Performing Semi-Quantitative Serum Ketones Testing

Purpose

The use of the AimTab Ketone Tablet provides a rapid method for the semi-quantitative determination of ketones (acetoacetic acid and acetone) in serum or plasma.

Principle

Acetoacetic acid or acetone in serum or plasma will form a colored complex with nitroprusside in the presence of glycine. A buffer provides the optimum pH for this reaction.

The presence of ketones bodies is important in the evaluation of carbohydrate metabolism. The test is based on the nitroprusside reaction with ketone bodies to give a purple color.

Reagents and Supplies Needed

Reagents:

- AimTab Ketone Tablets (Germaine Laboratories, Inc. REF 13100), 100 tablets/bottle.
    - Store between 15˚C to 30˚C.
    - Do not store the bottle in direct sunlight.
    - Once opened, the tablet stability is decreased on exposure to moisture.
    - The bottle must be recapped promptly after removing the tablet.
    - Tablets should be used on a regular basis and not stored for an extended period of time after bottle is opened.
    - Do not use when deterioration is noted by a tan-to-brown or darkening color of the tablet.
- Ketone Serum Controls (Germaine Laboratories, Inc. REF 13112), contains Negative control (1x2mL) and Positive control (1x2mL)
    - Store between 2˚C to 8˚C.
    - Bring to room temperature before use.
    - Once opened, controls are stable up to 3 months.
    - Mix gently by inversion before use.

Supplies:

- Plastic droppers (transfer pipettes)
- Clean white paper or filter paper
- Timer

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Specimen Requirements

Specimen:

- Plasma – Lithium heparin (preferred)
- Serum (acceptable)

Stability:

- Refrigerated (2˚C to 8˚C): Up to 72 hours.
- Frozen (below -20˚C): Up to 6 months

Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.

Quality Control

Perform quality control testing using the Positive and Negative Ketone Serum Controls:

- With each run of patient samples.
- With each new lot number and/or shipment of Tablets.

Procedure

Step	Action
1.	Remove a tablet from the bottle for each patient and QC sample. Replace the cap promptly. Place the tablet on clean, dry, white paper.
2.	Put one drop of patient sample or QC material directly on top of each tablet.
3.	Wait two (2) minutes.
4.	Wipe off any excess sample or QC material.
5.	Compare the color of the tablet to the color chart provided in the product Package Insert.

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Interpreting Results

If	Then
No purple color is present	The test is **Negative**. NOTE: Disregard any pink, tan, or yellow color
Purple color is present	The test is **Positive.** • Patient samples: Grade the intensity of change of color as Small, Moderate or Large according to color chart on package insert:

If	Then 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

• QC: Positive

Reporting of Results

Step	Action
1.	Record all QC and Patient results on the "Manual Test Patient Log". Include Patient ID, date/time, initials and/or tech code.
2.	Report patient results using Sunquest LIS and the following prompts: • Function: **MEM** • Worksheet: **RVMSA**
3.	Verify the accuracy of result entry by using function WO to review result(s) on a completed worksheet. Confirm by initialing or writing your tech code in the "RVS" column on the Manual Test Patient Log.

Expected Value

Negative
Ketones are not found in serum or urine under normal conditions of carbohydrate metabolism.

Limitation

Improper handling of the product to allow moisture absorption will adversely affect results.

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Performance Characteristics

- AimTab Ketone Tablets are specific for the detection of acetoacetic acid and acetone.
- The Tablets are about 10 times more sensitive to acetoacetic acid than acetone and will not react with betahydroxybutyric acid.
- The lower limit of detection in serum or plasma is approximately 10 mg acetoacetic acid per dL.
- This method considered CLIA moderately complex for serum/plasma and testing with this sample type is for clinical laboratory testing only.

References

- AimTab Ketone Tablets Package Insert, Germaine Laboratories, Inc. #64-13100, Rev. 12-15.
- Ketone Serum Controls Package Insert, Germaine Laboratories, Inc. #64-13112, Rev. 02-18.