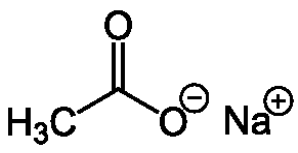


¹³C-Sodium-Acetate Breath Test

| ¹³ C-Sodium-Acetate | |
|---|---|
|  | Molecular weight: 145.21 g/mol Enrichment: 99 % Labeled C-atoms: 1 Dosage: 75 mg |

Metabolism

¹³C-Sodium-Acetate is administered together with a liquid or semi-solid test meal. After passing the stomach, where it is not absorbable, it is absorbed in the small intestine and metabolized in the liver ¹. Whilst some of the labeled carbon is incorporated in different metabolic pathways, about 50 % enters the body's bicarbonate pool and is exhaled ². As the rate-limiting step in this process is the stomach-emptying rate, this test is a reliable application to assess liquid gastric emptying ^{3,4}.

Applications of ¹³C-Sodium-Acetate Breath Test

The ¹³C-Sodium-Acetate Breath Test is very useful for the investigation of functional dyspepsia and autonomic diabetic neuropathy ⁵. Gastroparesis has also been shown to be associated with functional gastrointestinal ^{6,7} and inflammatory disorders of the gastrointestinal tract ⁸.

The patient should have fasted for 10 hours prior to the test. The patient should not drink carbonated water or soft drinks prior to the test since that might interfere with the results. In addition, oxygen supplementation should be avoided because increased oxygen content in exhaled breath can influence ¹³CO₂ measurement by NDIRS ⁹.

Test Performance Procedure (see IRIS[®] Operating Manual for additional information)

1. Collect zero (basal) breath sample as described in manual.
2. Enter patient height and weight into the IRIS[®]-3 or IRIS[®]-Doc Software.
3. Patient takes ¹³C-Sodium-Acetate (75 mg) dissolved in a liquid or semi-solid test-meal with about 250 kcal (e.g. 200 ml Fresubin[®], Fresenius Kabi AG, Switzerland)
4. Collect breath samples as shown below (Table 1).
5. Analyze all 13 breath samples with IRIS[®]-3 or IRIS[®]-Doc.

| #1 Bag | #2 Bag | #3 Bag | #4 Bag | #5 Bag | #6 Bag | #7 Bag | #8 Bag | #9 Bag | #10 Bag | #11 Bag | #12 Bag | #13 Bag |
|--------|--------|--------|--------|--------|--------|--------|---------|---------|---------|---------|---------|---------|
| 0 min | 15 min | 30 min | 45 min | 60 min | 75 min | 90 min | 105 min | 120 min | 150 min | 180 min | 210 min | 240 min |

Table 1: ¹³C-Sodium-Acetate Test Sample Collection

Results and interpretation

Gastric emptying parameters are assessed by calculation of the half-emptying time ($T_{1/2B}$), the lag phase (T_{lagB}) and the gastric emptying coefficient (GEC), which have been introduced and validated against scintigraphy by Ghooos *et al* ¹⁰. This method is still the most frequently applied method, although different analytical methods are currently under validation. These parameters are estimated by non-linear regression analysis directly with the IRIS[®]-3 or IRIS[®]-Doc Software (please refer to the manual).

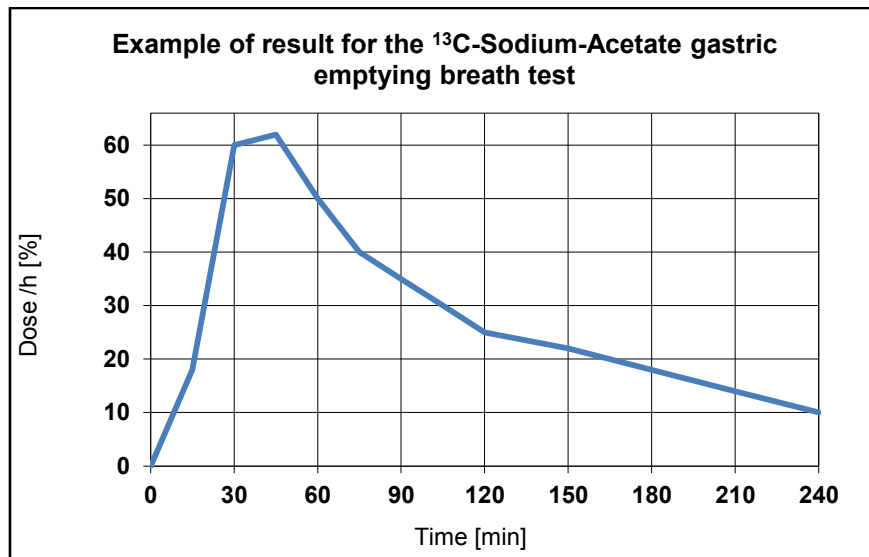


Fig. 1: Example of ^{13}C -Sodium-Acetate gastric emptying breath test, Dose/h curve

As the results are dependent on the test meal, it is strongly recommended that each laboratory establishes its own reference values. For semi-solid test meals, Braden *et al.* found cut-off values of 106 minutes (mean + 2 SD) for the half-emptying time and 55 minutes (mean + 2 SD) for the peak excretion in 20 healthy patients³. Another study by Braden *et al.* resulted in half-emptying times of 90 minutes as cut-off value in children¹¹. In 2006, Hauser *et al.* found median values of 81 minutes for $T_{1/2B}$ and 47 minutes for T_{lagB} with a liquid test meal in children¹².

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