

Evidence Based Practice for POCT:

Reproductive Testing

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Reproductive Testing

- **Pregnancy Tests (urine & serum)**
- **Ovulation Tests (urine & bioelectric)**
- **PROM (ferning & pH testing)**
- **Preterm delivery (fFN)**



NACB LMPG Website

http://www.nacb.org/lmpg/poct_lmpg_draft.stm



Pregnancy Tests (urine & serum)



Clinical Settings for POC Pregnancy Tests

- Hospital for dx pregnancy
- Hospital for dx ectopic pregnancy
- Home for early dx of pregnancy



Q: Does the use of urine hCG POCT for dx of pregnancy improve outcomes (i.e. reduce clinic visits or reduce LOS in ER or reduce # of contraindicated drugs or therapies) compared to serum core laboratory hCG?

Recommendation: No studies.

Therefore, not sufficient evidence for or against.



**Q: Is the diagnostic accuracy of urine hCG
POCT equivalent to serum core
laboratory hCG?**

Recommendation:

Hospital Laboratory dx pregnancy

Great brand by brand variation.

No recent studies (after 1990).

**Further studies are needed on
contemporary devices.**



Accuracy of POC Pregnancy Tests: Hospital Setting

Year	Population	% Accuracy		# Devices	
		Sens	Spec		
1979	known preg/ non preg	89-100	95-100	7	
1985	Eval in ED	82	97	95	1
1986	Submitted for hCG	86-98	95-100	89-99	8
1990	Pre&post Abortion	71-91	93-100	74-92	3
1990	Pre&post Abortion	67-94	79-100	72-92	3



Q: Is the diagnostic accuracy of urine hCG POCT equivalent to serum core laboratory hCG?

Recommendation:

Hospital Laboratory dx ectopic pregnancy

May have utility in dx of ectopic, but not adequately compared to in-lab testing. Therefore, not sufficient evidence for or against.



Accuracy of POC Pregnancy Tests: Diagnosis of Ectopic

Year	Population	n	# Ectopic	% Sens
1985	Patients eval for preg in ED	607	N/R	60
1986	Patients eval for preg (68% ED)	884	27	96
1986	Patients w/ gyn Emergencies	46	30	90-100
1987	Suspected ectopic	909	71	100
1987	Suspected ectopic	107	17	94
1989	Suspected ectopic	51	6	100
2000	Known ectopics	207	207	97



**Q: Is the diagnostic accuracy of urine hCG
POCT equivalent to serum core
laboratory hCG?**

Recommendation:

Home for early dx pregnancy

Great brand by brand variation.

No recent studies (after 1989).

**Further studies are needed to determine
which devices are most accurate.**



Accuracy of POC Pregnancy Tests: Home Devices

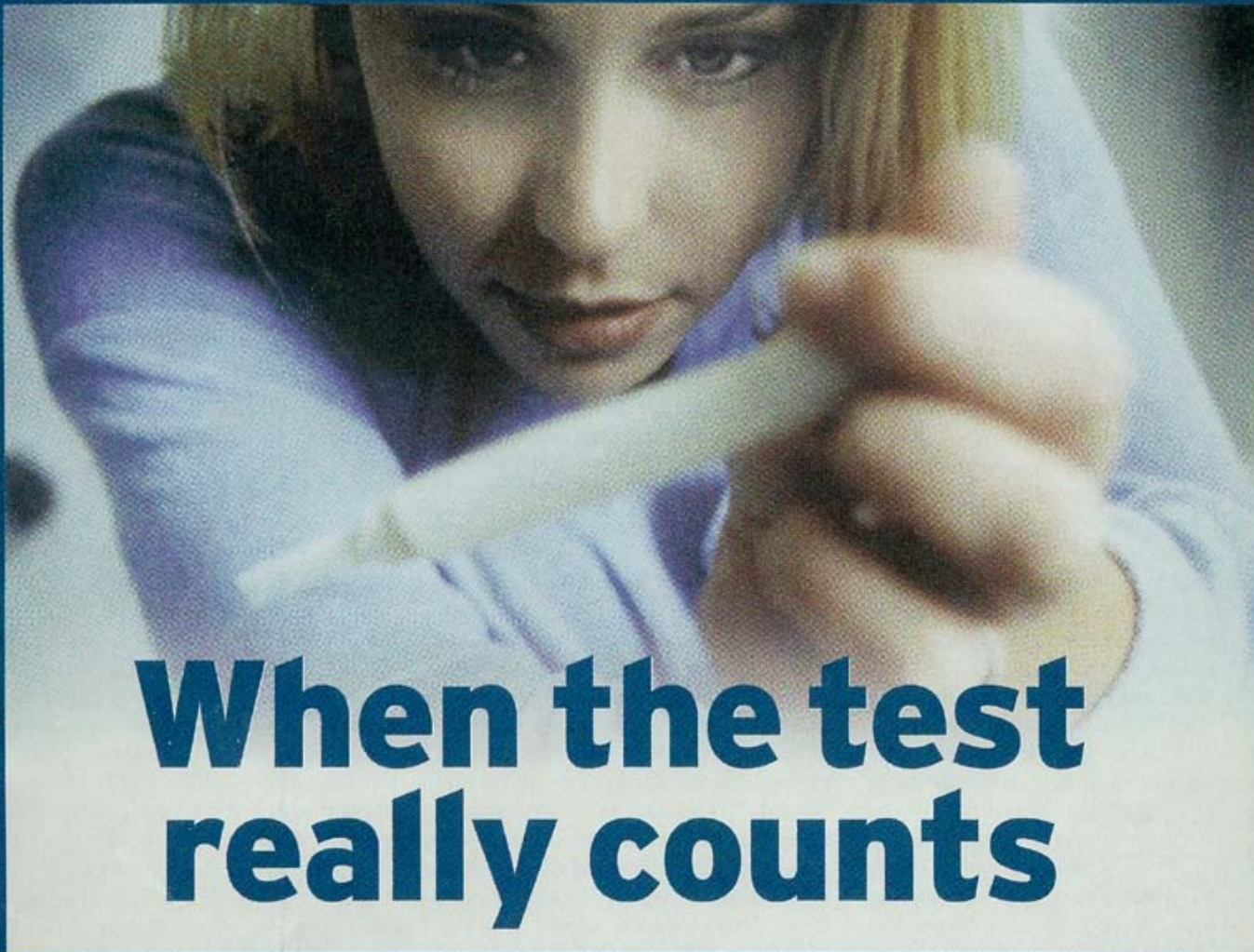
Latman & Bruot. Biomed Inst Tech 1989;23:144-9.

Nine devices

Urine from women non-preg & 3 months preg

	Observed	Purported
Accuracy	70-97%	97-99%
Sensitivity	52-100%	98-99%
Specificity	61-100%	94-100%





When the test really counts

PART ONE Earliest pregnancy detection

We tested 18 pregnancy-test kits to find out which brands work best. Buy the top performers and follow our tips for the most accurate results.



Consumer Reports February, 2003
Cole, Am J Obstet Gyn 2004;190:100-5

2Q: What is the diagnostic accuracy of urine hCG POCT when performed by a layperson compared to the diagnostic accuracy of serum or urine core laboratory hCG AND compared to the diagnostic accuracy of urine POCT in a core laboratory?

Recommendation Summary:

**No studies on serum or urine core lab.
3 studies (<1993) on POCT in core lab.
Clearly decreased Accuracy with layperson.
Physicians should confirm results with
quantitative serum hCG.**



Ovulation Tests: Urine



Q: Is the diagnostic accuracy of urine LH tests sufficient for predicting ovulation using progesterone or US as a gold std for confirming ovulation?

Recommendation:

Excellent predictive value.

Recommend use of these devices to predict ovulation within 48 hours.



Accuracy of POC Ovulation Tests: Predicting Ovulation

- 11 published reports 1988-2001
- Predictive Value 85-100%



Q: Does the use of urine LH tests for predicting ovulation in women *not treated* in a fertility clinic improve outcomes (i.e. increase conception rates; decrease # clinic visits, # unwanted pregnancies) compared to no use of prediction tests?

Recommendation:

No studies.

Insufficient evidence to make recommendations for or against the use of home urine LH testing to improve conception rates in women not seeking fertility treatments.



Q: Does the use of urine LH tests for predicting ovulation in women *undergoing fertility treatment* improve outcomes (i.e. increase conception rates; decrease # clinic visits, # unwanted pregnancies) compared to no use of prediction tests?

Recommendation:

Insufficient evidence to make recommendations for or against the use of home urine LH testing to improve conception rates in women seeking fertility treatments.



Effect of POC Ovulation Tests on Conception Rate in Infertility Patients

- 7 Published reports 1988-1998
- 2 - Significantly lower pregnancy rates
- 5 – No benefit



Effect of POC Ovulation Tests on # Clinic Visits & Insemination Cycles

- **1 – Significantly fewer clinic visits/trt cycle**
- **1 – No difference in # of insemination cycles required to achieve conception**



2Q: What is the diagnostic accuracy of urine LH POCT ovulation tests when performed/interpreted by a layperson as compared to the diagnostic accuracy of urine or serum LH in a core laboratory?

Recommendation:

Insufficient evidence to evaluate diagnostic accuracy of results obtained by layperson.



Ovulation Tests: Non-urine

Electrical admittance
or resistance
(saliva or vaginal mucus)



Ferning
(saliva or vaginal mucus)



Q: Is the diagnostic accuracy of non-urine POCT ovulation tests sufficient to predict ovulation using progesterone or ultrasound as a gold standard for confirming ovulation?

Recommendation:

**Limited evidence to support use.
Therefore no recommendation
for or against use.**



Accuracy

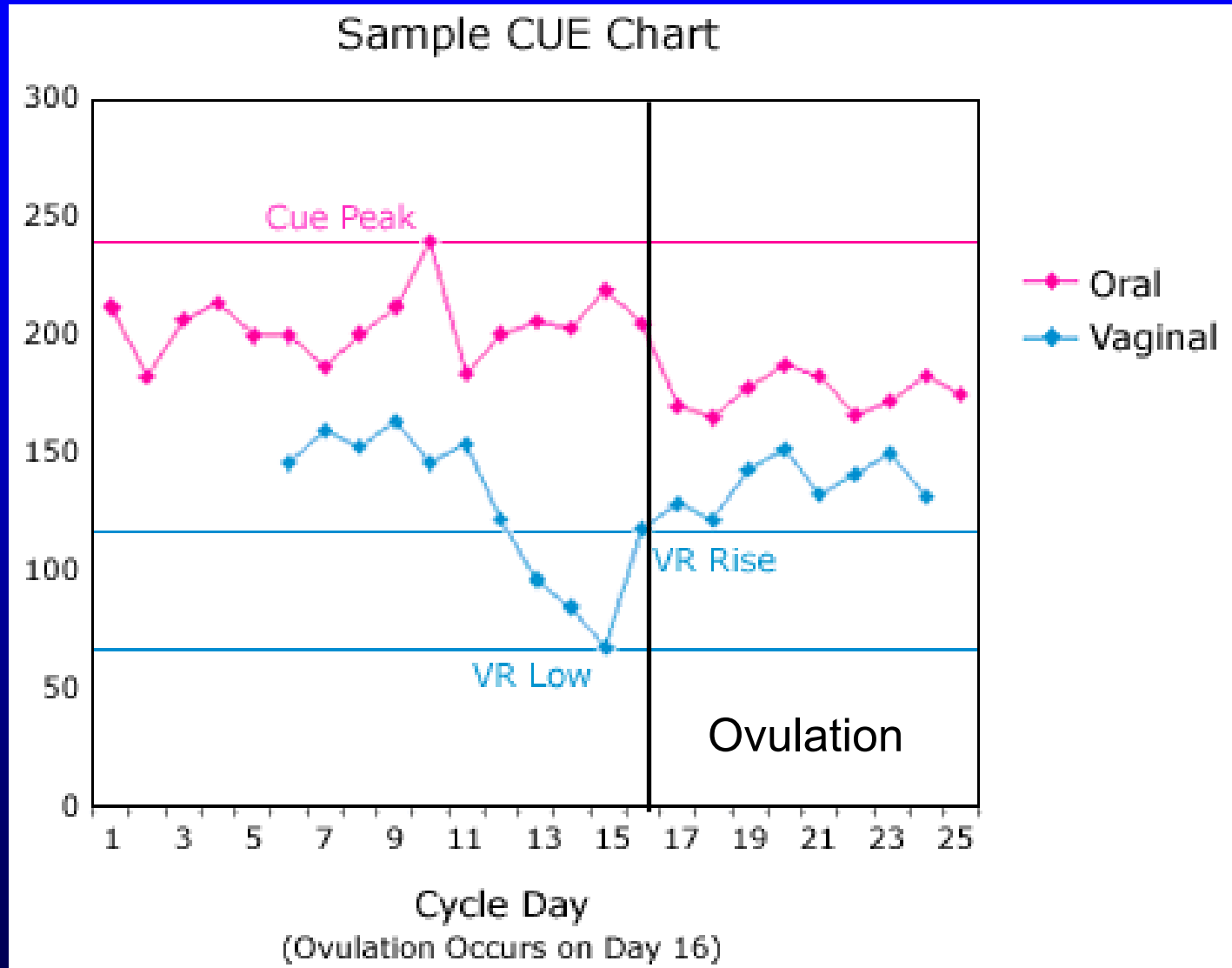
Electrical POC Ovulation Tests

- 10 – Studies have evaluated use
- 4 – Provided sufficient data to predict ovulation within 48 hrs

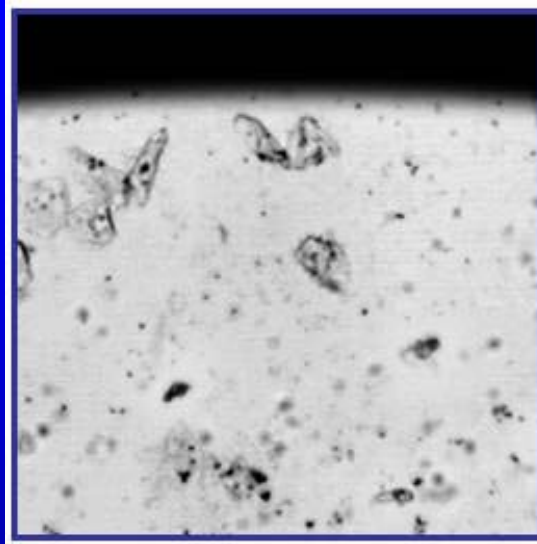
Gold Standard	Sensitivity
Ultrasound	93%
Urine or serum LH	74%, 52%, 55%



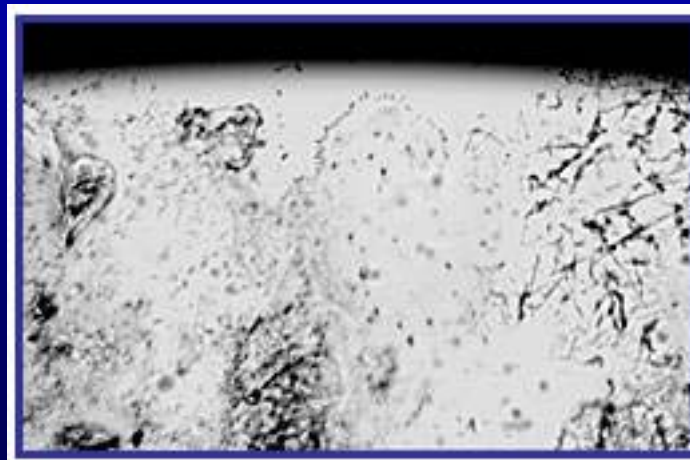
CUE™ Ovulation Monitor



Ferning POC Ovulation Tests



Not Fertile



Fertile

Accuracy

Ferning POC Ovulation Tests

- 4 – Studies have evaluated use
- 2 – Ultrasound gold standard
- 1 – Reported predictive ability

Guida et al. Fertil Steril. 1999;72:900-4

125 cycles from 40 women

Predicted ovulation day before in 21%
day of in 21%

59% tests excluded because “uninterpretable”





PROM (pH/nitrazine & Ferning)



Q: Does the pH/nitrazine test accurately identify women with ruptured membranes ^{and/or} women whose membranes have not ruptured?

Recommendation:

Sensitive only when used in women whose membrane status is known.

When used in women with unknown status not sensitive or specific.

We do not recommend for detection of PROM.



Accuracy pH/Nitrazine Tests

Year	Membrane Status	<i>n</i>	pH Cutoff	Sens	Spec
1995	Known	51	≥7.0	100%	79%
1995	Unknown	40	≥7.0	72%	64%
1990	Known	45	≥6.0	91%	73%
1995	Known	103	≥6.5	92%	53%
1977	Known	39	not given	100%	92%
1987	Known	79	≥7.0	77%	81%
1995	Known	30	not given	100%	41%



Q: Does the fern test accurately identify women with ruptured membranes and/or women whose membranes have not ruptured?

Recommendation:

Not sensitive or specific.

We do not recommend fern test alone for detection of PROM.



Accuracy of Fern Tests

Year	Membrane Status	<i>n</i>	Sens	Spec
1990	Known	43	97%	100%
1987	Known	48	62%	100%
1995	Known	51	84%	95%
1994	Suspected	100	51%	71%
1994	Unknown	40	50%	86%



Preterm Delivery (fFN)



Q: Does performing a single rfFN improve outcomes (# patient admissions, LOS, tocolytics, \$\$, neonatal morbid/mortal, maternal morbidity due to intervention therapy) compared to cervical dilation, Bishop score, contraction # or cervical length by U.S. in women with symptoms of preterm labor, intact membranes and cervical dilation <3 cm?

Recommendation:

Limited evidence to support use.

**Therefore no recommendation
for or against use.**



Effect of rfFN on Outcomes

- No studies → neonatal morbid/mortal
- 2003 study – no effect on LOS,
in patients with >6 hr stay fFN ↓ LOS 2 hr
- 2000 study – 51% ↓ in maternal transports
- 1998 study – Sig ↓ in patients receiving tocolysis



Q: What are rfFN PPV and NPV values for preterm delivery? Does rfFN reliably identify women at risk of preterm delivery and/or women at no risk of preterm delivery?

Recommendation:

NPV >95% to predict delivery <7d.

PPV poor & should not be used to guide therapeutic decisions.



rfFN Positive Predictive Value

Year	<i>n</i>	PPV within 7 days	PPV within 14 days	PPV <34 wks	PPV <37 wks
2003	133	4%	6%		
2003	108		10%		
2000	85	40%	40%	55%	85%
1998	70			45%	



rfFN Negative Predictive Value

Year	<i>n</i>	NPV within 7 days	NPV within 14 days	NPV <34 wks	NPV <37 wks
2003	133	97%	94%		
2003	108		98%		
2000	85	98%	95%	94%	52%
1998	70			98%	



Conclusions

- **Few studies have been published on the effect of reproductive POCT on outcomes.**
- **More studies are needed to validate the clinical utility of these tests.**

