# Creatinine (CRE) Assay Kit (EnzymaticMethod)

**[Product name]**

Creatinine (CRE) Assay Kit (EnzymaticMethod)

English abbreviation: CRE Kit

**[Packing Specifications]**

Reagent 1 (R1): 60 mL×2, Reagent 2 (R2): 20 mL×2;

Calibrator: 1ml×1(Optional)

**[Intended use]**

This kit is used for quantitative determination of creatinine concentration in human serum and urine in vitro.

Creatinine is the end product of creatine metabolism and is excreted by the kidneys. Serum creatinine comes from creatine and phosphocreatine in muscles and is not affected by diet and urine output. Determination of creatinine content is mainly used to detect changes in renal function, to detect that renal function is in a state of potential failure or is improving.

**[Test principle]**

$$\text{Creatinine} + H_2O \xleftarrow{\text{Creatinine Amidohydrolase}} \text{Creatine}$$

$$\text{Creatine} + H_2O + O_2 \xleftarrow{\text{Creatine Amidinohydrolase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + H_2O + O_2 \xleftarrow{\text{Sarcosine Oxidase}} \text{Glycine} + HCHO + H_2O_2$$

$$\text{TOOS} + \text{4-Aminoantipyrine} + H_2O_2 \xleftarrow{POD} \text{Quinone Imine} + H_2O$$

*HCHO represents formaldehyde.

The absorbance of the quinone imine generated by the reaction was detected at 546nm, and the absorbance was positively correlated with the concentration of CRE.

**[Main components]**

| Component | | Concentration |
|---|---|---|
| Reagent 1(R1) | Creatine Amidinohydrolase | ≥10.0KU/L |
| | Sarcosine oxidase | ≥10.0KU/L |
| | TOPS | ≥1.4mmol/L |
| Reagent 2(R2) | POD | ≥20.0KU/L |
| | Creatinine Amidohydrolase | ≥200.0KU/L |
| | 4-Aminoantipyrine | ≥1.5mmol/L |
| Calibrator (Optional) | Creatinine<br>This calibrator is a water-based liquid calibrator | Target concentration: 200μmol/L |

**Note:** 1. Calibrator traceable to national standard GBW09175
2. Avoid mixing reagent components of different batch numbers
3. The calibrator is batch-specific, please refer to the bottle label for specific values

**[Storage conditions and shelf-life]**

The kit in the original packaging should be stored at 2℃ to 8℃ in the dark, and the validity period is 18 months. After the kit is opened, store it at 2℃-8℃ in the dark, and it can be stable for 28 days. See the product label for production date, batch number and expiration date.

**[Applicable Instruments]**

This kit is suitable for HITACHI 7020, 7060, 7100, 7170, 7180, 7600, 3100, 3500, LABOSPECT 006/008 AS;

**[Sample Requirements]**

1. Sample type: Serum and urine. Please centrifuge the sample in time.

**[Procedure]**

**Calibration**

1. The calibrator is liquid and used directly.
2. Carry out two-point calibration with deionized water and CRE calibrator.
3. For the calibration procedure, see the instruction manual of the analytical instrument used.
4. Calibration and frequency requirements: Under normal circumstances, the measurement should be calibrated at least once every week. When the following situations occur (such as: when the batch number of the used reagent changes, after the instrument is repaired, maintained, or key components are replaced, or the measurement results of the quality control product drift or exceed the specified range, etc.), the measurement should be recalibrated and the patient's sample should be tested.

**Quality Control**

1. Measure the quality control products manufacturer recommends, and only when the test results are within the quality control range can specimens be tested.
2. Quality control requirements: Under normal circumstances, the selected quality control should be tested at least once each time a patient sample is tested. When the following situations occur (such as: when the batch number of the reagent used is changed, the instrument used is repaired, maintained or the key parts are replaced, the measurement result of the quality control product drifts or exceeds the specified range, etc.), at least the Selected quality controls were tested once.
3. Processing procedures for the measurement results of quality control products to drift or exceed the specified range:
   A. Retest of the selected controls.
   B. If the determination results remain unchanged, consider changing to a new bottle of quality control product and then test again.
   C. If the measurement results remain unchanged, it should be considered to re-calibrate the measurement and then measure the quality control product.
   D. If the determination results remain unchanged, consider changing a bottle (or batch) of reagents for the test.
   E. If the determination results remain unchanged, consider contacting the technical services.

**Procedure**

| | Blank space (B) | Calibration (S) | Sample (T) |
|---|---|---|---|
| Reagent 1 (μL) | **300** | **300** | **300** |
| Deionized water (μL) | **6** | — | — |
| Calibrator (μL) | — | **6** | — |
| Sample (μL) | — | — | **6** |
| Mix well, measure the absorbance A1 after incubating at 37℃ for 5 minutes, then add: | | | |
| Reagent 2 (μL) | **100** | **100** | **100** |
| Mix well, read absorbance A2 after constant temperature at 37℃ for 5 minutes, and calculate ΔA=A2-A1 | | | |

| Test method | End-point | Wavelength | 546nm |
|---|---|---|---|
| Reaction direction | Rise | Observed temperature | 37℃ |

**Note: For detailed operation methods, please refer to the operating instructions of the instrument used.**

**Calculation**

$$\text{CRE concentration} = \frac{\Delta A_{Sample}}{\Delta A_{Calibration}} \times \text{Calibrator concentration}$$

**[Reference Interval]**

Select 200 samples as reference individuals, the reference value distribution is skewed distribution, calculated according to the 95% confidence interval, serum reference value range: 17.7-107μmol/L, urine reference value range: 3537-11494 μmol/L.

Due to differences in geography, race and age, it is recommended that each laboratory establish its own reference range.

**[Interpretation of the test results]**

Professionals are responsible for reviewing the inspection results. The results will be affected by the age, sex, weight, diet, etc. Generally, the results are considered normal if in the reference interval; in the critical area, the rheumatoid factor result is considered abnormal in the sample. If the test results are inconsistent with clinical or even contrary to the clinic, the reasons should be analyzed and found.

**[Limitations of the test method]**

1. This kit is only used for the determination of human serum samples, and the reliability of other body fluid samples has not been fully confirmed.
2. The CRE concentration obtained by other methods is not directly comparable with the measurement results of this kit.

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3. Microbial-contaminated samples should not be used for testing.
4. If the specimen contains the following concentrations of distractors, there is no significant effect on the test results: Hemoglobin≤1g/L, Chyle≤0.30%, VC≤0.5g/L, Heparin Sodium≤100IU/mL.

**[Product Performance Index]**

1. Appearance: Reagent 1: colorless to light yellow solution, no turbidity, no undissolved matter; Reagent 2: colorless solution, no turbidity, no undissolved matter. Calibrator: colorless solution, no turbidity, no undissolved matter.
2. Net content: the net content of the liquid reagent shall not be lower than the labeled volume.
3. The reagent blank absorbance should be ≤ 0.300.
4. Analysis sensitivity: When measuring the analyte at a concentration of 100 μmol/L, the absorbance difference ( ΔA) should not be less than 0.008.
5. Accuracy: Test reference material, the relative deviation should not exceed ±10%.
6. In-batch precision CV ≤ 5%; in-batch relative extreme difference (R) ≤ 5%.
7. Linear: In the range of [10,8000] μmol/L, the linear correlation coefficient r of the CRE kit should not be lower than 0.9900; in the range of [10,70], the absolute deviation should not exceed 7μmol/L, and in the range of (70,8000], the relative deviation should be No more than ±10%.

**[Matters Need Attention]**

1. Avoid direct contact with the skin and eyes, do not swallow.
2. The product instructions should be read carefully before use, and the appliances after use should be treated in accordance with the relevant medical waste treatment regulations.
3. Products that produce lefts or leakage due to the transportation process, or reagents that are not maintained according to the instructions in the transportation and storage, should not be used.
4. This product is only applicable for clinical in vitro diagnosis and used by professionals.
5. If the hospital uses other models of automatic biochemical analyzer, each hospital should verify it according to the actual needs.
6. If the hospital uses other company calibrators or quality control, the calibrator should be verified and the quality control should re-accumulate the target value.
7. Do not freeze the kit during storage and transportation.

**[Interpretation of the logo]**

| | | | |
|---|---|---|---|
| | Term of validity | | Refer to instructions |
| LOT | Lot number | IVD | In-vitro diagnostic medical devices |
| | Date of Manufacture | | Temperature extremes |

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