

**PCR-/NAT Urogenital Panel
 (RV 547) Mai 2024**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

Proben Nr.	Erwartet / expected	Probenzusammensetzung / Sample composition
547A 240521 01	++ / +++ / ++	<i>Ureaplasma parvum</i> (~ 5x10 ⁴ CFU/mL) <i>Gardnerella vaginalis</i> (~ 2x10 ⁵ CFU/mL) <i>Mycoplasma genitalium</i> (~ 1x10 ⁴ CFU/mL)
547A 240521 02	∅	<i>Escherichia coli</i> K12
547A 240521 03	++	<i>Trichomonas vaginalis</i> (~ 1x10 ⁴ CFU/mL)
547A 240521 04	++	<i>Gardnerella vaginalis</i> (~ 5x10 ⁴ CFU/mL)

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

Absolute numbers of reported individual results.

*Note: only the **M.genitalium-specific results** are depicted in this table*

n = 179	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
Befund <i>Result</i>									
Positiv	141	1	0	0	n.d.	1	1	1	1
Negativ	34	178	179	179	nein no	178	178	178	178
Fraglich <i>Questionable</i>	4	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 *Mycoplasma genitalium* dargestellt.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

*Note: only the **M.genitalium -specific results** are depicted in this table.*

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ <i>True negative results</i>					
	01		02		03		04	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AID RDB 2335 STI (n= 1)	0	0	1	100	1	100	1	100
Abbott Alinity m STI assay (n= 9)	7	78	9	100	9	100	9	100
Amplex eazyplex STD complete (n= 3)	2	67	3	100	3	100	3	100
AmpliGnost M. genitalium (n= 1)	1	100	1	100	1	100	1	100
AmpliGnost STI Urethritis (n= 1)	0	0	1	100	1	100	1	100

BIORON RealLine M.hom./ gen. (n= 2)	2	100	2	100	2	100	2	100
BioGX Mycoplasma / Ureaplasma (n=9)	9	100	9	100	9	100	9	100
Bruker-Hain FluoroType STI (n= 5)	5	100	5	100	5	100	5	100
CerTest VIASURE STD (n= 5)	5	100	5	100	5	100	5	100
DNA-TECHNOLOGY M. genitalium (n= 1)	1	100	1	100	1	100	1	100
EUROIMMUN EUROArray STI-11 (n= 6)	1 [§]	17	6	100	6	100	6	100
GeneProof CT/NG/MG Multiplex (n= 3)	3	100	3	100	3	100	3	100
GeneProof M.gen./ hom. PCR Kit (n= 5)	5	100	5	100	5	100	5	100
KOGENE PowerChek STI Multiplex Kit I (n=1)	1	100	1	100	1	100	1	100
ampliCube STD Panel 1 (n= 11)	10	91	11	100	11	100	11	100
Cobas 5800, 6800, 8800 TV / MG (n= 1)	1	100	1	100	1	100	1	100
Roche Cobas TV/ MG (n= 5)	5	100	5	100	5	100	5	100
Seegene Allplex CT/NG/MG/TV Assay (n= 7)	6	86	7	100	7	100	7	100
Seegene Allplex STI Essential (n= 68)	54 [§]	79	68	100	68	100	68	100
Seegene Anyplex II STI-7 (n= 3)	3	100	3	100	3	100	3	100
LightMix modular M. genitalium (n= 5)	2	40	4	80	5	100	5	100
aprimeo/ BOSCH Vivalytic STI (n= 2)	2	100	2	100	2	100	2	100
RIDAGENE STI Mycopl. Panel (n= 7)	4	57	7	100	7	100	7	100
In house PCR assay (n= 8)	5 [§]	63	8	100	8	100	8	100
Other commercial tests (n= 10)	7	70	10	100	10	100	10	100

[§] Fraglich Due to reporting questionable results, the number of true results has been reduced.

Tabelle 4: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Gardnerella vaginalis* dargestellt.

Absolute numbers of reported individual results.

*Note: only the **G.vaginalis-specific results** are depicted in this table*

n = 36	Proben Nr. (Sample no.)			
Befund Result	01	02	03	04
Positiv	35	1	0	34
Negativ	1	35	36	2
Fraglich Questionable	0	0	0	0

	Inhibition			
	01	02	03	04
n.d.	1	1	1	1
nein no	35	35	35	35
ja yes	0	0	0	0

Tabelle 5: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwenden verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Gardnerella vaginalis* dargestellt.

*Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods. Note: only the *G.vaginalis*-specific results depicted.*

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>				NAT richtig negativ <i>True negative results</i>			
	01		04		02		03	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AID GenID STI (n= 1)	1	100	1	100	1	100	1	100
AmpliGnost STI Urethritis (n= 1)	1	100	1	100	1	100	1	100
BIORON RealLine G. vaginalis (n= 1)	1	100	1	100	1	100	1	100
Bruker-Hain FluoroType STI (n= 1)	0	0	0	0	1	100	1	100
GeneProof G. vaginalis PCR Kit (n= 2)	2	100	2	100	2	100	2	100
KOGENE PowerChek STI Multiplex Kit II (n= 1)	1	100	1	100	1	100	1	100
Allplex Bacterial Vaginosis plus (n= 12)	12	100	12	100	12	100	12	100
<i>In house</i> PCR assay [28] (n= 7)	7	100	7	100	6	86	7	100
Other commercial tests (n= 10)	10	100	9	90	10	100	10	100

Tabelle 6: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Ureaplasma parvum* dargestellt.

Absolute numbers of reported individual results.

*Note: only the *U.parvum*-specific results are depicted in this table*

<i>n</i> = 142	Proben Nr. (<i>Sample no.</i>)			
Befund <i>Result</i>	01	02	03	04
Positiv	139	0	0	0
Negativ	3	141	141	141
Fraglich <i>Questionable</i>	0	0	0	0

	Inhibition			
	01	02	03	04
n.d.	1	1	1	1
nein <i>no</i>	141	141	141	141
ja <i>yes</i>	0	0	0	0

Tabelle 7: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Ureaplasma parvum* dargestellt.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

Note: only the *U.parvum* -specific results are depicted in this table.

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ <i>True negative results</i>					
	01		02		03		04	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AID RDB 2335 STI (n= 1)	1	100	1	100	1	100	1	100
BIORON RealLine U. ureal. / U. parv. (n= 2)	2	100	2	100	2	100	2	100
BioGX Mycoplasma / Ureaplasma (n= 9)	9	100	9	100	9	100	9	100
Bruker-Hain FluoroType STI (n= 5)	5	100	5	100	5	100	5	100
CerTest VIASURE STD (n= 5)	5	100	5	100	5	100	5	100
EUROIMMUN EUROArray STI-11 (n= 6)	6	100	6	100	6	100	6	100
GeneProof MH/UU/UP Multiplex PCR Kit (n= 5)	5	100	5	100	5	100	5	100
GeneProof Ureaplasma (UUP) PCR Kit (n= 2)	2	100	2	100	2	100	2	100
KOGENE PowerChek STI Multiplex Kit II (n= 1)	1	100	1	100	1	100	1	100
ampliCube STD Panel 2.1/2.1 LC (n= 13)	13	100	13	100	13	100	13	100
Seegene Allplex STI Essential (n= 69)	68	99	69	100	69	100	69	100
Seegene Anyplex II STI-7 (n= 3)	3	100	3	100	3	100	3	100
LightMix modular U. ureal. /U.parv. (n= 6)	5	83	6	100	6	100	6	100
In house PCR assay (n= 9)	9	100	9	100	9	100	9	100
Other commercial tests (n= 6)	5	83	6	100	6	100	6	100

Tabelle 8: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Trichomonas vaginalis* dargestellt.

Absolute numbers of reported individual results.

Note: only the *T. vaginalis* -specific results are depicted in this table

<i>n = 168</i>	Proben Nr. (<i>Sample no.</i>)			
Befund <i>Result</i>	01	02	03	04
Positiv	0	1	166	0
Negativ	168	167	2	168
Fraglich <i>Questionable</i>	0	0	0	0

	Inhibition			
	01	02	03	04
n.d.	1	1	1	1
nein <i>no</i>	167	167	167	167
ja <i>yes</i>	0	0	0	0

Tabelle 9: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Trichomonas vaginalis* dargestellt.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

Note: only the *T. vaginalis* -specific results are depicted in this table.

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ <i>True negative results</i>					
	03		01		02		04	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AID RDB 2335 STI (n= 2)	2	100	2	100	2	100	2	100
Abbott Alinity m STI assay (n= 10)	10	100	10	100	10	100	10	100
AmpliGnost STI Urethritis (n= 1)	1	100	1	100	1	100	1	100
BD MAX CT/GC/TV (n= 9)	9	100	9	100	9	100	9	100
BIORON RealLine T.vaginalis (n= 2)	2	100	2	100	2	100	2	100
Bruker-Hain FluoroType STI (n= 5)	5	100	5	100	5	100	5	100
CerTest VIASURE STD (n= 6)	6	100	6	100	6	100	6	100
DNA-TECHNOLOGY T. vaginalis (n= 1)	1	100	1	100	1	100	1	100
EUROIMMUN EUROArray STI-11 (n= 6)	6	100	6	100	6	100	6	100
GeneProof T. vaginalis (n= 5)	5	100	5	100	5	100	5	100
KOGENE PowerChek STIMultiplex Kit I (n=1)	1	100	1	100	1	100	1	100
ampliCube STD Panel 2.1/2.1 LC (n= 12)	12	100	12	100	12	100	12	100
Cobas 5800, 6800, 8800 TV/ MG (n= 1)	1	100	1	100	1	100	1	100
Roche Cobas TV/ MG (n= 5)	5	100	5	100	5	100	5	100
Seegene Allplex CT/NG/MG/TV Assay (n= 7)	7	100	7	100	7	100	7	100
Seegene Allplex STI Essential (n= 69)	68	99	69	100	68	99	69	100
Seegene Anyplex II STI-7 (n= 3)	3	100	3	100	3	100	3	100
LightMix modular T.vaginalis (n= 5)	5	100	5	100	5	100	5	100
aprimo/ BOSCH Vivalytic STI (n= 2)	2	100	2	100	2	100	2	100
In house PCR assay (n= 8)	8	100	8	100	8	100	8	100
Other commercial tests (n= 8)	7	88	8	100	8	100	8	100

Comments:

1. *Mycoplasma hominis*-detection was performed by 160 laboratories. With the exception of 69 laboratories (62 with false positive and 5 questionable results for sample # 547A 240521 01), all reported results were correct.
2. *Ureaplasma urealyticum*-detection was performed by 151 laboratories. With the exception of 2 laboratories, all reported results were correct.
3. *Treponema pallidum*-detection was performed by 82 laboratories. With the exception of one laboratory, all reported results were correct.
4. Only *Ureaplasma* spp. detection was performed by 2 laboratories. All reported results were correct

5. The following tests are listed under "Other commercial tests": AmpliGnost *Trichomonas vaginalis* (1x), AmpliSens *M. genitalium* FRT PCR kit (1x), Amplex eazyplexUroGenCheck (1x), Anatolia Geneworks Bosphore STD Panel (1x), AusDiagnostics STI 16-well (1x), Bioeksen Bio-Speedy Sexual transmitted infection RT-qPCR Panel (RUO) (1x), CerTest VIASURE MULTIPLEX *Candida albicans* + *G. vaginalis* + *T. vaginalis* Real Time PCR Detection Kit (2x), CerTest VIASURE MULTIPLEX Herpes Virus 1 + 2 + *Treponema pallidum* Real Time PCR Detection Kit (1x), CerTest VIASURE Sexual Health Panel I Real Time PCR Detection Kit (2x), DNA-TECHNOLOGY Urogenital Microbiota (1x), ELITech Molecular Diagnostics STI PLUS ELITE MGB Kit (1x), eSens *Ureaplasma parvum/urealyticum* QL PCR kit (1x), HOLOGIC Panther (1x), EUROIMMUN EUROArray STI-GV (1x), Immundiagnostik MutaPLEX STI-2 (1x), Progenie RealCycler TPHD-U Kit (1x), r-Biopharm RIDAGENE STI Mycoplasma Panel (1x), Sacace Biotechnologies *C. trachomatis/Ureaplasma/M. genitalium/M. hominis* Real TM (1x), Sacace Biotechnologies *T. pallidum* Real TM (1x), TIB Molbiol LightMix *Gardnerella* (2x) and vitro master diagnostica STD direct flow Chip Kit(1x).