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 ketois 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.

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

D3 Hydroxybutyrate dehydrogenase
D3 Hydroxybutyrate + NAD → acetic acid + NADH+H+
Diaphorase
NADH + INT (Oxidized) → NAD + + INT (Prototype)

【STABILITY AND STORAGE】
Unopened, avoid light preservation in 2~8 ℃, valid for 12 months;Opened, avoid light preservation in 2~8 ℃, valid for 1 month.
Reagent is not allowed frozen.

【SPECIMEN COLLECTION AND HANDLING】
It is best to test fresh Serum or Heparin plasma.
Stability of sample: 2~8 ℃ 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 ℃
- 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】
D3H (mmol/L) = \frac{\text{Sample ΔA/min} - \text{Calibrator ΔA/min}}{\text{Calibrator concentration} × \text{Reagent 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 clinician 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 ≤ 10%.
3. Accuracy: relative deviation ≤ 10%.
4. Linearity range: 0~4.5mmol/L, r > 0.990.
5. Stability: this reagent at 2~8 ℃, 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!