

STD External Molecular Quality Assessment Scheme 2

Survey Period	STD External Molecular Quality Assessment Scheme 2021.2 November 23, 2021 - December 19, 2021
Report for	4244 CG CYTOGENOMICS Molecular Diagnostics dr. A. Giakoumaki
Subscriptions Supervision and report authorisation	21 dr. J.J. van Hellemond (Coördinator) reachable at office@skml.nl
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 each analyte the overview shows the source of the target value, the tolerance and what it is based on. The type of material and the specification of the commutability, homogeneity and stability have been included as well.

	reported
Qualitative	23%

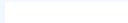
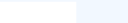


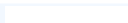
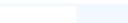
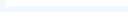
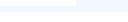
Comments

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 2021.2C, the presence of *Trichomonas vaginalis* could not be sufficiently validated for the assignment of a performance score (all results rated with 0 out of 0 performance score points). Finally, the concentration of *Neisseria gonorrhoea* in material 2021.2D was so low (median and mean Cq value of all participants > 35), that no performance score was assigned for this target in this material either.

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Analyte	Unit	Trueness				Precision		Performance			
		your mean	ref.	cons.	SDBI	your SD	SDwl	this survey	PS	cumulative	PSc
Trichomonas vaginalis (TMA)	{RLU}				556624		292				
Chlamydia trachomatis (TMA)	{RLU}				1050698		67				
Neisseria gonorrhoeae (TMA)	{RLU}				506032		6				

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		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 kwalitatief 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	708259 ^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 :	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 kwalitatief 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	644306 ^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

STD External Molecular Quality Assessment Scheme 2

Sample :	C Urogenital swab in stabilisation solution.
Patient :	A Dutch gay 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 kwalitatief 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				
Trichomonas vaginalis (TMA)		^E Positive	58413 ^M	Positive		
Chlamydia trachomatis (real-time PCR)	{RLU}	^E Negative				<input type="checkbox"/>
Chlamydia trachomatis (TMA)		^E Negative		Negative		
Neisseria gonorrhoeae (real-time PCR)	{RLU}	^E Positive				<input type="checkbox"/>
Neisseria gonorrhoeae (TMA)		^E Positive	342430 ^M	Positive		

E = Expert value; M = Method group consensus

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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 kwalitatief 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)						<input type="checkbox"/>
Trichomonas vaginalis (TMA)	{RLU}	^E Positive	85589 ^M	Positive		<input checked="" type="checkbox"/>
Chlamydia trachomatis (real-time PCR)		^E Positive				<input type="checkbox"/>
Chlamydia trachomatis (TMA)	{RLU}	^E Positive	713312 ^M	Positive		<input type="checkbox"/>
Neisseria gonorrhoeae (real-time PCR)		^E Positive				
Neisseria gonorrhoeae (TMA)		^E Positive		Negative		

E = Expert value; M = Method group consensus

Total 2

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Trichomonas vaginalis (TMA)

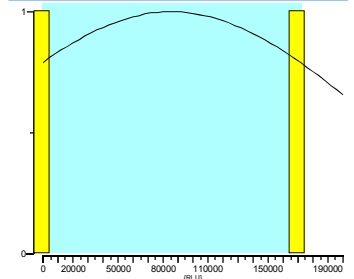
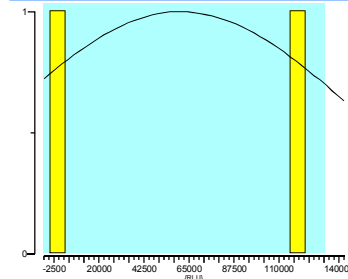
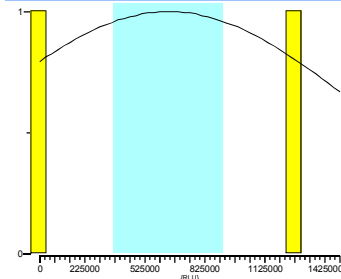
units : {RLU}

2021.2 A

2021.2 B

2021.2 C

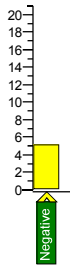
2021.2 D



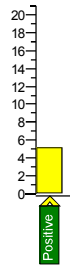
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mean	44306	44306	44306	
SD				
n	2	2	2	
no	0	0	0	
rec.				

	cons.	meth.	ALTM	lab
mean	58413	58413	58413	
SD				
n	2	2	2	
no	0	0	0	
rec.				

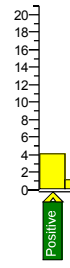
	cons.	meth.	ALTM	lab
mean	85589	85589	85589	
SD				
n	2	2	2	
no	0	0	0	
rec.				



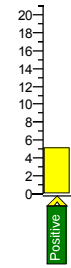
score : 5



score : 5



score : 4



score : 5

Legend

Aptima

Chlamydia trachomatis (TMA)

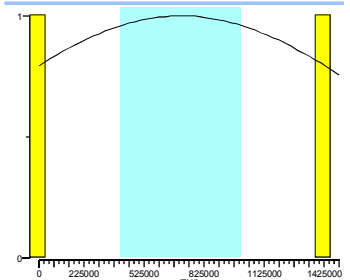
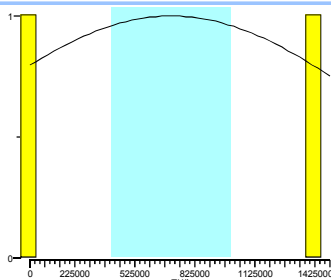
units : {RLU}

2021.2 A

2021.2 B

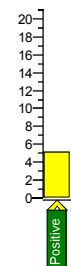
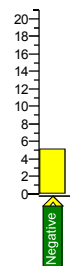
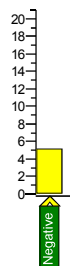
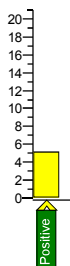
2021.2 C

2021.2 D



	cons.	meth.	ALTM	lab
mean	708259	708259	708259	
SD				
n	2	2	2	
no	0	0	0	
rec.				

	cons.	meth.	ALTM	lab
mean	713312	713312	713312	
SD				
n	2	2	2	
no	0	0	0	
rec.				



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Chlamydia trachomatis (TMA)

units : {RLU}

Legend

 Aptima

Neisseria gonorrhoeae (TMA)

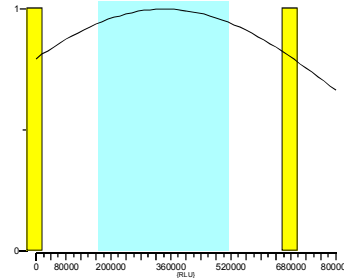
units : {RLU}

2021.2 A

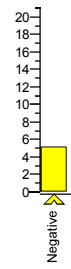
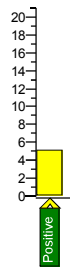
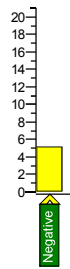
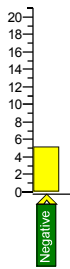
2021.2 B

2021.2 C

2021.2 D



	cons.	meth.	ALTM	lab
mean	42430	42430	42430	
SD				
n	2	2	2	
no	0	0	0	
rec.				



Legend

 Aptima

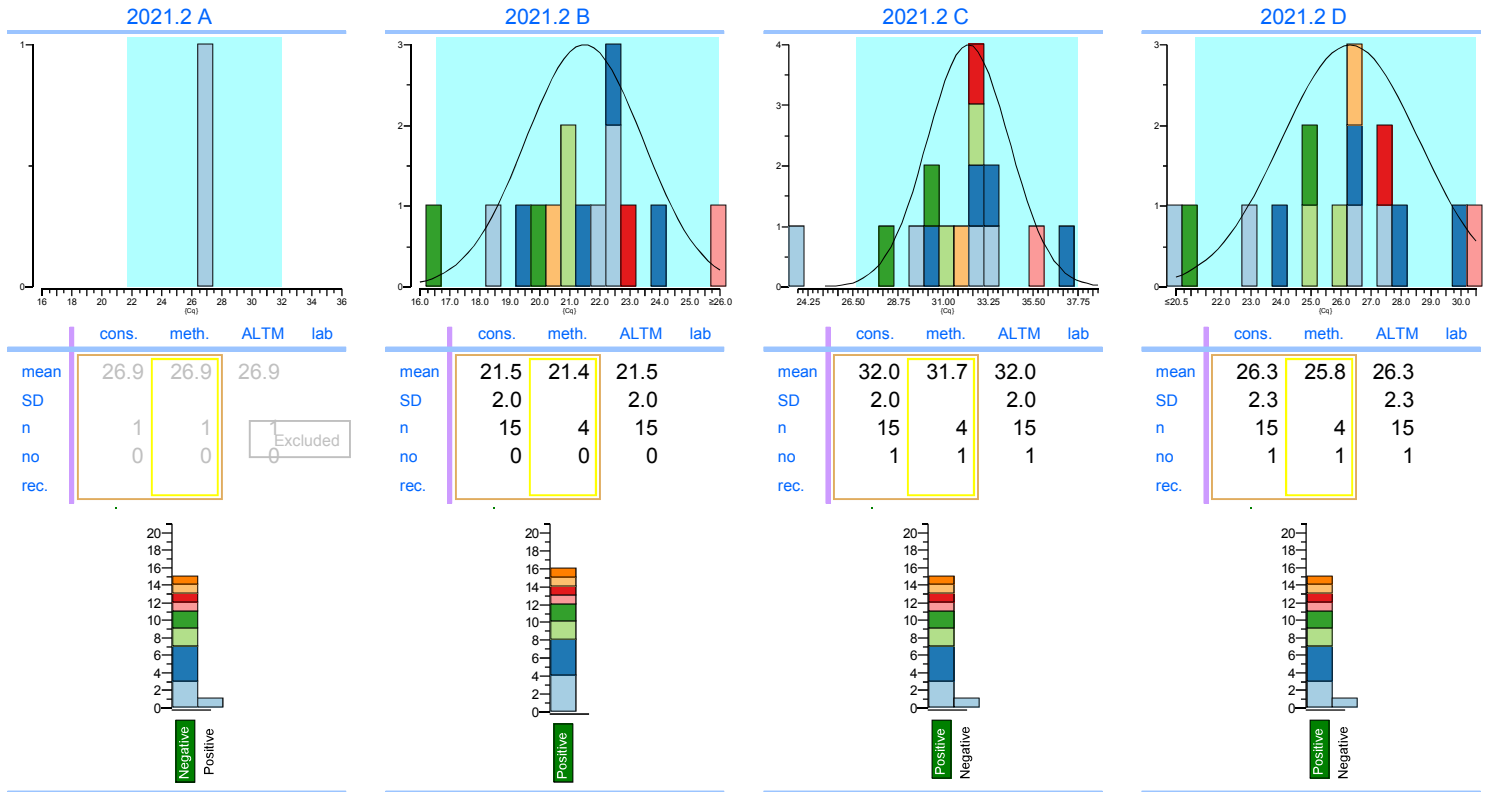
Trichomonas vaginalis (real-time PCR)

units : {Cq}

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Trichomonas vaginalis (real-time PCR)

units : {Cq}

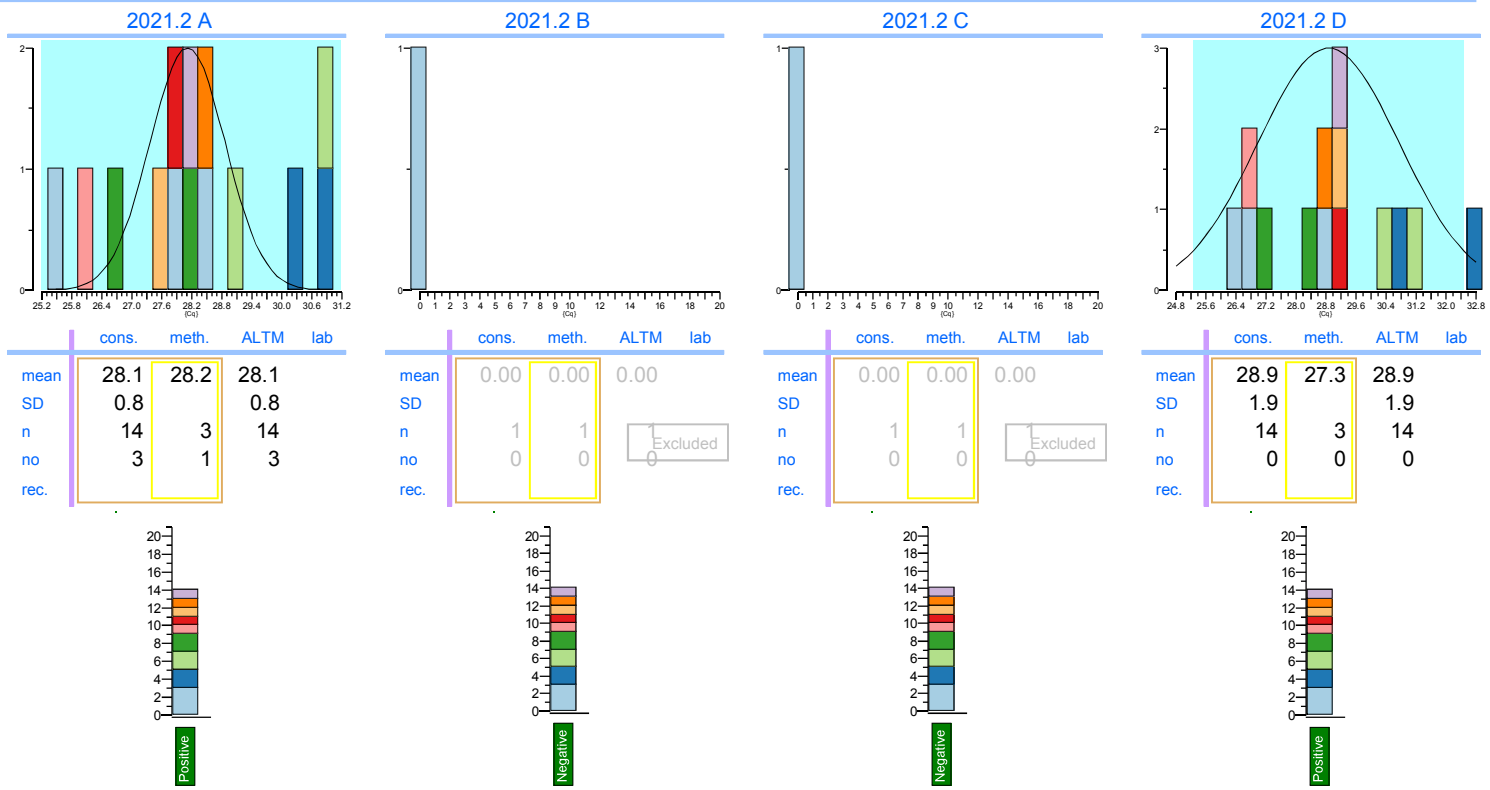


Legend

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

Chlamydia trachomatis (real-time PCR)

units : {Cq}

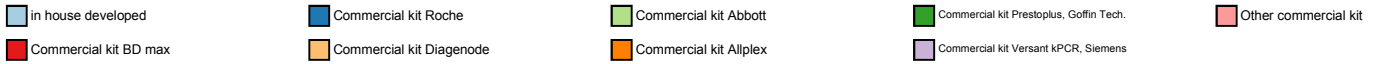


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Chlamydia trachomatis (real-time PCR)

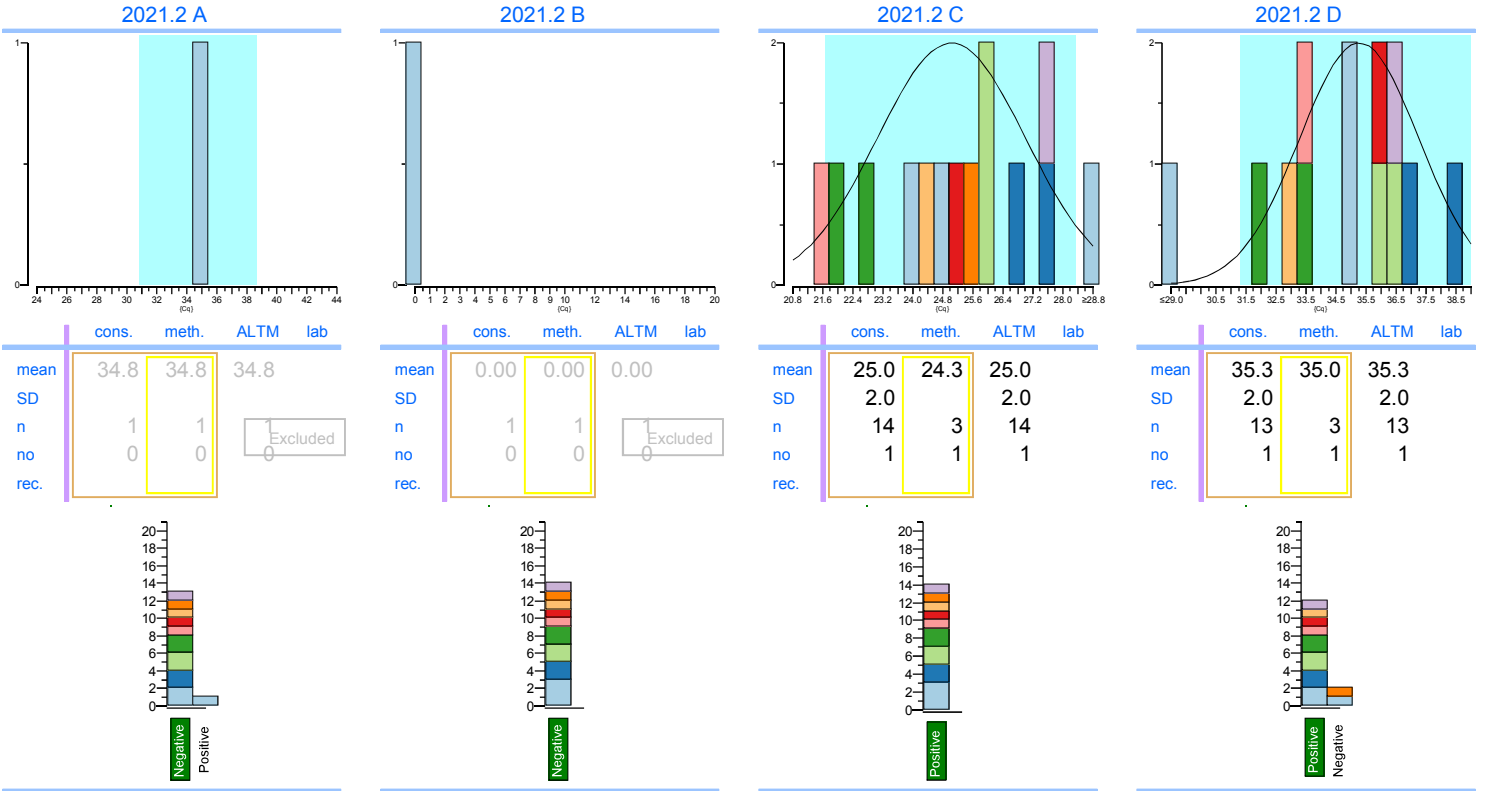
units : {Cq}

Legend



Neisseria gonorrhoeae (real-time PCR)

units : {Cq}



Legend

