Calcium (OCPC) Kit
CliniQuant – FSR
OCPC Method, End Point

Meril Diagnostics

For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 Calcium AMP Reagent	R2 Calcium OCPC Reagent	R3 Calcium Standard	Plastic Test Tube
CAOFSR-01	2x 25ml	1 x 25ml	1 x 25ml	1 x 5ml	10 Nos.

INTENDED USE
This reagent is intended for quantitative determination of calcium concentration in human serum or plasma.

CLINICAL SIGNIFICANCE
In human body, circulating calcium is used for several functions, in skeletal metabolism as well as in neuromuscular function and in hemostasis. Serum calcium is affected by mal-absorption, parathyroidal problems, bones disease, circulating albumin diseases.

Typical variations:

Greater than normal levels in hyperparathyroidism, metastatic bone tumor, milk – alkali syndrome, multiple myeloma, Paget' s disease, sarcoidosis, vitD intoxication;

Lower than normal levels in hypoparathyroidism, malabsorption, osteomalacia, pancreatitis, renal failure, vitD deficiency.

The amount of calcium excreted into the urine reflects intestinal absorption, skeletal resorption, and renal tubular filtration and reabsorption. Under fasting conditions, the intestinal and renal components are relatively fixed and calcium excretion (mg/dl of glomerular filtrate) in the fasting state is used to assess the skeletal components.

PRINCIPLE OF THE METHOD
o-cresolphtalein complexone combines with calcium at alkaline pH to form a purple color complex, the absorbance of which is measured at 578 nm.

Calcium cresolphthalein complexone $\xrightarrow{\text{Alkaline pH}}$ purple complex

KIT COMPONENTS
Composition:

R1 - Calcium AMP Reagent : AMP 1 mol/l, Surfactant

R2 - Calcium OCPC Reagent : 8-Hydoxy Quinoline 13.77 mmol/l, OCPC 0.117 mmol/l, Surfactant, HCl 79.45 mmol/l ,

R3 - Calcium Standard : 10 mg/dl, Calcium Carbonate 0.25 g/l

4 - Plastic test tube

MATERIALS REQUIRED BUT NOT PROVIDED
Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/ rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY
All reagents are ready to use and are stable till the expiry date mentioned on the bottle label at 2-8 °C.

REAGENT DETERIORATION
1. Discard the reagent if absorbance exceeds 0.50 against distilled water.
2. Keep the Standard vial plugged after use, in order to avoid deterioration.

WARNINGS AND PRECAUTIONS
1. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Care must be taken to avoid calcium contamination. The use of plastic tubes or cuvettes free from calcium contamination is strongly recommended. Glassware used be soaked in dilute HCl or dilute HNO3 and thoroughly rinsed with distilled water.
4. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN
Serum (preferred), plasma (heparinate). Venostasis should be avoided in specimen collection. Samples are stable for 7 days at 2-8 °C & 6 months when frozen.

Urine specimen should be collected in 20 to 30 ml of HCl 6M per 24/h specimen (1-2 ml for random urine) in order to prevent calcium salt precipitation.

Dilute sample urine 1:2 with distilled water and multiply results by two.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	End Point
Standard Conc.	10 (mg/dl)
Filter – 1 (nm)	578
Filter – 2 (nm)	670
Temperature	37 °C
Volume (µl)	500

CE
Meril Diagnostics Pvt. Ltd., Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India. T+91-260-3052100, F +91-260-3052125, W www.merillife.com
EC REP Obelis s.a., Bd General Wahis 53, 1030, Brussels, Belgium. T +(32) 2 732-59-54, F +(32) 2 732-60-03, E mail@obelis.net

Reaction Direction	Increase
Reference Low	8.4
Reference High	10.4
Linearity Limit	20

TEST PROCEDURE

Dispense	Blank	Standard	Sample
Reagent 1	0.5ml	0.5ml	0.5ml
Reagent 2	0.5ml	0.5ml	0.5ml
Distilled water	10 µl	-	-
Standard	-	10 µl	-
Sample	-	-	10 µl
Mix, incubate for 1 min at 37°C. Read absorbance of standard (As) and samples (Ax) against reagent blank.			

RESULT CALCULATION

Serum/plasma:

Calcium mg/dl = Ax/As x Concentration of Standard

Urine sample:

Calcium mg/dl = Ax/As x Concentration of Standard x 2

24 hours urine sample:

Calcium mg/24h = Ax/As x Concentration of Standard x 2 x urine volume

SI conversion factor: 1 mg/dl x 0.25= 1 mmol/l

EXPECTED VALUES

Serum/plasma: 8.4 – 10.4 mg/dl	OR	2.1 – 2.6 mmol/l
Urine (men): up to 300 mg/24h	OR	7.49 mmol/24h
Urine (women): up to 250 mg/24h	OR	6.25 mmol/24h

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended Calibrator (BioCal) or the Standard included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

The linearity is up to 20 mg/dl or 5 mmol/l.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 0.1 mg/dl.

The limit of quantification is 0.3 mg/dl.

3. Interferences

Gross hemolysis and lipaemia may cause falsely elevated results, a sample blank be set by adding 10 µl sample in 1ml saline.

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	mg/dl	mg/dl	%
sample 1	7.65	0.02	0.32
sample 2	11.88	0.03	0.29

Inter-assay precision

	Mean	SD	CV
n = 20	mg/dl	mg/dl	%
sample 1	8.05	0.50	6.2
sample 2	12.47	0.64	5.1

5. Methods Comparison

Comparison was done between reference Calcium Reagent and CliniQuant - FSR Calcium OCPC Reagent (test)

N = 24 y = 1.303x - 0.569

r^2 = 0.88

LIMITATIONS

Samples with values above 20 mg/dl should be diluted with 0.9% saline, re-run and results multiplied by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 1887 - 1906.

2. Data on file: Meril Diagnostics.

IFU/CAOFSR01/01

05-12-2018

Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged
EC REP	Authorized European Representative in the European Community		