Basic Performance of β-hCG Assay on PATHFAST®

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Background/Purpose: Human chorionic gonadotropin (hCG) is one of the most commonly measured pregnancy marker both in clinical laboratories and in point-of-care testing (POCT) settings. Assays that detect intact and nicked hCG forms as well as the free β subunit provide the most useful clinical information. As the importance of good analytical performance of rapid assays is increasingly emphasized, more sophisticated immunoassay techniques are needed to meet the future challenges of rapid and quantitative POCT. The aim of study is to assess the assay performance and the clinical utility of PATHFAST β-hCG.
Principles/Methods: The PATHFAST β-hCG assay procedure is a one-step sandwich immunoassay based upon CLEIA-MAGTRATION® technology. In the assay, two monoclonal antibodies recognizing β-hCG are used so that the PATHFAST β-hCG assay detects free β-hCG fragment in addition to intact hCG molecule. Since the reagent is "all in one" reagent cartridge, no water supply, drain system, washing buffer, and substrate bottles are required. The assay data for β-hCG can be obtained within 17 minutes. In this study, whole blood and plasma samples were tested on the PATHFAST analyzer using the PATHFAST β-hCG reagent kits.
Results: The PATHFAST β-hCG has an analytical assay range of 2.00 to 500 mIU/mL (WHO 4th IS 75/537). Calibration frequency is every 4 weeks for any one lot. Good correlation was obtained between whole blood and plasma samples; n = 25 specimens, r = 0.998, y=1.00x+2.37. Repeatability and within-device C.Vs were ranged from 2.55% to 3.36% and 3.33% to 3.99%, respectively. Samples from 500 to 2,000,000 mIU/mL were reported as >500 mIU/mL without sample predilution. The PATHFAST β-hCG assay detected intact and nicked hCG forms as well as free β-hCG fragment. Assay correlation with other commercial hCG tests were determined: n = 30 specimens; r = 0.992, y = 1.22 x + 7.14 (PATHFAST β-hCG vs. Dade Behring Stratus® CS βhCG), n = 15 specimens; r = 0.993, y = 1.07 x + 6.36 (PATHFAST β-hCG vs. Biomerieux VIDAS® HCG), n = 21 specimens; r = 0.993, y = 1.00x + 6.68 (PATHFAST β-hCG vs. DPC IMMULITE® HCG). ***Conclusions:*** The PATHFAST β-hCG is a rapid, easy, and quantitative assay suitable for diagnosis of pregnancy without compromise of assay performance. The reagent cartridges are ready-to-use, and whole blood testing is available as well as plasma testing. The β-hCG assay can also be performed simultaneously with other PATHFAST assays including troponin I, creatine kinase M/B, myoglobin, D-Dimer, CRP and NT-proBNP in one batch (up to 6 tests per one batch).

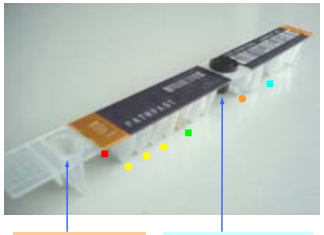
Assay Principle	**MAGTRATION® -CLEIA**
Assay Time	**approx. 17 min**
Sample	**whole blood/plasma (heparin)**
Assay Range	**2.00 – 500 mIU/mL**

Conclusions

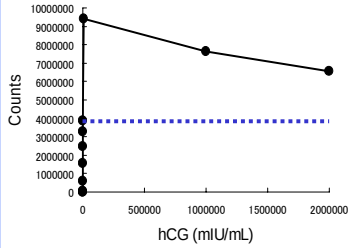
- ***rapid*** ***easy*** ***compact*** ***sensitive***
- ***accurate*** ***whole blood/plasma*** ***no waste***
- ***good correlation with commercial hCG assays***
- ***simultaneous assay with cTnI, CKMB, Myo, D-Dimer, CRP and NT-proBNP***

PATHFAST

Reagent Cartridge



High-Dose Hook Effect



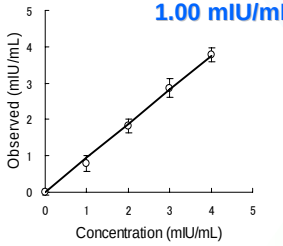
Day-to-Day Imprecision

	Low (mIU/mL)	High (mIU/mL)
Mean	20.8	221
SD	0.837	7.41
CV%	3.99	3.33
Max	23.7	241
Min	18.5	201
Range	5.24	40.6

QC controls were analyzed in triplicate for 20 days using PATHFAST instrument.

Lower Detection Limit

Lower detection limit
1.00 mIU/mL

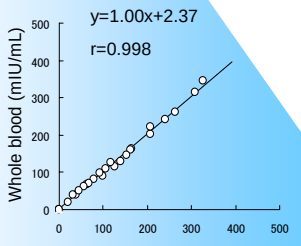


Lower detection limit was defined as the concentration corresponding to:

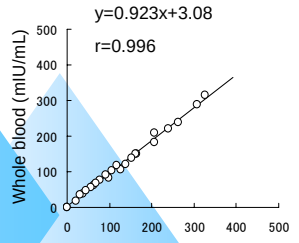
the detection limit (mIU/mL) – 2 SD is more than the 0 mIU/mL + 2 SD.

Correlation between Plasma and Whole Blood

adjusted with individual Hct% value

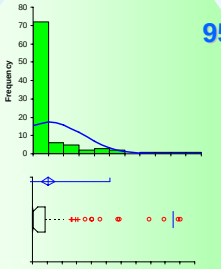


adjusted with constant Hct% value (40%)



Sodium heparin was used as an anticoagulant agent.

Reference Interval



95th percentile 3.20 mIU/mL

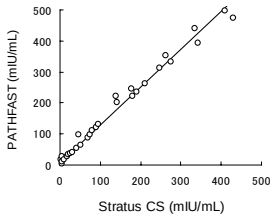
max 5.03 mIU/mL

min 0.000 mIU/mL

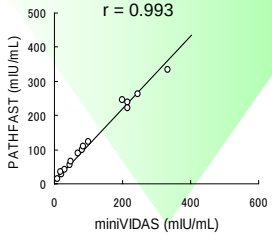
Specimen: heparin plasma (n =94)

Comparison to Other hCG Assays

y = 1.22x+ 7.14
r = 0.992



y = 1.07x+ 6.36
r = 0.993



y = 1.00x+ 6.68
r = 0.993