

PCR-/NAT *C. trachomatis* & GO (RV 530) Mai 2020



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>	<i>Probenzusammensetzung / Sample composition</i>
2015301	+ / ++	<i>Chlamydia trachomatis</i> (~ 5x10 ³ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 5x10 ⁴ CFU/mL)
2015302	∅ / ∅	<i>Escherichia coli</i> K12
2015303	++ / (+)	<i>Chlamydia trachomatis</i> (~ 1x10 ⁴ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 5x10 ² CFU/mL)
2015304	++ / +	<i>Chlamydia trachomatis</i> (~ 5x10 ⁴ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 1x10 ³ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Chlamydia trachomatis* dargestellt.

Absolute numbers of reported individual results. Note: only the C. trachomatis-specific results are depicted in this table.

<i>n</i> = 269	Probennummer (Sample no.)				Inhibition				
	2015301	2015302	2015303	2015304	2015301	2015302	2015303	2015304	
Befund <i>Result</i>									
Positiv	268	2	267	269	n.d.	2	2	2	2
Negativ	0	267	2	0	nein / <i>no</i>	267	267	267	267
Fraglich <i>Questionable</i>	1	0	0	0	ja / <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwenden verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Chlamydia trachomatis* dargestellt.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods. Note: only the C. trachomatis-specific results are depicted.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	2015301		2015302		2015303		2015304	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Abbott RealTime CT (n = 28)	28	100	28	100	28	100	28	100
BD MAX CT (n = 18)	18	100	17	94	18	100	18	100
Cepheid Xpert CT (n = 38)	38	100	38	100	38	100	37	97
GeneProof <i>C.trachomatis</i> (n = 6)	6	100	6	100	6	100	6	100
HAIN FluoroType CT (n = 22)	22	100	22	100	22	100	22	100
Hologic Aptima Combo 2 assay (n = 9)	9	100	9	100	9	100	9	100

Roche COBAS CT (n = 61)	61	100	60	98	61	100	60	98
Seegene Allplex STI Essential (n = 11)	11	100	11	100	11	100	11	100
Seegene Anyplex II STI-7 Detect. (n = 6)	6	100	6	100	6	100	6	100
LightMix CT (n = 6)	6	100	6	100	6	100	6	100
Other commercial tests (n = 51)	50	98	51	100	51	100	51	100
In house PCR assay (n = 13)	13	100	13	100	13	100	13	100

Tabelle 4: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Neisseria gonorrhoeae* dargestellt. Absolute numbers of reported individual results. Note: only the *N. gonorrhoeae*-specific results are depicted in this table

n = 267	Probennummer (Sample no.)				Inhibition			
	2015301	2015302	2015303	2015304	2015301	2015302	2015303	2015304
Befund Result								
Positiv	262	6	250	255	n.d.	2	2	2
Negativ	5	261	17 ¹⁾	12 ¹⁾	nein / no	265	265	265
Fraglich Questionable	0	0	0	0	ja / yes	0	0	0

Tabelle 5: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Neisseria gonorrhoeae* dargestellt. Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods. Note: only the *N. gonorrhoeae*-specific results are depicted.

NAT-Methode [Code] (total number *)	NAT richtig positiv True positive results						NAT richtig negativ	
	2015301		2015303		2015304		2015302	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
Abbott RealTime NG (n = 28)	28	100	28	100	28	100	26	93
BD MAX NG (n = 17)	17	100	16	94	17	100	17	100
Cepheid Xpert NG (n = 34)	34	100	34	100	34	100	34	100
GeneProof <i>N. gonorrhoeae</i> (n = 6)	6	100	6	100	6	100	5	83
HAIN FluoroType NG (n = 22)	21	95	22	100	22	100	21	95
Hologic Aptima Combo 2 assay (n = 8)	8	100	1	13	1	13	8	100
Roche COBAS NG (n = 62)	61	96	61	98	62	100	60	97
Seegene Allplex STI Essential (n = 11)	11	100	11	100	11	100	11	100
Seegene Anyplex II STI-7 Detect. (n = 6)	6	100	6	100	6	100	6	100

LightMix NG (n = 6)	6	100	6	100	6	100	6	100
Other commercial tests (n = 55)	53	96	48	87	50	91	55	100
In house PCR assay (n = 12)	11	92	11	92	12	100	12	100

Comments: ¹⁾ As samples #2015303 and #2015304 contained a low number of *Neisseria gonorrhoeae* target organisms, negative PCR results were not rated "false negative" in this EQAS distribution.