BECKMAN COULTER

CE 2797

IRMA PTH

Instruction for use in local language is available at beckmancoulter.com/techdocs.

REVISION HISTORY

Previous version: PI-A11930-B89461-08	**Current version:** IFU-A11930-B89461-01
—	IVDR requirements incorporated
Chapter INTENDED USE removed	Chapter INTENDED PURPOSE added
—	Chapter APPENDIX: Interference data added

REF A11930, B89461

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

IRMA PTH is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of parathyroid hormone (PTH) in human serum and plasma. Measurement of parathyroid hormone is intended to be used for the differential diagnosis of hypercalcemia and hypocalcemia in general population [1, 2, 3, 4].

PRINCIPLE

The immunoradiometric assay of PTH is a two-step sandwich-type assay. Two antibodies directed against two different epitopes of PTH and hence not competing are used. Samples or calibrators are first incubated in tubes coated with the first polyclonal antibody. After the first incubation, the contents of the tubes are aspirated and the presence of PTH in the sample is revealed by incubation with a second, ^{125}I-labeled monoclonal antibody. The contents of the tubes are rinsed so as to remove unbound ^{125}I-labeled antibody. The bound radioactivity is then determined in a gamma counter. The PTH concentrations in the samples are obtained by interpolation from the standard curve. The concentration of PTH in the samples is directly proportional to the radioactivity.

WARNING AND PRECAUTIONS

General remarks:

- The vials with calibrators and controls should be opened as shortly as possible to avoid excessive evaporation.
- Do not mix the reagents from kits of different lots.
- A standard curve must be established with each assay.
- It is recommended to perform the assay in duplicate.
- Each tube must be used only once.

Basic rules of radiation safety

The purchase, possession, utilization, and transfer of radioactive material is subject to the regulations of the country of use. Adherence to the basic rules of radiation safety should provide adequate protection:

- No eating, drinking, smoking or application of cosmetics should be carried out in the presence of radioactive materials.
- No pipetting of radioactive solutions by mouth.
- Avoid all contact with radioactive materials by using gloves and laboratory overalls.
- All manipulation of radioactive substances should be done in an appropriate place, distant from corridors and other busy places.
- Radioactive materials should be stored in the container provided in a designated area.
- A record of receipt and storage of all radioactive products should be kept up to date.
- Laboratory equipment and glassware which are subject to contamination should be segregated to prevent cross-contamination of different radioisotopes.
- Each case of radioactive contamination or loss of radioactive material should be resolved according to established procedures.
- Radioactive waste should be handled according to the rules established in the country of use.

Sodium azide

Some reagents contain sodium azide as a preservative. Sodium azide can react with lead, copper or brass to form explosive metal azides. Sodium azide disposal must be in accordance with appropriate local regulations.

Materials of human origin

The materials of human origin, contained in this kit, were found negative for the presence of antibodies to HIV 1 and HIV 2, antibodies to HCV, as well as of Hepatitis B surface antigen (HBsAg). However, they should be handled as if capable of transmitting disease. No known test method can offer total assurance that no virus is present. Handle this kit with all necessary precautions.

All patient specimens should be handled as potentially infectious and waste should be discarded according to the country rules.

GHS HAZARD CLASSIFICATION

Tracer	WARNING	
	H316	Causes mild skin irritation.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
		Sodium Hydroxide < 1%
Wash Solution U (20x)	DANGER	
		
	H360	May damage fertility or the unborn child.
	P201	Obtain special instructions before use.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P308+P313	IF exposed or concerned: Get medical advice/attention.
		Boric Acid 0.1 - 0.3%
		Sodium Borate Decahydrate 0.1 - 0.3%

SDS Safety Data Sheet is available at beckmancoulter.com/techdocs

SPECIMEN COLLECTION, PROCESSING, STORAGE AND DILUTION

- Serum or EDTA plasma are the recommended sample types.
- Allow serum samples to clot completely before centrifugation.
- Serum and plasma samples may be stored at 2-8°C, if the assay is to be performed within 12 hours. For longer storage keep frozen (at < -18°C, 6 months maximum), after aliquoting so as to avoid repeated freezing and thawing. Thawing of sample should be performed at room temperature.
- If samples have concentrations greater than the highest calibrator, they must be diluted in the zero calibrator.

Serum and EDTA plasma values for 15 samples (serum values ranging from 261.2 to 2,083 pg/mL) were compared using the A11930 IRMA PTH. Results are as follows:

[EDTA-plasma] = 0.9742 [serum] + 29.023, R = 0.9950

MATERIALS PROVIDED

All reagents of the kit are stable until the expiry date indicated on the kit label, if stored at 2-8°C. Expiry dates printed on vial labels apply to the long-term storage of components by the manufacturer only, prior to assembly of the kit. Do not take into account.

Storage conditions for reagents after reconstitution or dilution are indicated in paragraph Procedure.

Kit for determination of PTH, 100 tubes (REF. A11930)

Tubes: 2 x 50 tubes (ready-to-use)

^{125}I-Tracer: one 11 mL vial (ready-to-use)

The vial contains 855 kBq, at the date of manufacture, of ^{125}I-labeled immunoglobulins in liquid form containing bovine serum albumin, sodium azide (<0.1%), and a dye.

Calibrators: five vials (lyophilized) **and one 5 mL vial of «zero» calibrator** (ready-to-use)

The vials contain from 0 to approximately 2,500 pg/mL of PTH in buffer with bovine serum albumin and preservatives. The exact concentration is indicated on each vial label. The calibrators are traceable to an internal reference standard.

Control samples: two vials (lyophilized)

The vials contain PTH lyophilized in buffer with bovine serum albumin and preservatives. The concentration range is indicated on a supplement. The control samples are traceable to an internal reference standard.

Wash solution U (20X): one 50 mL vial

Concentrated solution has to be diluted before use. It may be ordered separately, too (REF. A54825).

Kit for determination of PTH, 50 tubes (REF. B89461)

Tubes: 1 x 50 tubes (ready-to-use)

^{125}I-Tracer: one 11 mL vial (ready-to-use)

Calibrators: five vials (lyophilized) **and one 5 mL vial of «zero» calibrator** (ready-to-use)

Control samples: two vials (lyophilized)

Wash solution U (20X): one 50 mL vial

MATERIALS REQUIRED, BUT NOT PROVIDED

In addition to standard laboratory equipment, the following items are required:

- Precision micropipette (200 µL).
- Semi-automatic pipette (100 µL, 2 mL).
- Vortex type mixer.
- Horizontal or orbital shaker.
- Aspiration system.
- Gamma counter set for ^{125}I.

PROCEDURE

Preparation of reagents

Let all the reagents come to room temperature.

Reconstitution of calibrators and control samples

The content of the vials is reconstituted with the volume of distilled water indicated on the vial label. Wait at least 10 minutes and mix gently to avoid foaming before dispensing. Store the reconstituted solutions frozen below -18°C until the expiry date of the kit. Do not repeat freezing and thawing more than 3 times.

Preparation of wash solution

Pour the content of the vial into 950 mL of distilled water and homogenize. The diluted solution may be stored at 2-8°C until the expiry date of the kit.

Assay procedure

Step 1 Additions	Step 2 1st incubation
To coated tubes, add successively: 200 µL of calibrator, control or sample. Vortex gently 1-2 seconds.	Incubate 45 minutes at 18-25°C with shaking (≥ 280 rpm). Aspirate carefully the content of each tube.

Step 3 2nd incubation	Step 4 Counting
Add 100 µL of tracer to all tubes.* Vortex gently 1-2 seconds. Incubate 2 hours at 18-25°C with shaking (≥ 280 rpm).	Aspirate carefully the content of tubes (except of the 2 tubes «total cpm»). Wash twice with 2 mL of wash solution. Count bound cpm (B) and total cpm (T) for 1 minute.

*Add 100 µL of tracer to 2 additional tubes to obtain total cpm.

RESULTS

Results are obtained from the calibrator curve by interpolation. The curve serves for the determination of analyte concentrations in samples measured at the same time as the calibrators.

Standard curve

The results in the quality control department were calculated using *spline* curve fit with log of determined radioactivity *(cpm_{cal}-cpm_{cal0})* or *B/T* **after subtraction of Blank** on the vertical axis and log of analyte concentration of the calibrators on the horizontal axis.

Other calculation methods may give slightly different results.

Total activity: 324,854 cpm				
Calibrators	**PTH (pg/mL)**	**cpm (n=3)**	**B/T (%)**	**$cpm_{cal} - cpm_{cal0}$**
0	0	539	-	-
1	17.0	1,553	0.31	1,014
2	42.0	2,747	0.68	2,208
3	152	9,111	2.64	8,572
4	647	36,145	11.0	35,606
5	2,621	121,964	37.4	121,425

(Example of standard curve, do not use for calculation)

Samples

For each sample, locate cpm (cpm_{sample} - cpm_{cal0}) or B/T **after subtraction of Blank** on the vertical axis and read off the corresponding analyte concentration on the horizontal axis.

EXPECTED VALUES

We recommend each laboratory to establish its own reference values. The following values, obtained on blood donor samples containing at least 25 ng/mL of 25-OH Vitamin D, are indicative only.

	N	Min.	Max.	Median	2.5th percentile	97.5th percentile
PTH (pg/mL)	97	< 4.89	85.76	32.61	6.87	64.87

QUALITY CONTROL

Good laboratory practices imply that control samples be used regularly to ensure the quality of the results obtained. These samples must be processed exactly in the same way as the assay samples, and it is recommended that their results be analyzed using appropriate statistical methods.

Failure to obtain the appropriate values for controls may indicate imprecise manipulations, improper sample handling or deterioration of reagents.

In case of packaging deterioration or if data obtained show some performance alteration, please contact your local distributor or use the following e-mail address: imunochem@beckman.com

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of EU Member State in which the user and/or patient is located.

PERFORMANCE CHARACTERISTICS

(For more details, see the data sheet "APPENDIX")

Representative data are provided for illustration only. Performance obtained in individual laboratories may vary.

Sensitivity

Analytical sensitivity: 4.89 pg/mL

Functional sensitivity: 13.68 pg/mL

Specificity

The antibodies used in the immunoassay are highly specific for the intact PTH. Extremely low cross reactivities were obtained against several fragments (1-34; 53-84; 46-68).

Precision

Intra-assay

Serum samples were assayed 25 times in the same series. The coefficients of variation were found below or equal to 9.8%.

Inter-assay

Serum samples were assayed in duplicate in 10 different series. Coefficients of variation were found below or equal to 11.1%.

Accuracy

Dilution test

High-concentration serum samples were serially diluted with the zero calibrator. The recovery percentages obtained were between 86.3% and 102%.

Recovery test

Low-concentration serum samples were spiked with known quantities of PTH. The recovery percentages obtained were between 87.9% and 118%.

Measurement range (from analytical sensitivity to the highest calibrator): 4.89 to approximately 2,500 pg/mL.

LIMITATIONS

Failure to follow these instructions for use (IFU) may significantly affect results.

Results should be interpreted in the light of the total clinical presentation of the patient, including clinical history, data from additional tests and other appropriate information.

Do not use hemolyzed, lipemic or icteric samples. For more details, see Appendix, § Interference.

For assays employing antibodies, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interfere with immunoassays. Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies [5,6].

"Hook effect": there is no hook effect, when the two-step procedure is used [7].

APPENDIX

PERFORMANCE CHARACTERISTICS

Representative data are provided for illustration only. Performance obtained in individual laboratories may vary.

Interference

Serum samples containing PTH concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using IRMA PTH. Values were calculated as described in CLSI EP07, 3rd ed. [8]. Interference was determined by testing controls (no interfering substance added) and matched test samples (with interfering substance added). No interference (defined as a shift in dose > 15 %) was found for addition of interferent up to concentration stated in the table below.

Interferent	Test concentration
Biotin	1,639 ng/mL
Conjugated bilirubin	483.0 µg/mL
Hemoglobin	10,541 µg/mL
Triglycerides	7.7 mg/mL
Unconjugated bilirubin	533.4 µg/mL

In spite of hemoglobin, bilirubin (conjugated, unconjugated) and triglyceride interference data in the table, we advise to avoid using hemolyzed, lipemic or icteric samples.

Specificity

Cross-reactivity of the assay was determined by measuring the equivalents of PTH given by high concentrations of related molecules in the absence of PTH.

These assays were done with zero calibrator to which the related molecules had been added.

Related molecules	Concentration of related molecules (pg/mL)	Measured PTH concentration (pg/mL)
PTH 1-34	6,250	0
PTH 53-84	25,000	0
PTH 46-68	100,000	0

Precision

Intra-assay

Serum	S1	S2	S3
Number of determinations	25	25	25
Mean (pg/mL)	37.51	508.0	1,044
C.V., (%)	9.79	3.35	2.51

EDTA plasma	P1	P2	P3
Number of determinations	25	25	25
Mean (pg/mL)	46.15	522.1	1,199
C.V., (%)	13.31	2.71	2.69

Inter-assay

Serum	S1	S2	S3
Number of determinations	10	10	10
Mean (pg/mL)	25.09	218.1	1,326
C.V., (%)	6.35	5.55	11.07

EDTA plasma	P1	P2	P3
Number of determinations	10	10	10
Mean (pg/mL)	43.40	499.1	1,147
C.V., (%)	11.74	3.17	2.86

Accuracy

Dilution test

Samples were diluted in zero calibrator and assayed according to the assay procedure of the kit.

Serum	Dilution factor	Measured (pg/mL)	Expected (pg/mL)	Ratio (%) Measured/ Expected
S1	-	1,445	-	-
	1:2	719.2	722.7	99.51
	1:4	346.9	361.3	99.00
	1:8	159.4	180.7	88.24
	1:16	83.49	90.33	92.42
	1:32	45.20	45.17	100.1
S2	-	1,265	-	-
	1:2	616.8	632.6	97.51
	1:4	295.3	316.3	93.36
	1:8	152.4	158.2	96.35
	1:16	68.27	79.08	86.33
	1:32	36.65	39.54	92.70
S3	-	880.2	-	-
	1:2	431.9	440.1	98.14
	1:4	218.3	220.1	99.22
	1:8	105.5	110.0	95.86
	1:16	52.34	55.01	95.14
	1:32	28.02	27.51	101.9

EDTA plasma	Dilution factor	Measured (pg/mL)	Expected (pg/mL)	Ratio (%) Measured/ Expected
P1	-	719.9	-	-
	1:2	354.5	359.9	98.48
	1:4	170.2	180.0	94.59
	1:8	78.45	89.98	87.18
	1:16	41.22	44.99	91.62
	1:32	24.39	22.50	108.4
P2	-	734.8	-	-
	1:2	351.9	367.4	95.78
	1:4	171.0	183.7	93.10
	1:8	80.53	91.85	87.68
	1:16	41.80	45.82	91.02
P3	-	431.1	-	-
	1:2	231.9	215.6	107.6
	1:4	117.9	107.8	109.3
	1:8	59.55	53.89	110.5
	1:16	29.09	26.95	108.0
	1:32	15.39	13.47	114.2

Recovery test

Samples were spiked with known quantities of PTH and assayed according to the assay procedure of the kit.

Serum	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(pg/mL)				
S1	23.37	18.18	41.55	48.97	117.9
	23.17	36.07	59.24	57.79	97.55
	22.99	53.66	76.64	75.50	98.51
S2	46.93	18.18	65.11	62.94	96.67
	46.17	53.66	99.82	95.94	96.11
	45.07	104.8	149.8	139.8	93.29
S3	137.6	53.66	191.3	176.8	92.41
	132.2	137.5	269.7	252.6	93.64
	128.2	200.0	328.2	288.6	87.91

EDTA plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(pg/mL)				
P1	40.52	18.18	58.70	58.35	99.40
	39.86	53.66	93.52	88.06	94.16
	38.61	121.3	159.9	146.7	91.75
P2	71.99	18.18	90.17	86.72	96.17
	70.25	70.97	141.2	131.6	93.16
	68.05	137.5	205.6	183.6	89.33
P3	127.8	53.66	181.4	172.2	94.89
	122.8	137.5	260.3	249.5	95.85
	119.1	200.0	319.1	299.4	93.82

^{125}I Characteristics

$T_{1/2}$ (^{125}I) = 1443 h = 60.14 d

^{125}I	E (MeV)	%
γ	0.035	
X	0.027	114
	0.032	25

Symbols Key

DANGER — Danger / Danger / Gefahr / Pericolo / Peligro / Perigo / Fara / Κίνδυνος / 危険 / Pavojus / Veszély! / Niebezpieczeństwo / Nebezpečí / Nebezpečenstvo / 위험 / Tehlike / Опасно! / Опасност / 危險

REF — Product Reference / Référence du produit / Produktreferenz / Riferimento prodotto / Número de referencia del producto / Referência do produto / Produktreferens / Κωδικός αναφοράς προϊόντος / 产品参考 / Gaminio nuoroda / Termékszám / Dane referencyjne produktu / Reference k produktu / Referenčné označenie výrobku / 제품 참조 자료 / Ürün Referansı / Ссылка на продукт / Референца за производ / 產品參考

IVD — In Vitro Diagnostic / Diagnostic in vitro / In-vitro-Diagnostikum / Diagnostica in vitro / Para diagnóstico in vitro / Diagnóstico in vitro / InVitro-diagnostik / Για διάγνωση in vitro / 体外诊断 / In vitro diagnostika / In vitro diagnosztikai felhasználásra / Diagnostyka in vitro / Diagnostika in vitro / 체외 진단 / İn Vitro Diagnostik / Диагностика in vitro / За ин витро диагностика / 體外診斷

CONTENTS — Contents / Contenu / Inhalt / Contenuto / Contenido / Conteúdo / Περιεχόμενο / 组成 / Rinkinio sudėtis / Tartalom / Zawartość / Obsah / Obsah / 내용물 / İçindekiler / Содержание / Съдържание / 目錄

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Expiration Date / Date D'expiration / Verfallsdatum, Verw. bis: / Data Di Scadenza / Fecha De Caducidad / Data de validade / Utgångsdatum / Ημερομηνία λήξης / 失效日期 / Galiojimo data / Lejárati idő / Data ważności / Datum exspirace / Dátum exspirácie / 만료 날짜 / Son Kullanma Tarihi / Срок годности / Срок на годност / 到期日

LOT — Lot Number / Numéro de lot / Chargennummer / Numero di lotto / Lote número / Número de lote / Satsnummer / Αριθ. παρτίδας / 批次号 / partijos numeris / Tételszám / Numer serii / Číslo šarže / 로트 번호 / Lot Numarası / Номер партии / Номер на партида / 批號

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Radioactive / Radioactif / Radioaktiv / Radioattivo / Radiactivo / Radioactivo / Radioaktivt / Ραδιενεργό / 放射性 / Radioaktyvioji medžiaga / Radioaktív / Radioaktywny / Radioaktivní / Rádioaktívny / 방사성 / Radyoaktif / Радиоактивный / Радиоактивен / 具放射性

Ag 125I / Ab 125I — Tracer / Traceur / Tracer / Marcato / Trazador / Marcador / Tracer / Ανιχνευτής / 追踪剂 / Atsekamoji medžiaga / Nyomjelző / Znacznik / Radioindikátor / Indikátor (tracer) / 트레이서 / Tracer´lar / метка / Индикатор / 追蹤劑

CAL / CAL 0 — Calibrator / Calibrateur / Kalibrator / Calibratore / Calibrador / Calibrador / Kalibrator / Βαθμονομητής / 校准品 / Kalibravimo medžiaga / Kalibrátor / Kalibrator / kalibrátor / Kalibrátor / 보정 물질 / Kalibratör / Калибратор / Калибратор / 校正液

CTRL — Control / Contrôle / Kontrolle / Controllo / Control / Controlo / Kontrolle / Μάρτυρας / 质控品 / Kontrolinė / Kontroll / Kontrola / Kontrola / Kontrola / 정도관리 / Kontrol / Контроль / Контролна / 質控品

TUBE — Tubes / tubes / Röhrchen / provette / tubos / Tubos de amostra / Provrör / σωληνάρια / 试管 / Mėgintuvėliai / Csövek / Probówki / Zkumavky / Skúmavky / 튜브 / Tüpler / пробирки / Епруветки / 試管

IFU — Instruction for Use / Mode d'emploi / Gebrauchsanweisung / Istruzioni per l'uso / Instrucciones de uso / Instruções de utilização / Bruksanvisning / Οδηγίες χρήσης / 使用说明 / Naudojimo instrukcija / Használati utasítás / Instrukcja użycia / Návod k použití / Návod na použitie / 사용 안내 / Kullanma Talimatı / Инструкции / Инструкции за употреба / 使用說明

SOLN WASH 20X — Wash Solution Concentrate 20X / Solution de lavage concentrée 20X / Waschlösungskonzentrat 20X / Concentrato di soluzione di lavaggio 20X / Solución de lavado concentrada 20X / Concentrado de solução de lavagem 20X / Tvättlösningskoncentrat 20X / Συμπυκνωμένο διάλυμα πλύσης 20X / 浓缩清洗液 20X / Plovimo tirpalo koncentratas 20X / 20X mosóoldat-koncentrátum / Koncentrat 20X roztworu płuczącego / Koncentrát mycího roztoku 20X / Koncentrát premývacieho roztoku 20X / 농축 세척액(20배) / Yıkama Çözeltisi Konsantresi 20X / Концентрат промывочного раствора 20X / Концентрат на разтвор за промиване 20X / 清洗溶液濃縮 20X

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