Atlas Medical CE

Urine Reagent Strips (1 Parameter: Ketone)

IVD *For in vitro diagnostic use only.*

Store at15-30°C

INTENDED USE

Urine Reagent Strips are firm plastic strips onto which several separate reagent areas are affixed. The test is for the detection of Ketone (Acetoacetic acid) in urine.

INTRODUCTION

Urine undergoes many changes during states of disease or body dysfunction before blood composition is altered to a significant extent. Urinalysis is a useful procedure as an indicator of health or disease, and as such, is a part of routine health screening. Urine Reagent Strips can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract.

PRINCIPLE AND EXPECTED VALUES

Ketone: This test is based on ketones reacting with nitroprusside and acetoacetic acid to produce a color 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. In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively high concentration before serum ketones are elevated.

MATERIALS

MATERIALS PROVIDEDE

- Strips.
- Package insert.

MATERIALS NEEDE BUT NOT PROVIDED

- Specimen collection container.
- Timer.

REAGENTS AND PERFORMANCE CHARACTERISTICS

- Based on the dry weight at the time of impregnation, the concentrations given may vary within manufacturing tolerances. The following table below indicates read times and performance characteristics for Ketone parameter.

Reagent	Read Time	Composition	Description
Ketone (KET)	40 seconds	5% w/w sodium nitroprusside; 95% w/w buffer	Detects acetoacetic acid as low as 2.5-5 mg/dL (0.25-0.5 mmol/L).

- The performance characteristics of the Urine Reagent Strips have been determined in both laboratory and clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy and precision. Generally, this test has been developed to be specific for the parameters to be measured with the exceptions of the interferences listed.
- Please refer to the Limitations section in this package insert.
- Interpretation of visual results is dependent on several factors:
  - The variability of color perception.
  - The presence or absence of inhibitory factors.
  - The lighting conditions when the strip is read.
  - Each color block on the chart corresponds to a range of analyte concentrations.

PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The strip should remain in the closed canister until use.
- Do not touch the reagent areas of the strip.
- Discard any discolored strips that may have deteriorated.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used strip should be discarded according to local regulations after testing.

STORAGE AND STABILITY

- Store as packaged in the closed canister either at room temperature (15-30°C).
- Keep out of direct sunlight.
- The strip is stable through the expiration date printed on the canister label.
- Do not remove the desiccant. Remove only enough strips for immediate use.
- Replace cap immediately and tightly.
- Do not freeze.
- Do not use beyond the expiration date.

Note:

Once the canister has been opened, the remaining strips are stable for up to 3 months. Stability may be reduced in high humidity conditions.

SPECIMEN COLLECTION AND PREPARATION

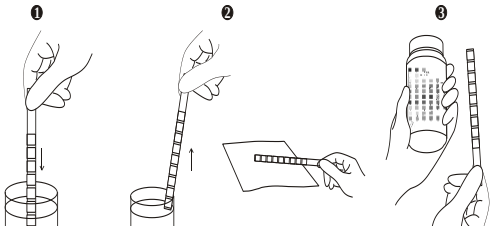
- A urine specimen must be collected in a clean and dry container and tested as soon as possible.
- Do not centrifuge.
- The use of urine preservatives is not recommended.
- If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing.
- Prolonged storage of unpreserved urine at room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test area.
- Urine containing glucose may decrease in pH as organisms metabolize the glucose.
- Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent, specific gravity and bilirubin) test results.

DIRECTION FOR USE

1. Remove the strip from the closed canister and use it as soon as possible. Immediately close the canister tightly after removing the required number of strip(s). Completely immerse the reagent areas of the strip in fresh, well-mixed urine and immediately remove the strip to avoid dissolving the reagents. See illustration 1 below.
2. While removing the strip from the urine, run the edge of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position and bring the edge of the strip into contact with an absorbent material (e.g. a paper towel) to avoid soiling hands with urine. See illustration 2 below.
3. Compare the reagent areas to the corresponding color blocks on the canister label at the specified times. Hold the strip close to the color blocks and match carefully. See illustration 3 below.

Note:

Results may be read up to 2 minutes after the specified times.



INTERPRETATION OF RESULTS

- Results are obtained by direct comparison of the color blocks printed on the canister label.
- The color blocks represent nominal values; actual values will vary close to the nominal values.
- In the event of unexpected or questionable results, the following steps are recommended;
    - Confirm that the specimens have been tested within the expiration date printed on the canister label.
    - Compare results with known positive and negative controls and repeat the test using a new strip.
    - If the problem persists, discontinue using the strip immediately and contact your local distributor.

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls whenever a new test is performed, or whenever a new canister is first opened. Each laboratory should establish its own goals for adequate standards of performance.

LIMITATIONS

- As with all diagnostic and therapeutic tests, all results must be considered with other clinical information available to thephysician.
- **Ketone:** The test does not react with acetone or β-hydroxybutyrate. Urine specimens of high pigment, and other substances containing sulfhydryl groups occasionally give reactions up to and including trace (+).

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size.		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry