Amylase (Amyl)
(CNPG3/Kinetic Method)

- **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: **AY0011**	R.1: ٥ x ٢٥ ml total ١٠٥ ml	2-8°C
Cat. No.: **AY0017**	R.1: 5 x 20 ml total 100 ml	2-8°C

- **Intended Use:**
In Vitro Diagnostic reagent pack for the quantitative determination of Alfa amylase, Amylase in human serum/plasma and urine on automated and semi-automated photometric systems.

- **Summary and Explanation:**
Amylase is available in two forms type S or saliva and type P or pancreas. The most applicable of measuring this enzyme is to diagnosis and treatment all pancreas diseases such as acute pancreatitis, pancreatic failure and parotids with virus/ bacteria origin where the enzyme going high. The most amylase is going to be ward off by urine. The direct relation is existing on increase concentration of amylase in urine and serum. Although, the amylase in the urine is more stable. This enzyme is hydrolytic and convert the starch to maltose in human body. The amylase pancreatic produces in pancreas and release in the bowl. The saliva amylase produces in saliva glands and release in saliva. The amylase removed by kidney and ward off by urine. The amylase assay is not the especially for diagnostic the pancreas disease as in mumps and kidney failure the amylase goes high so further diagnostic such as lipase assay is recommended.

Principle of the Method:
This assay, Alfa amylase is catalyzing activity the Oligosaccharide such as 2-chloro-4-nitro Alfa maltorioside (CNPG3) to short chain oligosaccharides termed chloro-nitrophenol or CNP. The intensity of the color will have measured on 405 Nano meter wavelength which is correlate with the amount of Amylase on the sample.

CNPG3 → (Alfa amylase) → Chlorophenol-nitrophenol

- **Reagent Preparation and Stability:**
Reagents is ready for use.
Before use, mix reagent by gently inverting each bottle.
Reagent is stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.
Do not use reagents over the expiration date.
Do not freeze and protect from light.
The reagent is transparent and colorless.

Waste Management:
Refer to local legal requirements for chemical disposal regulations.
Warning: Handle waste as potentially biohazardous material.
Dispose of waste according to accepted laboratory instructions and procedures.

- **Warnings and Precautions:**
For In Vitro Diagnostics Use Only.
For Professional Use Only.
Carefully read instructions for use.
In case of serious damage to the bottle or cap, resulting in product leakage or contamination, do not use the reagent pack and contact your distributor.
Take all necessary precautions required when handling laboratory reagents.
Do not use components past the expiry date stated on the Bottles.
Do not interchange caps among components as contamination may occur and compromise test results. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.

- **Type of Specimen:**
Use Urine, fresh serum, non-hemolysis, plasma heparinized and/ or EDTA can be used. The stability of Amylase in the samples at 2-8°C for 30 days and at-20°C for 1 year. Should prevent to contaminated samples.
The serum and plasma should have collected during 8 hours after blood collection.
Be careful do not pipetting by mouth as the skin and mouth have this enzyme. The amylase stability in urine at 2-8°C for 10 days and at-20°C for 3 weeks.
The Amylase stability in Acidic urine is not stable. So the measurement should be done immediately or before storage the PH should be on around 7. avoid any sample contamination.

- **Required but not Supplied:**
General chemistry calibrator from TKS or other valid calibrators.
General chemistry control Level 1 & 2 from TKS or other valid controls.
Saline solution 0.9 % NaCl
General laboratory equipments

- **Notes:**
Carefully read instructions for use.
It is recommended to use disposable material. If glassware is used the material should be scrupulously cleaned with hydrochloric acid 1 N and then thoroughly rinsed it with distilled water.
Use clean disposable pipette tips for its dispensation.

- **Performance Characteristics:**
Performance results can vary with the instrument used.
Data obtained in each individual laboratory may differ from these values.

Maximum determination in this assay is 2200U/L
LOQ: 3 U/L
For samples with a higher concentration (2200U/L), dilute 1:2 with 0.9 % NaCl and re-assay. Multiply result by 3.

Precision:
Intra Assay-Within run Amylase

Sample	n	Mean (U/L)	SD (U/L)	CV (%)
1	20	77	1.12	1.45
2	20	194	2.22	1.15

Inter Assay-Between run Amylase

Sample	n	Mean (U/L)	SD (U/L)	CV (%)
1	20	77	1.08	1.39
2	20	197	2.96	1.50

- **Accuracy:**
Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).
Correlation coefficient (r): 0.986
Regression equation: Y = 0.746 (X) - 1.2697 U/L
The results of the performance characteristics depend on the analyzer used.

- **Interfering Substances:**
the less concentration of hemoglobin is interfering in this assay.

Bilirubin (mixed isomer)	Less than 10% interference up to 600 µmol/L Bilirubin
Lipaemia	Less than 10% interference up to 5 g/L Intralipid.

- **Reference Values:**

Serum/Plasma	**Up to 90 U/L**
Urine	**Up to 450U/L**

Each laboratory should establish its own expected values. The Amylase results should always be reviewed with the patient's medical examination and history.

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- **Assay Procedure:**

Allow reagents to reach working temperature before using.

A proportional variation of the reaction volumes indicated does not change the result

Assay conditions:

405nm	**Wavelengths**
37 °C	**Incubation Temperature**
1 cm	**Cuvette**

Adjust the instrument to zero with distilled water.

Control/Sample/Calibrator	**Blank**	
1000 µl	1000 µl	**R**
25 µl	-	**Control/Sample/Calibrator**
10 µl		**Urine**
Gently mix and incubate for 1 minute at 37°C. then measure the absorbance from sample and A calibrator. Turn on the counter 1, 2 and 3 minutes before start absorbance. **ΔOD/min**		

- **Calculations:**

ALP (U/L) = Abs. Sample/min x Cal.Conc. (U/L)

Abs. Calibrator/min

405nm = ΔA/min x 3954 in serum/plasma. 405nm = ΔA/min x 7908 in urine

If the urine collection done in (2.4.8.12.24) hours follow up the above calculation.

U/ x h = Amylase (U/L) x Volume (ml)

100

X = times of Urine collection

TOSE'E KIMIA SA'ADAT has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

- **References:**

1-Burtis CA. Ashwood ER. Tietz Fund of Clin.Chem. 5th ed.: 30-54. 327-378 and 964.

2-Tietz NW.ed Clinical Guide to Laboratory tests, 3rd ed. Philadelphia, PA: WB Saunders, 1995; 46-51.

3-Honenwallner W. Hagele EO, Scholer A et al. Ber Oster Ges Klin Chem. 1983;6:101-112.

4-Wootlon, I.D.P and Freeman, Microanalysis Medical Biochemistry (1982).

- **Symbols:**

The following symbols are used in the labelling of TOSE'E KIMIA SA'ADAT systems:

IVD	In Vitro Diagnostics		Contains sufficient for <n> tests
LOT	Batch Code		Temperature limit
REF	Catalogue No.		Consult instruction for use
	Expiry Date		Caution
	Date of Manufacture		Keep dry
	Manufactured by		This way up
	Biological Risks		Keep away from sunlight

ISO 13485:2016
ISO 9001:2015

IVD