

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



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

Proben Nr.	Erwartet / expected	Probenzusammensetzung / Sample composition
530A 240521 01	+++ / +	<i>Chlamydia trachomatis</i> (~ 5x10 ⁵ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 1x10 ⁴ CFU/mL)
530A 240521 02	++ / ∅	<i>Chlamydia trachomatis</i> (~ 5x10 ⁴ IFU/mL)
530A 240521 03	++ / ++	<i>Chlamydia trachomatis</i> (~ 1x10 ⁵ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 5x10 ⁴ CFU/mL)
530A 240521 04	∅ / +++	<i>Neisseria gonorrhoeae</i> (~ 5x10 ⁵ 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.

n = 307	Proben Nr. (Sample no.)				Inhibition				
	01	02	03	04	01	02	03	04	
Befund <i>Result</i>									
Positiv	307	306	307	5	n.d.	3	3	3	3
Negativ	0	1	0	302	nein / no	304	304	304	304
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		03		04	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AB Analytica RQ-STI CT (n = 1)	1	100	1	100	1	100	1	100
AID RDB 2110 STD (n = 1)	1	100	1	100	1	100	1	100
Abbott Alinity m STI Assay (n = 19)	19	100	19	100	19	100	17	89
Abbott RealTime CT (n = 12)	12	100	12	100	12	100	11	92
Amplex eazyplex STD complete (n = 1)	1	100	1	100	1	100	1	100
AmpliSens CT FRT PCR Kit (n = 2)	2	100	2	100	2	100	2	100

BD MAX CT (n = 24)	24	100	24	100	24	100	23	96
BD ProbeTec (n = 2)	2	100	2	100	2	100	2	100
BIORON RealLine CT (n = 3)	3	100	3	100	3	100	3	100
Bruker-HAIN FluoroType CT (n = 12)	12	100	12	100	12	100	12	100
Bruker-HAIN FluoroType STI (n = 2)	2	100	2	100	2	100	2	100
Cepheid Xpert CT (n = 29)	29	100	29	100	29	100	28	97
CerTest VIASURE STD (n = 2)	2	100	2	100	2	100	2	100
DNA-TECHNOLOGY CT (n = 2)	2	100	2	100	2	100	2	100
STI PLUS ELITe MGB Kit (n = 1)	1	100	1	100	1	100	1	100
EUROIMMUN EUROArray STI (n = 6)	6	100	6	100	6	100	6	100
GeneProof C. trachomatis (n = 11)	11	100	11	100	11	100	11	100
GeneProof CT/NG/MG Multiplex (n = 1)	1	100	1	100	1	100	1	100
Goffin Presto CT/NG Assay (n = 1)	1	100	1	100	1	100	1	100
Hologic Aptima Combo 2 assay (n=18)	18	100	18	100	18	100	18	100
ampliCube STD Panel 1 (n = 10)	10	100	10	100	10	100	10	100
Qiagen NeuMoDx CT/NG (n = 3)	3	100	3	100	3	100	3	100
artus CT/NG QS-RGQ Kit (n = 2)	2	100	2	100	2	100	2	100
Roche Cobas 4800 CT (n = 15)	15	100	15	100	15	100	15	100
Cobas 5800, 6800, 8800 CT (n = 57)	57	100	57	100	57	100	57	100
Sacace C. trachomatis Real TM (n = 6)	6	100	6	100	6	100	6	100
Seegene Allplex CT/NG/MG/TV (n=10)	10	100	10	100	10	100	10	100
Seegene Allplex STI Essential (n = 34)	34	100	34	100	34	100	34	100
Seegene Anyplex II STI-7 (n = 1)	1	100	1	100	1	100	1	100
LightMix CT (n = 2)	2	100	2	100	2	100	2	100
Aprimeo/BOSCH Vivalytic STI (n = 4)	4	100	4	100	4	100	4	100
In house PCR assay (n = 7)	7	100	7	100	7	100	7	100
Other commercial tests (n = 6)	6	100	5	83	6	100	6	100

Comments:

1. The following tests are listed under "Other commercial tests": Analitica RQ-STI CT/NG/MG (1x), AB Analitica RQ-SevenSTI (1x), Altona FlexStar CT & NG PCR Detection Mix (1x), Astra Biotech Chlamydia trachomatis PCR Kit (1x), AusDiagnostics STI 16-well (1x) and Genematrix NeoPlex STI-7 Detection kit (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> = 307	Proben Nr. (Sample no.)				Inhibition				
	01	02	03	04	01	02	03	04	
Befund <i>Result</i>									
Positiv	306	1	307	305	n.d.	3	3	3	3
Negativ	1	306	0	1	nein / <i>no</i>	304	304	304	303
Fraglich <i>Questionable</i>	0	0	0	1	ja / <i>yes</i>	0	0	0	1

Tabelle 5: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwenden 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		03		04		02	
	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 = 19)	19	100	19	100	19	100	19	100
Abbott RealTime NG (n = 12)	12	100	12	100	12	100	12	100
Amplex eazyplex STD complete (n = 1)	1	100	1	100	1	100	1	100
AmpliSens NG FRT PCR Kit (n = 2)	2	100	2	100	2	100	2	100
BD MAX NG (n = 24)	24	100	24	100	24	100	24	100
BD ProbeTec (n = 2)	2	100	2	100	2	100	2	100
BIORON RealLine NG (n = 3)	3	100	3	100	3	100	3	100
Bruker-HAIN FluoroType NG (n = 10)	10	100	10	100	9*	100	10	100
Bruker-HAIN FluoroType STI (n = 2)	2	100	2	100	2	100	2	100
Cepheid Xpert NG (n = 28)	28	100	28	100	28	100	27	96
CerTest VIASURE STD (n = 2)	2	100	2	100	2	100	2	100
DNA-TECHNOLOGY NG (n = 3)	3	100	3	100	3	100	3	100
STI PLUS ELITE MGB Kit (n = 1)	1	100	1	100	1	100	1	100
EUROIMMUN EUROArray STI (n = 6)	6	100	6	100	6	100	6	100
GeneProof CT/NG/MG Multiplex (n = 1)	1	100	1	100	1	100	1	100

GeneProof N. gonorrhoeae (n = 9)	9	100	9	100	9	100	9	100
Goffin Presto CT/NG Assay (n = 1)	1	100	1	100	1	100	1	100
Hologic Aptima Combo 2 assay (n =18)	18	100	18	100	18	100	18	100
ampliCube STD Panel 1 (n = 10)	10	100	10	100	10	100	10	100
Qiagen NeuMoDx CT/NG (n = 3)	3	100	3	100	3	100	3	100
artus CT/NG QS-RGQ Kit (n = 2)	2	100	2	100	2	100	2	100
Roche Cobas 4800 CT (n = 15)	15	100	15	100	15	100	15	100
Cobas 5800, 6800, 8800 CT (n = 57)	57	100	57	100	57	100	57	100
Sacace N. gonorrhoeae Real TM (n = 6)	6	100	6	100	6	100	6	100
Seegene Allplex CT/NG/MG/TV (n =10)	10	100	10	100	10	100	10	100
Seegene Allplex STI Essential (n = 36)	36	100	36	100	36	100	36	100
Seegene Anyplex II STI-7 (n = 1)	1	100	1	100	1	100	1	100
LightMix NG (n = 2)	2	100	2	100	2	100	2	100
Aprimeo/BOSCH Vivalytic STI (n = 4)	4	100	4	100	4	100	4	100
In house PCR assay (n = 6)	6	100	6	100	6	100	6	100
Other commercial tests (n = 9)	8	89	9	100	8	89	9	100

* Inhibition Due to reporting questionable results, the number of true results has been reduced.

Comments:

1. The following tests are listed under "Other commercial tests": AB Analytica RQ-STI CT/NG/MG (1x), AB Analytica RQ-STI CT/NG (1x), AB Analytica RQ-SevenSTI (1x), Altona FlexStar CT & NG PCR Detection Mix (1x), Astra Biotech Neisseria gonorrhoeae PCR Kit (1x), AusDiagnostics STI 16-well (1x), Genematrix NeoPlex STI-7 Detection kit (1x), NADAL PCR Analyzer (1x) and Roche LightMix Modular N. gonorrhoeae (1x).