

Core Technology Co.,Ltd.

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Certificate of Analysis

Product Name	HCG pregnancy Test Strip		
Lot No.	20200622	Date of Mfg.	June 22 nd , 2020
Quantity	60000PCs	Date of Exp.	June 21 st , 2023
Test Item	Specification		Result
Appearance	Must be suitable of product-licensing status.		Pass
Sensitivity	In-house reference panels for the sensitivity test (Tested with urine samples P1-P10 with HCG concentration from 10mIU/ML-10000mIU/ML) 1) All panels must be interpreted as positive. 2) Sensitivity (%) = $\frac{\text{No. of panels with positive result}}{\text{No. of positive panels tested}} \times 100$		1) Pass 2) 100%
Specificity	In-house reference panels for the specificity test 1) Tested with free HCG solutions respectively containing 500mIU/mL(hLH),1000mIU/mL (hFSH),1000 μ IU/mL (hTSH), all test results shall be negative . 2) Tested with free HCG Urine N1- N10, all test results must be interpreted as negative. 3) Specificity (%) = $\frac{\text{No. of panels with negative result}}{\text{No. of negative panels tested}} \times 100$		1) Pass 2) Pass 3) 100%
Precision	Take 10 pcs of HCG test kits from same lot number and test them with HCG solution at concentration of 25mIU/mL, the test results and color intensity should be consistent.		1) Pass 2) Pass
Conclusion	Pass		Date of Testing July 3 rd , 2020

- * Method: Immunochromatography (Rapid testing)
- * Shelf-life: 36months from the date of manufacturing
- * Storage temperature: Room temperature (2~30°C)
- * Issuing Date: July 3rd, 2020

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