

PCR-/NAT Urogenital Panel (RV 547) Mai 2025



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

Proben Nr.	Erwartet / expected	Probenzusammensetzung / Sample composition
547A 250520 01	++ / ++	<i>Ureaplasma parvum</i> (~ 1x10 ⁴ CFU/mL) <i>Trichomonas vaginalis</i> (~ 2x10 ⁴ CFU/mL)
547A 250520 02	Ø	<i>Escherichia coli</i> K12
547A 250520 03	++	<i>Trichomonas vaginalis</i> (~ 5x10 ⁴ CFU/mL)
547A 250520 04	+++	<i>Gardnerella vaginalis</i> (~ 5x10 ⁵ CFU/mL)

Tabelle 2: 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*

<i>n</i> = 39	Proben Nr. (Sample no.)				Inhibition			
Befund Result	01	02	03	04	01	02	03	04
Positiv	1	1	0	39	n.d.	1	1	1
Negativ	38	38	39	0	nein no	38	38	38
Fraglich Questionable	0	0	0	0	ja yes	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 *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		NAT richtig negativ True negative results					
	04		01		02		03	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
AID RDB 2335 STI (n= 3)	3	100	3	100	3	100	3	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
VIASURE Multiplex (C.a+G.v+T.v) (n=1)	1	100	1	100	1	100	1	100
CerTest VIASURE Sexual Health Panel 1 (n= 2)	2	100	1	50	2	100	2	100
GeneProof G. vaginalis PCR Kit (n= 2)	2	100	2	100	1	50	2	100

Seegene Allplex Bact. Vaginosis plus (n= 13)	13	100	13	100	13	100	13	100
TIB Molbiol modular G. vaginalis (n= 2)	2	100	2	100	2	100	2	100
In house PCR assay [28] (n= 8)	8	100	8	100	8	100	8	100
Other commercial tests (n= 6)	6	100	6	100	6	100	6	100

The following tests are listed under "Other commercial tests": Amplex eazyplexUroGenCheck (1x), Anatolia Geneworks Bosphore STD Combo Kit v2 (1x), Bioeksen Bio-Speedy STD Panel (1x), DNA-TECHNOLOGY Real Time PCR Kit (1x), Immundiagnostik MutaPLEX BV-1 (1x) and PANAGENE PANA RealTyper Kit STD (1x).

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

Absolute numbers of reported individual results.

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

<i>n</i> = 167	Proben Nr. (Sample no.)				Inhibition			
Befund Result	01	02	03	04	01	02	03	04
Positiv	166	0	0	0	n.d.	1	1	1
Negativ	1	167	166	167	nein no	166	166	166
Fraglich Questionable	0	0	1	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 *Ureaplasma urealyticum* dargestellt.

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

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

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ True negative results					
	01		02		03		04	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
AID RDB 2335 STI (n= 3)	3	100	3	100	3	100	3	100
Amplex eazyplex STD complete (n= 2)	2	100	2	100	2	100	2	100
AmpliGnost U. urealyticum / U.parvum (n= 2)	2	100	2	100	2	100	2	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
CerTest VIASURE Sexual Health Panel 1 (n= 1)	1	100	1	100	1	100	1	100
EUROIMMUN EUROArray STI-11 (n= 3)	3	100	3	100	3	100	3	100

GeneProof MH/UU/UP Multiplex PCR Kit (n= 2)	2	100	2	100	2	100	2	100
GeneProof Ureaplasma (UUP) PCR Kit (n= 3)	3	100	3	100	3	100	3	100
Immundiagnostik MutaPLEX U.u./ U.p. (n= 1)	1	100	1	100	1	100	1	100
ampliCube STD Panel 2.1/2.1 LC (n= 17)	17	100	17	100	17	100	17	100
Seegene Allplex STI Essential (n= 81)	80	99	81	100	81	100	81	100
Seegene Anyplex II STI-7e (n= 2)	2	100	2	100	2	100	2	100
TIB Molbiol modular U. ureal. /U.parv. (n= 6)	6	100	6	100	5§	100	6	100
Aprimeo/BOSCH Vivalytic STI (n= 2)	2	100	2	100	2	100	2	100
In house PCR assay (n= 11)	11	100	11	100	11	100	11	100
Other commercial tests (n= 10)	10	100	10	100	10	100	10	100

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

The following tests are listed under "Other commercial tests": Anatolia Geneworks Bosphore STD Combo Kit v2 (1x), AusDiagnostics STI 16-well (3x), aprimeo/ BOSCH Vivalytic STI (n= 1), DNA-TECHNOLOGY UMC Multiplex (U.urealyticum+parvum/M.genitalium /C.trachomatis Multiplex (1x), eSens Ureaplasma parvum/urealyticum QL PCR kit (1x), PANAGENE PANA RealTyper Kit STD (1x), VECTOR BEST RealBest DNA U.urealyticum/U.parvum (1x) and Vitassay qPCR STI (1x).

Tabelle 6: 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

n = 192	Proben Nr. (Sample no.)				Inhibition			
Befund Result	01	02	03	04	01	02	03	04
Positiv	190	0	191	0	n.d.	1	1	1
Negativ	2	192	1	192	nein no	191	191	191
Fraglich Questionable	0	0	0	0	ja yes	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 *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 True positive results				NAT richtig negativ True negative results			
	01		03		02		04	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
AID RDB 2335 STI (n= 4)	4	100	4	100	4	100	4	100
Abbott Alinity m STI assay (n= 12)	12	100	12	100	12	100	12	100

AmpliGnost STI Urethritis (n= 1)	1	100	1	100	1	100	1	100
BD MAX CT/GC/TV (n= 8)	8	100	8	100	8	100	8	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 Multiplex (C.a+G.v+T.v) (n=1)	1	100	1	100	1	100	1	100
CerTest VIASURE STD (n= 5)	5	100	5	100	5	100	5	100
EUROIMMUN EUROArray STI-11 (n= 3)	3	100	3	100	3	100	3	100
GeneProof T. vaginalis (n= 2)	2	100	2	100	2	100	2	100
Immundiagnostik MutaPLEX STI-2 (n= 2)	2	100	2	100	2	100	2	100
ampliCube STD Panel 2.1/2.1 LC (n= 16)	16	100	15	94	16	100	16	100
Cobas 5800, 6800, 8800 TV/ MG (n= 11)	11	100	11	100	11	100	11	100
Seegene Allplex CT/NG/MG/TV Assay (n= 9)	9	100	9	100	9	100	9	100
Seegene Allplex STI Essential (n= 79)	77	97	79	100	79	100	79	100
Seegene Anyplex II STI-7e (n= 2)	2	100	2	100	2	100	2	100
TIB Molbiol 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
Master Diagnostica STD direct flow Chip (n= 1)	1	100	1	100	1	100	1	100
In house PCR assay (n= 9)	9	100	9	100	9	100	9	100
Other commercial tests (n= 13)	13	100	13	100	13	100	13	100

The following tests are listed under "Other commercial tests": AmpliGnost *Trichomonas vaginalis* (1x), Anatolia Geneworks Bosphore STD Combo Kit v2 (1x), AusDiagnostics STI 16-well (3x), Bioeksen Bio-Speedy Sexual transmitted infection RT-qPCR Panel (1x), aprimo/ BOSCH Vivalytic STI (n= 1), DNA-TECHNOLOGY T. vaginalis Real Time PCR Kit (1x), ELITech Molecular Diagnostics STI PLUS ELITE MGB Kit (1x), HOLOGIC Aptima *Trichomonas vaginalis* assay (1x), PANA RealTyper Kit STD (1x), VECTOR BEST RealBest DNA *Trichomonas vaginalis* (1x) Master Diagnostica STD direct flow Chip (1x) and Vitassay qPCR STI (1x).

Comments:

1. *Mycoplasma hominis*-detection was performed by 178 laboratories. With the exception of 4 laboratories (with false positive results), all reported results were correct.
2. The following tests are listed for *Mycoplasma hominis*: Seegene Allplex STI Essential (80x), r-Biopharm RIDAGENE STI Mycoplasma Panel (10x), BioGX Mycoplasma / Ureaplasma (9x), Bruker-Hain FluoroType STI (5x), EUROIMMUN EUROArray STI-11 (3x), BIORON diagnostics RealLine M. hominis / genitalium (2x), TIB Molbiol modular M.hominis (4x), AmpliGnost M. hominis (1x), AID RDB 2335 STI (3x), Amplex eazyplex STD complete (2x), MIKROGEN ampliCube STD Panel 1 (18x), CerTest VIASURE STD (5x), AmpliGnost STI Urethritis (1x), GeneProof Mycoplasma genitalium/hominis PCR Kit (4x), Immundiagnostik MutaPLEX STI-2 (2x), GeneProof MH/UU/UP Multiplex PCR Kit (1x), CerTest VIASURE Sexual Health Panel I Real Time PCR Detection Kit (1x), Seegene Anyplex II STI-7e Detection (2x) Anatolia Geneworks Bosphore STD Combo Kit v2 (1x), AusDiagnostics STI 16-well (3x), Bioeksen Bio-Speedy STD Panel (1x), Aprimo/BOSCH Vivalytic STI (2x), DNA-TECHNOLOGY UMC Multiplex (U.urealyticum+parvum/M.genitalium /C.trachomatis Multiplex (1x), ECOLI eDetect MG-MH-Uspp QL PCR Kit (1x), PANAGENE PANA RealTyper Kit STD (1x), VECTOR BEST RealBest DNA M.hominis/M.genitalium (1x), Master Diagnostica STD direct flow Chip (1x) and Vitassay qPCR STI (1x).
3. *Mycoplasma genitalium*-detection was performed by 204 laboratories. With the exception of 1 laboratory (with questionable results), all reported results were correct.

4. The following tests are listed for *Mycoplasma genitalium*: Seegene Allplex STI Essential (79x), r-Biopharm RIDAGENE STI Mycoplasma Panel (8x), BioGX Mycoplasma / Ureaplasma (9x), Bruker-Hain FluoroType STI (5x), EUROIMMUN EUROArray STI-11 (3x) TIB Molbiol modular M.genitalium (5x), AmpliGnost M. genitalium (1x), BIORON diagnostics RealLine M. hominis / genitalium (2x), AID RDB 2335 STI (3x), Amplex eazypex STD complete (2x), MIKROGEN ampliCube STD Panel 1 (15x), Abbott Alinity m STI assay (11x), Seegene Allplex CT/NG/MG/TV (9x), CerTest VIASURE STD (5x), AmpliGnost STI Urethritis (1x), GeneProof Mycoplasma genitalium/hominis PCR Kit (5x), Immundiagnostik MutaPLEX STI-1 (1x), GeneProof CT/NG/MG Multiplex PCR Kit (2x), Cobas 5800, 6800, 8800 TV/ MG (n= 11), DNA-TECHNOLOGY UMC Multiplex (U.urealyticum+parvum /M.genitalium /C.trachomatis Multiplex (1x), CerTest VIASURE Sexual Health Panel I Real Time PCR Detection Kit (1x), Seegene Anyplex II STI-7e Detection (2x), Anatolia Geneworks Bosphore STD Combo Kit v2 (1x), AusDiagnostics STI 16-well (3x), Bioeksen Bio-Speedy STD Panel (1x), Aprimeo/BOSCH Vivalytic STI (2x), ECOLI eDetect MG-MH-Uspp QL PCR Kit (1x), HOLOGIC Aptima Mycoplasma genitalium Assay (2x), PANAGENE PANA RealTyper Kit STD (1x), VECTOR BEST RealBest DNA M.hominis/M.genitalium (1x), Master Diagnostica STD direct flow Chip (1x) and Vitassay qPCR STI (1x).
5. *Ureaplasma parvum*-detection was performed by 157 laboratories. All reported results were correct.
6. The following tests are listed for *Ureaplasma parvum*: Seegene Allplex STI Essential (81x), TIB Molbiol LightMix modular U. urealyticum/ U.parvum (6x), BIORON diagnostics RealLine U. urealyticum / U. parvum (2x), BioGX Mycoplasma / Ureaplasma (9x), Bruker-Hain FluoroType STI (5x), EUROIMMUN EUROArray STI-11 (3x), AID RDB 2335 STI (3x), MIKROGEN ampliCube STD Panel 2.1 or 2.1 LC (10x), CerTest VIASURE STD Real Time PCR Detection Kit (5x), GeneProof Ureaplasma (UUP) PCR Kit (3x), Immundiagnostik MutaPLEX U. urealyticum / U. parvum (1x), GeneProof MH/UU/UP Multiplex PCR Kit (2x), erTest VIASURE Sexual Health Panel I Real Time PCR Detection Kit (1x), Seegene Anyplex II STI-7e Detection (2x), Anatolia Geneworks Bosphore STD Combo Kit v2 (1x), AusDiagnostics STI 16-well (3x), DNA-TECHNOLOGY UMC Multiplex (U.urealyticum+parvum/M.genitalium /C.trachomatis Multiplex (1x), eSens Ureaplasma parvum/urealyticum QL PCR kit (1x), PANAGENE PANA RealTyper Kit STD (1x), VECTOR BEST RealBest DNA U.urealyticum/U.parvum (1x) and Vitassay qPCR STI (1x).
7. *Treponema pallidum*-detection was performed by 87 laboratories. All reported results were correct.
8. The following tests are listed for *Treponema pallidum*: aprimeo/BOSCH Vivalytic STI (1x), EUROIMMUN EUROArray STI-11 (3x), TIB Molbiol LightMix modular T. pallidum (3x), Seegene Allplex Genital ulcer (37x), AID RDB 2335 STI (3x), Amplex eazypex STD complete (3x), MIKROGEN ampliCube STD Panel 3 (8x), GeneProof T. pallidum (5x), CerTest VIASURE Sexual Health Panel I Real Time PCR Detection Kit (2x), CerTest VIASURE MULTIPLEX Herpes Virus 1 + 2 + Treponema pallidum Real Time PCR Detection Kit (2x), Sacace Biotechnologies T. pallidum Real TM (1x), Anatolia Geneworks Bosphore STD Combo Kit v2 (1x), AusDiagnostics STI 16-well (3x), Bioeksen Bio-Speedy Sexual transmitted infection RT-qPCR Panel (1x), Progenie RealCycler TPHD-U Kit (1x), PANAGENE PANA RealTyper Kit STD (1x) and Master Diagnostica STD direct flow Chip (1x).
9. Only *Ureaplasma* spp. detection was performed by 15 laboratories. All reported results were correct.
10. The following tests are listed for *Ureaplasma* spp.: r-Biopharm RIDAGENE STI Mycoplasma Panel (8x), Bioeksen Bio-Speedy Sexual transmitted infection RT-qPCR Panel (1x), ECOLI eDetect MG-MH-Uspp QL PCR Kit (1x), Immundiagnostik MutaPLEX STI-2 (1x) and Master Diagnostica STD direct flow Chip (1x).
11. Only *Mycoplasma* spp. detection was performed by only one laboratory with Procomcure Biotech PhoenixDX Mycoplasma Mix. The reported results were correct.