Parameters	pH	Specific gravity
Mean	7.01	1.011
Standard Deviation	0.408	0.0026
Coefficient Of Variation	5.80%	2.60%
Mean + 2sd	7.82	1.016
Mean - 2sd	6.19	1.006

The average pH value is 7.01, in this slot of 100 strips had variations ranging between 6.19 and 7.82. Whereas specific gravity the average value is 1.011, in this slot of 100 strips had variations ranging between 1.006 and 1.016.

**Discussion**

In probability hypothesis and insights, the coefficient of variation (CV), otherwise called relative standard deviation (RSD), is a standardized proportion of dispersion of a probability dissemination or recurrence appropriation/frequency distribution. Usually communicated as a rate, and is characterized as the ratio of the standard deviation ( $\sigma$ ) sigma to the mean ( $\mu$ )<sup>[13]</sup>. The CV or RSD is broadly utilized in systematic / analytical science to express the exactness and repeatability of a test. The coefficient of

variation is valuable in light of the fact that the standard deviation of information should dependably be comprehended with regards to the mean of the information. Interestingly, the genuine estimation of the CV is free of the unit in which the estimation has been taken, so it is a dimensionless number. For examination between informational collections with various units or broadly extraordinary methods, one should utilize the coefficient of variety rather than the standard deviation.

CV measures are regularly utilized as quality controls for quantitative lab examination. The standard deviation (SD, also represented by the lower-case Greek letter sigma  $\sigma$  or the Latin letters) is a measure that is used to quantify the amount of variation or dispersion of a set of data values. A urine test strip or dipstick test is a basic diagnostic tool used to determine pathological changes in a patient's urine in standard urinalysis [14]. A single lot had 100 multi reagent strips was manually verified by dipping it in artificially prepared urine sample, semi-quantitative analysis were done to detect changes in pH and specific gravity. Out of 10 parameters pH and specific gravity alone showed variations for each strip in a same lot. There are semi-quantitative ones that in addition giving a positive or negative response likewise give an estimation of a quantitative outcome, in the last the colour responses are around corresponding to the centralization of the substance being tried for in the sample [15]. Urine test strips can be utilized in numerous regions of the human healthcare services chain including screening for routine examinations, treatment checking, self-observing by patients and additionally broad preventive drug. Urine test strips are utilized for screening both in medical clinics and all in all training. The point of screening is early distinguishing proof of likely patients by examination of extensive gatherings of the population. The significance of screening for diabetes and kidney infection among high-hazard populaces is ending up high. In treatment Monitoring, Treatment observing with the guide of urine test strips enables a wellbeing expert to beware of the aftereffects of the endorsed treatment, and if important to bring any progressions into the course of treatment. Spontaneous self-testing has turned into a well-known measure as of late as different pee test strips wind up accessible by means of drug store and online stores. Self-checking for regular urinary tract diseases is a famous model as sufferers screen their very own urine once a day and talk about the outcomes with their wellbeing proficient. Some urine test strips are protected against the interference with iodate, which eliminates ascorbic acid by oxidation [16]. Consolidating symptomatic data given by urinary stream cytometry and increasingly quantitative test strip examination in this manner offers a hypothetical reason for the improvement of indicative master frameworks [17, 18]. Bacterial peroxidases can also contribute to total peroxidase activity in urine [19]. This leads to improved elimination of occasional errors in the WBC and RBC counting channels of the flow cytometer. Because of the procedure for applying the urine to the test strips on the URISYS 2400, improper dipping is no longer a problem, nor is confusion about sample identification or urine contamination caused by dipping the strip in the tube, which potentially leads to interferences with chromatographic methods [20]. Various low- and high-molecular mass inhibitors have been found in urine [21, 22].

## Conclusion

The average pH value is 7.01, in this slot of 100 strips had variations ranging between 6.19 and 7.82. Whereas specific gravity the average value is 1.011, in this slot of 100 strips it had variations ranging between 1.006 and 1.016. When manually analyzed it shows difference and variations in each strip in a single lot for pH and specific gravity of 5.8% and 2.6% respectively. Therefore it is applicable for manual urine analysis method.

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