



OBJECTIVE

The M6 model stratifies pregnancies of unknown location (PUL) into low- and high-risk categories for ectopic pregnancy using β -hCG and progesterone at presentation and β -hCG at 48 hours. This study evaluated whether point-of-care testing (POCT) β -hCG can replace laboratory measurements within the M6 model without compromising predictive accuracy.



METHODS

- Prospective cohort of 111 PUL cases at Whipps Cross Hospital (London, UK).
- Agreement between AQT90 FLEX POCT and laboratory β -hCG at baseline and 48 hours assessed using Passing-Bablok regression.
- Serial values incorporated into the M6 model.
- Agreement between POCT- and laboratory-based M6 predictions evaluated using Cohen's kappa.



KEY RESULTS (SUMMARY)

$r = 0.997$

Strong correlation at baseline

$r = 0.992$

Strong correlation at 48 hours

$\kappa = 0.976$

Excellent agreement in M6 classification



Median laboratory result delay:
6 h 07 min overall

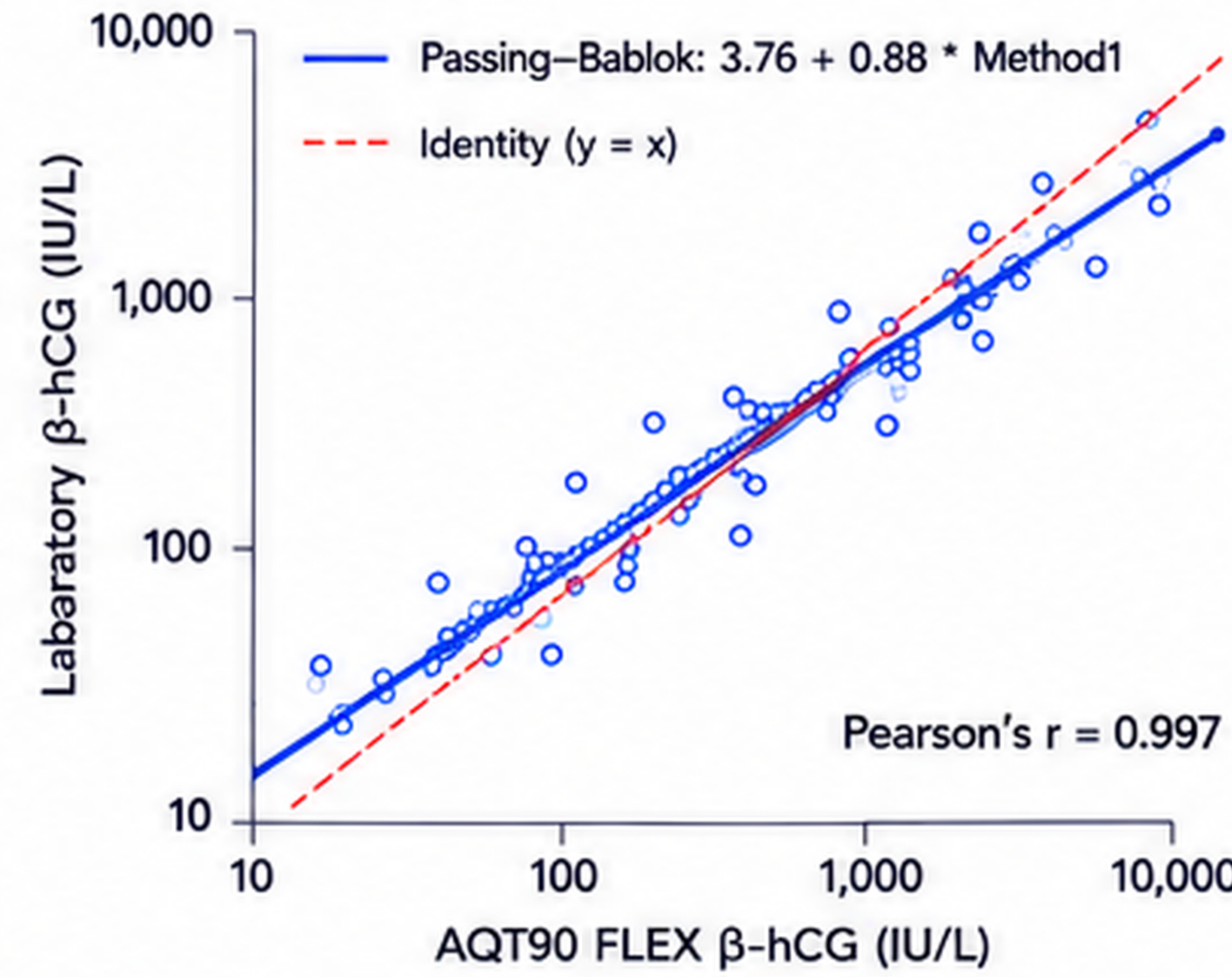
(Baseline: 9 h 20 min; 48 h sample: 3 h 42 min)



Median laboratory result delay
6 h 07 min overall

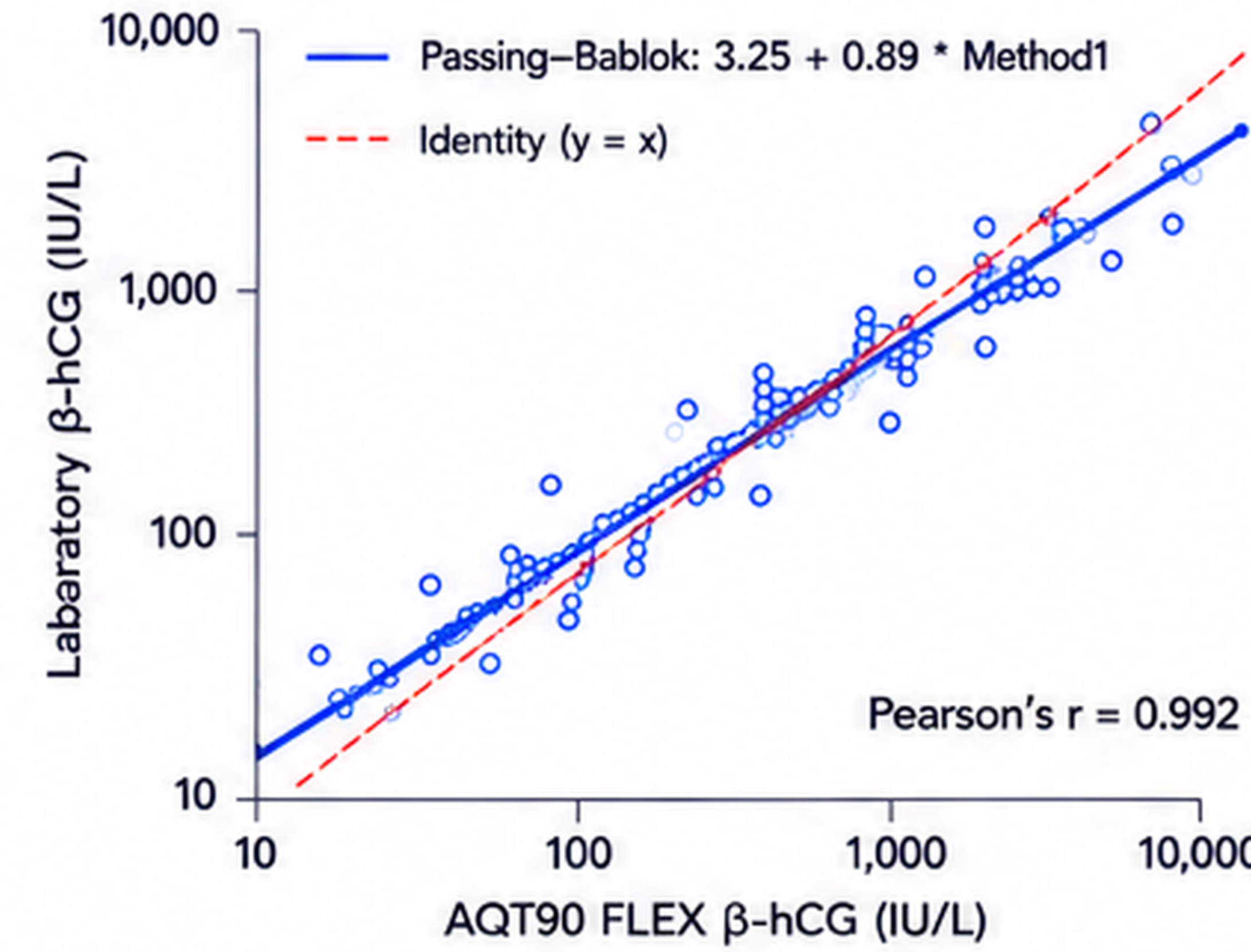
(Baseline: 9 h 20 min;
48 h sample: 3 h 42 min)

BASELINE (TIME 0): AQT90 FLEX vs LABORATORY β -hCG



Passing-Bablok regression and identity line for β -hCG at baseline.
Solid line: regression; dashed line: identity ($y = x$).

48 HOURS (TIME 48h): AQT90 FLEX vs LABORATORY β -hCG



Passing-Bablok regression and identity line for β -hCG at 48 hours.
Solid line: regression; dashed line: identity ($y = x$).

M6 MODEL PERFORMANCE — SENSITIVITY, SPECIFICITY, PPV And NPV (%)

Outcome	AQT90 FLEX (POCT)				Laboratory (Reference)			
	Sensitivity	Specificity	PPV	NPV	Sensitivity	Specificity	PPV	NPV
EP (Ectopic Pregnancy)	91.3	100.0	100.0	99.0	95.7	99.5	95.7	99.5
FPUL (Non-viable PUL)	95.5	97.0	97.2	95.1	96.4	98.0	98.2	96.1
IUP (Intrauterine Pregnancy)	97.4	95.5	92.7	98.5	96.2	96.3	93.8	97.7

EP = Ectopic Pregnancy; FPUL = Non-viable Pregnancy of Unknown Location;

IUP = Intrauterine Pregnancy; PPV = Positive Predictive Value; NPV = Negative Predictive Value.

M6 MODEL PERFORMANCE (%)

AQT90 FLEX POCT vs Laboratory



EP (Ectopic Pregnancy)

Excellent sensitivity and specificity



FPUL (Non-viable PUL)

High accuracy in excluding non-viable cases



IUP (Intrauterine Pregnancy)

High specificity and NPV for intrauterine pregnancies



CONCLUSIONS

AQT90 FLEX POCT β -hCG provides equivalent M6 model classification compared with laboratory testing, with excellent agreement and a substantial reduction in result delays (up to one day).

POCT offers efficient, reliable stratification of pregnancies of unknown location.



Up to 1 day
reduction in
turnaround time



Improved workflow and
patient experience



Clinical accuracy
maintained