

<b>Performance Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
			Checked by	Lingling Su
Doc. No.	EGENS/CE- Appendix 4-1		Approved by	WeiJun Ou
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## Performance Test Report

### I. Precision/Reproducibility/Detection limit Study Protocol

To establish detection limit of Ovulation(LH) Test, more than 30 female negative urine specimens were spiked with hLH standard samples (provided by NICPBP 150531-201003, Traceable to hLH international standard NIBSC 80/552) concentrations. The spiked samples were measured in 10 replicates using 3 different lots each format. The detection limit shall be the 1<sup>st</sup> sample concentration with all 30 test results positive.

#### Strip format

hLH Concentration (mIU/mL)	Lot 1 1303010201		Lot 2 1304010201		Lot 3 1305010201	
	# of negative	# of positive	# of negative	# of positive	# of negative	# of positive
0	10	0	10	0	10	0
5	10	0	10	0	10	0
10	10	0	10	0	10	0
12.5	10	0	10	0	10	0
18.75	10	0	10	0	10	0
25	0	10	0	10	0	10
50	0	10	0	10	0	10
75	0	10	0	10	0	10
100	0	10	0	10	0	10
250	0	10	0	10	0	10

#### Cassette format

hLH Concentration (mIU/mL)	Lot 1 1303010202		Lot 2 1304010202		Lot 3 1305010202	
	# of negative	# of positive	# of negative	# of positive	# of negative	# of positive
0	10	0	10	0	10	0
5	10	0	10	0	10	0
10	10	0	10	0	10	0
12.5	10	0	10	0	10	0
18.75	10	0	10	0	10	0
25	0	10	0	10	0	10
50	0	10	0	10	0	10
75	0	10	0	10	0	10
100	0	10	0	10	0	10

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250	0	10	0	10	0	10	

**Midstream format**

hLH Concentration (mIU/mL)	Lot 1 1303010203		Lot 2 1304010203		Lot 3 1305010203	
	# of negative	# of positive	# of negative	# of positive	# of negative	# of positive
0	10	0	10	0	10	0
5	10	0	10	0	10	0
10	10	0	10	0	10	0
12.5	10	0	10	0	10	0
18.75	10	0	10	0	10	0
25	0	10	0	10	0	10
50	0	10	0	10	0	10
75	0	10	0	10	0	10
100	0	10	0	10	0	10
250	0	10	0	10	0	10

**Lots of Product Used for Each Format:** Three lots

**Numbers of Operators:** Three

**Result:**

Results will be filled in the following form:

**Strip Format**

**Lot No.:** 1303010201

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	0	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	10	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	12.5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	18.75	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	25	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	50	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	75	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	100	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	250	+	+	+
002		+	+	+
003		+	+	+

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

**Strip Format**

**Lot No.:1304010201**

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	0	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	10	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	12.5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	18.75	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	25	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	50	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	75	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+



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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	100	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	250	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

**Strip Format**

**Lot No.:1305010201**

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	0	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	10	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	12.5	—	—	—

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	18.75	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	25	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	50	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	75	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	100	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	250	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

**Cassette Format**

**Lot No.:1303010202**

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	0	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	10	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	12.5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	18.75	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	25	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	50	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	75	+	+	+

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	100	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	250	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+



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Cassette Format

Lot No.:1304010202

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	0	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	10	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	12.5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	18.75	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	25	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	50	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	75	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	100	+	+	+
002		+	+	+

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	250	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

**Cassette Format**

**Lot No.:1305010202**

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	0	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	10	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	12.5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	18.75	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	25	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	50	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	75	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	100	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	250	+	+	+
002		+	+	+
003		+	+	+

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

**Midstream Format**  
**Lot No.:1303010203**

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	0	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—



<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	10	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	12.5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	18.75	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	25	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	50	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	75	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	100	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	250	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

**Midstream Format**  
**Lot No.:1304010203**

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	0	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	10	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	12.5	—	—	—

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	18.75	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	25	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	50	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	75	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	100	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	250	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

**Midstream Format**  
**Lot No.:1305010203**

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	0	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—

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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	10	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	12.5	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	18.75	—	—	—
002		—	—	—
003		—	—	—
004		—	—	—



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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
005		—	—	—
006		—	—	—
007		—	—	—
008		—	—	—
009		—	—	—
010		—	—	—

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	25	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	50	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	75	+	+	+

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	100	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

Sample Numbers	Concentration	Viewer A	Viewer B	Viewer C
001	250	+	+	+
002		+	+	+
003		+	+	+
004		+	+	+
005		+	+	+
006		+	+	+
007		+	+	+
008		+	+	+
009		+	+	+
010		+	+	+

<b>Performance Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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**Conclusion:**

Based on the results, a cut-off value or detection limit is 25 mIU/mL.

## II. Specificity / Cross Reactivity Protocol

### 1) Specificity/Cross-Reactivity

To evaluate cross-reactivity, negative and positive urine samples (0 and 25 mIU/mL LH) were spiked with various concentrations of other glycoprotein hormones such as FSH (200mIU/mL) and TSH (100µIU/mL). (provided by NICPBP, Traceable to NIBSC standard 08/282, 81/565 relevantly). The Each sample was tested by 3 different lots and 3 different operators. For the LH 0mIU/mL, if there is no positive result, then the conclusion can be there is no interference from these substances at the certain concentration. For LH 25mIU/mL, if there is no negative result, then the conclusion can be there is no interference from these substances at the certain concentration.

**Strip Format**

**Lot No.:1303010201**

Sample Numbers	Negative Urine Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	—	—	—
002	TSH (100µIU/mL)	—	—	—

Sample Numbers	Positive Urine (25mIU/mL LH) Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	+	+	+
002	TSH (100µIU/mL)	+	+	+

**Strip Format**

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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**Lot No.:1304010201**

Sample Numbers	Negative Urine Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	—	—	—
002	TSH (100µIU/mL)	—	—	—

Sample Numbers	Positive Urine (25mIU/mL LH) Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	+	+	+
002	TSH (100µIU/mL)	+	+	+

**Strip Format**

**Lot No.:1305010201**

Sample Numbers	Negative Urine Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	—	—	—
002	TSH (100µIU/mL)	—	—	—

Sample Numbers	Positive Urine (25mIU/mL LH) Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	+	+	+
002	TSH (100µIU/mL)	+	+	+

**Cassette Format**

**Lot No.:1303010202**

Sample Numbers	Negative Urine Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	—	—	—
002	TSH (100µIU/mL)	—	—	—

Sample Numbers	Positive Urine (25mIU/mL LH) Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	+	+	+
002	TSH (100µIU/mL)	+	+	+

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
			Checked by	Lingling Su
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**Cassette Format**

**Lot No.:1304010202**

Sample Numbers	Negative Urine Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	—	—	—
002	TSH (100µIU/mL)	—	—	—

Sample Numbers	Positive Urine (25mIU/mL LH) Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	+	+	+
002	TSH (100µIU/mL)	+	+	+

**Cassette Format**

**Lot No.:1305010202**

Sample Numbers	Negative Urine Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	—	—	—
002	TSH (100µIU/mL)	—	—	—

Sample Numbers	Positive Urine (25mIU/mL LH) Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	+	+	+
002	TSH (100µIU/mL)	+	+	+

**Midstream Format**

**Lot No.:1303010203**

Sample Numbers	Negative Urine Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	—	—	—
002	TSH (100µIU/mL)	—	—	—

Sample Numbers	Positive Urine (25mIU/mL LH) Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	+	+	+
002	TSH (100µIU/mL)	+	+	+

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
			Checked by	Lingling Su
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**Midstream Format**

**Lot No.:1304010203**

Sample Numbers	Negative Urine Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	—	—	—
002	TSH (100μIU/mL)	—	—	—

Sample Numbers	Positive Urine (25mIU/mL LH) Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	+	+	+
002	TSH (100μIU/mL)	+	+	+

**Midstream Format**

**Lot No.:1305010203**

Sample Numbers	Negative Urine Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	—	—	—
002	TSH (100μIU/mL)	—	—	—

Sample Numbers	Positive Urine (25mIU/mL LH) Spiked with	Viewer A	Viewer B	Viewer C
001	FSH (200mIU/mL)	+	+	+
002	TSH (100μIU/mL)	+	+	+

**Conclusion:**

The results indicate that FSH TSH exhibited no cross reactivity when dissolved in urine.

**2) Interferants**

To evaluate potential interference from certain exogenous compounds, male urine samples containing 0 and 25 mIU/mL LH were tested after interferants application. 3 Lots shall be tested, and conclusion of no interference can be granted if there is no false positive or false negative relevantly.

**Strip Format**

**Lot 1: 1303010201    Lot 2: 1304010201    Lot 3: 1305010201**

Interferants	0mIU/mL LH			25 mIU/mL LH		
	Lot1	Lot2	Lot3	Lot1	Lot2	Lot3

<b>Performacnce Test report</b>				Prepared by		Xuemei Bao	
Ovulation(LH) Test				Checked by		Lingling Su	
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Acetaminophen (20mg/dl)	—	—	—	+	+	+	
Acetosalicyclic Acid (20mg/dl)	—	—	—	+	+	+	
Ascorbic Acid (20mg/dl)	—	—	—	+	+	+	
Atropine (20mg/dl)	—	—	—	+	+	+	
Caffeine (20mg/dl)	—	—	—	+	+	+	
Gentisic Acid (20mg/dl)	—	—	—	+	+	+	
Glucose (1g/dl)	—	—	—	+	+	+	
Hemoglobin (10mg/dl)	—	—	—	+	+	+	
Ampicillin (20mg/dl)	—	—	—	+	+	+	
Tetracycline (20mg/dl)	—	—	—	+	+	+	

**Cassette Format**

Lot 1:1303010202      Lot 2: 1304010202      Lot 3: 1305010202

Interferants	0mIU/mL LH			25 mIU/mL LH		
	Lot1	Lot2	Lot3	Lot1	Lot2	Lot3
Acetaminophen (20mg/dl)	—	—	—	+	+	+
Acetosalicyclic Acid (20mg/dl)	—	—	—	+	+	+
Ascorbic Acid (20mg/dl)	—	—	—	+	+	+
Atropine (20mg/dl)	—	—	—	+	+	+
Caffeine (20mg/dl)	—	—	—	+	+	+
Gentisic Acid (20mg/dl)	—	—	—	+	+	+
Glucose (1g /dl)	—	—	—	+	+	+
Hemoglobin (10mg/dl)	—	—	—	+	+	+
Ampicillin (20mg/dl)	—	—	—	+	+	+
Tetracycline (20mg/dl)	—	—	—	+	+	+

**Midstream Format**

Lot 1: 1303010203      Lot 2: 1304010203      Lot 3: 1305010203

Interferants	0mIU/mL LH			25 mIU/mL LH		
	Lot1	Lot2	Lot3	Lot1	Lot2	Lot3
Acetaminophen (20mg/dl)	—	—	—	+	+	+
Acetosalicyclic Acid (20mg/dl)	—	—	—	+	+	+
Ascorbic Acid (20mg/dl)	—	—	—	+	+	+
Atropine (20mg/dl)	—	—	—	+	+	+
Caffeine (20mg/dl)	—	—	—	+	+	+
Gentisic Acid (20mg/dl)	—	—	—	+	+	+
Glucose (1g /dl)	—	—	—	+	+	+
Hemoglobin (10mg/dl)	—	—	—	+	+	+

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by		Xuemei Bao		
			Checked by		Lingling Su		
Doc. No.	EGENS/CE- Appendix 4-1		Approved by		WeiJun Ou		
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Ampicillin (20mg/dl)		—	—	—	+	+	+
Tetracycline (20mg/dl)		—	—	—	+	+	+

**Conclusion:**

The results demonstrate that no significant interference was observed in above samples with results that were either positive or negative for LH.

**3) pH**

To evaluate potential interference from changes in pH, negative and positive urine samples containing 0 and 25 mIU/mL LH were tested at pH values from 4 to 9 by 3 different lots and 3 operators. Conclusion of no interference can be granted if there is no false positive or false negative relevantly.

**Strip Format**

**Lot No.:1303010201**

Sample Numbers	pH	0 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	4	—	—	—	+	+	+
002	5	—	—	—	+	+	+
003	6	—	—	—	+	+	+
004	7	—	—	—	+	+	+
005	8	—	—	—	+	+	+
006	9	—	—	—	+	+	+

**Strip Format**

**Lot No.:1304010201**

Sample Numbers	pH	0 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	4	—	—	—	+	+	+
002	5	—	—	—	+	+	+
003	6	—	—	—	+	+	+
004	7	—	—	—	+	+	+
005	8	—	—	—	+	+	+
006	9	—	—	—	+	+	+

**Strip Format**

**Lot No.:1305010201**



Performacnce Test report Ovulation(LH) Test			Prepared by		Xuemei Bao		
			Checked by		Lingling Su		
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Sample Numbers	pH	0 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	4	—	—	—	+	+	+
002	5	—	—	—	+	+	+
003	6	—	—	—	+	+	+
004	7	—	—	—	+	+	+
005	8	—	—	—	+	+	+
006	9	—	—	—	+	+	+

**Cassette Format**

**Lot No.:1303010202**

Sample Numbers	pH	0 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	4	—	—	—	+	+	+
002	5	—	—	—	+	+	+
003	6	—	—	—	+	+	+
004	7	—	—	—	+	+	+
005	8	—	—	—	+	+	+
006	9	—	—	—	+	+	+

**Cassette Format**

**Lot No.:1304010202**

Sample Numbers	pH	0 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	4	—	—	—	+	+	+
002	5	—	—	—	+	+	+
003	6	—	—	—	+	+	+
004	7	—	—	—	+	+	+
005	8	—	—	—	+	+	+
006	9	—	—	—	+	+	+

**Cassette Format**

**Lot No.:1305010202**

Sample		0 mIU/mL LH	25mIU/mL LH
--------	--	-------------	-------------

Performacnce Test report Ovulation(LH) Test				Prepared by		Xuemei Bao	
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		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	4	—	—	—	+	+	+
002	5	—	—	—	+	+	+
003	6	—	—	—	+	+	+
004	7	—	—	—	+	+	+
005	8	—	—	—	+	+	+
006	9	—	—	—	+	+	+

**Midstream Format**

**Lot No.:1303010203**

Sample Numbers	pH	0 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	4	—	—	—	+	+	+
002	5	—	—	—	+	+	+
003	6	—	—	—	+	+	+
004	7	—	—	—	+	+	+
005	8	—	—	—	+	+	+
006	9	—	—	—	+	+	+

**Midstream Format**

**Lot No.:1304010203**

Sample Numbers	pH	0 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	4	—	—	—	+	+	+
002	5	—	—	—	+	+	+
003	6	—	—	—	+	+	+
004	7	—	—	—	+	+	+
005	8	—	—	—	+	+	+
006	9	—	—	—	+	+	+

**Midstream Format**

**Lot No.:1305010203**

Sample Numbers	pH	0 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C

Performacnce Test report Ovulation(LH) Test			Prepared by		Xuemei Bao		
			Checked by		Lingling Su		
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Sample Numbers	pH	0 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	4	—	—	—	+	+	+
002	5	—	—	—	+	+	+
003	6	—	—	—	+	+	+
004	7	—	—	—	+	+	+
005	8	—	—	—	+	+	+
006	9	—	—	—	+	+	+

**Conclusion:**

The results indicate that changing in PH does not interfere in the results that were either positive or negative for LH.

**4) Density**

To evaluate potential interference from changes in specific gravity, negative and positive urine samples containing 5 and 25 mIU/mL LH were tested at density values ranging from 1.000 to 1.035 by 3 different lots and 3 operators. Conclusion of no interference can be granted if there is no false positive or false negative relevantly.

**Strip Format**

**Lot No.:1303010201**

Sample Numbers	Specific Gravity (g/mL)	5 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	1.000	—	—	—	+	+	+
002	1.010	—	—	—	+	+	+
003	1.015	—	—	—	+	+	+
004	1.025	—	—	—	+	+	+
005	1.035	—	—	—	+	+	+

**Strip Format**

**Lot No.:1304010201**

Sample Numbers	Specific Gravity (g/mL)	5 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	1.000	—	—	—	+	+	+
002	1.010	—	—	—	+	+	+
003	1.015	—	—	—	+	+	+

Performacnce Test report Ovulation(LH) Test			Prepared by		Xuemei Bao		
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Sample Numbers	Specific Gravity (g/mL)	5 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
004	1.025	—	—	—	+	+	+
005	1.035	—	—	—	+	+	+

**Strip Format**

Lot No.:1305010201

Sample Numbers	Specific Gravity (g/mL)	5 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	1.000	—	—	—	+	+	+
002	1.010	—	—	—	+	+	+
003	1.015	—	—	—	+	+	+
004	1.025	—	—	—	+	+	+
005	1.035	—	—	—	+	+	+

**Cassette Format**

Lot No.:1303010202

Sample Numbers	Specific Gravity (g/mL)	5 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	1.000	—	—	—	+	+	+
002	1.010	—	—	—	+	+	+
003	1.015	—	—	—	+	+	+
004	1.025	—	—	—	+	+	+
005	1.035	—	—	—	+	+	+

**Cassette Format**

Lot No.:1304010202

Sample Numbers	Specific Gravity (g/mL)	5 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	1.000	±	±	±	+	+	+
002	1.010	±	±	±	+	+	+
003	1.015	±	±	±	+	+	+
004	1.025	±	±	±	+	+	+
005	1.035	±	±	±	+	+	+

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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**Cassette Format**

**Lot No.:1305010202**

Sample Numbers	Specific Gravity (g/mL)	5 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	1.000	—	—	—	+	+	+
002	1.010	—	—	—	+	+	+
003	1.015	—	—	—	+	+	+
004	1.025	—	—	—	+	+	+
005	1.035	—	—	—	+	+	+

**Midstream Format**

**Lot No.:1303010203**

Sample Numbers	Specific Gravity (g/mL)	5 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	1.000	—	—	—	+	+	+
002	1.010	—	—	—	+	+	+
003	1.015	—	—	—	+	+	+
004	1.025	—	—	—	+	+	+
005	1.035	—	—	—	+	+	+

**Midstream Format**

**Lot No.:1304010203**

Sample Numbers	Specific Gravity (g/mL)	5 mIU/mL LH			25mIU/mL LH		
		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	1.000	—	—	—	+	+	+
002	1.010	—	—	—	+	+	+
003	1.015	—	—	—	+	+	+
004	1.025	—	—	—	+	+	+
005	1.035	—	—	—	+	+	+

**Midstream Format**

**Lot No.:1305010203**

Sample		5 mIU/mL LH	25mIU/mL LH
--------	--	-------------	-------------

Performacnce Test report Ovulation(LH) Test				Prepared by		Xuemei Bao	
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		Viewer A	Viewer B	Viewer C	Viewer A	Viewer B	Viewer C
001	1.000	—	—	—	+	+	+
002	1.010	—	—	—	+	+	+
003	1.015	—	—	—	+	+	+
004	1.025	—	—	—	+	+	+
005	1.035	—	—	—	+	+	+

**Conclusion:**

The results indicate that changing in specific gravity does not interfere in the results that were either positive or negative for LH.

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
			Checked by	Lingling Su
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### III. Method Comparison Protocol (for all formats)

A method comparison study was performed comparing results obtained from Egens Ovulation Test to results from predicate devices (ACON).

#### Summary of Research

Entrusted by Nantong Egens Biotechnology Co., Ltd. (hereinafter referred to as “Egens”), Nantong Hongqiao Hospital implemented the study on ovulation test detection kits(Abbreviation: assessed reagent ) researched and produced by Nantong Egens Biotechnology Co., Ltd. during September, 2013~October, 2013. The study applies Luteinizing hormone (LH) test kit (colloidal gold method) (Abbreviation: control reagent) produced by ACON Biotech (Hangzhou) Co. Ltd. and is widely believed with good quality, to carry out synchronous blind contrast experimental research and, to investigate the consistency between the test results of examine test reagent and similar products that have been marketed through the synchronous operation between sample provider (lay person) and researcher.

300 cases of urine samples were used for this study, the test result are shown as follows:

#### Strip Type

It is shown by the test results of 100 cases of urine samples that:

There are 100 cases of samples of which the results tested by assessed and control reagents are the same, among, 43 cases are tested as positive and 57 are negative.

The compared result of the two kinds of reagent kits: positive conformance is 100% and the negative is 100%, which indicates that the clinical coincidence rate between assessed and control reagents is high and the test result has high consistency.

#### Cassette Type

It is shown by the test results of 100 cases of urine samples that:

The result of assessed reagent is completely in consistent with that of control reagent. Among, 48 cases are positive samples and 52 are negative.

The compared result of the two kinds of reagent kits: positive conformance is 100% and the negative is 100%, which indicates that the clinical coincidence rate between assessed and control reagents is high and the test result has high consistency.

#### Midstream Type

It is shown by the test results of 100 cases of urine samples that:

The result of assessed reagent is completely in consistent with that of control reagent. Among, 41 cases are positive samples and 59 are negative.

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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The compared result of the two kinds of reagent kits: positive conformance is 100% and the negative is 100%, which indicates that the clinical coincidence rate between assessed and control reagents is high and the test result has high consistency.

**Result:**

The results are filled in the following Tables.

**Strip Format**

**Lot 1: 1303010201, Lot 2:1304010201, Lot 3: 1305010201**

Sample Number	Viewer A Result				Viewer B Result				Viewer C Result			
	lot 1	lot 2	lot 3	A C O N	lot 1	lot 2	lot 3	A C O N	lot 1	lot 2	lot 3	A C O N
A001	—	—	—	—	—	—	—	—	—	—	—	—
A002	—	—	—	—	—	—	—	—	—	—	—	—
A004	—	—	—	—	—	—	—	—	—	—	—	—
A005	—	—	—	—	—	—	—	—	—	—	—	—
A009	—	—	—	—	—	—	—	—	—	—	—	—
A010	—	—	—	—	—	—	—	—	—	—	—	—
A013	—	—	—	—	—	—	—	—	—	—	—	—
A014	—	—	—	—	—	—	—	—	—	—	—	—
A017	—	—	—	—	—	—	—	—	—	—	—	—
A020	—	—	—	—	—	—	—	—	—	—	—	—
A022	—	—	—	—	—	—	—	—	—	—	—	—
A024	—	—	—	—	—	—	—	—	—	—	—	—
A025	—	—	—	—	—	—	—	—	—	—	—	—
A026	—	—	—	—	—	—	—	—	—	—	—	—
A027	—	—	—	—	—	—	—	—	—	—	—	—
A028	—	—	—	—	—	—	—	—	—	—	—	—
A029	—	—	—	—	—	—	—	—	—	—	—	—
A030	—	—	—	—	—	—	—	—	—	—	—	—
A031	—	—	—	—	—	—	—	—	—	—	—	—
A033	—	—	—	—	—	—	—	—	—	—	—	—
A034	—	—	—	—	—	—	—	—	—	—	—	—
A036	—	—	—	—	—	—	—	—	—	—	—	—
A038	—	—	—	—	—	—	—	—	—	—	—	—
A040	—	—	—	—	—	—	—	—	—	—	—	—



Performacnce Test report Ovulation(LH) Test								Prepared by			Xuemei Bao		
								Checked by			Lingling Su		
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A043	-	-	-	-	-	-	-	-	-	-	-	-	
A045	-	-	-	-	-	-	-	-	-	-	-	-	
A046	-	-	-	-	-	-	-	-	-	-	-	-	
A048	-	-	-	-	-	-	-	-	-	-	-	-	
A049	-	-	-	-	-	-	-	-	-	-	-	-	
A052	-	-	-	-	-	-	-	-	-	-	-	-	
A053	-	-	-	-	-	-	-	-	-	-	-	-	
A054	-	-	-	-	-	-	-	-	-	-	-	-	
A056	-	-	-	-	-	-	-	-	-	-	-	-	
A057	-	-	-	-	-	-	-	-	-	-	-	-	
A058	-	-	-	-	-	-	-	-	-	-	-	-	
A059	-	-	-	-	-	-	-	-	-	-	-	-	
A060	-	-	-	-	-	-	-	-	-	-	-	-	
A062	-	-	-	-	-	-	-	-	-	-	-	-	
A063	-	-	-	-	-	-	-	-	-	-	-	-	
A066	-	-	-	-	-	-	-	-	-	-	-	-	
A071	-	-	-	-	-	-	-	-	-	-	-	-	
A075	-	-	-	-	-	-	-	-	-	-	-	-	
A078	-	-	-	-	-	-	-	-	-	-	-	-	
A081	-	-	-	-	-	-	-	-	-	-	-	-	
A082	-	-	-	-	-	-	-	-	-	-	-	-	
A083	-	-	-	-	-	-	-	-	-	-	-	-	
A086	-	-	-	-	-	-	-	-	-	-	-	-	
A087	-	-	-	-	-	-	-	-	-	-	-	-	
A088	-	-	-	-	-	-	-	-	-	-	-	-	
A089	-	-	-	-	-	-	-	-	-	-	-	-	
A090	-	-	-	-	-	-	-	-	-	-	-	-	
A091	-	-	-	-	-	-	-	-	-	-	-	-	
A093	-	-	-	-	-	-	-	-	-	-	-	-	
A094	-	-	-	-	-	-	-	-	-	-	-	-	
A098	-	-	-	-	-	-	-	-	-	-	-	-	
A099	-	-	-	-	-	-	-	-	-	-	-	-	
A100	-	-	-	-	-	-	-	-	-	-	-	-	
A003	+	+	+	+	+	+	+	+	+	+	+	+	
A006	+	+	+	+	+	+	+	+	+	+	+	+	
A007	+	+	+	+	+	+	+	+	+	+	+	+	
A008	+	+	+	+	+	+	+	+	+	+	+	+	
A011	+	+	+	+	+	+	+	+	+	+	+	+	

<b>Performacnce Test report</b> Ovulation(LH) Test								Prepared by				Xuemei Bao	
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A012	+	+	+	+	+	+	+	+	+	+	+	+	+
A015	+	+	+	+	+	+	+	+	+	+	+	+	+
A016	+	+	+	+	+	+	+	+	+	+	+	+	+
A018	+	+	+	+	+	+	+	+	+	+	+	+	+
A019	+	+	+	+	+	+	+	+	+	+	+	+	+
A021	+	+	+	+	+	+	+	+	+	+	+	+	+
A023	+	+	+	+	+	+	+	+	+	+	+	+	+
A032	+	+	+	+	+	+	+	+	+	+	+	+	+
A035	+	+	+	+	+	+	+	+	+	+	+	+	+
A037	+	+	+	+	+	+	+	+	+	+	+	+	+
A039	+	+	+	+	+	+	+	+	+	+	+	+	+
A041	+	+	+	+	+	+	+	+	+	+	+	+	+
A042	+	+	+	+	+	+	+	+	+	+	+	+	+
A044	+	+	+	+	+	+	+	+	+	+	+	+	+
A047	+	+	+	+	+	+	+	+	+	+	+	+	+
A050	+	+	+	+	+	+	+	+	+	+	+	+	+
A051	+	+	+	+	+	+	+	+	+	+	+	+	+
A055	+	+	+	+	+	+	+	+	+	+	+	+	+
A061	+	+	+	+	+	+	+	+	+	+	+	+	+
A064	+	+	+	+	+	+	+	+	+	+	+	+	+
A065	+	+	+	+	+	+	+	+	+	+	+	+	+
A067	+	+	+	+	+	+	+	+	+	+	+	+	+
A068	+	+	+	+	+	+	+	+	+	+	+	+	+
A069	+	+	+	+	+	+	+	+	+	+	+	+	+
A070	+	+	+	+	+	+	+	+	+	+	+	+	+
A072	+	+	+	+	+	+	+	+	+	+	+	+	+
A073	+	+	+	+	+	+	+	+	+	+	+	+	+
A074	+	+	+	+	+	+	+	+	+	+	+	+	+
A076	+	+	+	+	+	+	+	+	+	+	+	+	+
A077	+	+	+	+	+	+	+	+	+	+	+	+	+
A079	+	+	+	+	+	+	+	+	+	+	+	+	+
A080	+	+	+	+	+	+	+	+	+	+	+	+	+
A084	+	+	+	+	+	+	+	+	+	+	+	+	+
A085	+	+	+	+	+	+	+	+	+	+	+	+	+
A092	+	+	+	+	+	+	+	+	+	+	+	+	+
A095	+	+	+	+	+	+	+	+	+	+	+	+	+
A096	+	+	+	+	+	+	+	+	+	+	+	+	+
A097	+	+	+	+	+	+	+	+	+	+	+	+	+

<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
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**Summary Results for Strip**

<b>Nantong Egens</b> <b>(assessed reagent)</b>	<b>Control reagent</b>		
		+	-
	+	<b>43</b>	<b>0</b>
	-	<b>0</b>	<b>57</b>

**Cassette Format**

**Lot 1: 1303010202, Lot 2: 1304010202, Lot 3: 1305010202**

Sample Number	Viewer A Resultt				Viewer B Result				Viewer C Result			
	lot 1	lot 2	lot 3	A C O N	lot 1	lot 2	lot 3	A C O N	lot 1	lot 2	lot 3	A C O N
B002	—	—	—	—	—	—	—	—	—	—	—	—
B004	—	—	—	—	—	—	—	—	—	—	—	—
B009	—	—	—	—	—	—	—	—	—	—	—	—
B011	—	—	—	—	—	—	—	—	—	—	—	—
B012	—	—	—	—	—	—	—	—	—	—	—	—
B013	—	—	—	—	—	—	—	—	—	—	—	—
B014	—	—	—	—	—	—	—	—	—	—	—	—
B019	—	—	—	—	—	—	—	—	—	—	—	—
B022	—	—	—	—	—	—	—	—	—	—	—	—
B024	—	—	—	—	—	—	—	—	—	—	—	—
B026	—	—	—	—	—	—	—	—	—	—	—	—
B027	—	—	—	—	—	—	—	—	—	—	—	—
B028	—	—	—	—	—	—	—	—	—	—	—	—
B031	—	—	—	—	—	—	—	—	—	—	—	—
B032	—	—	—	—	—	—	—	—	—	—	—	—
B033	—	—	—	—	—	—	—	—	—	—	—	—
B034	—	—	—	—	—	—	—	—	—	—	—	—
B036	—	—	—	—	—	—	—	—	—	—	—	—
B037	—	—	—	—	—	—	—	—	—	—	—	—
B038	—	—	—	—	—	—	—	—	—	—	—	—
B040	—	—	—	—	—	—	—	—	—	—	—	—
B041	—	—	—	—	—	—	—	—	—	—	—	—
B044	—	—	—	—	—	—	—	—	—	—	—	—
B051	—	—	—	—	—	—	—	—	—	—	—	—

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B052	-	-	-	-	-	-	-	-	-	-	-	-
B053	-	-	-	-	-	-	-	-	-	-	-	-
B054	-	-	-	-	-	-	-	-	-	-	-	-
B055	-	-	-	-	-	-	-	-	-	-	-	-
B056	-	-	-	-	-	-	-	-	-	-	-	-
B057	-	-	-	-	-	-	-	-	-	-	-	-
B059	-	-	-	-	-	-	-	-	-	-	-	-
B060	-	-	-	-	-	-	-	-	-	-	-	-
B061	-	-	-	-	-	-	-	-	-	-	-	-
B063	-	-	-	-	-	-	-	-	-	-	-	-
B068	-	-	-	-	-	-	-	-	-	-	-	-
B074	-	-	-	-	-	-	-	-	-	-	-	-
B078	-	-	-	-	-	-	-	-	-	-	-	-
B079	-	-	-	-	-	-	-	-	-	-	-	-
B080	-	-	-	-	-	-	-	-	-	-	-	-
B084	-	-	-	-	-	-	-	-	-	-	-	-
B085	-	-	-	-	-	-	-	-	-	-	-	-
B086	-	-	-	-	-	-	-	-	-	-	-	-
B087	-	-	-	-	-	-	-	-	-	-	-	-
B088	-	-	-	-	-	-	-	-	-	-	-	-
B089	-	-	-	-	-	-	-	-	-	-	-	-
B090	-	-	-	-	-	-	-	-	-	-	-	-
B092	-	-	-	-	-	-	-	-	-	-	-	-
B093	-	-	-	-	-	-	-	-	-	-	-	-
B094	-	-	-	-	-	-	-	-	-	-	-	-
B095	-	-	-	-	-	-	-	-	-	-	-	-
B096	-	-	-	-	-	-	-	-	-	-	-	-
B100	-	-	-	-	-	-	-	-	-	-	-	-
B001	+	+	+	+	+	+	+	+	+	+	+	+
B003	+	+	+	+	+	+	+	+	+	+	+	+
B005	+	+	+	+	+	+	+	+	+	+	+	+
B006	+	+	+	+	+	+	+	+	+	+	+	+
B007	+	+	+	+	+	+	+	+	+	+	+	+
B008	+	+	+	+	+	+	+	+	+	+	+	+
B010	+	+	+	+	+	+	+	+	+	+	+	+
B015	+	+	+	+	+	+	+	+	+	+	+	+
B016	+	+	+	+	+	+	+	+	+	+	+	+
B017	+	+	+	+	+	+	+	+	+	+	+	+

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B018	+	+	+	+	+	+	+	+	+	+	+	+
B020	+	+	+	+	+	+	+	+	+	+	+	+
B021	+	+	+	+	+	+	+	+	+	+	+	+
B023	+	+	+	+	+	+	+	+	+	+	+	+
B025	+	+	+	+	+	+	+	+	+	+	+	+
B029	+	+	+	+	+	+	+	+	+	+	+	+
B030	+	+	+	+	+	+	+	+	+	+	+	+
B035	+	+	+	+	+	+	+	+	+	+	+	+
B039	+	+	+	+	+	+	+	+	+	+	+	+
B042	+	+	+	+	+	+	+	+	+	+	+	+
B043	+	+	+	+	+	+	+	+	+	+	+	+
B045	+	+	+	+	+	+	+	+	+	+	+	+
B046	+	+	+	+	+	+	+	+	+	+	+	+
B047	+	+	+	+	+	+	+	+	+	+	+	+
B048	+	+	+	+	+	+	+	+	+	+	+	+
B049	+	+	+	+	+	+	+	+	+	+	+	+
B050	+	+	+	+	+	+	+	+	+	+	+	+
B058	+	+	+	+	+	+	+	+	+	+	+	+
B062	+	+	+	+	+	+	+	+	+	+	+	+
B064	+	+	+	+	+	+	+	+	+	+	+	+
B065	+	+	+	+	+	+	+	+	+	+	+	+
B066	+	+	+	+	+	+	+	+	+	+	+	+
B067	+	+	+	+	+	+	+	+	+	+	+	+
B069	+	+	+	+	+	+	+	+	+	+	+	+
B070	+	+	+	+	+	+	+	+	+	+	+	+
B071	+	+	+	+	+	+	+	+	+	+	+	+
B072	+	+	+	+	+	+	+	+	+	+	+	+
B073	+	+	+	+	+	+	+	+	+	+	+	+
B075	+	+	+	+	+	+	+	+	+	+	+	+
B076	+	+	+	+	+	+	+	+	+	+	+	+
B077	+	+	+	+	+	+	+	+	+	+	+	+
B081	+	+	+	+	+	+	+	+	+	+	+	+
B082	+	+	+	+	+	+	+	+	+	+	+	+
B083	+	+	+	+	+	+	+	+	+	+	+	+
B091	+	+	+	+	+	+	+	+	+	+	+	+
B097	+	+	+	+	+	+	+	+	+	+	+	+
B098	+	+	+	+	+	+	+	+	+	+	+	+
B099	+	+	+	+	+	+	+	+	+	+	+	+

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**Summary Results for Cassette**

<b>Nantong Egens</b> <b>(assessed reagent)</b>				<b>Control reagent</b>	
				+	-
	+			<b>48</b>	<b>0</b>
	-			<b>0</b>	<b>52</b>

**Midstream Format**

**Lot 1: 1303010203, Lot 2: 1304010203, Lot 3: 1305010203**

Sample Number	Viewer A Resultt				Viewer B Result				Viewer C Result			
	lot 1	lot 2	lot 3	A C O N	lot 1	lot 2	lot 3	A C O N	lot 1	lot 2	lot 3	A C O N
C001	—	—	—	—	—	—	—	—	—	—	—	—
C002	—	—	—	—	—	—	—	—	—	—	—	—
C003	—	—	—	—	—	—	—	—	—	—	—	—
C005	—	—	—	—	—	—	—	—	—	—	—	—
C006	—	—	—	—	—	—	—	—	—	—	—	—
C009	—	—	—	—	—	—	—	—	—	—	—	—
C011	—	—	—	—	—	—	—	—	—	—	—	—
C013	—	—	—	—	—	—	—	—	—	—	—	—
C015	—	—	—	—	—	—	—	—	—	—	—	—
C016	—	—	—	—	—	—	—	—	—	—	—	—
C017	—	—	—	—	—	—	—	—	—	—	—	—
C018	—	—	—	—	—	—	—	—	—	—	—	—
C019	—	—	—	—	—	—	—	—	—	—	—	—
C021	—	—	—	—	—	—	—	—	—	—	—	—
C022	—	—	—	—	—	—	—	—	—	—	—	—
C023	—	—	—	—	—	—	—	—	—	—	—	—
C024	—	—	—	—	—	—	—	—	—	—	—	—
C027	—	—	—	—	—	—	—	—	—	—	—	—
C028	—	—	—	—	—	—	—	—	—	—	—	—
C029	—	—	—	—	—	—	—	—	—	—	—	—
C033	—	—	—	—	—	—	—	—	—	—	—	—
C034	—	—	—	—	—	—	—	—	—	—	—	—
C035	—	—	—	—	—	—	—	—	—	—	—	—
C036	—	—	—	—	—	—	—	—	—	—	—	—

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C039	-	-	-	-	-	-	-	-	-	-	-	-
C040	-	-	-	-	-	-	-	-	-	-	-	-
C044	-	-	-	-	-	-	-	-	-	-	-	-
C045	-	-	-	-	-	-	-	-	-	-	-	-
C047	-	-	-	-	-	-	-	-	-	-	-	-
C048	-	-	-	-	-	-	-	-	-	-	-	-
C049	-	-	-	-	-	-	-	-	-	-	-	-
C050	-	-	-	-	-	-	-	-	-	-	-	-
C052	-	-	-	-	-	-	-	-	-	-	-	-
C054	-	-	-	-	-	-	-	-	-	-	-	-
C056	-	-	-	-	-	-	-	-	-	-	-	-
C057	-	-	-	-	-	-	-	-	-	-	-	-
C059	-	-	-	-	-	-	-	-	-	-	-	-
C060	-	-	-	-	-	-	-	-	-	-	-	-
C061	-	-	-	-	-	-	-	-	-	-	-	-
C062	-	-	-	-	-	-	-	-	-	-	-	-
C063	-	-	-	-	-	-	-	-	-	-	-	-
C066	-	-	-	-	-	-	-	-	-	-	-	-
C067	-	-	-	-	-	-	-	-	-	-	-	-
C068	-	-	-	-	-	-	-	-	-	-	-	-
C069	-	-	-	-	-	-	-	-	-	-	-	-
C070	-	-	-	-	-	-	-	-	-	-	-	-
C071	-	-	-	-	-	-	-	-	-	-	-	-
C072	-	-	-	-	-	-	-	-	-	-	-	-
C075	-	-	-	-	-	-	-	-	-	-	-	-
C079	-	-	-	-	-	-	-	-	-	-	-	-
C081	-	-	-	-	-	-	-	-	-	-	-	-
C082	-	-	-	-	-	-	-	-	-	-	-	-
C087	-	-	-	-	-	-	-	-	-	-	-	-
C089	-	-	-	-	-	-	-	-	-	-	-	-
C092	-	-	-	-	-	-	-	-	-	-	-	-
C094	-	-	-	-	-	-	-	-	-	-	-	-
C097	-	-	-	-	-	-	-	-	-	-	-	-
C099	-	-	-	-	-	-	-	-	-	-	-	-
C100	-	-	-	-	-	-	-	-	-	-	-	-
C004	+	+	+	+	+	+	+	+	+	+	+	+
C007	+	+	+	+	+	+	+	+	+	+	+	+
C008	+	+	+	+	+	+	+	+	+	+	+	+

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C010	+	+	+	+	+	+	+	+	+	+	+	+
C012	+	+	+	+	+	+	+	+	+	+	+	+
C014	+	+	+	+	+	+	+	+	+	+	+	+
C020	+	+	+	+	+	+	+	+	+	+	+	+
C025	+	+	+	+	+	+	+	+	+	+	+	+
C026	+	+	+	+	+	+	+	+	+	+	+	+
C030	+	+	+	+	+	+	+	+	+	+	+	+
C031	+	+	+	+	+	+	+	+	+	+	+	+
C032	+	+	+	+	+	+	+	+	+	+	+	+
C037	+	+	+	+	+	+	+	+	+	+	+	+
C038	+	+	+	+	+	+	+	+	+	+	+	+
C041	+	+	+	+	+	+	+	+	+	+	+	+
C042	+	+	+	+	+	+	+	+	+	+	+	+
C043	+	+	+	+	+	+	+	+	+	+	+	+
C046	+	+	+	+	+	+	+	+	+	+	+	+
C051	+	+	+	+	+	+	+	+	+	+	+	+
C053	+	+	+	+	+	+	+	+	+	+	+	+
C055	+	+	+	+	+	+	+	+	+	+	+	+
C058	+	+	+	+	+	+	+	+	+	+	+	+
C064	+	+	+	+	+	+	+	+	+	+	+	+
C065	+	+	+	+	+	+	+	+	+	+	+	+
C073	+	+	+	+	+	+	+	+	+	+	+	+
C074	+	+	+	+	+	+	+	+	+	+	+	+
C076	+	+	+	+	+	+	+	+	+	+	+	+
C077	+	+	+	+	+	+	+	+	+	+	+	+
C078	+	+	+	+	+	+	+	+	+	+	+	+
C080	+	+	+	+	+	+	+	+	+	+	+	+
C083	+	+	+	+	+	+	+	+	+	+	+	+
C084	+	+	+	+	+	+	+	+	+	+	+	+
C085	+	+	+	+	+	+	+	+	+	+	+	+
C086	+	+	+	+	+	+	+	+	+	+	+	+
C088	+	+	+	+	+	+	+	+	+	+	+	+
C090	+	+	+	+	+	+	+	+	+	+	+	+
C091	+	+	+	+	+	+	+	+	+	+	+	+
C093	+	+	+	+	+	+	+	+	+	+	+	+
C095	+	+	+	+	+	+	+	+	+	+	+	+
C096	+	+	+	+	+	+	+	+	+	+	+	+
C098	+	+	+	+	+	+	+	+	+	+	+	+



<b>Performacnce Test report</b> Ovulation(LH) Test			Prepared by	Xuemei Bao
			Checked by	Lingling Su
Doc. No.	EGENS/CE- Appendix 4-1		Approved by	WeiJun Ou
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**Summary Results for Midstream**

Nantong Egens (assessed reagent)		Control reagent	
		+	-
	+	41	0
	-	0	59

**From the results of the above tables, the total results are shown as below:**

The average positive conformity rate of Egens Strip Test is 100 %.

The average negative conformity rate of Egens Strip Test is 100 %.

The average positive conformity rate of Egens Cassette Test is 100 %.

The average negative conformity rate of Egens Cassette Test is 100 %.

The average positive conformity rate of Egens Midstream Test is 100 %.

The average negative conformity rate of Egens Midstream Test is 100 %.