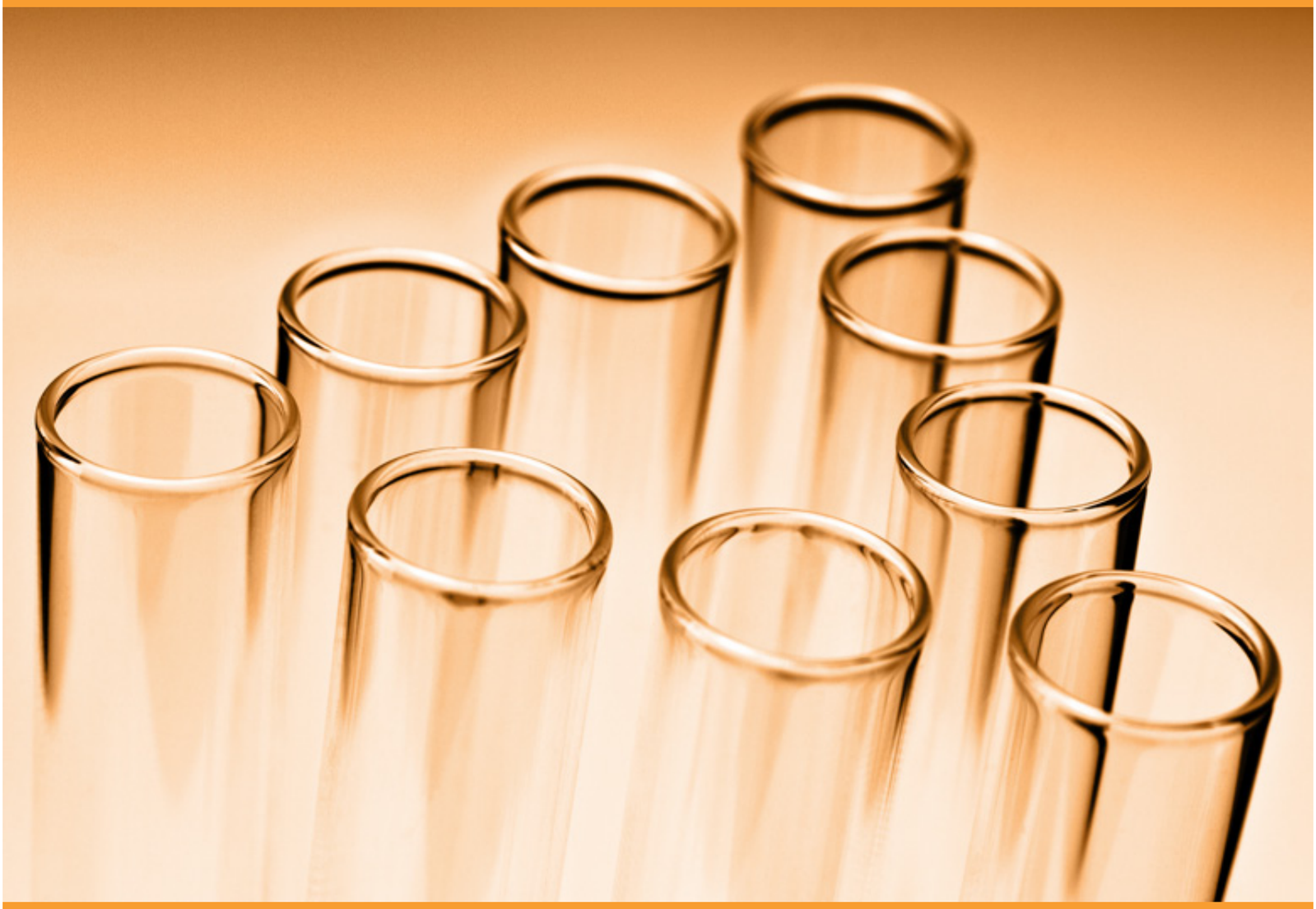
Trinity Biotech

YOUR DIAGNOSTICS PARTNER

POINT OF CARE | INFECTIOUS DISEASE | HAEMOGLOBINS | CLINICAL CHEMISTRY

Clinical Chemistry Catalogue



Angiotensin Converting Enzyme (ACE)

Angiotensin Converting Enzyme is a glycoprotein peptidlypeptide hydrolase.

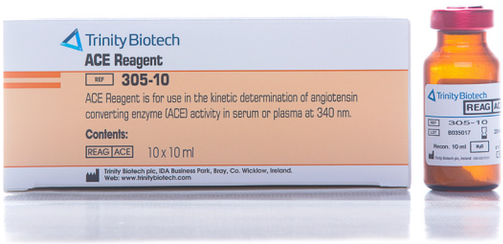
METHOD Ultraviolet, Kinetic

PRINCIPLE FAPGG $\xrightarrow{ACE}$ FAP + GG

Furylacryloylphenylalanylglycylglycine (FAPGG) is hydrolyzed to Furylacryloylphenylalanine (FAP) and glycylglycine (GG). Hydrolysis of FAPCGG results in a decrease in absorbance at 340 nm. The rate of decrease in absorbance at 340 nm is directly proportional to ACE activity in the sample.

DIAGNOSTIC IMPLICATIONS Elevated levels of ACE activity occur in serum of patients with active sarcoidosis, and occasionally in premature infants with respiratory distress syndrome, in adults with tuberculosis, leprosy and in many other pathologic conditions involving lung and liver diseases.

PRODUCT DESCRIPTION	PRODUCT NO.	QTY
ACE KIT (100 manual assays) Contents: ACE Reagent, 10x10mL	305-10	1 Kit
ACE CALIBRATOR Lyophilized preparation containing ACE in buffered human serum base For use with bichromatic analysers or other instruments that require calibration Reconstituted stability: 7 days at 2-8ºC	305-50	6x1 mL
ACE CONTROLS Angiotensin converting enzyme in a buffered human serum base with stabilisers and preservatives. Reconstituted stability: 7 days at 2-8ºC		
Normal	A6040	6x1 mL
Elevated	A7040	6x1 mL



Bile Acids

The test for serum bile acids will detect liver changes before the formation of more advanced clinical signs of illness. This early sensitivity is very important to the practitioner because it allows for the possibility of treatment before extensive and irreversible damage is done.

Bile Acids are indicators of a liver function. However, the test will not provide a definitive diagnosis of the primary problem, merely an early confirmation that there is a hepatobiliary deficiency.

There are a large number of diseases that can compromise hepatobiliary function in a primary or secondary manner.

METHOD Colormetric, Enzymatic

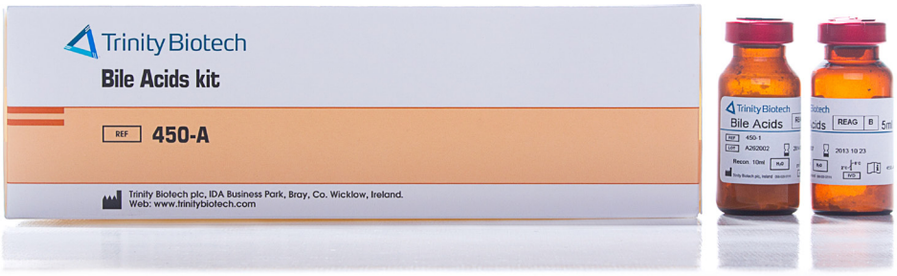
PRINCIPLE 3α -Hydroxybile Acids + NAD $\xrightarrow{3\alpha\ HSD}$ 3-Oxo Bile Acids + NADH

NADH + NBT $\xrightarrow{Diaphorase}$ NAD + Formazan

The intensity of the colour produced by the action of 3α -hydroxsteroid dehydrogenase (3α -HSD) and diaphorase is directly proportional to the bile acids concentration in sample.

DIAGNOSTIC IMPLICATIONS Liver diseases that can elevate bile acid levels include hepatic neoplasia, portosystemic shunt, hepatitis, bile duct obstruction, canine adenovirus, slowed gastrointestinal transit and almost any condition that causes a defect in hepatic uptake or portal circulation. Test results that appear low are usually due to normal variation or prolonged fasting, but can also indicate intestinal malabsorption or increased gastric motility. Normally, a small increase will be seen from the fasted to the post-prandial sample, however hepatobiliary disorders can cause elevated fasting and/or elevated post-prandial values.

PRODUCT DESCRIPTION	PRODUCT NO.	QTY
BILE ACIDS KIT (160 manual assays) Contents: Reagent A, 16x10 mL; Reagent B, 4x5 mL	450-A	1 Kit
BILE ACIDS STOP REAGENT (required for Bile Acids assay)	450-3	50 mL
BILE ACIDS REAGENT A	450-1-50	50 mL
BILE ACIDS REAGENT B	450-2 450-2-25	5 mL 25 mL
BILE ACIDS CALIBRATORS Liquid preparations of bile acids in calf serum. Sodium azide, 0.1% added as preservative Stable until expiration date after opening **Calibrator** 100µmol/L **Calibrator Set** 5x5mL Set contains 5 mL each at concentrations of 5, 25, 50, 100 and 200 µmol/L	 450-100 450-11	 5 mL 1 Set
BILE ACIDS CONTROLS Liquid preparations of bile acids in calf serum. Sodium azide, 0.1% added as preservative Set contains 3x5 mL each of a normal and abnormal level Stable until expiration date after opening (2-8ºC)	450-22	1 Set



Cholesterol

Blood total cholesterol levels have long been known to be related to coronary heart disease (CHD). Total Cholesterol count is composed of LDL, HDL, along with triglycerides and Lp(a) cholesterol.

HDL (High Density Lipoprotein) EZ LDL™ Homogeneous Method

High Density Lipoprotein Cholesterol (HDL-C) has become an important tool used to assess an individual's risk of developing CHD since a strong negative relationship between HDL-C concentration and the incidence of CHD has been reported. Most clinical laboratories routinely perform HDL-C analysis. The Trinity Biotech EZ HDL Cholesterol test employs the use of a specific antibody, and thus, can be applied on automated analysers.

METHOD Colormetric, immunological procedure for automated analysers.

PRINCIPLE Anti-human ß-lipoprotien antibody binds to lipoproteins (LDL, VLDL and chylomicrons) other than HDL cholesterol (HDL-C). The antigen-antibody complexes formed block enzyme reactions when the enzymatic cholesterol reagent is added. Cholesterol esterase and cholesterol oxidase react only with HDL-C. Hydrogen peroxide produced by the enzyme reactions with HDL-C yields a blue colour complex upon oxidase consideration with FDAOS (N-ethyl-N-2hydroxy-3-sulfopropyl)-3, 5-dimethoxy, 4-Fluoroanaline sodium salt and 4-aminoantipyrine in the presence of peroxidase. By measuring the absorbance of the blue colour complex produced at approximately 600 nm, the HDL-C concentration in the sample can be calculated when compared when the absorbance on the calibrator.

DIAGNOSTIC IMPLICATIONS About one-fourth to one-third of blood cholesterol is carried by high-density lipoprotein (HDL). HDL cholesterol is known as 'good' cholesterol, because high levels of HDL seem to protect against heart attack. Low levels of HDL (less than 40 mg/dL) also increase the risk of heart disease. Medical experts think that HDL tends to carry cholesterol away from the arteries and back to the liver, where it is passed from the body. Some experts believe that HDL removes excess cholesterol from arterial plaque, thus slowing its build up.

PRODUCT DESCRIPTION	PRODUCT NO.	QTY
EZ HDL KIT (444 assays*) Contents: Reagent 1, 2x60 mL; Reagent 2, 2x20 mL	354LB	1 Kit

*An assay is defined as 270µL of Reagent 1 + 90µL of Reagent 2 + 3 µL of sample. Maximum assays will vary by instrument application.

Glucose-6-Phosphate Dehydrogenase (G-6-PDH)

This X-linked disorder is the most common type of haemolytic anaemia due to an intrinsic red cell enzyme defect.
Males who inherit an abnormal gene are invariably affected. Heterozygote females usually have approximately 50% G6PD enzyme activity;
the random Lyonisation of X chromosomes means that rarely carrier females may be severely affected. It is most common in the Mediterranean,
the Middle East, South East Asia and West Africa. It is rare among Caucasians.

DIAGNOSTIC IMPLICATIONS Presentation is usually with an acute episode of intravascular haemolysis on exposure to certain drugs, infection or acute illness. Mediterranean forms may present with neonatal jaundice. The condition is also known as favism as sudden haemolysis may be precipitated by the ingestion of fava beans – Vicia faba. The deficiency is generally less severe in Africans and favism is rare in this population.

G-6-PDH

METHOD Ultraviolet, Kinetic (quantitative)

PRINCIPLE Glucose-6-phosphate + NADP + $\xrightarrow{\text{G-6-PDH}}$ 6-PG + NADPH + H^+

The rate of formation of NADPH is proportional to the G-6-PDH activity is measured spectrophotometrically as an increase in absorbance at 340nm.

PRODUCT DESCRIPTION	PRODUCT NO.	QTY
G-6-PDH KIT (20 manual assays) Contents: G-6-PDH Reagent, 20 x 1 mL single-assay vials; G-6-PDH Substrate, 50 mL	345-A	1 Kit
G-6-PDH KIT (50 assays) Contents: G-6-PDH Reagent, 10 x 5.5 mL assay vials; G-6-PDH Substrate, 2x50 mL	345-B	1 Kit
RED CELL LYSING REAGENT (For discrete analyzer applications)	R1129	4x25 mL

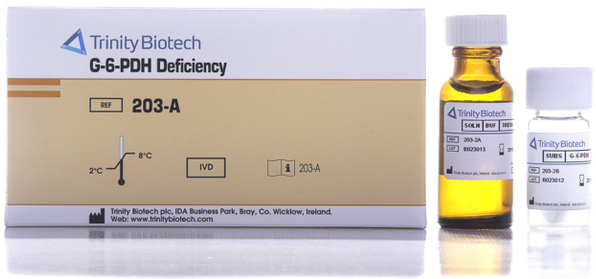
G-6-PDH Deficiency Screen by Spot Test

METHOD Spot Test, Visual Fluorescence (qualitative)

PRINCIPLE Glucose-6-phosphate + NADP (Not Fluorescent) $\xrightarrow{\text{G-6-PDH}}$ 6-Phosphogluconate+ NADPH (Fluorescent)

The reaction mixture containing glucose -6-phosphate+NADP (Not Fluorescent) and blood is incubated and, at timed intervals, drops of the mixture are applied to filter paper. The spots are visually inspected under long-wavelength (320-420nm) ultraviolet light. The observed rate of appearance of bright Fluorescence is proportional to the blood G-6-PDH activity.

PRODUCT DESCRIPTION	PRODUCT NO.	QTY
G-6-PDH DEFICIENCY SCREEN KIT (50 manual assays) Contents: TRIZMA® Buffer, 12 mL; G-6-PDH Screening Substrate, 5 vials	203-A	1 Kit



G-6-PDH Deficiency Screen by Dye Reduction

METHOD Dye Reduction, Visual Colour (qualitative)

PRINCIPLE Glucose-6-phosphate + NADP + $\xrightarrow{\text{G-6-PDH}}$ + 6-Phosphogluconate + NADPH

NADPH + Blue Dye $\xrightarrow{\text{PMS}}$ + NADP - Colourless Dye Complex

The rate at which the colour visually disappears in the reaction mixture is proportional to the G-6-PDH content of red cells.

PRODUCT DESCRIPTION	PRODUCT NO.	QTY
G-6-PDH DEFICIENCY SCREEN KIT (100 manual assays) Contents: G-6-PDH Substrate, 20 vials with 5 assays per vial; TRIZMA® Buffer, 50 mL; Mineral Oil, 2x100 mL	400K-100-5x20	1 Kit
G-6-PDH DEFICIENCY SCREEN KIT (100 manual assays) Contents: G-6-PDH Substrate, 10 vials with 10 assays per vial; TRIZMA® Buffer, 50 mL; Mineral Oil, 2x100 mL	400K-100X	1 Kit
G-6-PDH SUBSTRATE (10-Assay Vial)	400-10x10	10 Vials
G-6-PDH SUBSTRATE (5-Assay Vial)	400-5x10	10 Vials
TRIZMA® Buffer Solution, 0.3 mol/L, pH 8.5, 37°C	400-4-25 400-4-50	25 mL 50 mL
MINERAL OIL	400-5-1000	1L

G-6-PDH Controls

Lyophilized control containing G-6-PDH in a stablised human red cell hemolysate.

PRODUCT DESCRIPTION	PRODUCT NO.	QTY
G-6-PDH DEFICIENT CONTROL	G5888	6x0.5 mL
G-6-PDH INTERMEDIATE CONTROL	G5029	6x0.5 mL
G-6-PDH NORMAL CONTROL	G6888	6x0.5 mL

(Applications are available for most analyzers.)

Lactate

Lactic Acid is a by-product of carbohydrate metabolism. Blood lactate arises primarily from muscle cells and erthrocytes and is metabolised by the liver. Therefore, blood lactate levels reflect both production and metabolism.

METHOD Enzymatic, Colourimetric

PRINCIPLE Lactic acid is converted to pyruvate and the H_2O_2 (Hydrogen Peroxide) by lactate oxidase. In the presence of the H_2O_2 formed, peroxidase catalyzes the oxidative condensation of chromogen precursors to produce a coloured dye with an absorption maximum at 540 nm. The increase in absorbance at 540 nm is directly proportional to lactate concentration in the sample.

DIAGNOSTIC IMPLICATIONS Normal lactate acid levels are 4.5-19.8 mg/dL. Elevated lactate acid levels can result from severe oxygen deprivation leading to 'lactic acidosis' characterised by weakness, stupor, fatigue and coma. Lactate measurement can also be useful clinically in the diagnosis of angina pectoris or in liver function testing where reduced liver function is suspected.

PRODUCT DESCRIPTION	PRODUCT NO.	QTY
LACTATE KIT Content: Lactate Reagent, 10x10 mL	735-10	1 Kit
LACTATE STANDARD SOLUTION Aqueous solutions of L(+) Lactate 40 mg/dL Sodium azide, 0.1% added as preservative 40 mg/dL (reagent also required for procedure)	826-10	10 mL
LACTATE STANDARD SET Contents: 2x5 mL each of aqueous standards containing lactate at concentrations of 20, 80 and 120 mg/dL	735-11	1 Set

Lipase-PS™

The measurement of serum lipase activity is widely used for the diagnosis of acute pancreatitis.

METHOD Kinetic, Enzymatic

PRINCIPLE

$$\text{1, 2-Diglyceride} \xrightarrow{\text{Pancreatic Lipase}} \text{2-Monoglyceride + Fatty Acid}$$

$$\text{1, 2-Monoglyceride} \xrightarrow{\text{Monoglyceride Lipase}} \text{Glycerol + Fatty Acid}$$

$$\text{Glycerol + ATP} \xrightarrow{\text{Glycerol Kinase}} \text{G-3-P + ADP}$$

$$\text{G-3-P + } O_2 \xrightarrow{\text{GPO}} \text{Dihydroxyacetone Phosphate + } H_2O_2$$

$$2H_2O_2 + \text{4-Aminoantipyrine + TOOS*} \xrightarrow{\text{POD}} \text{Quinone + } 4H_2O$$
Diimine Dye

The rate of increase in absorbance at 550 nm due to the formation of quinone diimine dye is directly proportional to the lipase activity in the sample.

*N-Ethyl-N-(2-hydroxy-3-sulfopropyl)-m-toluidine

DIAGNOSTIC IMPLICATIONS A 10-fold increase of lipase activity above the upper reference limit is suggestive of pancreatitis, pancreatic injury, or inflammation of organs contiguous to the pancreas. It is recommended that other tests, such as trypsinogen and amylase isoenzymes be performed to supplement the diagnosis.

PRODUCT DESCRIPTION	PRODUCT NO.	QTY
LIPASE-PS™ (166 assays*) Contents: Substrate Reagent, 3 x 10mL; Substrate Diluent, 30mL; Activator Reagent, 10 mL; Activator Standard, 3 mL.	805A	1 Kit

*Hitachi® 717/911, Olympus® AU800. Maximum assays are instrument-dependent.

Oxalate

Oxalate was confirmed as a normal constituent of urine in 1951, but only recently has the significance of calcium oxalate crystalluria and its relationship to urinary tract stone formation been fully recognised. Formation of the sparingly soluble calcium salt of oxalate in the urinary tract is considered the major factor in urolithiasis.

METHOD Enzymatic, Colormetric, Endpoint

PRINCIPLE $\text{Oxalate} + O_2 \xrightarrow{\text{Oxalate Oxidise}} 2CO_2 + H_2O_2$

$H_2O_2 + \text{MBTH} + \text{DMAB} \xrightarrow{\text{Peroxidase}} \text{Indamine Dye } H_2O$

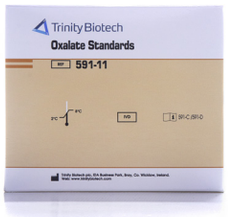
Indamine dye has an absorbance maximum of 590nm. The intensity of the colour produced is directly proportional to the concentration of Oxalate in the sample.

DIAGNOSTIC IMPLICATIONS A decreased excretion of oxalate in the urine is associated with hyperglycinemia or hyperglycinuria.

An Increased excretion of oxalate in the urine can be attributed to:

- Increases in ingestion of oxalate precursors or oxalate rich foods.
- Formation of oxalate due to metabolic defects such as in primary hyperoxaluria.
- Absorption of oxalate in a number of gastrointestinal disorders that produce severe fat malabsorption. This is indicative of patients with inflammatory bowel disease, ideal resection, biliary diversion, pancreatic insufficiency, small intestinal stasis with bacterial overgrowth, and following jejunoileal bypass or resection for the treatment of obesity.

PRODUCT DESCRIPTION	PRODUCT NO.	QTY
OXALATE KIT (20 manual assays) Contents: Oxalate Reagent A, 2x10 mL; Oxalate Reagent B, 2 mL; Sample Diluent,100 mL; Sample Purifier Tubes, 20	591- C	1 Kit
OXALATE KIT (100 manual assays) Contents: Oxalate Reagent A, 10x10 mL; Oxalate Reagent B, 5x2 mL; Sample Diluent, 5x100 mL; Sample Purifier Tubes, 100	591- D	1 Kit
OXALATE REAGENT A	591-10	10 mL
OXALATE REAGENT B	591- 2	2 mL
SAMPLE DILUENT	591-4	100 mL
SAMPLE PURIFIER TUBES Premeasured centrifuge tubes containing activated charcoal	591-20 591-100	20 Tubes 100 Tubes
OXALATE STANDARDS Aqueous solutions of oxalate in 0.1% benzoic acid **Standard:** 0.50 mmol/L **Set:** Contents: 2 x 25mL each of solutions with concentrations of 0.25, 0.50 and 1.0 mmol/L	 591-3 591-11	 25mL 1 Set
OXALATE URINE CONTROLS Lyophilized human urine preparations containing assayed levels of oxalate Reconstituted stability: 2 days at 2-8ºC and 4 weeks frozen **Elevated** **Normal**	 0 6502 0 6627	 6x5 mL 6x5 mL



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