Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

OneStep FSH Urine RapiCard™ InstaTest

REF 198220-1-20

IVD See external Label 2-30°C Σ 1 Test

Sensitivity	25 mIU/ml

INTENDED USE

Cortez Diagnostics OneStep FSH Urine RapiCard™ InstaTest is a test kit for the determination of FSH (human Follicular Stimulating Hormone) concentration in urine specimens.

TEST PRINCIPLE

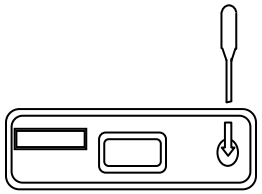
A urine specimen must be collected in a dry and clean container.

SPECIMEN COLLECTION AND PREPARATION

A urine specimen must be collected in a dry and clean container.
sample well of the cassette (see diagram).

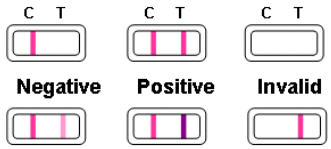
ASSAY PROCEDURE

1. Remove the test device from its protective pouch (bring the device to room temperature before opening the pouch to avoid condensation of moisture on the membrane). Remove the test from the pouch and use it a soon as possible. Label the device with patient or control identifications.
2. Draw the urine sample using the pipette provided, and dispense 3-4 drops (approx. 0.2ml) onto the sample well of the cassette (see diagram).
3. Wait 10-20 minutes and read result. It is important that the background is clear before the result is read. Do not read results after more than 30 minutes.



RESULTS

- **Negative:** Only one colored band appears on the control (C) region, or the test (T) band appears but is lighter than the control band. This indicates the FSH concentration of the sample is less than 25 mIU/mL.
- **Positive:** Two color bands are visible and the test (T) band is equal to or darker than the control (C) band. This indicates the FSH is present in the sample at or above the detection sensitivity of 25 mIU/mL.
- **Invalid:** No visible band at all or no colored band appears on the control (C) region. A total absence of color in both regions is an indication of procedure error and/or that test reagent deterioration has occurred. Repeat test with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



PERFORMANCE CHARACTERISTICS

Cross Reactivity

The cross reactivity of FSH test kits was evaluated with FSH homologous hormone. Homologous hormones, HCG, TSH, LH were added to urine samples containing FSH at concentration of 0, 25 or 100 mIU/mL. No cross reactivity was observed in the study (see Table 1).

Non-specific interference

One-Step FSH test was checked for possible interference from visibly hemolyzed, lipemic and icteric samples. Human hemoglobin, bilirubin or albumin was spiked into samples with different concentration of FSH and tested using un-spiked sample as controls. No significant interference was observed in 20 sample testing results that were either positive or negative for FSH. The results are shown in Table 2.

Table 1 – Cross-reactivity study of One-step FSH test kit
Urine samples spiked with homologous hormones

FSH conc. in urine sample (mIU/mL)	Unspiked urine samples	LH 1000mIU/mL	HCG 1000mIU/mL	TSH 1000mIu/mL
0	--	-	-	-
	-	-	-	-
	-	-	-	-
25	+	+	+	+
	+	+	+	+
	+	+	+	+
100	+	+	+	+
	+	+	+	+
	+	+	+	+

Table 2 – Non-specificity study of One-step FSH test kits

Sample No	Unspiked Samples	Urine samples spiked with (mg/mL)			
		Hemoglobin		Bilirubin	Albumin
		10	1	0.06	100
1	-	-	-	-	-
2	-	-	-	-	-
3	-	-	-	-	-
4	-	-	-	-	-
5	-	-	-	-	-
6	-	-	-	-	-
7	-	-	-	-	-
8	-	-	-	-	-
9	-	-	-	-	-
10	-	-	-	-	-
11	+	+	+	+	+
12	+	+	+	+	+
13	+	+	+	+	+
14	+	+	+	+	+
15	+	+	+	+	+
16	+	+	+	+	+
17	+	+	+	+	+
18	+	+	+	+	+
19	+	+	+	+	+
20	+	+	+	+	+

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LIMITATIONS OF PROCEDURE

1. As with all diagnostic tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. Single measurement of FSH level may give misleading result due to the pulsatile nature of FSH secretion. Samples drawn at different times of the day may vary. Elevated levels of FSH should be confirmed by more than one FSH measurement.
3. The test results should not be affected by pain relievers, antibiotics and other common drugs. After using the pill or patch that contains hCG or LH may affect the test result and should not be taken while using this test kit. In addition, the test will not work properly if you are pregnant or menopausal.
4. A positive FSH test only measures that FSH level is at or greater than 25 mIU/mL (above average) and the transition of menopause is suggested. Menopause by definition is having gone 12 months without a menstrual cycle. A positive FSH test does not give information on exactly when menopause will be reached.
5. If a negative result is given while some of the common symptoms associated with menopause are experienced, consult with the physician.
6. A low FSH level may be observed if there is a presence of a tumor in hypothalamus.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. Keep out of the reach of children.
5. The test kit can be stored at temperatures between 2 to 30ºC in the sealed pouch to the date of expiration.
6. The test kit should be kept away from direct sunlight, moisture and heat.

ISO 13485 ISO 9001	
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Date Adopted	**2016-01-31**
REF 198220-1-20	**CORTEZ- OneStep FSH Urine RapiCard™ InstaTest**
EC REP	**CEpartner4U, Esdoornlaan 13, 3951DB Maarn. The Netherlands.** www.cepartner4u.eu
Revision Date: **2003-10-11**	