Chloride Assay Kit （CL）

Method:Enzymatic

Cat.NO.	Package Size
GS5CL	**R1:1×50 ml R2:1×10 ml**

This assay kits apply to biochemistry analyzers: Hitachi7020/7080/7100/7180/7600,Hitachi LabospecT003/008&AU400/480/680/5800/DXC800,AbbottC4000/C8000/C16000,Simens Dimension EXL/RXL, BSBE G9800/, BS2000M, Cobas C701/C702/ C501/ C502/ C311/Modular P,TBA40FR/120FR/2000FR etc.

INTENDED USE

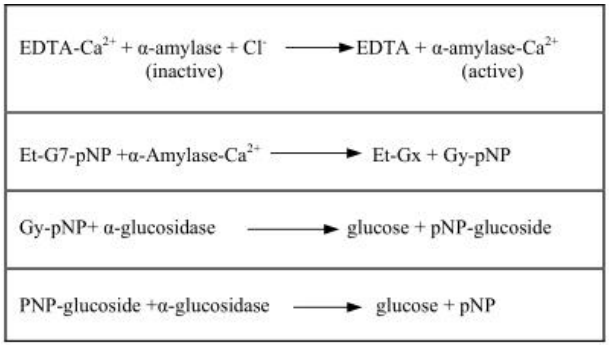
For quantitative determination of chloride in human serum.

CLINICAL SIGNIFICANCE

The determination of chloride in serum is the most commonly performed for the diagnosis of proper hydration, osmotic pressure, and acid/base equilibrium. Elevated serum chloride values may be seen in dehydration, hyperventilation, congestive heart valve, and
prostatic or other types of urinary obstruction. Low serum chloride values are found with extensive burns, excessive vomiting, intestinal obstruction, nephritis, and metabolic acidosis.

ASSAY PRINCIPLE

Mammalian α-amylase, which normally involves binding with calcium ion, is deactivated by removing calcium ion by adding a high concentration of EDTA in the absence of chloride anion. The deactivated α-amylase is reactivated by addition of chloride anion,which allows the calcium ion to reassociate with the enzyme. The reactivation of α-amylase activity is proportional to the concentration of chloride anion present. Ethylidene blocked pnitrophenyl-maltoheptaoside (EPS-G7) is used as the substrate. Reactivated α-amylase hydrolyzes EPS-G7 to Et-Gx and Gy-pNP. Gy-pNP is further hydrolyzed by a coupled enzyme, α-glucosidase to glucose and pNP which is quantitated colorimetrically at 405 nm. The amount of pNP formed is directly proportional to the α-amylase.



REAGENTCOMPOSITON

Contents	Concentration of Solutions
Reagent 1	
Hepes	≥100mmol/L
EPS-G7	≥1mmol/L
EDTA	≥10umol/L
α- Amylase	≥5KU/L
Reagent 2	
Hepes	≥100mmol/L
α- Glucosidase	≥5KU/L
EDTA.Ca	≥1mmol/L

SAMPLE COLLECTION AND PREPARATION

Fresh Serum samples.
Serum samples are stable for 3 days at 2-8°C, or for 14 days at -20°C. The samples should avoid repeated freeze-thaw.

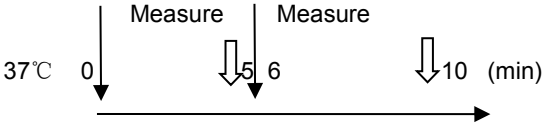
STABILITY AND PREPARATION OF REAGENTS

The reagents, calibrators, and controls should be stored at 2-8°C. Do not freeze. The reagents,
calibrators, and controls are stable when stored as instructed until the expiration date on the label.
Please prevent cross-contamination if opened.

ASSAY PROCEDURE

Test Procedure for Analyzers (Hitachi)
Assay Mode: Two End-point 20-26
Wave length (sub/main): 700/405nm

Sample 2 μl
R1: 200μl R2: 40 μl



CALIBRATION

Gcell Cl Calibrator (GC-CL) is recommended.

CALCULATION OF RESULTS

$$\text{Concentration} = \frac{\Delta A_{sample}\ /\text{min}}{\Delta A_{calibrator}\ /\text{min}} \times \text{Calibrator value}$$

QUALITY CONTROL

Gcell CL Control (GQ-CL) or Randox multi-bio control HN1530/HE1532 is recommended as daily quality control serum. Please confirm the values should be within a specific range. If not, Please check:

1. The instrument settings and light source;
2. Reaction temperature;
3. Expiration date of kit and contents.

REFERENCE RANGE

Serum:98-106mmol/L
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

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SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

Linearity is 60-140 mmol/L. Samples that exceeded the linearity limit (140 mmol/L) should be diluted with an equal volume of water. Multiply the result by two.

PRECISION

The coefficient of variation (CV) for both Intra assay precision and Inter assay precision is below 10%

Intra assay precision		
N=20	Sample 1	Sample 2
Mean(mmol/L)	102.11	113.02
SD	2.13	1.82
CV(%)	2.09%	1.61%

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mmol/L)	95.8	99	97.8
$\bar{x}$	97.53		
(Xmax-Xmin)/$\bar{x}$	3.28%		

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mmol/L)	113	114.2	110.6
$\bar{x}$	112.6		
(Xmax-Xmin)/$\bar{x}$	3.20%		

SENSITIVITY

For analysis sensitivity, the absorbance is 0.2000～0.6000 under the concentration of 100mmol/L.

INTERFERENCE

The following analytes were tested up to levels indicated and found not to interfere:

Intralipid : 500mg/dL
Bilirubin: 30 mg/dL
Hemoglobin: 500 mg/dL
VC: 50mg/dL

CORRELATION

Tested the serum samples with Gcell CL assay kit and ISE (x) at the same time. The correlation formula is Y=0.863X+12.78, R^2=0.939

SAFETY PRECAUTIONS AND WARNINGS

1. 1.For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. 2.Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. 5.Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Tietz, N.W.Fundamental of clinical chemistry, W.B. Saunders, Philadelphia, PA, p897 (1976).
2. White, W.L., et al., Chemistry for technologist, 3rd Ed, The C.V. Mosby Co, St. Louis, p182 (1970)
3. Ono, T., et al., Clin. Chem. 34: 552-553 (1988)
4. Klaus Lorentz. Clin. Chem. 46(5) 644-649 (2000)
5."National Clinical Laboratory Operating Procedures" (fourth edition), the Ministry of Health of the People's Republic of China

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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