HS-PROLAC-CHECK-1

High Sensitive quantitative determination of Prolactin in plasma or serum samples

FOR EASY READER® OR EASY READER+® USE ONLY

Ref. : HS9091

I- PRINCIPLE

Human Prolactin (hPRL), which is secreted by the anterior lobe of the pituitary gland (1, 2), is essential for breast development and lactation in women. High levels can be detected after the eighth week of pregnancy and continue until term. After birth, prolactin levels return to normal within three weeks in the absence of breast feeding (3, 4). Normal females show prolactin levels only slightly higher than males (2, 3). Abnormally high levels of hPRL are associated with infertility in men and women, male impotence and primary hypothyroidism.

The HS-PROLAC-CHECK-1 is a rapid, quantitative assay for the detection of human prolactin in serum and plasma samples. The method employs a unique combination of monoclonal-dye conjugate and polyclonal-solid phase antibodies to identify prolactin in the test samples selectively with a high degree of specificity.

As the test sample flows through the absorbent device, the labelled antibody-dye conjugate binds to the prolactin forming an antibody-antigen complex. This complex binds to the anti-prolactin antibody in the reaction zone (T) and produces a rose-pink coloured band. In the absence of prolactin, there is no line in the reaction zone (T). The mixture continues flowing through the absorbent device, past the reaction zone (T) and control zone (C). Unbound conjugate binds to the reagents in the control zone (C), producing a rose-pink coloured band, demonstrating that the reagents are functioning correctly.

II- HS-PROLAC-CHECK-1 KIT COMPONENTS

Each kit contains everything needed to perform 10 or 20 tests:

1- HS-PROLAC-CHECK-1 reaction devices	10	20
2- Disposable plastic pipettes	10	20
3- Instructions leaflet	1	1

III- STORAGE AND STABILITY

1- All HS-PROLAC-CHECK-1 kit components should be stored at room temperature (+4°C to +30°C) in the sealed pouch.
2- ***Do not freeze the test kit***.
3- The HS-PROLAC-CHECK-1 test is stable until the expiry date stated on the package label.

IV- PRECAUTIONS

1- This test is designed for *in vitro* diagnostic use and professional use only.
2- Read carefully the instructions before using this test.
3- Handle all specimens as if they contained infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving them for at least one hour. Alternatively, they can be treated with 0.5% to 1% solution of sodium hypochlorite for one hour before disposal.
4- Wear protective clothing such as laboratory coats and disposable gloves while assaying samples.
5- Do not eat, drink or smoke in the area where specimens and kit reagents are handled.
6- Avoid any contact between hands and eyes or nose during specimen collection and testing.
7- Do not use beyond the expiry date which appears on the package label.
8- Do not use a test from a damaged protective wrapper.

V- SPECIMEN COLLECTION AND PREPARATION

1- HS-PROLAC-CHECK-1 is to be performed on human serum or plasma sample.
2- The specimen should be collected under the standard laboratory conditions (aseptically in such a way as to avoid haemolysis).
3- If anticoagulant is needed, only EDTA or heparin should be used.
4- Each specimen should be treated as if potentially infectious.
5- If the test is to be run within 48 hours after collection the specimen should be stored in the refrigerator (+2°C to +8°C). If testing is delayed more than 48 hours, the specimen should be frozen. The frozen specimen must be completely thawed, thoroughly mixed and brought to room temperature prior to testing. Avoid repeated freezing and thawing.
6- In case of cloudiness, high viscosity or presence of particulate matter into the serum specimen, it should be diluted with equal volume (V/V) of diluting buffer (not provided but available upon request) before testing.

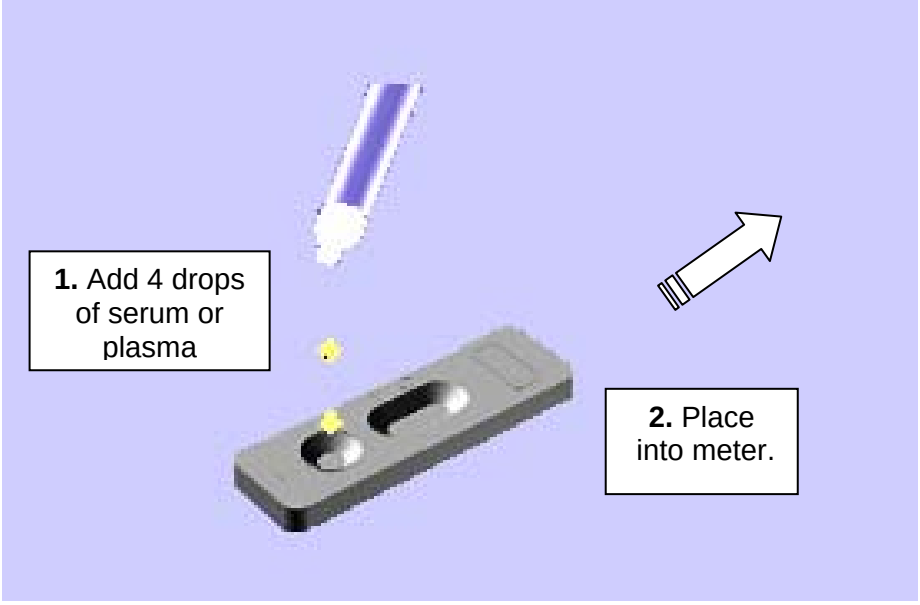
CE

VI- ASSAY PROCEDURE

Please follow the below instructions or refer to the picture n°1.

1. Allow specimen and HS-PROLAC-CHECK-1 test device to come to room temperature prior to testing.
2. Remove the reaction device from its protective wrapper by tearing along the split.
3. Label device with the patient's name or control number.
4. Fill the dropper with specimen and by holding it vertically, dispense drop-wise into sample well (▷). Add exactly 4 drops (150µL without air bubble) of plasma or serum in the sample well (▷).
5. Read the result **(in ng/mL**) at 10 minutes exactly either using the immediate or countdown reading mode (see corresponding leaflet). In case the result reading is made at different time, wrong results will be obtained.

For general instructions describing how to use the VEDALAB's rapid test readers refer to the corresponding leaflet.



Picture n°1

VII- PERFORMANCES CHARACTERISTICS

a) Linearity

The measuring range is 3-100 ng/mL.
For Prolactin concentration below 3 ng/mL, the result will be given as "< 3 ng/mL".
For Prolactin concentration over 100 ng/mL, the result will be given as "> 100 ng/mL".
Samples showing a concentration higher than 100 ng/mL must be diluted with saline and the assay repeated as per instructions of Part. VI.

b) Accuracy

A study has been performed using serum samples obtained from dilutions of the Prolactin international standard 84/500 (W.H.O.) covering a range of 0 to 100 ng/mL. Optical densities expressed as a function of Prolactin concentrations are described by following logarithmic curve:

$$Y = 13.8235 + 4.3656\ X\ -7.2657e\ -3X^2$$

The results show a good correlation ($r > 0.99$) of the values obtained with HS-PROLAC-CHECK-1 on VEDALAB's readers.

c) Analytical sensitivity and abnormal values

The analytical sensitivity of the HS-PROLAC-CHECK-1 rapid test is 3ng/mL according to W.H.O. 3rd international standard n° 84/500.
Levels higher than 20 ng/mL are generally considered as abnormal values.

d) Precision

A panel of 53 human sera samples pre-assayed using the ROCHE ECLIA-COBAS analyser (chemiluminescence) has been tested with HS-PROLAC-CHECK-1 rapid test.
Results were measured using the VEDALAB's readers. Results are shown in table I.

Table I

Human sera identification	ECLIA-COBAS Prolactin concentration **(ng/mL)**	Confidence range		**Easy Reader® Prolactin concentration (ng/mL)**
		Lower limit	**Upper limit**	
1	118.0	88.5	>100	>100
2	2.9	2.2	3.6	3.1
3	21.5	16.1	26.9	21.0
4	5.1	3.8	6.4	6.3
5	10.0	7.5	12.5	11.9
6	75.0	56.3	93.8	64.4
7	5.3	4.0	6.6	6.2
8	7.3	5.5	9.1	5.6
9	40.7	30.5	50.9	49.7
10	3.0	2.3	3.8	<3
11	11.3	8.5	14.1	11.0
12	105.4	79.1	>100	85.8
13	28.5	21.4	35.6	29.0
14	15.8	11.9	19.8	18.6
15	23.3	17.5	29.1	23.6
16	13.5	10.1	16.9	13.7
17	86.8	65.1	>100	84.1
18	16.5	12.4	20.6	18.3
19	33.6	25.2	42.0	37.8
20	17.2	12.9	21.5	13.9
21	10.8	8.1	13.4	9.6
22	5.0	3.8	6.3	5.4
23	59.0	44.3	73.8	65.0
24	3.7	2.7	4.6	<3
25	2.6	1.9	3.2	<3
26	37.5	28.1	46.9	40.9
27	2.7	2.0	3.3	<3
28	5.4	4.0	6.7	5.4
29	2.5	1.9	3.1	<3
30	29.5	22.1	36.9	36.4
31	1.8	1.4	2.3	<3
32	18.8	14.1	23.4	23.0
33	11.8	8.9	14.8	13.9
34	7.9	5.9	9.9	6.0
35	8.6	6.5	10.8	7.6
36	6.8	5.1	8.4	6.0
37	5.7	4.2	7.1	5.8
38	52.7	39.5	65.9	46.8
39	43.4	32.6	54.3	33.0
40	8.3	6.2	10.3	6.2
41	14.3	10.7	17.8	12.6
42	16.8	12.6	21.0	13.0
43	11.7	8.7	14.6	8.8
44	4.0	3.0	4.9	3.3
45	4.3	3.2	5.4	3.7
46	3.4	2.5	4.2	<3
47	2.8	2.1	3.5	<3
48	26.4	19.8	32.9	23.4
49	21.7	16.3	27.1	16.6
50	4.1	3.1	5.2	5.1
51	7.1	5.3	8.9	7.6
52	8.4	6.3	10.5	7.4
53	5.8	4.4	7.3	6.0

Negative, borderline and positive samples are correctly detected (a correlation of 98.0 % has been established between VEDALAB rapid test and ROCHE ECLIA-COBAS).

e) Intra-assay reproducibility
Within run precision was evaluated by using 20 replicates of three commercially available references containing 14.9 ng/mL, 38.6 ng/mL and 76.1 ng/mL of prolactin as determined with quantitative HS-PROLAC-CHECK-1 for VEDALAB's readers.
The obtained CV (coefficient of variation) were respectively 8.7%, 8.9% and 6.2%.

VIII- LIMITATIONS

1- HS-PROLAC-CHECK-1 test is specifically designed to detect prolactin in plasma or serum samples.
2- High levels of RF (Rheumatoid factor) or CRP (C-reactive protein) may create interferences and therefore lead to false positive results.
3- A monomeric and polymeric form of prolactin can be found in blood. The monomeric prolactin is dominant and is recognized preferably by the HS-PROLAC-CHECK-1 test. The polymeric protein, named 'big-big form', reacts partially with the anti-Prolactin antibodies and therefore can give falsely lower results.
4- The test is designed to eliminate the potential interference of human antibodies to murine IgG (HAMA). However high level of HAMA could give falsely positive results.
5- This format of test is to be only used with VEDALAB's rapid test readers (Easy Reader® or Easy Reader+®)
6- If the reading time (10 minutes) is not strictly respected, wrong results will be obtained.
7- This format of test should not be used for visual reading.
8- As it is true for any diagnostic method or for any measurements through analysers, there is a variability of the obtained result. Therefore, a confidence range of +/- 25% should be considered for the final value and for the clinical significance of the result.

IX- BIBLIOGRAPHY

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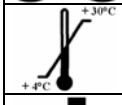
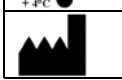
4- **Allolio, B. Hoeppener, A., Leonhardt, U. Deuss, U. and Winkelman, W**. (1987). Size heterogeneity of immunoreactive prolactin in patients with prolactinoma. Acta Endocrinologica (Copenh), 114: 475-482

	Read the instructions before use		For *in vitro* diagnostic use
	Temperature limitations		Do not reuse
	Manufacturer		

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