

STD External Molecular Quality Assessment Scheme 2

Survey Period	STD External Molecular Quality Assessment Scheme 2020.1 September 15, 2020 - October 17, 2020
Report for	4244 CG CYTOGENOMICS Molecular Diagnostics dr. A. Giakoumaki
Subscriptions Supervision	23 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 20%

Comments

The presence or absence of a detectable amount of RNA from *Neisseria gonorrhoea* and *Chlamydia trachomatis* in the distributed materials has not been validated, as stabilization of both DNA and RNA in a single solution suitable for further analysis for both Transcription Mediated Amplification (TMA) as real-time PCR is unfortunately not possible. Therefore, no performance score is assigned for the results obtained by TMA analysis for these bacterial targets (0 out of 0). However, it is of course possible to compare your TMA result with that of other participants. Previous validation studies have shown that the materials prepared by the SKML for *Trichomonas vaginalis* are suitable for both TMA and real-time PCR analysis, which means that a performance score is assigned for the TMA results for this target. However, no performance score has been assigned for material 2020.1D of this distribution, because > 50% of the TMA participants reported a different result than the expected result. It is therefore plausible that the RNA of *Trichomonas vaginalis* was not sufficiently stable in this material.

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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}				511048		228				
Chlamydia trachomatis (TMA)	{RLU}				600470		30				
Neisseria gonorrhoeae (TMA)	{RLU}				44503		29305				

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)	3	0	3		3	0	6	
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 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	47503 ^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 :	After unsafe sex with a new partner a 25-year old Dutch woman has complaints of irritated vaginal mucosa and discharge. The general practitioner takes a vaginal smear and requests molecular examination for 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)	{RLU}	^E Positive				<input type="checkbox"/>
Trichomonas vaginalis (TMA)		^E Positive	595291 ^M	Positive		<input checked="" type="checkbox"/>
Chlamydia trachomatis (real-time PCR)		^E Negative				<input type="checkbox"/>
Chlamydia trachomatis (TMA)		^E Negative			Negative	
Neisseria gonorrhoeae (real-time PCR)		^E Negative				<input type="checkbox"/>
Neisseria gonorrhoeae (TMA)		^E Negative			Negative	

E = Expert value; M = Method group consensus

Total 2

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Sample :	C Urogenital swab in stabilisation solution.
Patient :	After unsafe sex with several partners a 28-year old Dutch woman has complaints of irritated vaginal mucosa and a burning sensation when urinating. The general practitioner takes a vaginal smear and requests molecular examination for 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	576165 ^M	Positive		<input type="checkbox"/>
Neisseria gonorrhoeae (real-time PCR)		^E Negative				<input type="checkbox"/>
Neisseria gonorrhoeae (TMA)		^E Negative		Negative		<input type="checkbox"/>

E = Expert value; M = Method group consensus

Total 2

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Sample :	D Urogenital swab in stabilisation solution.
Patient :	After unprotected sexual contacts with several partners in the last two months, a 23-year old Dutch woman complains about vaginal discharge and a burning sensation when urinating. The general practitioner takes a vaginal smear and requests molecular examination for 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).

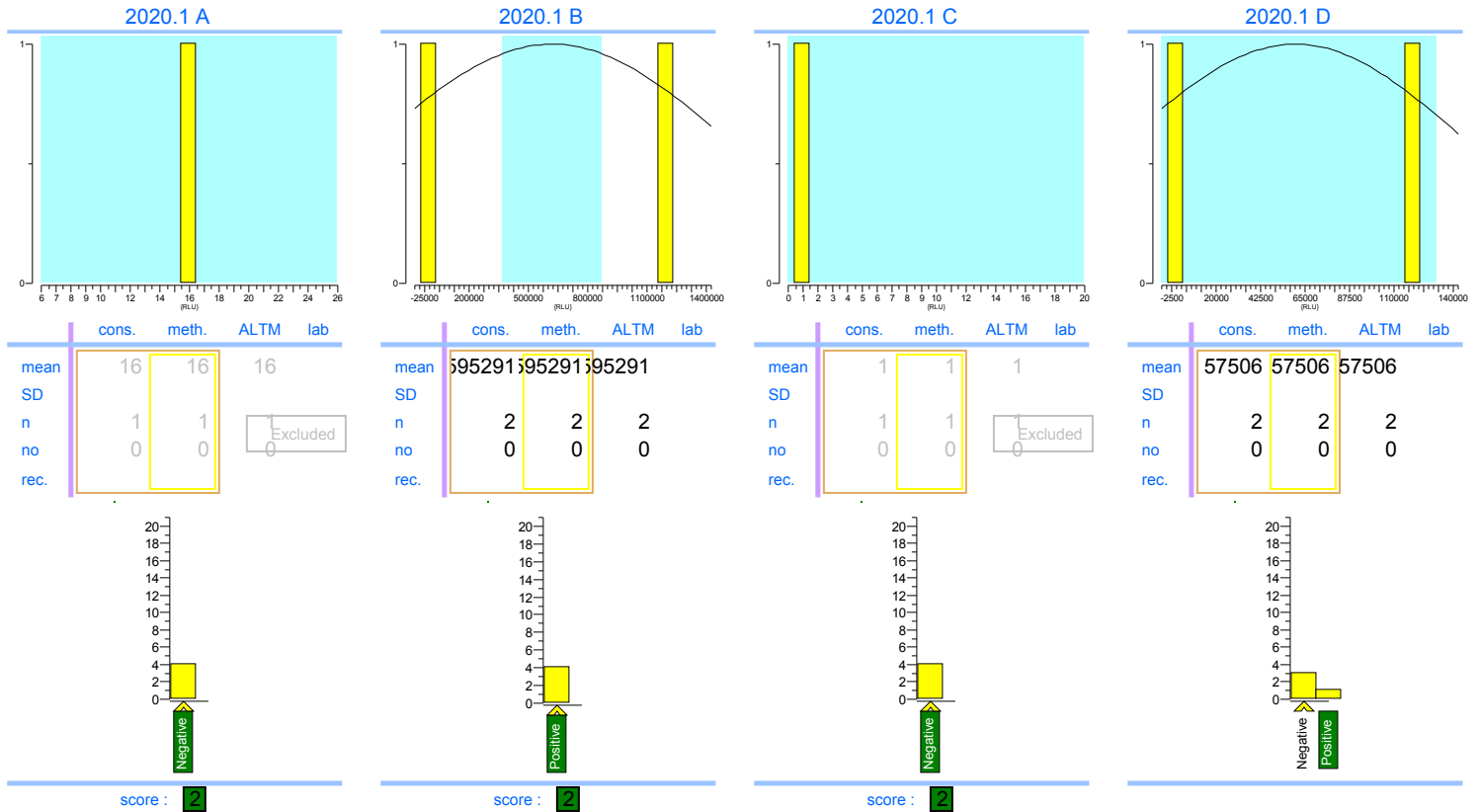
Results	Unit	Target values		Your results		
		qual.	quant.	qual.	quant.	
Trichomonas vaginalis (real-time PCR)		^E Positive				<input type="checkbox"/>
Trichomonas vaginalis (TMA)	{RLU}	^E Positive	57506 ^M	Negative		<input type="checkbox"/>
Chlamydia trachomatis (real-time PCR)		^E Positive				<input type="checkbox"/>
Chlamydia trachomatis (TMA)	{RLU}	^E Positive	404003 ^M	Positive		<input type="checkbox"/>
Neisseria gonorrhoeae (real-time PCR)		^E Positive				<input type="checkbox"/>
Neisseria gonorrhoeae (TMA)	{RLU}	^E Positive	1 ^M	Positive		<input type="checkbox"/>

E = Expert value; M = Method group consensus

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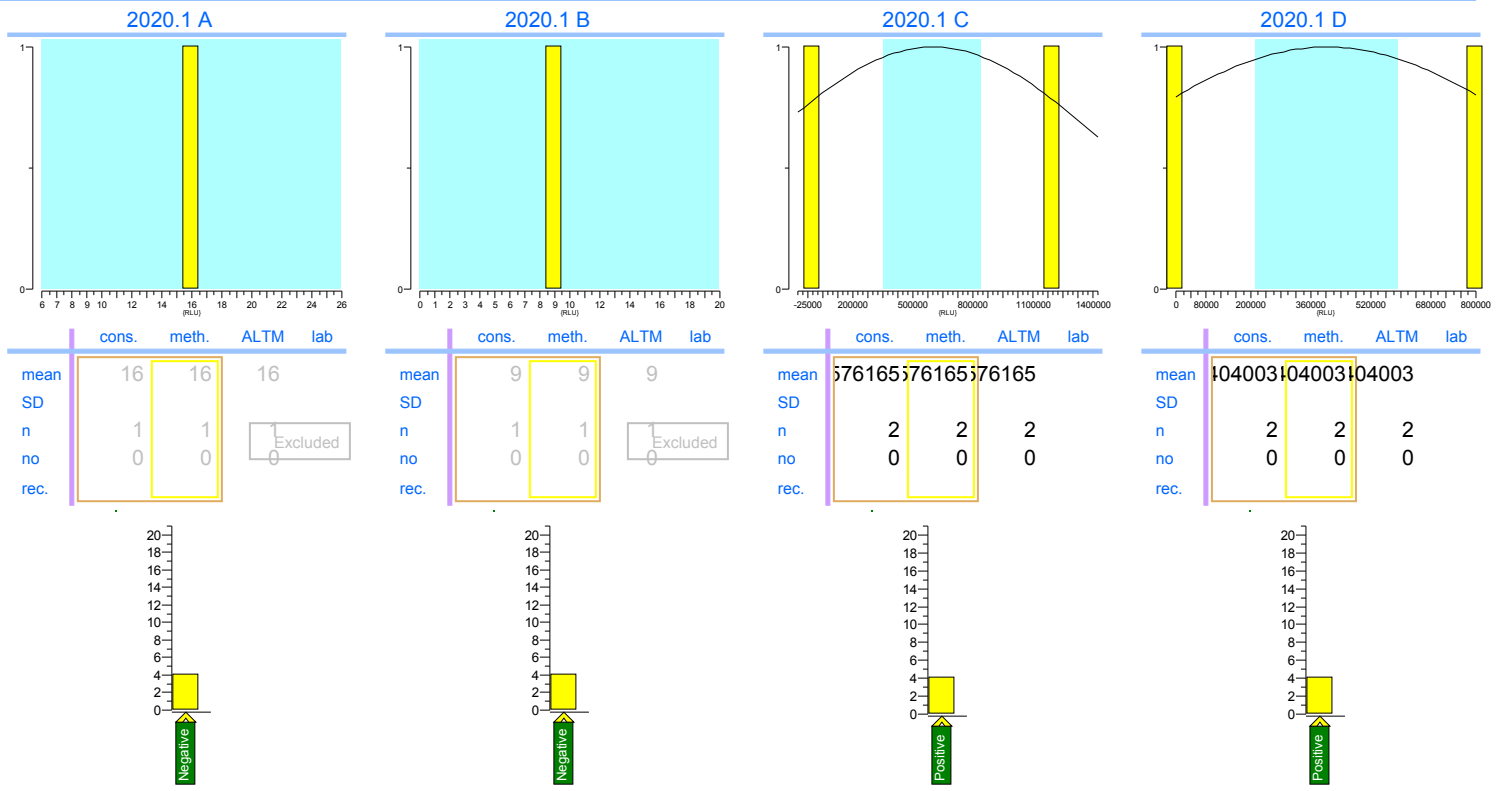
Trichomonas vaginalis (TMA)

units : {RLU}



Chlamydia trachomatis (TMA)

units : {RLU}



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Chlamydia trachomatis (TMA)

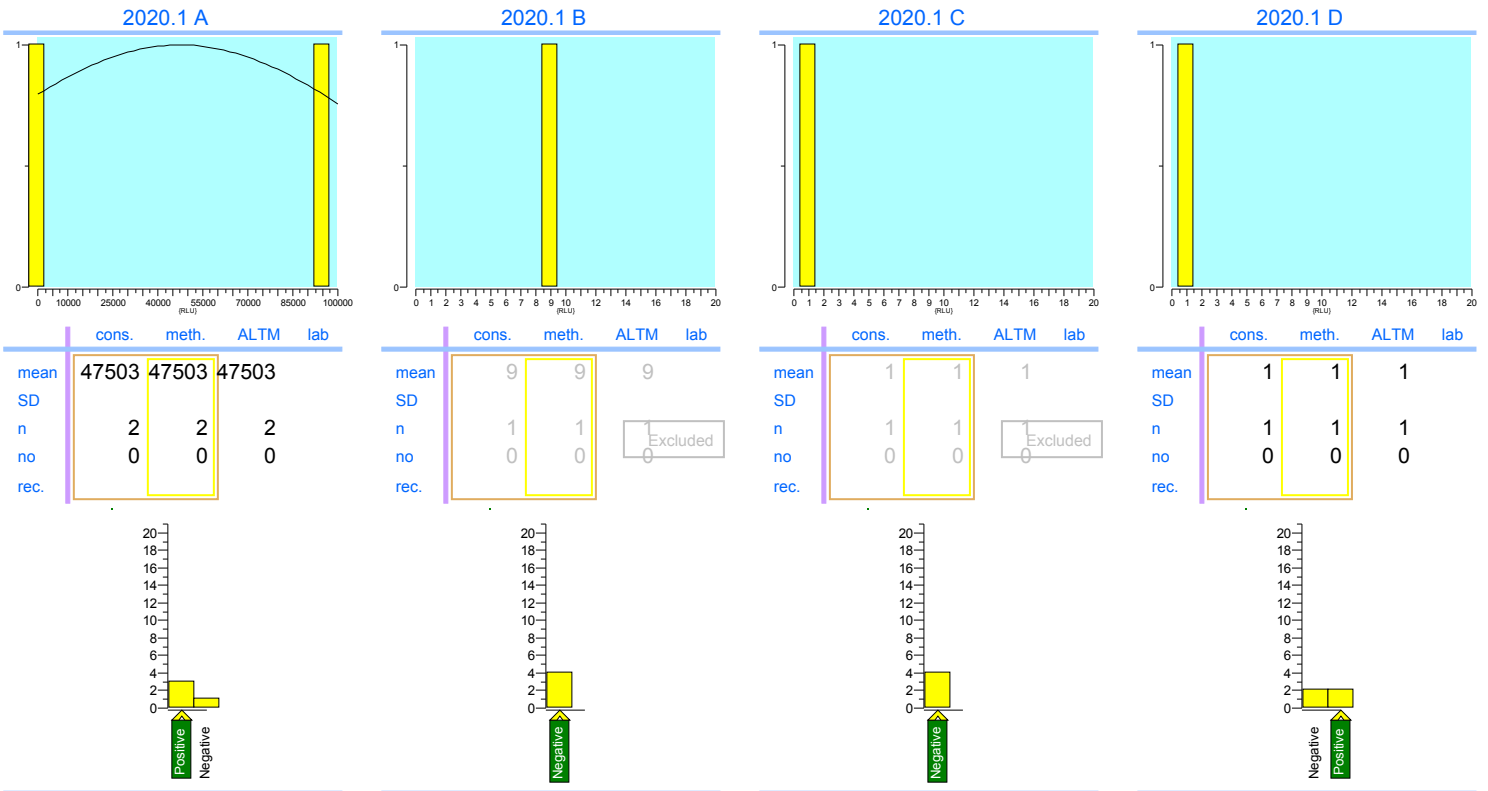
units : {RLU}

Legend

 Aptima

Neisseria gonorrhoeae (TMA)

units : {RLU}



Legend

 Aptima

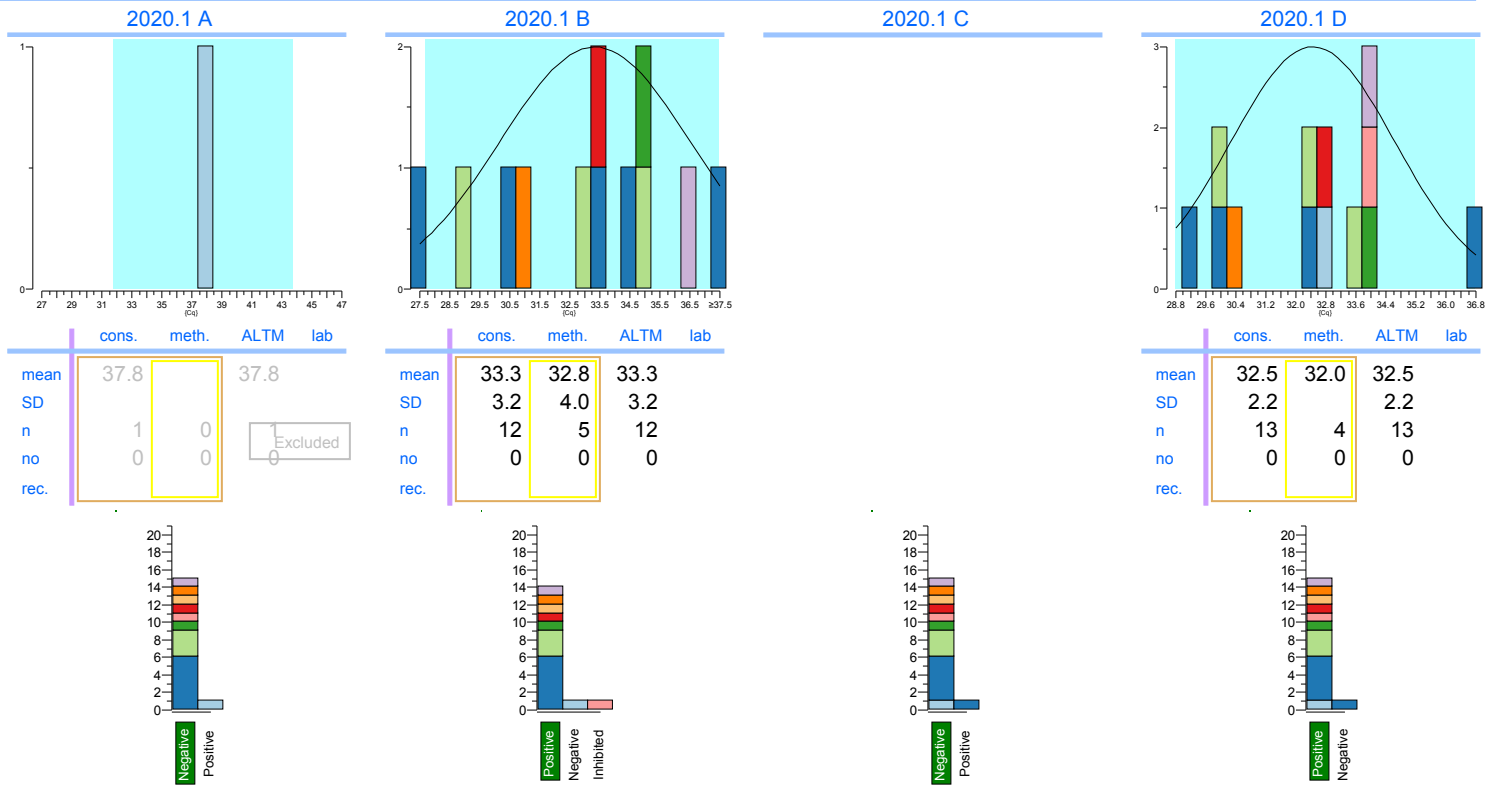
Trichomonas vaginalis (real-time PCR)

units : {Cq}

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Trichomonas vaginalis (real-time PCR)

units : {Cq}

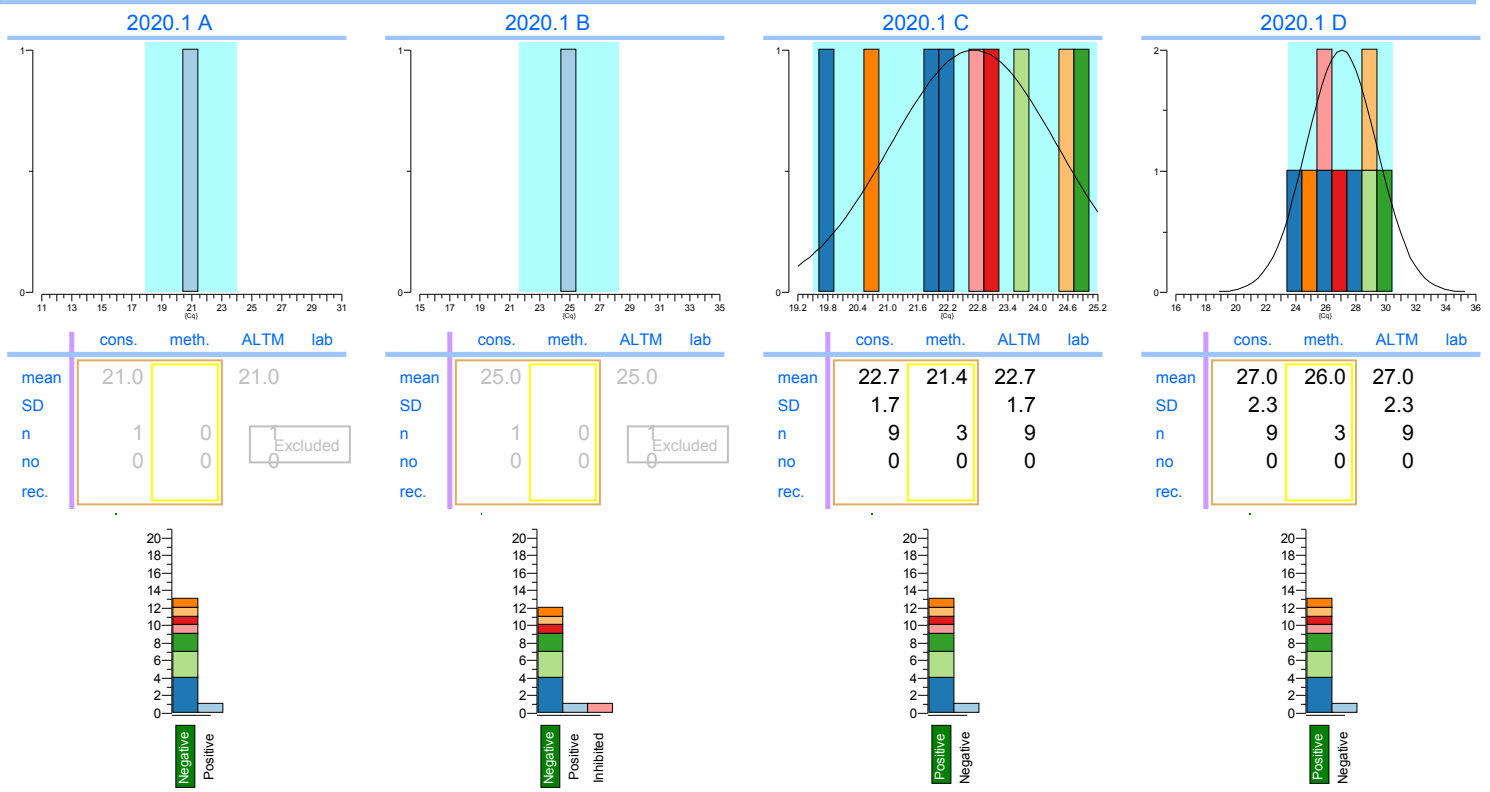


Legend

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

Chlamydia trachomatis (real-time PCR)

units : {Cq}

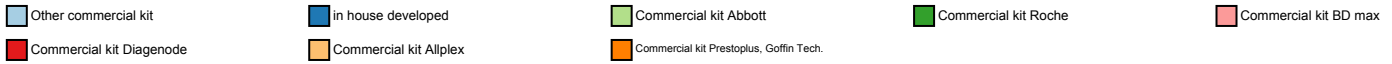


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Chlamydia trachomatis (real-time PCR)

units : {Cq}

Legend



Neisseria gonorrhoeae (real-time PCR)

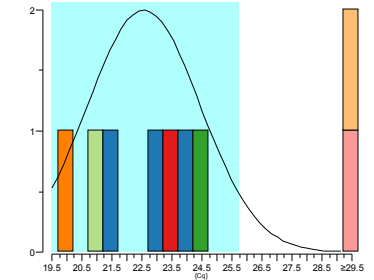
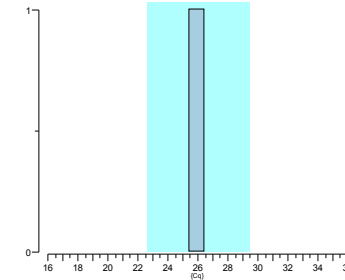
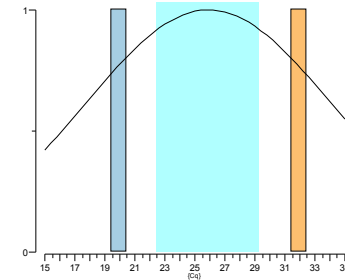
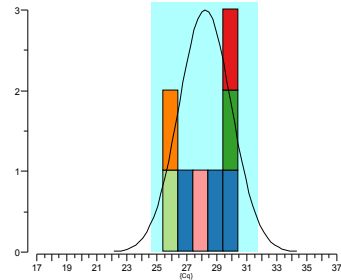
units : {Cq}

2020.1 A

2020.1 B

2020.1 C

2020.1 D

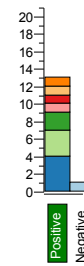
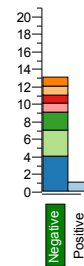
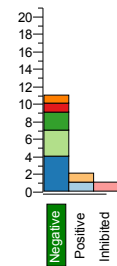
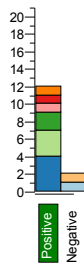


	cons.	meth.	ALTM	lab
mean	28.2	28.6	28.2	
SD	1.7		1.7	
n	8	3	8	
no	0	0	0	
rec.				

	cons.	meth.	ALTM	lab
mean	25.9		25.9	
SD				
n	2	0	2 Excluded	
no	0	0	0	
rec.				

	cons.	meth.	ALTM	lab
mean	26.1		26.1	
SD				
n	1	0	1 Excluded	
no	0	0	0	
rec.				

	cons.	meth.	ALTM	lab
mean	22.6	22.9	22.6	
SD	1.9		1.9	
n	9	3	9	
no	2	0	2	
rec.				



Legend

