IVD

CE

PRL-IRMA

KIP1441

DIAsource ImmunoAssays S.A. - Rue du Bosquet, 2 - B - 1348 Louvain-la-Neuve – Belgium

History

Summary of change:

<table>
<tr><th>Previous Version:
200224-1</th><th>Current Version:
200720</th></tr>
<tr><td>

IX. SPECIMEN COLLECTION AND PREPARATION

- Do not use haemolysed samples.
- Serum or plasma (EDTA and heparin) provides similar results.

Y (serum) = 1.09x (hep. plasma) + 0.05 r = 0.95
n = 30
Y (serum) = 0.96x (EDTA plasma) + 0.14 r = 0.98
n = 30

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IX. SPECIMEN COLLECTION AND PREPARATION

- Do not use lipemic samples.
- Serum or plasma (EDTA and heparin) provides similar results.

Y (hep. plasma) = 0.90x (serum) + 0.06 r = 0.98
n = 19
Y (EDTA plasma) = 0.91x (serum) + 0.46 r = 0.99
n = 19

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XII. TYPICAL DATA

PRL-IRMA		cpm	B/T (%)
Total count		135774	100
Calibrator	0.0 ng/ml	224	0.16
	2.8 ng/ml	1266	0.93
	9.4 ng/ml	3401	2.5
	30.0 ng/ml	8124	5.98
	80.0 ng/ml	17778	13.09
	133.0 ng/ml	25312	18.64

Detection range : 0.35 to 133 ng/ml

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XII. TYPICAL DATA

PRL-IRMA		cpm	B/T (%)
Total count		144108	100
Calibrator	0.0 ng/ml	254	0.18
	2.88 ng/ml	1544	0.90
	8.41 ng/ml	3913	2.54
	25.50 ng/ml	9828	6.64
	87.20 ng/ml	24551	16.86
	205.00 ng/ml	41925	28.92

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XIII. PERFORMANCE AND LIMITATIONS

A. Detection Limit

Twenty zero calibrators were assayed along with a set of other calibrators. The detection limit, defined as the apparent concentration two standard deviations above the average counts at zero binding, was 0.35 ng/ml.

B. Specificity

added Hormone	PRL CAL 1 ng/ml	PRL CAL 2 ng/ml
-	2.4	66
LH 300 mIU/ml	2.6	62
FSH 300 mIU/ml	2.5	62
hCG 300000 mIU/ml	2.5	63
hPL 50000 ng/ml	2.9	67
hGH 1000 ng/ml	2.3	68
TSH 300 µIU/ml	2.1	59

The potentially interfering effects of hemoglobin at 7.5 mg/ml and of bilirubin at 0.2 mg/ml have been evaluated.

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XIII. PERFORMANCE AND LIMITATIONS

A. Detection Limit

The LoB (Limit of Blank) was calculated by measuring the blank several times and was calculated as the mean + 2 Standard Deviations of the distribution of the test values ; the LoB was calculated to be 0.18 ng/ml.
The LoD (Limit of Detection) was calculated as the LoB + 1.645 Standard Deviation of a low concentration sample tested in 9 different runs. The LoD was calculated to be 0.76 ng/ml.
The LoQ(Limit of Quantification) was calculated by testing 5 low values samples, 9 times. The LoQ was calculated to be 1.26 ng/ml.

B. Specificity

Added Hormone	Sample 1 ng/ml	Sample 2 ng/ml
-	16.8	57.1
LH 750 mIU/ml	18.0	55.0
hCG 500000 mIU/ml	18.8	56.1
-	16.9	51.9
FSH 500 mIU/ml	17.4	58.8
-	17.0	54.4
hPL 100000 ng/ml	18.0	56.4
-	18.0	56.5
hGH 125 ng/ml	18.3	57.1
-	16.9	52.2
TSH 740 mIU/ml	17.8	54.8

The potentially interfering effects of hemoglobin at 500 mg/dl and of bilirubin at 100 mg/dl have been evaluated.

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The results of this test do not demonstrate any significant interference (see the table below).

Sample	Initial value (ng/ml)	Value + Hemoglobin (ng/ml)	Value + Bilirubin (ng/ml)
Plasma 1	7.5	7.6	6.8
Plasma 2	40.8	41	38
Serum 1	6.1	6.2	5.6
Serum 2	5.7	5.6	5.5

C. Precision

INTRA ASSAY

Serum	N	<X> ± S.D. (ng/ml)	CV (%)
A	10	7.5 ± 0.2	3.3
B	10	26.6 ± 1.4	5.2

INTER ASSAY

Serum	N	<X> ± S.D. (ng/ml)	CV (%)
C	20	7.4 ± 0.7	9.2
D	20	49.1 ± 2.2	4.5

D.Accuracy

RECOVERY TEST

Sample	Added PRL (ng/ml)	Recovered PRL (ng/ml)	Recovery (%)
A	2	1.8	90.0
	5	5.0	100.0
	10	9.8	98.0
	20	19.5	97.5
	50	45.6	91.2

DILUTION TEST

Sample	Dilution	Theoretical Concent. (ng/ml)	Measured Concent. (ng/ml)
1	1/1	-	192.0
	1/2	96.0	97.0
	1/4	48.0	57.0
	1/8	24.0	30.6
	1/16	12.0	10.3
2	1/1	-	232.0
	1/2	116.0	122.0

The results of this test do not demonstrate any significant interference as shown in the table below.
However an interference with triglycerides has been observed from a concentration of 62.5 mg /dl as shown in the table below.
So lipemic samples should be avoided.

Interfering substance	Plasma 1 (ng/ml)	Plasma 2 (ng/ml)	Serum 1 (ng/ml)
-	17.8	56.6	13.2
Hemoglobin	18.2	57.1	13.4
-	18.7	54.8	14.0
Bilirubin	18.0	57.5	13.8
-	19.3	64.1	13.1
Triglycerides	16.7	47.6	11.3

C. Precision

INTRA ASSAY

Sample	N	<X> ± S.D. (ng/ml)	CV (%)
A	10	19.4 ± 0.5	2.6
B	10	63.1 ± 1.5	2.4

INTER ASSAY

Sample	N	<X> ± S.D. (ng/ml)	CV (%)
A	15	20.3 ± 0.7	3.5
B	15	63.6 ± 2.4	3.7

D.Accuracy

RECOVERY TEST

Sample	Added PRL (ng/ml)	Recovered PRL (ng/ml)	Recovery (%)
1	63	59.7	94.7
	78.1	80.7	103.3
	104.7	102.4	97.7
	112.7	117.3	104.1
2	63	58..0	92.0
	78.1	75.7	96.9
	104.7	101.3	96.7
	112.7	112.1	99.5

DILUTION TEST

Sample	Dilution	Theoretical Concent. (ng/ml)	Measured Concent. (ng/ml)
1	1/1	-	151.5
	1/2	75.7	81.6
	1/4	37.9	38.5
	1/8	18.9	16.7
2	1/1	-	183.4
	1/2	91.7	104.1
	1/4	45.8	47.9

	1/4	58.0	65.0
	1/8	29.0	27.4
	1/16	14.5	15.3

E. Time Delay

	0' (ng/ml)	15' (ng/ml)	30' (ng/ml)	60' (ng/ml)
Serum 1	5.4	5.8	6.4	6.3
Serum 2	23.2	22.3	26.8	25.9

F. Hook effect

A serum sample with a concentration of 18000 ng/ml PRL gives a signal above the highest calibrator concentration.

XVI. REFERENCE INTERVALS

Identification	Number of subjects	Mean (ng/ml)	Range (ng/ml)
Males	97	4.8	1.8 - 15.9
Pre-menopausal women	95	8.6	2.7 - 19.7
Post-menopausal women	47	6.1	1.9 - 17.9

"Room temperature"

XI. CALCULATION OF RESULTS

2. On semi logarithmic or linear graph paper plot the c.p.m. (ordinate) for each calibrator against the corresponding concentration of PRL (abscissa) and draw a calibration curve through the calibrator points, reject the obvious outliers.

	1/8	22.9	22.4
	1/16	11.5	10.1

E. Time Delay

	0' (ng/ml)	15' (ng/ml)	30' (ng/ml)	60' (ng/ml)
Sample 1	19.5	20.2	21.3	20.4
Sample 2	67.4	65.2	64.3	63.4

F. Hook effect

A serum sample with a concentration of 16000 ng/ml PRL gives a signal above the highest calibrator concentration.
Measuring range: 1.26 (LoQ) to 16000 ng/ml (hook effect)

XVI. REFERENCE INTERVALS

Identification	Number of subjects	Mean (ng/ml)	Range (2.5-97.5 percentiles) (ng/ml)
Males	40	8.5	3.0 – 18.8
Women (18-60 years old)	31	9.2	3.0 – 16.5
Women (> 60 years old)	37	7.2	3.8 – 18.1

Full revision of the KR version

"Room temperature (18-25°C)"

XI. CALCULATION OF RESULTS

2. Plot the c.p.m. (ordinate) for each calibrator against the corresponding concentration of PRL (abscissa) and draw a calibration curve through the calibrator points, reject the obvious outliers.

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Read entire protocol before use.

PRL-IRMA

I. INTENDED USE

Immunoradiometric assay kit for the in vitro quantitative measurement of human prolactin (PRL) in serum and plasma.

II. GENERAL INFORMATION

A. Proprietary name : DIAsource PRL-IRMA Kit

B. Catalog number : KIP1441: 96 tests

C. Manufactured by : DIAsource ImmunoAssays S.A.
Rue du Bosquet, 2, B-1348 Louvain-la-Neuve, Belgium.

For technical assistance or ordering information contact :
Tel : +32 (0)10 84.99.11 Fax : +32 (0)10 84.99.91

III. CLINICAL BACKGROUND

A. Biological activities

Prolactin (PRL) is a polypeptide hormone (molecular weight 20,000 Da) secreted by the pituitary gland, which plays a key role in the development of the mammary gland, the production and secretion of milk and the control of male and female gonadal functions. Prolactin secretion is under hypothalamic control exerted directly by dopamine, several prolactin releasing factors (PRF) and perhaps VIP (vasoactive intestinal polypeptide) or a closely related peptide. Thyrotropin releasing hormone (TRH) also acts directly at the pituitary level to stimulate prolactin release but its physiological role in the control of prolactin secretion has not been established yet. Several neuroendocrine factors, involving serotoninergic or noradrenergic pathways are also involved in the control of prolactin secretion. The plasma concentration of prolactin increases in various physiological situations such as stress, pregnancy and lactation. Physiological levels fluctuate according to a nycthemeral rhythm, a significant rise being observed at night. Drugs with anti-dopamine activity (psychotropic agents) and ovulatory supressants, increase prolactin secretion.

B. Clinical application

- *Prolactinoma* : Circulating prolactin levels are elevated in patients with a prolactin secreting pituitary adenoma. Amenorrhea and impotence are characteristic clinical symptoms in such cases.
- *Other pituitary diseases* : Increased prolactin levels are also observed in 5% to 20% of patients with acromegaly and when pituitary control by the hypothalamus is suppressed (pituitary stalk section). Decreased PRL levels may be observed in cases of complete destruction of the pituitary as in Sheehan's syndrome.
- *Galactorrhea and amenorrhea* : The measurement of the prolactin levels in serum is a useful test in the differential diagnosis of galactorrhea and amenorrhea.

IV. PRINCIPLES OF THE METHOD

The DIAsource PRL-Irma is an immunoradiometric assay based on coated-tube separation. Mabs1, the capture antibodies, are attached to the lower and inner surface of the plastic tube. Calibrators or samples added to the tubes will at first show low affinity for Mabs1. Addition of Mab2, the signal antibody labelled with ^{125}I, will complete the system and trigger the immunological reaction. After washing, the remaining radioactivity bound to the tube reflects the antigen concentration. The use of several distinct Mabs avoids hyperspecificity.

V. REAGENTS PROVIDED

Reagents	Quantity 96 tests	Colour Code	Reconstitution
Tubes coated with anti PRL (monoclonal antibodies)	2 x 48	orange	**Ready** for use
Ab | **^{125}I** Anti-PRL-^{125}I (monoclonal antibodies) in TRIS Buffer with bovine serum albumin, sodium azide (0.5 %) and inert red dye	1 vial 22 ml 340 kBq	red	**Ready** for use
CAL | **0** Zero Calibrator in bovine serum with thymol	1 vial lyophil.	yellow	**Add** 2 ml distilled water
CAL | **N** Calibrators 1-5 in bovine serum with thymol (see exact values on vial labels)	5 vials lyophil.	yellow	**Add** 0.5 ml distilled water
WASH | **SOLN** | **CONC** Wash solution (TRIS-HCl)	1 vial 10 ml	brown	**Dilute** 70 x in distilled water (use a magnetic stirrer).
CONTROL | **N** Controls 1 and 2 in human plasma with thymol	2 vials lyophil.	silver	**Add** 0.5 ml distilled water

Note: 1. Use the zero calibrator for sera dilutions.
2. 1 ng of the calibrator preparation is equivalent to 29 µIU NIBSC 3rd IS 84/500.
3. Conversion factor : :ng/ml x 29= µUI / ml

VI. SUPPLIES NOT PROVIDED

The following material is required but not provided in the kit:
1. Distilled water
2. Pipettes for delivery of: 25 µl, 200 µl, 500 µl and 2 ml. (the use of accurate pipettes with disposable plastic tips is recommended)
3. Vortex mixer
4. Magnetic stirrer
5. 5 ml automatic syringe (Cornwall type) for washing
6. Aspiration system (optional).
7. Any gamma counter capable of measuring ^{125}I may be used (minimal yield 70%).

VII. REAGENT PREPARATION

A. **Calibrators**: Reconstitute the zero calibrator with 2 ml distilled water and the other calibrators with 0.5 ml distilled water.
B. **Controls**: Reconstitute the controls with 0.5 ml distilled water.
C. **Working Wash solution**: Prepare an adequate volume of Working Wash solution by adding 69 volumes of distilled water to 1 volume of Wash Solution (70x). Use a magnetic stirrer to homogenize. Discard unused Working Wash solution at the end of the day.

VIII. STORAGE AND EXPIRATION DATING OF REAGENTS

- Before opening or reconstitution, all kit components are stable until the expiry date, indicated on the label, if kept at 2 to 8°C.
- After reconstitution, calibrators and controls are stable for 7 days at 2-8°C. For longer storage periods, aliquots should be made and kept at –20°C for 3 months. Avoid subsequent freeze-thaw cycles.
- Freshly prepared Working Wash solution should be used on the same day.
- After its first use, tracer is stable until expiry date, if kept in the original well-closed vial at 2 to 8°C.
- Alterations in physical appearance of kit reagents may indicate instability or deterioration.

IX. SPECIMEN COLLECTION AND PREPARATION

- Serum and plasma must be kept at 2 – 8°C.
- If the test is not run within 24 hours, storage at –20°C is recommended.
- Avoid subsequent freeze-thaw cycles.
- Do not use lipemic samples.
- Serum or plasma (EDTA and heparin) provides similar results.
  Y (hep. plasma) = 0.90 x (serum) + 0.06 r = 0.98 n = 19
  Y (EDTA plasma) = 0.91 x (serum) + 0.46 r = 0.99 n = 19

X. PROCEDURE

A. Handling notes

Do not use the kit or components beyond expiry date. Do not mix materials from different kit lots. Bring all the reagents to room temperature (18-25°C) prior to use.
Thoroughly mix all reagents and samples by gentle agitation or swirling. In order to avoid cross-contamination, use a clean disposable pipette tip for the addition of each reagent and sample.
High precision pipettes or automated pipetting equipment will improve the precision. Respect the incubation times.
Prepare a calibration curve for each run, do not use data from previous runs.

B. Procedure

1. Label coated tubes in duplicate for each calibrator, control and sample. For determination of total counts, label 2 normal tubes.
2. Briefly vortex calibrators, samples and controls and dispense 25 µl of each into the respective tubes.
3. Dispense 200 µl of anti-PRL-^{125}I tracer into each tube, including the uncoated tubes for total counts.
4. Shake the rack containing the tubes gently by hand to liberate any trapped air bubbles.
5. Incubate for 2 hours at room temperature (18-25°C).
6. Aspirate (or decant) the content of each tube (except total counts). Be sure that the plastic tip of the aspirator reaches the bottom of the coated tube in order to remove all the liquid.
7. Wash the tubes with 2 ml Wash Solution (except total counts). Avoid foaming during the addition of the Working Wash Solution.
8. Aspirate (or decant) the content of each tube (except total counts).
9. Let the tubes standing upright for two minutes and aspirate the remaining drop of liquid.
10. Count the tubes in a gamma counter for 60 seconds.

XI. CALCULATION OF RESULTS

1. Calculate the mean of duplicate determinations.
2. Plot the c.p.m. (ordinate) for each calibrator against the corresponding concentration of PRL (abscissa) and draw a calibration curve through the calibrator points, reject the obvious outliers.
3. Read the concentration for each control and sample by interpolation on the calibration curve.
4. Computer assisted data reduction will simplify these calculations. If automatic result processing is used, a 4-parameter logistic function curve fitting is recommended.

XII. TYPICAL DATA

The following data are for illustration only and should never be used instead of the real time calibration curve.

PRL-IRMA		cpm	B/T (%)
Total count		144108	100
Calibrator	0.0 ng/ml	254	0.18
	2.88 ng/ml	1544	0.90
	8.41 ng/ml	3913	2.54
	25.50 ng/ml	9828	6.64
	87.20 ng/ml	24551	16.86
	205.00 ng/ml	41925	28.92

XIII. PERFORMANCE AND LIMITATIONS

A. Detection Limit

The LoB (Limit of Blank) was calculated by measuring the blank several times and was calculated as the mean + 2 Standard Deviations of the distribution of the test values ; the LoB was calculated to be 0.18 ng/ml.
The LoD (Limit of Detection) was calculated as the LoB + 1.645 Standard Deviation of a low concentration sample tested in 9 different runs. The LoD was calculated to be 0.76 ng/ml.
The LoQ (Limit of Quantification) was calculated by testing 5 low values samples, 9 times. The LoQ was calculated to be 1.26 ng/ml.

B. Specificity

Cross-reactive hormones were added to a low and to a high PRL value calibrator. The apparent PRL response was measured.

Added Hormone	Sample 1 ng/ml	Sample 2 ng/ml
-	16.8	57.1
LH 750 mIU/ml	18.0	55.0
hCG 500000 mIU/ml	18.8	56.1
-	16.9	51.9
FSH 500 mIU/ml	17.4	58.8
-	17.0	54.4
hPL 100000 ng/ml	18.0	56.4
-	18.0	56.5
hGH 125 ng/ml	18.3	57.1
-	16.9	52.2
TSH 740 mIU/ml	17.8	54.8

The DIAsource PRL-IRMA measures total PRL, which means both the active prolactin monomer and the biologically inactive macroprolactin (see references 10 and 11).
For patients showing an elevated PRL level with this kit, additional information should be obtained in order to establish a correct diagnosis.

The potentially interfering effects of hemoglobin at 500 mg/dl and of bilirubin at 100 mg/dl have been evaluated. The results of this test do not demonstrate any significant interference as shown in the table below.
However an interference with triglycerides has been observed from a concentration of 62.5 mg /dl as shown in the table below.
So lipemic samples should be avoided.

Interfering substance	Plasma 1 (ng/ml)	Plasma 2 (ng/ml)	Serum 1 (ng/ml)
-	17.8	56.6	13.2
Hemoglobin	18.2	57.1	13.4
-	18.7	54.8	14.0
Bilirubin	18.0	57.5	13.8
-	19.3	64.1	13.1
Triglycerides	16.7	47.6	11.3

C. Precision

INTRA ASSAY / INTER ASSAY

Sample	N	<X> ± S.D. (ng/ml)	CV (%)	Sample	N	<X> ± S.D. (ng/ml)	CV (%)
A	10	19.4 ± 0.5	2.6	A	15	20.3 ± 0.7	3.5
B	10	63.1 ± 1.5	2.4	B	15	63.6 ± 2.4	3.7

D. Accuracy

RECOVERY TEST

Sample	Added PRL (ng/ml)	Recovered PRL (ng/ml)	Recovery (%)
1	63	59.7	94.7
	78.1	80.7	103.3
	104.7	102.4	97.7
	112.7	117.3	104.1
2	63	58..0	92.0
	78.1	75.7	96.9
	104.7	101.3	96.7
	112.7	112.1	99.5

DILUTION TEST

Sample	Dilution	Theoretical Concent. (ng/ml)	Measured Concent. (ng/ml)
1	1/1	-	151.5
	1/2	75.7	81.6
	1/4	37.9	38.5
	1/8	18.9	16.7
2	1/1	-	183.4
	1/2	91.7	104.1
	1/4	45.8	47.9
	1/8	22.9	22.4
	1/16	11.5	10.1

Samples were diluted with zero calibrator.

E. Time Delay

As shown below, assay results remain accurate even when a sample is dispensed up to 60 minutes after the calibrator has been added to the coated tubes.

TIME DELAY

	0' (ng/ml)	15' (ng/ml)	30' (ng/ml)	60' (ng/ml)
Sample 1	19.5	20.2	21.3	20.4
Sample 2	67.4	65.2	64.3	63.4

F. Hook effect

A serum sample with a concentration of 16000 ng/ml PRL gives a signal above the highest calibrator concentration.

Measuring range: 1.26 (LoQ) to 16000 ng/ml (hook effect)

XIV. LIMITATIONS

- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits which employ mouse monoclonal antibodies.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays.
  Patients routinely exposed to animals or animal serum products can be prone to this interference and anomalous values may be observed in case of the presence of heterophelic antibodies. Carefully evaluate the results of patients suspected of having these antibodies.
  If results are not consistent with other clinical observations, additional information should be required before diagnosis.

XV. INTERNAL QUALITY CONTROL

- If the results obtained for Control 1 and/or Control 2 are not within the range specified on the vial label, the results cannot be used unless a satisfactory explanation for the discrepancy has been given.
- If desirable, each laboratory can make its own pools of control samples, which should be kept frozen in aliquots.
- Acceptance criteria for the difference between the duplicate results of the samples should rely on Good Laboratory Practises

XVI. REFERENCE INTERVALS

The values provided below are given only for guidance; each laboratory should establish its own normal range of values.
PRL concentrations were measured in serum samples obtained from different categories of healthy subjects.

Identification	Number of subjects	Mean (ng/ml)	Range (2.5-97.5 percentiles) (ng/ml)
Males	40	8.5	3.0 – 18.8
Women (18-60 years old)	31	9.2	3.0 – 16.5
Women (> 60 years old)	37	7.2	3.8 – 18.1

XVII. PRECAUTIONS AND WARNINGS

Safety
For in vitro diagnostic use only.
This kit contains ^{125}I (half-life: 60 days), emitting ionizing X (28 keV) and γ (35.5 keV) radiations.
This radioactive product can be transferred to and used only by authorized persons; purchase, storage, use and exchange of radioactive products are subject to the legislation of the end user's country. In no case the product must be administered to humans or animals.
All radioactive handling should be executed in a designated area, away from regular passage. A logbook for receipt and storage of radioactive materials must be kept in the lab. Laboratory equipment and glassware, which could be contaminated with radioactive substances, should be segregated to prevent cross contamination of different radioisotopes.
Any radioactive spills must be cleaned immediately in accordance with the radiation safety procedures. The radioactive waste must be disposed of following the local regulations and guidelines of the authorities holding jurisdiction over the laboratory. Adherence to the basic rules of radiation safety provides adequate protection.
The human blood components included in this kit have been tested by European approved and/or FDA approved methods and found negative for HBsAg, anti-HCV, anti-HIV-1 and 2. No known method can offer complete assurance that human blood derivatives will not transmit hepatitis, AIDS or other infections. Therefore, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.
All animal products and derivatives have been collected from healthy animals. Bovine components originate from countries where BSE has not been reported. Nevertheless, components containing animal substances should be treated as potentially infectious.
Avoid any skin contact with reagents (sodium azide as preservative). Azide in this kit may react with lead and copper in the plumbing and in this way form highly explosive metal azides. During the washing step, flush the drain with a large amount of water to prevent azide build-up.
Do not smoke, drink, eat or apply cosmetics in the working area. Do not pipette by mouth. Use protective clothing and disposable gloves.

XVIII. BIBLIOGRAPHY

1. Archer D.F. (1977).
Current concepts of prolactin physiology in normal and abnormal conditions.
Fertil Steril 28:125.

2. Laufer N., Botero-Ruiz W., De Chemey A.H., et al. (1984).
Gonadotropin and prolactin levels in follicular fluid of human ova successfully fertilized in vitro.
J. Clin. Endocrinal. Metab. 58:430.

3. Leong D.A., Frawley L.S., Neil J.D. (1983).
Neuroendocrine control of prolactin secretion.
An. Rev. of Physiol. 45:109.

4. Seppala M. (1978).
Prolactin and female reproduction.
An. Clin. Res. 10:164.

5. Taylor T.J., Trouson A, Besanko M., Burger H.G., Stockdale J. (1986).
Plasma progesterone and prolactin changes in superovulated women before, during and immediatemy after laparoscopy for in vitro fertilisation and their relation to pregnancy
Fertil. Steril 45:680.

6. Tyson J.E. (1980)
Changing role of placental lactogen and prolactin in human gestation.
Clin. Obstet.Gynecol 23:737.

7. Kamel M.A et al (1994)
Comparison between prolactin, gonadotropins and steroid hormones in serum and follicular fluid after stimulation with gonadotrophin-releasing hormone agonist and human menopausal gonadotrophin for an in-vitro fertilization program.
Hum. Reprod. 9(10):1803-6.

8. Patel D.D. et al (1994).
Plasma prolactin in patients with colorectal cancer. Value in follow-up and as a prognosticator
Cancer 73(3):570-74.

9. Hattori et al (1994).
Effects of anti-prolactin autoantibodies on serum prolactin mesurements.
Eur. J. Endocrinol. 130(5):434-7.

10. Suh H.K. et al (1974).
Size heterogeneity of human Prolactin in plasma and pituitary extracts.
J. Clin. Endocrinol Metab 39 : 928-935.

11. Bonhoff A. et al (1995)
Identification of macroprolactin in a patient with asymptomatic hyperprolactinemia as a stable PRL-IgG complex.
Exp. Clin. Endocrinol. 103 : 252-5

XIX. SUMMARY OF THE PROTOCOL

	TOTAL COUNTS ml	CALIBRATORS ml	SAMPLE(S)/ CONTROLS ml
Calibrators (0-5) Samples, Controls Tracer	- 0.200	0.025 - 0.200	- 0.025 0.200
Incubation	2 hours at room temperature (18-25°C)		
Separation Washing solution Separation	- - -	Aspirate (or decant) 2 ml Aspirate (or decant)	
Counting	Count tubes for 60 seconds		

Other translations of this Instruction for Use can be downloaded from our website: https://www.diasource-diagnostics.com/

DIAsource Catalogue Nr : KIP1441	Date of issue : 200720

Revision date : 20/07/2020

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