Ketones/Acetone by Bayer Acetest Tablets

Purpose

The use of ACETEST reagent tablets provides a rapid method for the semi-quantitative determination of ketones in urine, serum or plasma.

Principle

Acetoacetic acid or acetone in urine or blood will form a purple-colored complex with nitroprusside in the presence of glycine. A buffer provides the optimum pH for this reaction.
ACETEST is a reagent tablet composed of several ingredients, which is used primarily to test for the presence of ketones (acetoacetic acid and acetone) in urine. Serum or plasma may also be used with ACETEST for the presence of ketones. The presence of ketone bodies is important in the evaluation of carbohydrate metabolism.

Reagents, Supplies& Equipment

- Timer, filter paper, plastic transfer pipette
- Store Reagent at room temperature, 15-30C.
- Once opened, Acetest stability is decreased on exposure to moisture.
- Bottle must be recapped promptly after removing a tablet
- Expires on manufacturer's expiration date

Product Note:

Protection against exposure to light, heat and moisture is mandatory to guard against altered reagent reactivity

IF	THEN
Tan-to-brown discoloration or darkening of the tablet is noticed	• Confirm product expiration date • Check performance against known positive control • If proper result not obtained, discard and retest with fresh product
Color or shade appears irregular or "mottled" in appearance	
Test results questionable or inconsistent with expected findings	

Specimen Requirements & Stability

- Urine Ketone is performed by Urine dipstick. ACETEST is only used if the dipstick method is not available. Tablets should be used with fresh urine specimens. When necessary, specimen may be refrigerated.
- Serum or plasma samples should be fresh, and may be refrigerated prior to testing.

Quality Control

Quality Control is run:

- With each patient test.
- With new lot # and/or shipment of ACETEST Tablets following Procedure outlined below.
- Positive: Diluted Acetone (1:2 with DI water).
- Negative: normal patient sample.

IF	THEN
QC acceptable	ACETEST bottle can be placed in use
QC unacceptable	Repeat QC. For negative, choose new normal patient sample
Repeat QC unacceptable	Open new bottle of product. If further problems exist, contact manufacturer

Procedure

Step	Action
1.	Place 3 ACETEST tablets on a clean, dry, piece of filter paper • 1 for Neg QC • 1 for Pos QC • 1 for Patient
2.	**Recap bottle immediately!**
3.	Place a drop of patient sample, neg control and pos control directly on top of a tablet.
4.	• For urine sample, compare color of tablet to Color Chart at *30 seconds* after urine application. • For serum or plasma sample, compare color of tablet with Color Chart at *2 minutes* after sample application.
5.	If QC results are not acceptable do not report patient. Patient can only be reported when run with QC that is acceptable.

IF	THEN
QC acceptable	Report patient
QC not acceptable	Repeat QC and patient
Repeat QC is also not acceptable	Open new bottle of tablets and repeat both QC and patient

6.	Record all results on Acetone log, including QC.
7.	Enter patient result only in LIS using Function MEM Worksheet RVMSA Test Code KET Method is RVCM
8.	Verify the accuracy of result entry by using function WO to review result on a completed worksheet. **Confirm by writing RVS and your initials on the log entry.**

Performance Characteristics

The lower limit of detection in serum or plasma is approximately 10 mg/dL acetoacetic acid per dL. Small color block corresponds to approximately 20 mg acetoacetic acid /dL, Moderate to 30-40 mg/dL and the large result may be interpreted as approximately 80-100 mg/dL.

Result Interpretation & Reporting

Results with ACETEST reagent tablets are recorded as Negative if no purple color is apparent on the tablet at the appropriate reading time. Disregard any pink, tan or yellow color. Positive results are recorded as small, moderate, or large on comparison with the Color Chart. No calculations are necessary.

IF	REPORT AS:
Negative on Color Chart	NEG
Small on Color Chart	POS-SM
Moderate on Color Chart	POS-MOD
Large on Color Chart	POS-LRG

Normal

Expected result is Negative, as ketones are not found in blood or urine under normal conditions of carbohydrate metabolism.

Safety Precautions

BODY FLUID PRECAUTIONS

BLOOD IS A BODY FLUID CAPABLE OF TRANSMITTING INFECTIOUS DISEASES. UNIVERSAL PRECAUTIONS FOR THE PREVENTION OF THE TRANSMISSION OF BLOOD BORN PATHOGENS ARE IN EFFECT AT ALL TIMES. WEAR GLOVES WHEN HANDLING SPECIMEN, IF CHANCE OF BLOOD CONTAMINATION WEAR GOWN AND FACE SHIELD

Limitations

- Improper handling of the product to allow moisture absorption will adversely affect results.
- Urine containing bromsulfalein, sulfhydryls, or very high quantities of phenylketones may give false positive results, as will urines preserved with 8-hydroxyquinoline. L-dopa metabolites may give an atypical reaction which could be interpreted as a positive result.
- When a drop of urine is put onto a tablet, the drop should be absorbed within 30 seconds. If absorption takes longer than 30 seconds, the tablets have been exposed to moisture and may not give reliable results. Discard the rest of the bottle and start with a new one.

References

Bayer Acetest Product Insert, Bayer HealthCare LLC, revised 8/2010