

**PCR-/NAT *C. trachomatis* & GO
 (RV 530) November 2024**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

Proben Nr.	Erwartet / expected	Probenzusammensetzung / Sample composition
530A 241015 01	++ / +	<i>Chlamydia trachomatis</i> (~ 5x10 ⁴ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 5x10 ⁴ CFU/mL)
530A 241015 02	++ / (+)	<i>Chlamydia trachomatis</i> (~ 1x10 ⁵ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 5x10 ³ CFU/mL)
530A 241015 03	∅ / ++	<i>Neisseria gonorrhoeae</i> (~ 5x10 ⁵ CFU/mL)
530A 241015 04	+++ / ∅	<i>Chlamydia trachomatis</i> (~ 5x10 ⁵ IFU/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.

n = 298	Proben Nr. (Sample no.)				Inhibition				
	01	02	03	04		01	02	03	04
Befund <i>Result</i>									
Positiv	296	298	3	297	n.d.	3	3	3	3
Negativ	2	0	295	1	nein / no	295	295	295	295
Fraglich <i>Questionable</i>	0	0	0	0	ja / yes	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern 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	
	01		02		04		03	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AID RDB 2110 STD (n= 1)	1	100	1	100	1	100	1	100
AID RDB 2335 STI (n= 1)	1	100	1	100	1	100	1	100
Abbott Alinity m STI Assay (n= 18)	17	94	18	100	18	100	18	100
Abbott RealTime CT (n= 10)	10	100	10	100	10	100	10	100
Amplex eazplex STD complete (n= 1)	1	100	1	100	1	100	1	100
AmpliSens CT FRT PCR Kit (= 1)	1	100	1	100	1	100	1	100

BD MAX CT (n= 23)	23	100	23	100	23	100	23	100
BD ProbeTec (n= 4)	4	100	4	100	4	100	4	100
BIORON RealLine CT (n= 1)	1	100	1	100	1	100	1	100
Bruker-HAIN FluoroType CT (n= 10)	10	100	10	100	10	100	10	100
Bruker-HAIN FluoroType STI (n= 2)	2	100	2	100	2	100	2	100
Cepheid Xpert CT (n= 32)	32	100	32	100	31	97	29	91
CerTest VIASURE STD (n= 1)	1	100	1	100	1	100	1	100
DNA-TECHNOLOGY CT (n= 1)	1	100	1	100	1	100	1	100
STI PLUS ELITe MGB Kit (n= 2)	2	100	2	100	2	100	2	100
EUROIMMUN EUROArray STI (n= 7)	7	100	7	100	7	100	7	100
GeneProof C. trachomatis (n= 3)	3	100	3	100	3	100	3	100
GeneProof CT/NG/MG Multiplex (n= 2)	2	100	2	100	2	100	2	100
Goffin Presto CT/NG Assay (n= 1)	1	100	1	100	1	100	1	100
Hologic Aptima Combo 2 assay (n= 17)	17	100	17	100	17	100	17	100
Immundiagnostik MutaPLEX STI-1 (n= 1)	1	100	1	100	1	100	1	100
ampliCube STD Panel 1 (n= 13)	13	100	13	100	13	100	13	100
Qiagen NeuMoDx CT/NG (n= 2)	2	100	2	100	2	100	2	100
artus CT/NG QS-RGQ Kit (n= 2)	2	100	2	100	2	100	2	100
Roche Cobas 4800 CT (n= 13)	13	100	13	100	13	100	13	100
Roche Cobas 5800, 6800, 8800 CT (n= 64)	64	100	64	100	64	100	64	100
Sacace C. trachomatis Real TM (n= 5)	5	100	5	100	5	100	5	100
Seegene Allplex CT/NG/MG/TV (n= 12)	12	100	12	100	12	100	12	100
Seegene Allplex STI Essential (n= 29)	29	100	29	100	29	100	29	100
LightMix CT (n= 4)	4	100	4	100	4	100	4	100
Aprimeo/BOSCH Vivalytic STI (n= 3)	3	100	3	100	3	100	3	100
In house PCR assay (n= 8)	8	100	8	100	8	100	8	100
Other commercial tests (n= 4)	3	75	4	100	4	100	4	100

The following tests are listed under "Other commercial tests": AB Analytica RQ-STI CT/NG/MG (1x), Altona FlexStar CT & NG PCR Detection Mix (1x), AusDiagnostics STI 16-well (1x) and Gerbion diarellaSTI-1 (1x).

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

<i>n</i> = 297	Proben Nr. (Sample no.)				Inhibition				
	01	02	03	04	01	02	03	04	
Befund <i>Result</i>									
Positiv	293	280	295	5	n.d.	3	3	3	3
Negativ	4	17	2	291	nein / no	294	294	294	294
Fraglich <i>Questionable</i>	0	0	0	1	ja / yes	0	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 <i>True positive results</i>						NAT richtig negativ	
	01		02		03		04	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AID RDB 2110 STD (n= 1)	1	100	1	100	1	100	1	100
AID RDB 2335 STI (n= 2)	2	100	2	100	2	100	2	100
Abbott Alinity m STI Assay (n= 18)	17	94	18	100	18	100	17	94
Abbott RealTime NG (n= 10)	10	100	10	100	10	100	10	100
Amplex eazypex STD complete (n= 1)	1	100	1	100	1	100	1	100
AmpliSens NG FRT PCR Kit (n= 1)	1	100	1	100	1	100	1	100
Bosphore CT/NG/MG Panel Kit v1 (n= 1)	1	100	1	100	1	100	1	100
BD MAX NG (n= 23)	23	100	23	100	23	100	23	100
BD ProbeTec (n= 4)	4	100	4	100	4	100	4	100
BIORON RealLine NG (n= 1)	1	100	1	100	1	100	1	100
Bruker-HAIN FluoroType NG (n= 7)	7	100	7	100	7	100	7	100
Bruker-HAIN FluoroType STI (n= 2)	2	100	2	100	2	100	2	100
Cepheid Xpert NG (n= 32)	32	100	32	100	32	100	30	94
CerTest VIASURE STD (n= 1)	1	100	1	100	1	100	1	100
DNA-TECHNOLOGY NG (n= 1)	1	100	1	100	1	100	1	100
STI PLUS ELITe MGB Kit (n= 2)	2	100	2	100	2	100	2	100
EUROIMMUN EUROArray STI (n= 7)	7	100	7	100	7	100	7	100

GeneProof CT/NG/MG Multiplex (n= 2)	2	100	2	100	2	100	2	100
GeneProof N. gonorrhoeae (n= 4)	4	100	4	100	4	100	4	100
Goffin Presto CT/NG Assay (n= 1)	1	100	1	100	1	100	1	100
Hologic Aptima Combo 2 assay (n= 17)	17	100	2	12	17	100	16 [§]	100
Immundiagnostik MutaPLEX STI-1 (n= 1)	1	100	1	100	1	100	1	100
ampliCube STD Panel 1 (n= 13)	11	84	13	100	11	85	13	100
Qiagen NeuMoDx CT/NG (n= 2)	2	100	2	100	2	100	2	100
artus CT/NG QS-RGQ Kit (n= 2)	2	100	2	100	2	100	2	100
Roche Cobas 4800 NG (n= 13)	13	100	13	100	13	100	13	100
Roche Cobas 5800, 6800, 8800 NG (n= 64)	64	100	64	100	64	100	62	97
Sacace N. gonorrhoeae Real TM (n= 4)	4	100	4	100	4	100	4	100
Seegene Allplex CT/NG/MG/TV (n= 12)	12	100	12	100	12	100	12	100
Seegene Allplex STI Essential (n= 29)	29	100	29	100	29	100	29	100
LightMix NG (n= 4)	4	100	4	100	4	100	4	100
Aprimeo/BOSCH Vivalytic STI (n= 3)	3	100	3	100	3	100	3	100
In house PCR assay (n= 7)	7	100	6	86	7	100	7	100
Other commercial tests (n= 5)	4	80	4	80	5	100	5	100

The following tests are listed under "Other commercial tests": AB Analytica RQ-STI CT/NG/MG (1x), Altona FlexStar CT & NG PCR Detection Mix (1x), AusDiagnostics STI 16-well (1x), Gerbion diarellaSTI-1 (1x), NADAL PCR Analyzer (1x) and Roche LightMix Modular N. gonorrhoeae (1x).

§ Fraglich *Due to reporting questionable results, the number of true results has been reduced*