

Evaluation of VirCell C. trachomatis IgG and Syphilis IgM Monotests

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A little Chlamydia history

- C. trachomatis
 - Common bacterial cause of sexually transmitted inclusion conjunctivitis & pneumonia in children, urethritis in men & cervicitis in women
 - Acute infection diagnosed by molecular means
 - Serology remains the means by which chronically infected patients can be diagnosed
 - Medac C. trachomatis IgG ELISA ceased production Nov 2018 replacement test available within Australia were evaluated



Comparison C. trachomatis methods

	Medac C. trachomatis IgG p-ELISA	VirClia C. trachomatis IgG monotest	Savyon MIF IgG
Max no. tests	96	24	7
Automation	Manual	Automated	Manual
Sample size	10 µL	5 µL	10 µL
Clot detection	Yes (operator)	Yes (instrument)	Yes (operator)
Controls	2 Neg, 2 Pos	1 Neg, 1 Pos	1 Neg, 1 Pos
Kit expiry	9-12 months	12 months	9-12 months
Specimen ID	Visual by operator	Barcode reader	Visual by operator
Entering results in LIS	Download to LIS	Download to LIS	Manual entry
Results	Signal/cut-off Positive ≥ 1.1	Signal/cut-off Positive ≥ 1.1	Titres ≥ 64 significant
QAP available	Yes, RCPA	Yes, RCPA	Yes, RCPA
TAT	2.5hrs	1hr	2hrs

Study Design & Results

- Sensitivity & specificity between VirClia, Savyon and Medac were determined using a panel of seventy samples (50 pos and 20 neg as determined by Medac).
- Results

	Monotest vs Medac	MIF vs Medac
Sensitivity	73%	29%
Specificity	91%	91%

ELISA vs NAT

- Sensitivity ELISA assays were further explored by comparison to 20 samples pos for *C. trachomatis* by nucleic acid detection (NAT).

	Medac vs NAT	Monotest vs NAT
Sensitivity	45% (missed 11)	60% (missed 8)*
Agreement	40%	60%

- * Different ag array detected cases earlier

A Little Syphilis History

- Syphilis resurgence worldwide in adults but also increase in congenital syphilis
- Four stages have been identified i.e. primary, secondary, latent and late syphilis and different diagnostic tests are helpful at different stages.
- Untreated syphilis in pregnancy is associated with stillbirth, foetal loss, premature birth, neonatal death, low birthweight & congenital syphilis
- Laboratory testing for syphilis largely involves detection of total antibody (i.e. IgG and IgM) to ensure cases are not missed.
- Laboratory diagnosis of congenital syphilis is complicated by the presence of maternal IgG antibody.
- IgM antibody's main use is in the confirmation of congenital syphilis.

Comparison of Methods

	VirClia Syphilis IgM Monotest	FTA IgM
Max no. tests	24	7
Automation	Automated	Manual
Sample size	5 μ L	10 μ L
Clot detection	Yes (instrument)	Yes (operator)
Controls	1 Neg, 1 Pos	1 Neg, 1 Pos
Kit expiry	12 months	9-12 months
Specimen ID	Barcode reader	Visual by operator
Entering results in LIS	Download to LIS	Manual entry
Results	Signal/cut-off Positive ≥ 1.1	Intensity +, ++, +++
QAP available	Yes, RCPA	Yes, RCPA
TAT	1hr	2.5hrs

Study Design

- Ninety routine patient serum samples submitted for syphilis testing were comprised the panel:
 - 30 negative (CMIA, TPPA, FTA - negative),
 - 30 positive (CMIA, TPPA positive, VDRL positive titre >8, FTA IgM positive)
 - 30 equivocal sera* (CMIA low positive, TPPA positive, VDRL negative)
- * one was FTA negative representing past infection – also Monotest negative

Results

			Predictive value of	
	Sensitivity %	Specificity %	Positive	Negative
VIRCLIA Syphilis IgM Monotest	88.89	96.61	92.31	95.00

Conclusions

- C. trachomatis IgG Monotest and Syphilis IgM Monotest were:
 - Fit for purpose
 - Suitable replacements in terms of sensitivity and specificity
 - VirClia instrument was easy to use and maintain
 - Removed the need to batch test
 - Facilitated stat and on call testing

Points to remember

- Numerous serology tests for infectious diseases are small in test number but important for patient care they are:
 - Not economically viable to run on large scale instruments
 - Frequently batched to manage workflow and cost
 - Often run manually
- Niche market for small to medium run sizes to be automated
 - Monotests are an elegant and economic solution
 - Removed the need for batch testing
 - VirClia instrument is an easy to use instrument that allows rapid testing particularly of small volume specialised tests

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