

STD External Molecular Quality Assessment Scheme 2

Survey Period	STD External Molecular Quality Assessment Scheme 2021.1 May 19, 2021 - June 20, 2021
Report for	4244 CG CYTOGENOMICS Molecular Diagnostics dr. A. Giakoumaki
Subscriptions Supervision	21 dr. J.J. van Hellemond (Coördinator)
Reference	MUSE manual and Analyte specifications On the SKML website you will find the MUSE manual and an overview of all analytes of all schemes. For every analyte the overview contains the source of the target value, the tolerance, the base of the tolerance and to what extent the commutability of the material has been determined for the specific analyte.
Qualitative	reported 18%






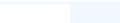
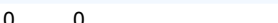
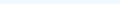
Comments

The distributed materials have been validated as external control materials for DNA amplification techniques (such as PCR), because the presence or absence of a detectable amount of DNA from *Neisseria gonorrhoea*, *Chlamydia trachomatis* and *Trichomonas vaginalis* has been validated. The presence or absence of RNA from *Neisseria gonorrhoea* and *Chlamydia trachomatis* in the distributed materials is not validated, as stabilization of both DNA and RNA in 1 solution suitable for further analysis for both Transcription Mediated Amplification (TMA) and real-time PCR is unfortunately not possible. Therefore, for the results obtained by TMA analysis for these bacterial targets no performance score (0 out of 0) is awarded. Of course it is possible to compare your TMA result with that of other participants. Previous validation studies have shown that the materials prepared by SKML for *Trichomonas vaginalis* are suitable for both TMA and real-time PCR analysis, and therefore, a performance score is assigned for the TMA results for this target. However, for material 2021.1B a relatively large number of false negative results were reported (40%), and therefore no performance score was awarded for this target in this material (0 out of 0 points).

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Analyte	Unit	Trueness				Precision		Performance			
		your mean	ref.	cons.	SDBI	your SD	SDwI	this survey	PS	cumulative	PSc
Trichomonas vaginalis (TMA)	{RLU}						9				
Chlamydia trachomatis (TMA)	{RLU}				172		1727				
Neisseria gonorrhoeae (TMA)	{RLU}				953		8				

Qualitative scores

Analyte	This survey				Cumulative			
	correct	incorrect	total	pictogram	correct	incorrect	total	pictogram
Trichomonas vaginalis (real-time PCR)	0	0	0		0	0	0	
Trichomonas vaginalis (TMA)	2	0	2		5	0	5	
Chlamydia trachomatis (real-time PCR)	0	0	0		0	0	0	
Neisseria gonorrhoeae (real-time PCR)	0	0	0		0	0	0	

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Sample :	A Urogenital swab in stabilisation solution.
Patient :	A Sexual Transmitted Diseases (STD) clinic sends vaginal swab material from an anonymous patient to your laboratory for molecular examination on Sexual Transmitted Diseases (STD).
Question :	Molecular analysis for STD; Chlamydia trachomatis, Neisseria gonorrhoea and Trichomonas vaginalis.
Remarks :	Indien één van onderstaande testen niet door laboratorium wordt uitgevoerd, demarkeer deze test dan in het 'instellingen tabblad'. Bij een negatief test resultaat, a.u.b. geen Cq waarde rapporteren (veld leeg laten).

Results	Unit	Target values		Your results		Score
		qual.	quant.	qual.	quant.	
Trichomonas vaginalis (real-time PCR)		^E Negative				<input type="checkbox"/>
Trichomonas vaginalis (TMA)		^E Negative		Negative		<input checked="" type="checkbox"/>
Chlamydia trachomatis (real-time PCR)		^E Positive				<input type="checkbox"/>
Chlamydia trachomatis (TMA)	{RLU}	^E Positive	1657 ^M	Positive		<input type="checkbox"/>
Neisseria gonorrhoeae (real-time PCR)		^E Positive				<input type="checkbox"/>
Neisseria gonorrhoeae (TMA)	{RLU}	^E Positive	911 ^M	Positive		<input type="checkbox"/>

E = Expert value; M = Method group consensus

Total 2

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Sample :	B Urogenital swab in stabilisation solution.
Patient :	A Sexual Transmitted Diseases (STD) clinic sends vaginal swab material from an anonymous patient to your laboratory for molecular examination on Sexual Transmitted Diseases (STD).
Question :	Molecular analysis for STD; Chlamydia trachomatis, Neisseria gonorrhoea and Trichomonas vaginalis.
Remarks :	Indien één van onderstaande testen niet door laboratorium wordt uitgevoerd, demarkeer deze test dan in het 'instellingen tabblad'. Bij een negatief test resultaat, a.u.b. geen Cq waarde rapporteren (veld leeg laten).

Results	Unit	Target values		Your results			
		qual.	quant.	qual.	quant.		
Trichomonas vaginalis (real-time PCR)	{RLU}	^E Positive				<input type="checkbox"/>	
Trichomonas vaginalis (TMA)		^E Positive	8 ^M	Positive		<input type="checkbox"/>	
Chlamydia trachomatis (real-time PCR)		^E Negative				<input type="checkbox"/>	
Chlamydia trachomatis (TMA)		^E Negative			Negative		<input type="checkbox"/>
Neisseria gonorrhoeae (real-time PCR)		^E Negative					<input type="checkbox"/>
Neisseria gonorrhoeae (TMA)		^E Negative			Negative		

E = Expert value; M = Method group consensus

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Sample :	C Urogenital swab in stabilisation solution.
Patient :	A Dutch man asks for an STD test because his partner has been diagnosed with an STD. The general practitioner takes a smear from the urethra and requests a molecular examination for Sexually Transmitted Diseases.
Question :	Molecular analysis for STD; Chlamydia trachomatis, Neisseria gonorrhoea and Trichomonas vaginalis.
Remarks :	Indien één van onderstaande testen niet door laboratorium wordt uitgevoerd, demarkeer deze test dan in het 'instellingen tabblad'. Bij een negatief test resultaat, a.u.b. geen Cq waarde rapporteren (veld leeg laten).

Results	Unit	Target values		Your results		Score
		qual.	quant.	qual.	quant.	
Trichomonas vaginalis (real-time PCR)		^E Negative				<input type="checkbox"/>
Trichomonas vaginalis (TMA)		^E Negative		Negative		<input checked="" type="checkbox"/>
Chlamydia trachomatis (real-time PCR)		^E Negative				<input type="checkbox"/>
Chlamydia trachomatis (TMA)		^E Negative		Negative		<input type="checkbox"/>
Neisseria gonorrhoeae (real-time PCR)		^E Positive				<input type="checkbox"/>
Neisseria gonorrhoeae (TMA)	{RLU}	^E Positive	19 ^M	Positive		<input type="checkbox"/>

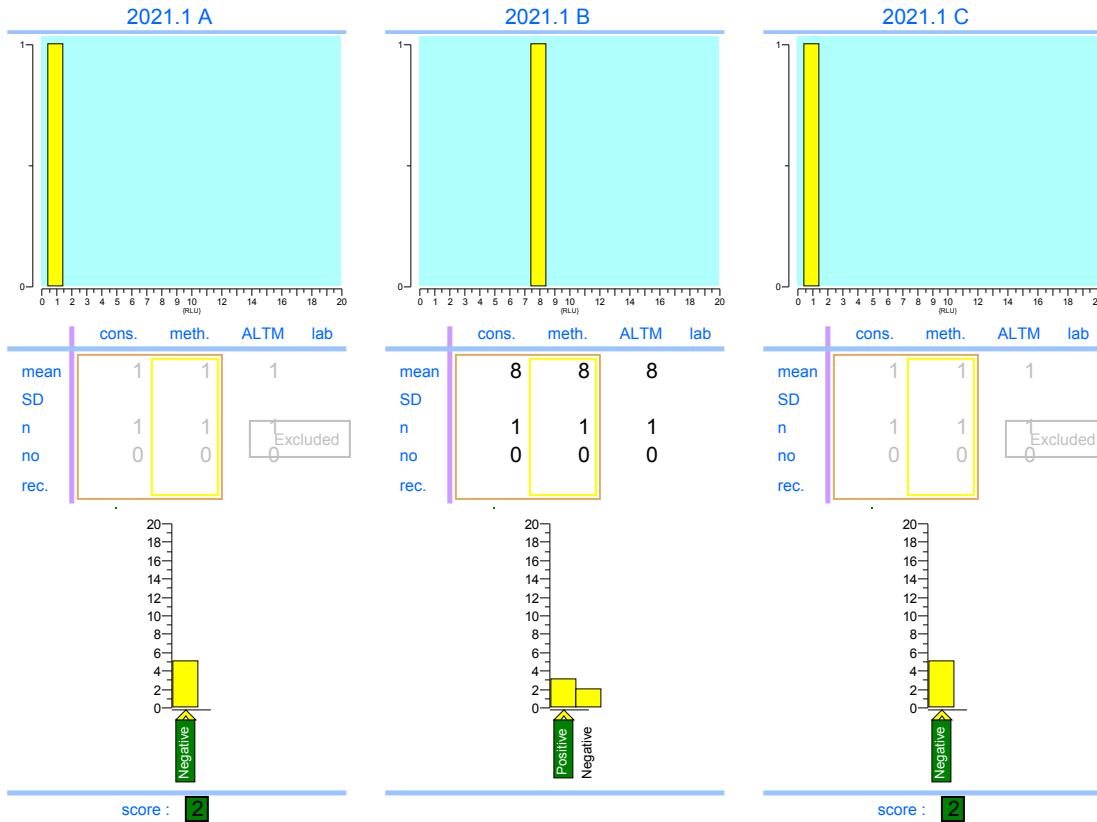
E = Expert value; M = Method group consensus

Total 2

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Trichomonas vaginalis (TMA)

units : {RLU}

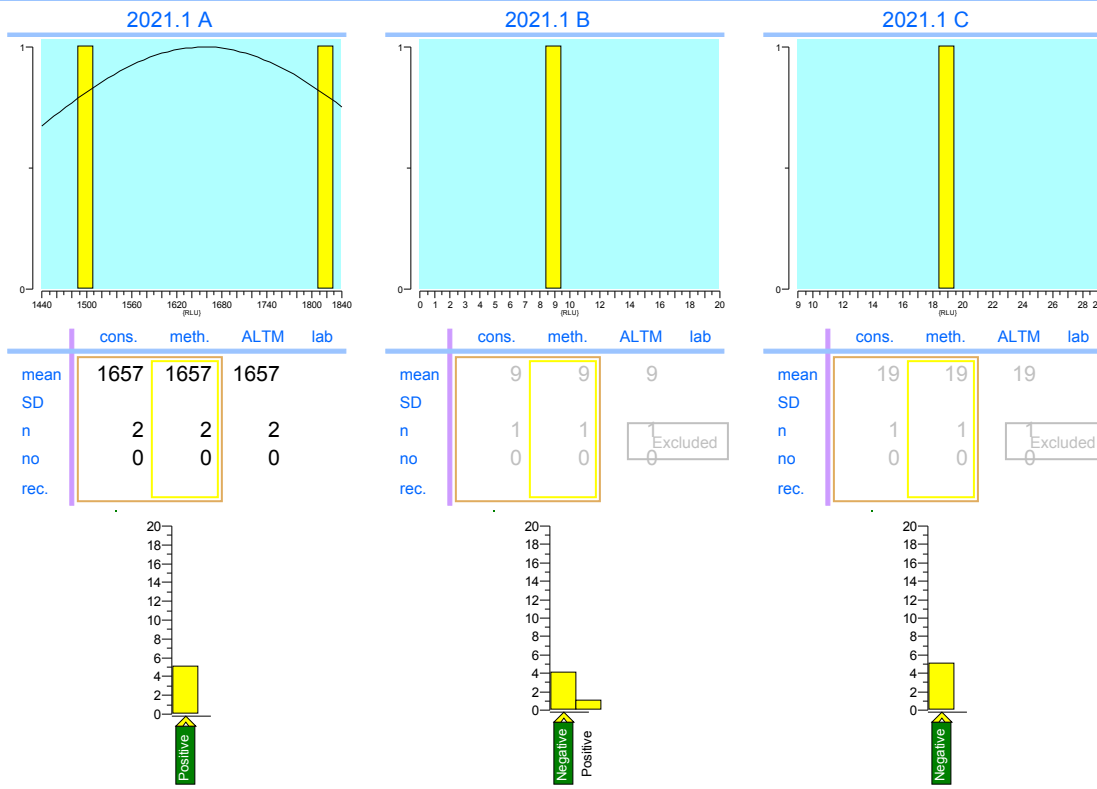


Legend

Aptima

Chlamydia trachomatis (TMA)

units : {RLU}



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Chlamydia trachomatis (TMA)

units : {RLU}

Legend

Aptima

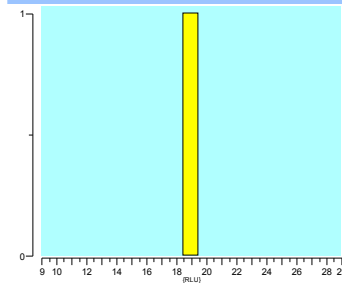
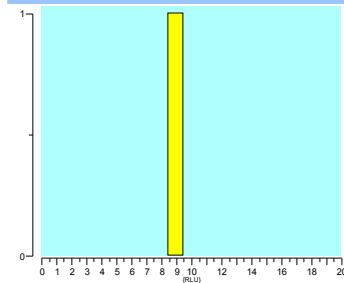
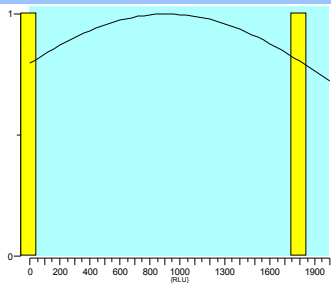
Neisseria gonorrhoeae (TMA)

units : {RLU}

2021.1 A

2021.1 B

2021.1 C

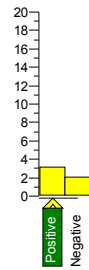
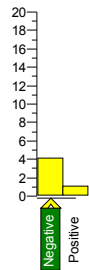
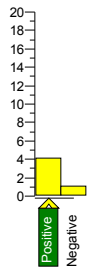


	cons.	meth.	ALTM	lab
mean	911	911	911	
SD				
n	2	2	2	
no	0	0	0	
rec.				

	cons.	meth.	ALTM	lab
mean	9	9	9	
SD				
n	1	1	1	
no	0	0	0	
rec.				

1 Excluded
0

	cons.	meth.	ALTM	lab
mean	19	19	19	
SD				
n	1	1	1	
no	0	0	0	
rec.				



Legend

Aptima

Trichomonas vaginalis (real-time PCR)

units : {Cq}

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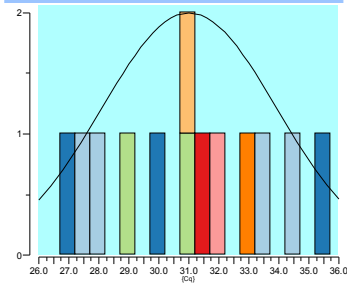
Trichomonas vaginalis (real-time PCR)

units : {Cq}

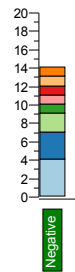
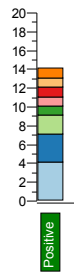
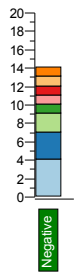
2021.1 A

2021.1 B

2021.1 C



	cons.	meth.	ALTM	lab
mean	31.0	31.0	31.0	
SD	2.9		2.9	
n	13	4	13	
no	0	0	0	
rec.				



Legend

- in house: 2kB repeat seq. (L23861)
- in house: other target
- Other commercial kit
- in house: G3 protein
- Commercial kit BD max
- Commercial kit Diagenode
- Commercial kit Allplex
- Commercial kit GeneXpert

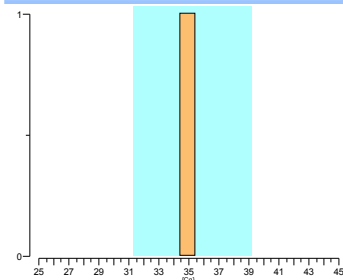
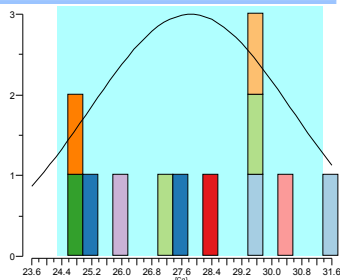
Chlamydia trachomatis (real-time PCR)

units : {Cq}

2021.1 A

2021.1 B

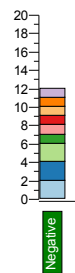
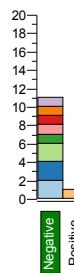
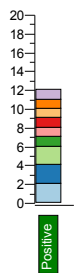
2021.1 C



	cons.	meth.	ALTM	lab
mean	27.8	26.4	27.8	
SD	2.7		2.7	
n	12	2	12	
no	0	0	0	
rec.				

	cons.	meth.	ALTM	lab
mean	35.3		35.3	
SD				
n	1	0		
no	0	0		
rec.				

1 Excluded
0

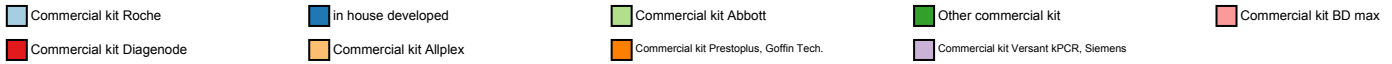


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Chlamydia trachomatis (real-time PCR)

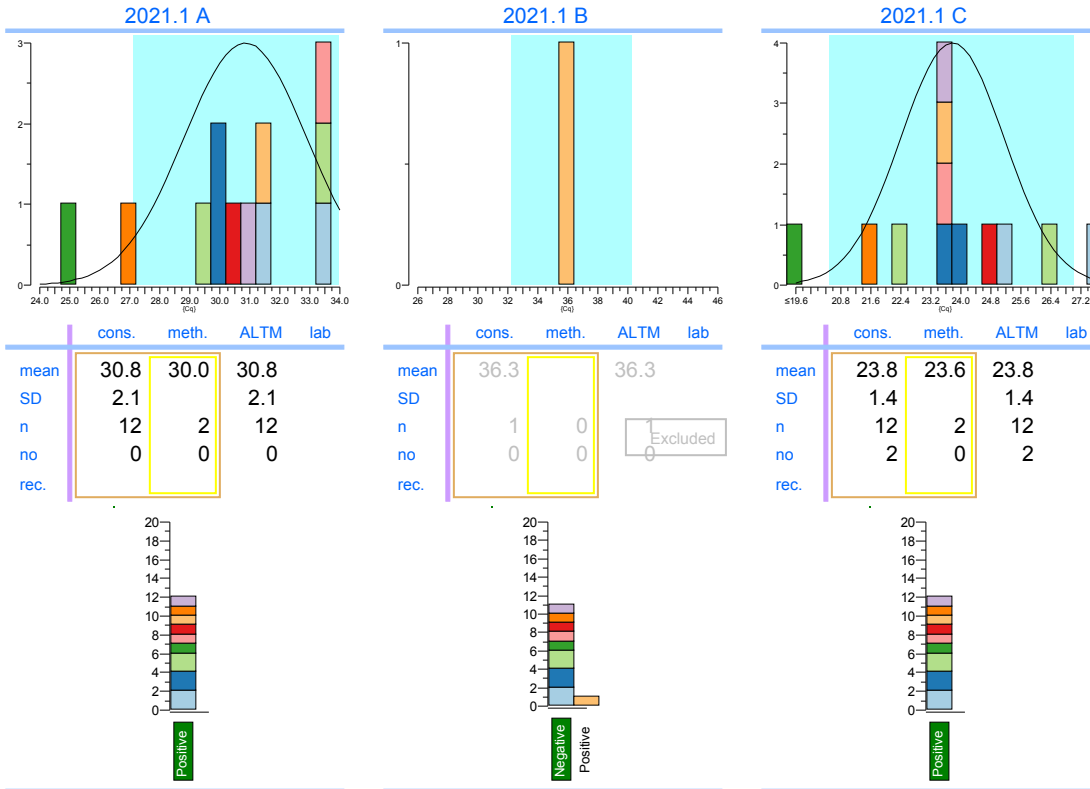
units : {Cq}

Legend



Neisseria gonorrhoeae (real-time PCR)

units : {Cq}



Legend

