



# GeneXpert NG/CT Test: Interpreting Results

Lorna Rabe

MTN Core Laboratory

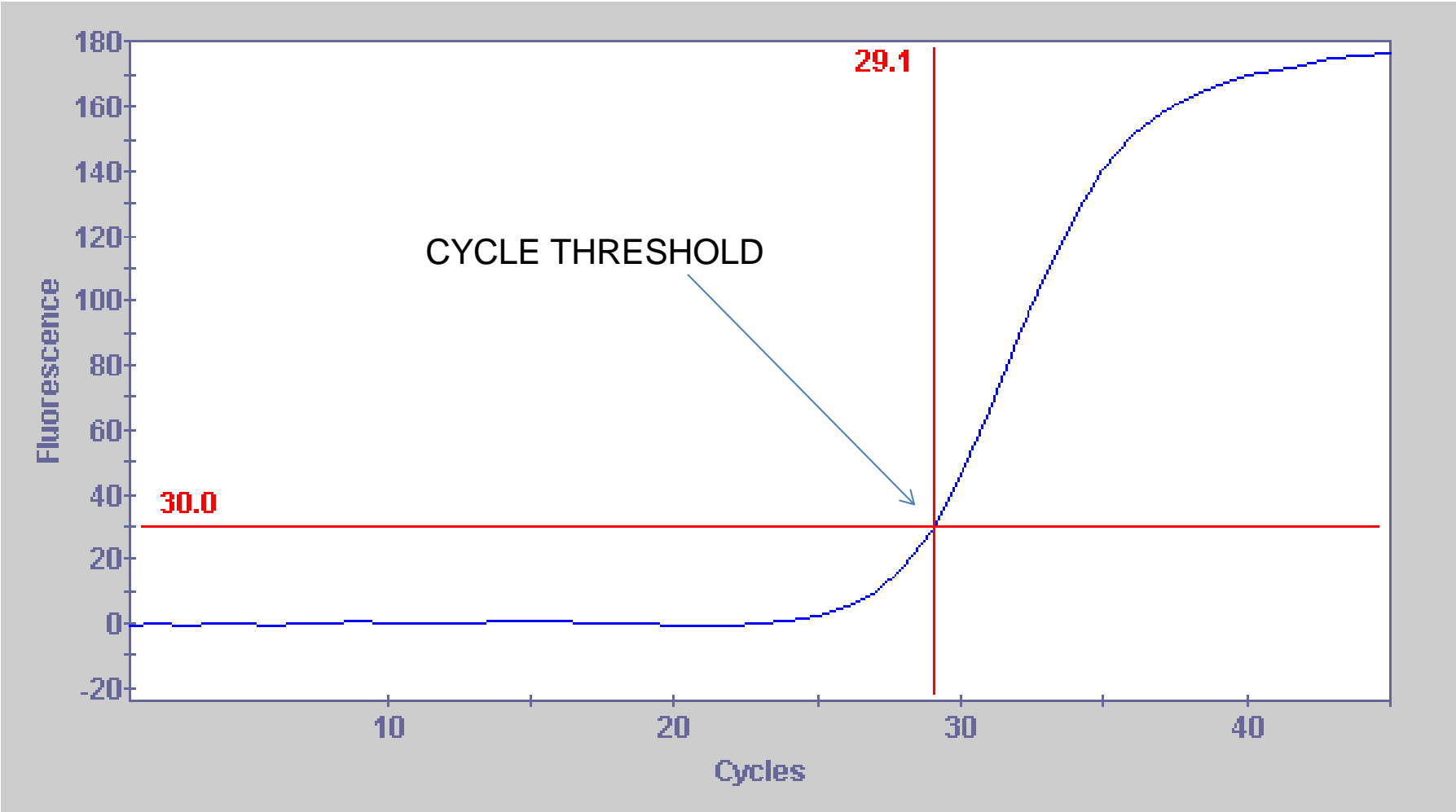
Pittsburgh, PA

MTN Regional Meeting, Cape Town, South Africa, October 4-8, 2015

# No analytical instrument is 100% accurate

- The limit of detection (LOD) is the lowest # of either CT or NG that can be distinguished from negative samples with 95% confidence.
  - *C. trachomatis*: ~75-134 Ebs/mL
  - *N. gonorrhoeae*: ~2-3 CFU/mL
- The RT-PCR cycle threshold is based on how many cycles it take to get the LOD.
- Specimens with quantities near the LOD may give inconsistent results.

# Amplification Curve and Cycle Threshold (Ct)



Test Result

Analyte Result

Detail

Errors

History

Support

Assay Name Xpert CT-NG

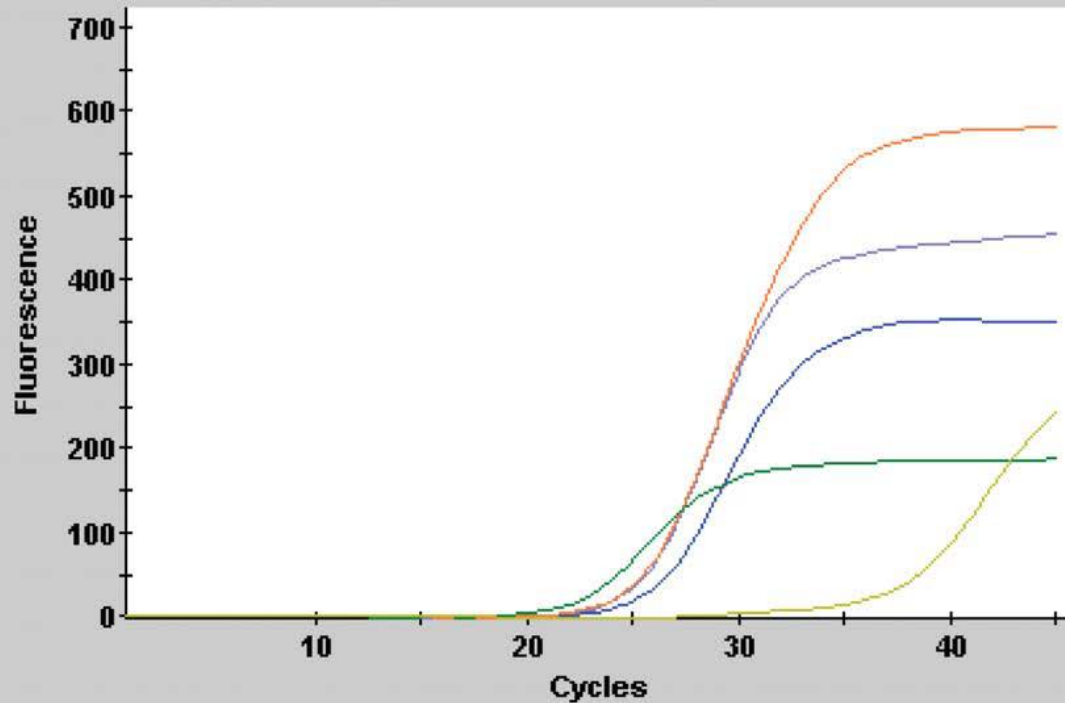
Version 1

Test Result

CT DETECTED;  
NG DETECTED

Cycles threshold numbers

For In Vitro Diagnostic Use Only.



Legend

- CT1; Primary
- NG2; Primary
- NG4; Primary
- SAC; Primary
- SPC; Primary

# Cepheid package insert: Reproducibility by Study Site

Urine , N=10		Site 1		Site 2		Site 3	
		Exp <sup>1</sup>	Inexp <sup>2</sup>	Exp	Inexp	Exp	Inexp
CT & NG high pos	CT	100%	100%	100%	100%	100%	100%
	NG	100%	100%	100%	100%	100%	100%
CT & NG low pos	CT	50%	60%	80%	40%	60%	100%
	NG	40%	70%	30%	30%	40%	20%

1. Exp=Experienced operator
2. Inexp= Inexperienced operator

# Factors affecting the cycle threshold

- Mix the urine sample immediately before transferring into transport tube.
- Filling the transport tube to the line on the tube.
- Mix the transport tube vigorously (not gently) immediately before transferring sample into cassette.

# Suggestions for Competency Assessment

- Using known positive samples, compare the cycle threshold (ct) for CT, NG, and SAC over multiple days and/or technologists.
- Duplicate samples with inconsistent ct suggest poor mixing or delay of pipetting after mixing for those with high ct.
- Compare the ct among technologists.

# Controls: internal

---

- System control
- Reagent and Probe Check Control
- Sample Processing Control (SPC)
- Sample Adequacy Control (SAC)



# Controls: External

- After showing reproducibility, month testing only.
- Commercially made
  - ZeptoMetrix: cost about \$172.00 to test 3 controls.
- Previously tested samples
  - CAP panels (only if using swab transporter)
  - Freeze left over samples at  $-80^{\circ}\text{C}$  (can be thawed and re-frozen)
  - Do not used left over ProbeTec samples

# Questions

---