CK

Creatine Kinase Test Kit
(Enzyme Coupling Method)

Instructions for Use

Version: A/0

REF HP-CK-25

Nombre del producto

Nombre general：Kit de prueba de creatina quinasa（Método de acoplamiento enzimático).

Especificaciones

Especificaciones del paquete

25 Pruebas/Kit

Uso previsto

Para la detección de la actividad de la creatina quinasa (CK) en el suero humano, se utiliza principalmente para el diagnóstico auxiliar del infarto de miocardio, la miopatía y otras enfermedades.

Principio de la prueba

$$\text{Creatinina quinasa + ADP} \xrightarrow{\text{CK}} \text{Creatine + ATP}$$

$$\text{ATP +Glucosa} \xrightarrow{\text{HK}} \text{ADP +G-6-P}$$

$$\text{G-6-P + NADP}^{+} \xrightarrow{\text{G-6-P-DH}} \text{6-PG + NADPH + H}^{+}$$

En la reacción anterior, la creatina quinasa (CK) cataliza el fosfato de creatina para formar creatina, y al mismo tiempo hace que la coenzima oxidada (NADP) sufra hidrógeno para formar coenzima reducida (NADPH), el aumento de la absorbancia de esta última a 340 nm está relacionado con la actividad de la CK proporcional.

Componentes

El kit de prueba CK consta de dos reactivos R1 y R2, como se muestra en la figura 1.

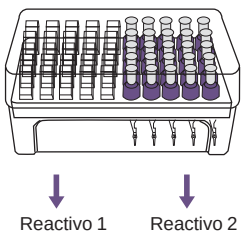


Figura 1

Nombre	Contenido	Cantidad
Reactivo 1 (R1)	Bu er de imidazol	100mmol/L
	N-acetilcisteína	20mmol/L
	Glucosa	20mmol/L
	Acetato de magnesio	10mmol/L
	EDTA	2mmol/L
	5,-Adenina Nucleótido	10mmol/L
	Monofosfato de adenosina	5mmol/L
	Hexoquinasa	⩾2.5KU/L
Reactvio 2 (R2)	Diadenosina pentafosfato	10mmol/L
	6-fosfoglucosa deshidrogenasa	⩾2.5KU/L
	Fosfocreatina	30mmol/L
	Coenzima oxidativa II	2mmol/L

No mezcle diferentes lotes de reactivos.

Almacenamiento y estabilidad

Guarde el kit de prueba a 2℃-8℃ hasta la fecha de caducidad indicada en la etiqueta. El kit de prueba es estable durante un año sin abrir.

Consuma el kit de análisis en el plazo de un mes desde la apertura del envase.

No congele el kit de prueba.

No mezcle diferentes lotes del kit de prueba.

Registros especiales de los instrumentos

Sistema automático de inmunoensayo HP-AFS/1

Sistema automático de inmunoensayo HP-AFS/3

Tipo de muestra

Suero, evitar la hemólisis. Extraer la sangre en ayunas y separar el suero lo antes posible. La muestra almacenar a 2-8℃ durante 3 días, -20℃ durante 1 mes. Evite la congelación repetida. Antes de la prueba, asegúrese de que esté completamente mezclada.

Procedimiento

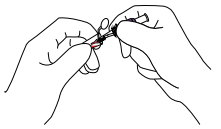
Sistema automático de inmunoensayo HP-AFS/1&HP-AFS/3

Nota:

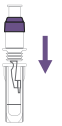
- Lea el manual de usuario de HP-AFS/1 y HP-AFS/3 antes de utilizarlos.
- El analizador finalizará la autocomprobación después de arranque.
- Se recomienda realizar la calibración del analizador mensualmente y para cada nuevo lote de kit de prueba.
- The analyzer will finish the self check after start-up.
- It is recommend to do analyzer calibration monthly and for each new lot of test kit.

Step 1 Sample Preparation

1a Allow the test kit back to room temperature for 30 minutes before use.



1b Use the R2 with quantitative capillary to collect sample.

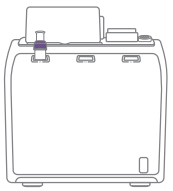


1c Insert the R2 into R1.

Note:

- Please update the standard curve with the barcode on the R1 cuvette if a new lot test kit is to be used.
- The capillary of the R2 should be fully filled.

Step 2 Testing



2a Insert the R1 into test channel of analyzer.

2b The analyzer will mix the sample from R2 capillary with R1 automatically.

2c The analyzer will mix the R2 and R1 automatically.

2d The analyzer will test and print the results automatically.

Calibration

The calibration values for the different lots of the kits are stored on the two-dimensional code on the cuvette. Before test the new lot of kits, the instrument automatically scan the two-dimensional code on the cup to obtain the corresponding calibration curve during testing.

Quality control

3- level calibration system guarantee theresults' reliability for each lot of test kits, including the instrument calibration, remote reagent calibration and the third party calibration.

The third party calibration applicable for:

1. The daily indoor quality control test.
2. New lots of reagent.

3. New operator training.

4. The results can not match the clinical symptoms.

5. The first use of the reagent.

If still can not be calibrated, contact the manufacture for further technical support.

Reference Value

＜164U/L

Recommended that each laboratory establish its own reference range.

Interpretation

1. If the test result is ⩾164U/L, indicating that there may be a risk of myocardial infarction or muscle damage, and it is recommended that the patient undergo further examination.
2. The result only for clinical reference, comprehensive consideration should be combined with the clinical management of patients with symptoms / signs, medical history, other laboratory tests and treatment response.
3. All laboratory tests depend on random errors. If the test results are in doubt, or if they do not match the clinical symptoms, re-test the sample or confirm the results with other methods.

Limitations

Bilirubin⩽340μmol/L, Hemoglobin⩽5 g/L, Triglyceride⩽5mmol/Lwill not affect the test result.

Performance Characteristics

1. Linearity range: 4U/L ～ 1200U/L，r⩾0.990.
2. Within-run precision: relative standard deviation (RSD) ⩽ 5%.
3. Between-run precision: Inter-batch relative range (R) ⩽ 10%.
4. Accuracy: relative deviation (B) should not exceed ±10%.
5. Blank limit: reagent blank absorbance⩽0.5.
6. Reagent blank absorbance change rate⩽0.002.
7. Analytical sensitivity: when the sample concentration is 500U/L, its absorbance change rate is between 0.060 and 0.160.

Precautions

⚠ Attention:

Only for in vitro diagnostic.

Only for professional use.

All samples and reactive wastes are treated as sources of infection.

Do not use the kits beyond shelf life.

Do not mix different batches of reagents.

⚠ Warning:

To avoid error, do not forced to take out the cuvette from the device. Follow the device operation manual strictly, If the problem cannot be solved, contact the manufacturer for further technical support.

SYMBOLS USED ON LABELS

Symbol	Usage	Symbol	Usage
	Use-By date		Do not freeze
LOT	Batch code		Biological risks
	Manufacturer		Do Not Reuse
2℃ 8℃	Temperature Limit		
Σ	Contains sufficient for <n> tests		
	Do not use if package is damaged		
	Consult Instructions for use		
	Keep Away from Sunlight		
IVD	In Vitro Diagnostic Medical device		
EC REP	Authorized Representative in the European Community		

References

Shang Hong, Wang Liu three, Shen Ziyu and so on. National Clinical Laboratory Practice (Fourth Edition) [M] Beijing: People's Medical Publishing House,2015:412-413.

Approval Date&Revision Date

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