

**D3 Hydroxybutyrate (D3H) Test Kit**  
(Enzymatic)

**【NAME】**

D3 Hydroxybutyrate (D3H) Test Kit (Enzymatic)

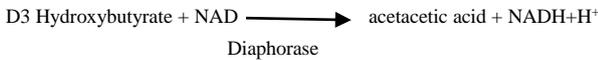
**【INTEND USE】**

This reagent is intended for the in vitro quantitative determination of D3 Hydroxybutyrate (D3H) in human serum ,plasma. Serum β -hydroxy butyric acid increased significantly in patients with diabetes, elevated levels associated with illness, patients with ketoacidosis higher than that of patients with diabetes ketosis, in the absence of ketosis β -hydroxy butyric acid in patients with diabetes were higher than that of ketone body, qualitative positive rate, beta hydroxy butyric acid determination for diabetes patients condition monitoring.

**【METHODOLOGY】**

D3 Hydroxybutyrate generates NADH, NADH reacts with INT creates NAD<sup>+</sup> the color change of INT can be monitored at 340nm wavelength, to get the content of D3 hydroxybutyric acid.

D3 Hydroxybutyrate dehydrogenase



**【STABILITY AND STORAGE】**

Unopened, avoid light preservation in 2 ~ 8 °C, valid for 12 months;  
Opened, avoid light preservation in 2 ~ 8 °C, valid for 1 month.  
Reagent is not allowed frozen.

**【SPECIMEN COLLECTION AND HANDLING】**

It is best to fresh Serum or Heparin plasma ,  
Stability of sample: 2~8°C preservation stability in 3 days;  
Do not use contaminated samples.  
When these composition in sample:Ascorbic acid ≤10mg/dL, Bilirubin ≤ 20mg/dL、 Lactate dehydrogenase ≤1500U/mL、 sodium lactate ≤96mg/dL, no obvious interference found.

**【APPLICABLE INSTRUMENT】**

Fully automatic biochemical analyzer.

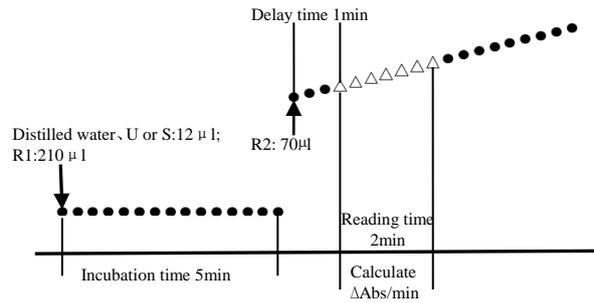
**【SYSTEM PARAMETERS】**

The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group.

Temperature	37° C
Cuvette light path	1.0cm
Primary Wavelength	340 nm
Secondary Wavelength	700nm
Assay Type	Fixed time method
Direction	Increase
Sample : Reagent Ratio	6:135:35
eg : Sample Vol	12 μL
Reagent1 Vol	270 μL
Reagent2 Vol	70 μL
Linearity	0.02~0.27mmol/L
Testing	Deducting the reagent blank

**【OPERATION STEPS】**

R1: Reagent 1    R2: Reagent 2    S: Calibrator    U: Sample



**【CALCULATION】**

$$\text{D3H (mmol/L)} = \frac{\text{Sample } \Delta\text{A/min}}{\text{Calibrator } \Delta\text{A/min}} \times \text{Calibrator concentration}$$

**【REFERENCE RANGE】**

Serum: 0.02~0.27mmol/L (0.2~2.81mg/dL)

By clinical trials, choose no less than 100 women or men blood specimens, tested by automatic biochemical analyzer, and then processing the testing value with statistical method, calculating out the reference range.

**Recommendation: The laboratory set up its own reference range!**

**【THE LIMITATION OF TEST RESULTS】**

D3H testing is just one of the standard that clinicist diagnose the patient. Clinical physicians should according to patients' bodies, history and other diagnostic program, to get comprehensive judgment.

**【THE INTERPRETATION OF TEST RESULTS】**

Human error, the processing of specimen, analysis instrument deviation, etc. all can affect the measurement result; When one sample deviates from the expected value too far, need to be tested again.

**【PERFORMANCE INDEX】**

1. Reagent blank absorbance ≤0.1500, (340nm, 1cm light path)).
2. Precision: repeatability CV ≤5%; batch variations R ≤10%.
3. Accuracy: relative deviation ≤10%.
4. Linearity range: 0~4.5mmol/L, r > 0.990
5. Stability: this reagent at 2 °C ~ 8 °C, avoid light environment without corrosive gas storage for 12 months.

**【ATTENTION】**

1. This reagent use to IVD diagnosis. Once contact with human body, please rinse with water;
2. Reagents for scrap, please with plenty of water to dilute before processing.
3. Other instrument model should verification by the lab; if you need the details parameters please contact us.
4. Different batches reagents cannot mix, when replacing reagents batch number, please calibration again!