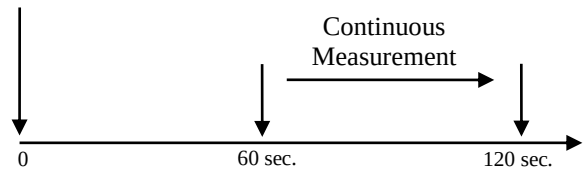
Bioway Chemistry Reagent Series
The AMY Reagent Kit

Detection of Amylase in Human Serum or Plasma on Chemistry Analyzers

Cat. No. R007K11 ***The AMY Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram



*Refer to Figure 1 and the package insert for detail

Table 1: Instrument Parameters*

F factor	3178	Slope of reaction	Increase
Calibration method	K factor	Reaction temperature	37℃
Testing wavelength	Pr:405 nm Sc:546 nm	Sample volume	5 µl
Test method	Rate Method	R1 volume	200 µl

INTENDED USE

Bioway Chemistry Reagent Series **AMY Reagent Kit** (the Kit) is an assay intended for *in vitro* quantitative detection of Amylase in human serum or plasma on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Amylase is a digestive enzyme which is secreted by salivary and pancreatic glands and also be found in adipose tissue and skeletal muscle. It is important for starches digestion and rapidly cleared by kidneys. Elevated level of amylase sometimes is represent of inflammation of salivary gland or abdominal cavity, like acute pancreatitis and obstruction of the parotid gland. Decreased values are found in acute or chronic hepatocellular damages.

TEST PRINCIPLES

The Kit utilizes enzymatic and kinetic reactions to measure the AMY activity (U/L) in human serum or plasma. $CNPG_3$ is ultilized as a substrate and break down by the catalysis of amylase to CNP and CNP_2. The process is quantified by measuring the absorabances at 405 nm in a kinetic fashion.

$$10\ CNPG_3 \xrightarrow{\alpha\text{-amylase}} 9CNP + CNPG_2 + 9G_3$$

The rate of increase in absorbance at 405 nm is directly proportional to the AMY activity in the sample.

MATERIALS PROVIDED

Reagents:

R1	MES buffer, Ph6.0	100 mmol/L
	Calcium acetate	12 mmol/L
	CNP-G_3	1.8 mmol/L
	Potassium thiocyanate	900 mmol/L
	Sodium chloride	15 mmol/L

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer
2. AMY control and calibrator set (commercially available)

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. The reagent is stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum preventing hemolysis. **Do not use EDTA or citrate-treated plasma samples.** It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, specimens may be stored at 2-8℃ for 14 days.

TEST PROCEDURE (see Figure 1)

Reagent 1 is liquid stable ready-to-use, no preparation needed.

Calibration: Recommend using commercially available calibrator set for optimal results.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 5 µl of sample and 200 µl of R1; mix well and incubate at 37℃ for 1 minutes.
2. Take continuous optical density measurement for 1 minute.
3. Calculate average Δ A/min

RESULT

The AMY activity in U/L can be obtained by the following calculation:

$$AMY\ (U/L) = (\Delta A_{test}/\min - \Delta A_{blank}/\min) \times \text{factor (F)}$$

The calculation factor for UV spectrophotometer is 3178 when the optical path is 10 mm. Please refer to instrument application if testing under different conditions.

EXPECTED VALUES

≦220 U/L

It is recommended for each laboratory to establish its own expected values

QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

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LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. The test result from the Kit should not be used as the only basis for definite diagnosis.
3. Samples with AMY exceeding the maximum measurement range should be diluted with saline and retested.

PERFORMANCE CHARACTERISTICS

Linearity: 0 - 1000 U/L (R≥0.990)

Accuracy: control recovery relative deviation ≤ 10%

Precision: Within Run: CV≤4%;
Run-to-Run: CV≤5%

Reagent Blank Absorbance: at 405nm wavelength and 10 mm optical diameter, O.D. ≤ 0.6

REFERENCES

1. Makoto Otsuki *et al.*, Cancer, 39: 1656-1663 (1977).
2. Norman Ende, Cancer, 14:1109-1114 (1960)

Not Intended for Sale in the United States.

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