CE IVD

TCH Reagent Kit-2
(CHOD-PAP Enzymatic-Colorimetric Method)

Instructions for Use REF CC1076

PRODUCT NAME

TCH Reagent Kit-2 (CHOD-PAP Enzymatic-Colorimetric Method)

PACKAGE SPECIFICATION

R1: 1×20 mL	R2: 1×10 mL	R1: 1×40 mL	R2: 1×20 mL
R1: 1×60 mL	R2: 1×30 mL	R1: 2×60 mL	R2: 2×30 mL
R1: 2×30 mL	R2: 2×15 mL	R1: 2×40 mL	R2: 2×20 mL
R1: 2×50 mL	R2: 1×50 mL	R1: 2×60 mL	R2: 1×60 mL
R1: 2×60 mL	R2: 3×20 mL	R1: 2×65 mL	R2: 1×65 mL
R1: 2×65 mL	R2: 1×70 mL	R1: 2×80 mL	R2: 1×80 mL
R1: 2×120 mL	R2: 2×60 mL	R1: 3×20 mL	R2: 3×10 mL
R1: 3×40 mL	R2: 3×20 mL	R1: 4×40 mL	R2: 4×20 mL
R1: 4×50 mL	R2: 2×50 mL	R1: 4×55 mL	R2: 2×55 mL
R1: 4×60 mL	R2: 2×60 mL	R1: 4×60 mL	R2: 4×30 mL
R1: 4×60 mL	R2: 6×20 mL	R1: 4×65 mL	R2: 2×65 mL
R1: 4×65 mL	R2: 2×70 mL		
R1: 4×100 mL R2: 2×100 mL			
12×72 T (R1: 12×16.8 mL R2: 12×8.4 mL)			
Calibrator (optional): 1×1 mL			

INTENDED USE

Used for the *in vitro* quantitative determination of total cholesterol (T-CH) in human serum and plasma. Mainly used clinically for the auxiliary diagnosis of hypercholesterolemia. For professional and laboratory use.

TEST PRINCIPLE

Cholesteryl ester + $H_2O \xrightarrow{CE}$ Free cholesterol + fatty acids

Free cholesterol + $O_2 \xrightarrow{CO}$ Cholestenone + H_2O_2

$2H_2O_2$ + 4-AAP + ESPMT $\xrightarrow{POD}$ Color reaction

The absorbance (△A) is directly proportional to the concentration of T-CH at a wavelength of 546 nm.

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	Piperazine-1,4-bis (2-ethanesulfonic acid) buffer (pH 7.0)	11 g/L
	Cholesterol esterase (CE)	3 KU/L
	N-ethyl-N-(3-propanesulfo)-3-methylaniline	0.5 g/L
Reagent 2	Peroxidase	5 KU/L
	4-aminoantipyrine (ampyrone)	0.5 g/L
	Cholesterol oxidase	5 KU/L
Calibrator (optional)	Cholesterol (CHOL), an aqueous matrix, a surfactant	3.5-6 mmol/L

The components in different batches of a multi-component kit are not interchangeable.
Calibrator traceability: Traceable to international Standard Reference Material (SRM) 909c.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

1. Human serum and plasma samples can be used for this test.
2. Serum and plasma anticoagulated with heparin should be separated in time after blood collection to avoid hemolysis.
3. The test results for serum and plasma will not change within 7 days of storage at 15-25°C, 7 days of storage at 2-8°C and 3 months of storage at -20°C.

TEST PROCEDURE

1. Reagent preparation: Use directly.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/secondary wavelengths	546 nm/700 nm	**Calibration type**	Linearity
Sample/R1/R2	3/200/100 μL	**Time of mixture of serum + R1**	1-5 min
Method	Two-point end point assay	**Reaction time after addition of R2**	5 min
Calibration method	Two-point calibration	**Direction of reaction**	Upward

(Absorbance (A) read by the instrument=$A_{\text{Primary wavelength}}$-$A_{\text{Secondary wavelength}}$)
Operating procedures:

Substances added	Blank tubes	Test tubes
Reagent 1	200 μL	200 μL
Sample	-	3 μL
Distilled water	3 μL	-
Mix well, incubate at 37°C for 3-5 min, and read the absorbance (A_0);		
Reagent 2	100 μL	100 μL
Mix well, incubate at 37°C for 5 min, and read the absorbance (A_1); then calculate the change in absorbance (ΔA) according to the formula $\Delta A=A_1-A_0$		

3. Calibration procedure: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control procedure: Select quality control serum from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
   4.1 Check whether the parameter settings and light source are correct.
   4.2 Check whether the cuvettes and sampling probes are clean.
   4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
   4.4 Check reaction temperature.

4.5 Check the expiration date of the kit.

5. Result calculation:

CHOL concentration (mmol/L)=Concentration of CHOL Standard Reference Material (SRM) × $\triangle A_{\text{test sample}} / \triangle A_{\text{Standard}}$

REFERENCE RANGE

Appropriate level: <5.17 mmol/L (200 mg/dL)

Critical level: 5.17-6.5 mmol/L (200 mg/dL-250 mg/dL)

The reference range is for reference only. Because there are differences in respect of factors including geography, race, gender and age, it is recommended that each laboratory should establish its own reference range.

RESULT INTERPRETATION

Since hemolysis interferes with determination, it should be avoided as much as possible during operation.

LIMITATIONS

There is no interference with measurement when hemoglobin is ≤ 200 mg/dL, ascorbic acid ≤ 10 mg/dL, bilirubin ≤ 10 mg/dL, and triglycerides ≤ 2000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 in the kit is a colorless or slightly yellow clear liquid, which may contain a small number of subvisible particles that do not affect determination. Reagent 2 is a slightly yellow clear liquid, which may contain a small number of subvisible particles that do not affect determination.
2. Reagent blank absorbance
   Reagent blank absorbance A_{546nm} ≤ 0.080.
3. Accuracy
   The relative deviation should be within ±10.0%.
4. Linear range
   Linear correlation coefficient (r) should be ≥ 0.990 in the range of [0.1, 12.9] mmol/L.
   a) When test a sample with concentration of [0.1, 1.0] mmol/L, the deviation should be within ±0.2 mmol/L.
   b) When test a sample with concentration of (1.0, 12.9] mmol/L, the deviation should be within ±10%.
   5. Analytical sensitivity
   When a sample has a concentration of 5.17 mmol/L, its absorbance difference should be ≤ 0.820.
6. Precision
   Within-run precision: Within-run precision should not be greater than 4.0%.
   Between-run precision: Between-run precision should not be greater than 6.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnosis only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
   1.4 Reagents from different manufacturers used to test the same sample may produce different results, which should be considered in conjunction with clinical findings.
2. Precautions for operation
   2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 The reagents cannot be used if they are cloudy.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
   5.5 Please do not mix reagents in different batches.

REFERENCE

Shang Hong, *et al*. National Standard Operating Procedure for Clinical Testing (4th Edition). People's Medical Publishing House, 2015: 309-312.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on TCH Reagent Kit-2 (CHOD-PAP Enzymatic-Colorimetric Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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