PARATHYROID HORMONE CONTROL - LEVEL 3 (PTH CONTROL 3)

Cat. No. PTH10112 **Lot No.** 019PTH
Size: 3 x 3 ml **Expiry:** 2018-01

INTENDED USE
This product is intended for *in vitro* diagnostic use, in the quality control of Parathyroid Hormone on immunoassay systems. This material can be used to monitor the control of accuracy or the control of reproducibility of Parathyroid Hormone.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.
However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY
OPENED: Store refrigerated (+2°C to + 8°C). Thawed serum is stable for 30 days at +2°C to +8°C, if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store frozen at –20°C to –70°C. Stable to expiration date printed on individual vials.

Bacterial contamination of thawed serum may cause a reduction in stability. If bacterial contamination is suspected, the vial should be discarded and a fresh vial used.

PREPARATION
The Parathyroid Hormone Control is supplied liquid frozen.
1. Allow the frozen control to thaw at room temperature (+15°C to +25°C) until completely thawed. Swirl the contents to ensure homogeneity. Do not shake.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED
Parathyroid Hormone Control - Level 3: 3 x 3 ml

MATERIAL REQUIRED BUT NOT PROVIDED
None

VALUE ASSIGNMENT
Each batch of Parathyroid Hormone Control is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories and internal testing conducted at Randox Laboratories Ltd. With each batch, a control range is provided for individual method. The control range is equivalent to the assigned mean ±2 S.D.

Analyte	Unit	Target	Low	High	Method
Parathyroid Hormone (PTH)	pmol/l	48.8	36.6	61.0	Roche Cobas E-411
	pg/ml	463	347	579	
	pmol/l	65.8	49.4	82.2	Siemens Advia Centaur
	pg/ml	625	469	781	
	pmol/l	143	107	179	Siemens Immulite 2000/2500
	pg/ml	1358	1019	1697	

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

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