

# CS1 Semen Test Cassette

User Manual For Professional use

Rev.30-0CS1000  
20200407

## Introduction

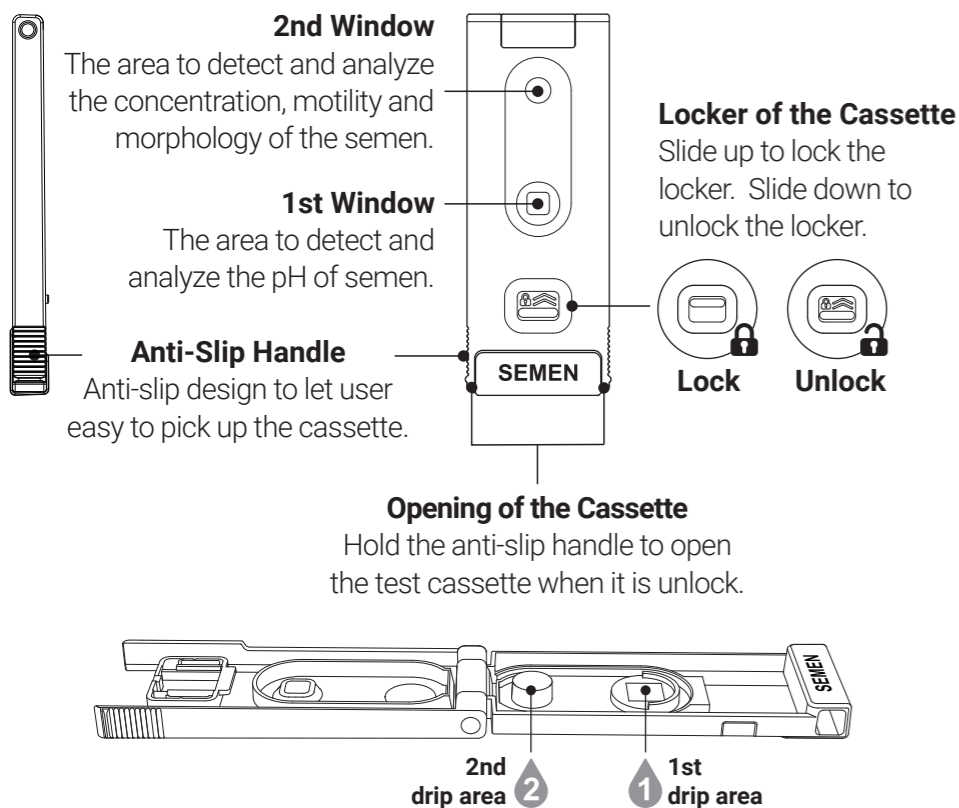
Please read this user manual carefully before using. This product is in vitro diagnostic use only. LensHooke® CS1 Semen Test Cassette is designed, manufactured and authorized by Bonraybio Co., LTD. If you have any questions about the product or require any assistance, please feel free to contact Bonraybio by calling the Service Hotline (+886-4-24912385) or contact your local distributor. Service Hotline time : Mon~Fri 08:30~17:30 (GMT+8)

## Intended Use

LensHooke® CS1 Semen Test Cassette is using the Quantitative analysis method to analyze the pH, concentration, motility and morphology of human semen. This cassette is NOT reusable, please dispose it after use.

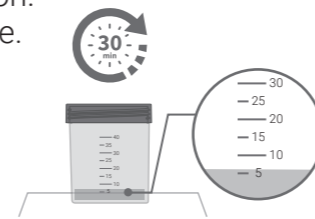
LensHooke® CS1 Semen Test Cassette is used with LensHooke® X series Semen Quality Analyzer (LensHooke® X1 PRO Semen Quality Analyzer, LensHooke® X1 Semen Quality Analyzer).

## LensHooke® CS1 Semen Test Cassette Illustration

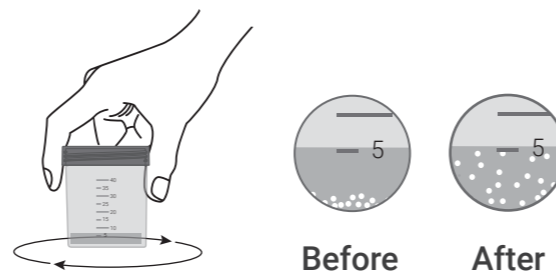


## LensHooke® CS1 Semen Test Cassette Operating Steps

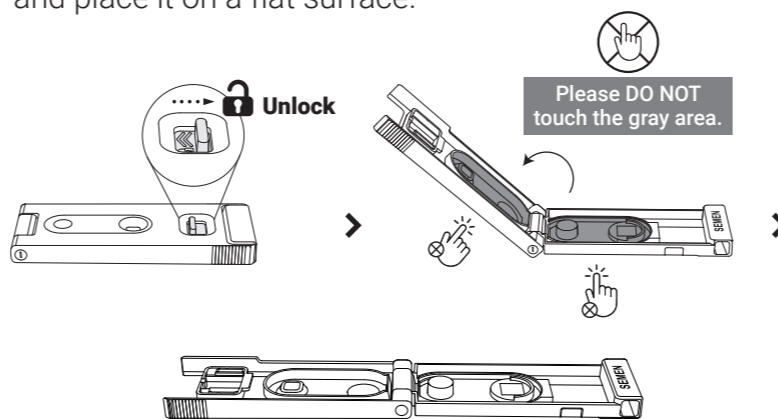
**Step 1** Wait 30 minutes for liquefaction. Observe the colour and volume.



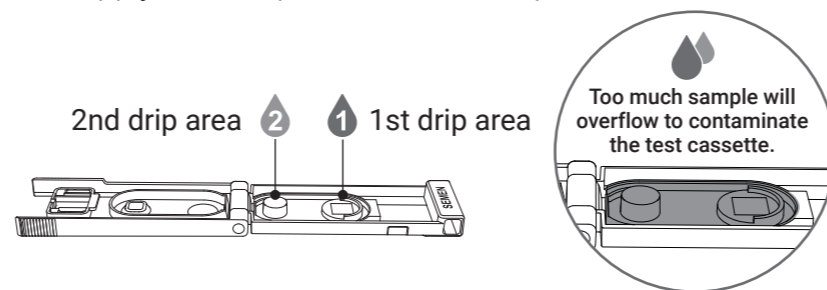
**Step 2** Rotate the sample collection cup (with sample) to fully mix the sample.



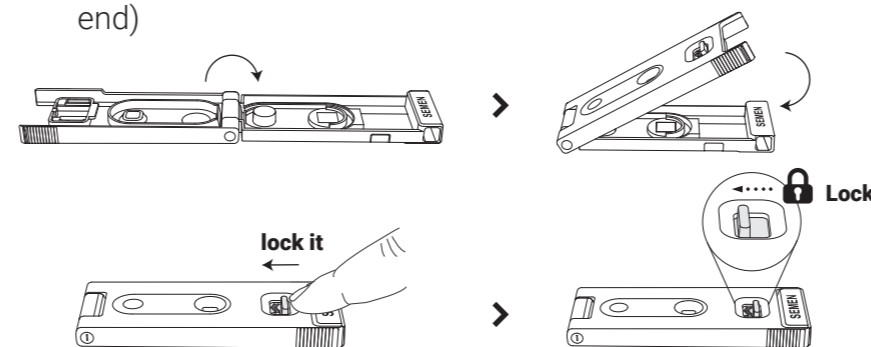
**Step 3** Unlock the locker of the new test cassette to open it, and place it on a flat surface.



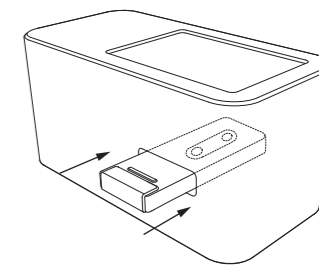
**Step 4** Apply the sample to the 1st drip area. Apply the sample to the 2nd drip area.



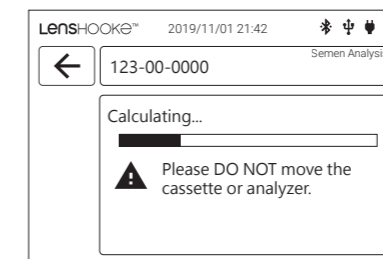
**Step 5** Close the test cassette, and lock it. (push the locker to the end)



**Step 6** Insert the cassette into the slot and push it to the end.



- Make sure that Test Cassette's 1st and 2nd windows both are inserted into the analyzer.
- Make sure to hear a "Click" sound after Test Cassette's 2 windows are inserted into the analyzer.
- DO NOT use an expired test cassette.
- DO NOT place the opened cassette on any unstable surface when applying the sample.
- DO NOT touch the window and drip area of the test cassette.
- DO NOT move the cassette or analyzer during the calculation.



- Insert the cassette into the analyzer within 30 seconds of applying the sample.
- LensHooke® CS1 Semen Test Cassette have to be used with LensHooke® X series Semen Quality Analyzer for test. If not, it might impact the test result. The test cassette is for single use only. Please throw away after use. DO NOT reuse.

## LensHooke® CS1 Semen Test Cassette Test Result

- The test result will appear in the devices of LensHooke® X series Semen Quality Analyzer.
- If you doubt the test result, please use another new test cassette to test again by following the semen analysis test steps of user manual.

## Reference of Parameter from WHO Laboratory Manual for the Examination and Processing of Human Semen

Reference	WHO 5 <sup>th</sup> Low Reference	WHO 4 <sup>th</sup> Low Reference
Concentration	15 x 10 <sup>6</sup> (12-16)/ ml	≥ 20 x 10 <sup>6</sup> / ml
Total Motility	40% (38-42%)	a + b ≥ 50% or a ≥ 25%
PR (Progressive Motility)	32% (31-34%)	
Morphology(Normal)	4% (3-4%)	≥ 15%

a : Rapid Progressive Motility (≥25µm/s)  
b : Slow or Sluggish Progressive Motility

## Caution

- ⚠ Please DO NOT let the children reach the LensHooke® CS1 Semen Test Cassette. If they swallow the cassettes by accident, please contact the professional doctor immediately for the assistance.

## Limitation

- When you see the symbol of “❄” displayed beside the concentration result, it means the sample has crystal or other impurity. Please consult your doctor since it will affect the result.
- LensHooke® CS1 Semen Test Cassette is designed ONLY for human semen testing, please DO NOT use it to test other kind of sample.
- It might affect the result, if the sample is contaminated by the lubricant or saliva.
- Please DO NOT test under the operating temperature lower than 15°C (59°F) or higher than 38°C (100°F), and the humidity higher than 70%.

## LensHooke® CS1 Semen Test Cassette Storage & Process

- Please Store the cassette under the temperature higher than 2°C (36°F) and lower than 30°C (86°F). Do not Refrigerate it.
- Please DO NOT touch the drip and window area.
- Please use it immediately when you open the package of the cassette. It will affect the pH test result if you leave the test cassette too long to absorb the humidity.
- Please follow the standard medical waste procedure to dispose the used LensHooke® CS1 Semen Test Cassette and gloves to prevent the cross contamination.

## LensHooke® License Dongle Operating Steps

All of the operation procedures should follow the instruction of user manuals of LensHooke® X series Semen Quality Analyzer.

## LensHooke® CS1 Semen Test Cassette Specification

Product Name	LensHooke® CS1 Semen Test Cassette
Size	L75 x W28.6 x H7.96 mm
pH	pH6.0 ~ 8.0 (Each Scale Range: 0.2)
Concentration	0.1 - 300 (10 <sup>6</sup> /ml)
Motility	1%~100%
Morphology	1%~100%
Operation Environment	15°C ~ 38°C (59°F ~ 100°F), humidity <70%
Storage Environment	2°C ~ 30°C (36°F ~ 86°F)
Transportation Environment	-10°C ~ 60°C (14°F~140°F)

## LensHooke® CS1 Semen Test Cassette Extra Information for Professional

### Detect Method

Optical Image Technology with Artificial Intelligence Algorithm to detect and analyze the semen.

### Operation Notice

- Please clean LensHooke® X series Semen Quality analyzer after testing.
- Please change the gloves for different sample's examination.

### Precision

The precision was evaluated including 6 concentration(Conc.) /motility(Mot.) levels.

Sample levels	LM40	LM60	MM40	MM60	HM40	HM60
Conc. Mean (10 <sup>6</sup> /mL)	17.3	17.9	107.9	114.4	183.4	182.9
Conc. SD (10 <sup>6</sup> /mL)	1.4	1.5	4.4	5.4	7.0	6.8
Conc. CV (%)	8.2	8.5	4.1	4.8	3.8	3.7

### Accuracy

Comparison studies on LensHooke® X series Semen Quality Analyzer with medical technologists' concurrent visual analysis results via using the microscope were performed in a clinical laboratory. Semen quality results were compared and the correlation of coefficient was > 0.96.

### Interference

Vitamin B, Testosterone, Yeast, E. coli, RBC, WBC, Urine, Saliva, Agglutination, D-norgestrel, and B-estradiol do not significantly affect results. However, abnormally high concentrations in semen may cause inaccurate results.

### Reagents










Each test Cassette includes the reagents as below :


w/w bromocresol green	3.3%
w/w bromthymol blue	55.0%
w/w nonreactive ingredients	41.7%

The test results above come from LensHooke® X series Semen Quality Analyzer.

### Reference

WHO laboratory manual for the Examination and processing of human semen.

 IVD	In vitro diagnostic	 Use by	
 i	Consult instructions for use	 LOT	Batch code
 ⌘	Do not use repetitively	 ⚠	Caution
 🏭	Manufacturer		
 EC REP	European authorized representative		
 CE	CE mark		

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