

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



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

Proben Nr.	Erwartet / expected	Probenzusammensetzung / Sample composition
547A 251014 01	++ / +++	<i>Ureaplasma parvum</i> (~ 2x10 ⁴ CFU/mL) <i>Trichomonas vaginalis</i> (~ 2x10 ⁵ CFU/mL)
547A 251014 02	++	<i>Gardnerella vaginalis</i> (~ 1x10 ⁵ CFU/mL)
547A 251014 03	Ø	<i>Escherichia coli</i> K12
547A 251014 04	+ / + / + / (+) / +	<i>Mycoplasma hominis</i> (~ 1x10 ³ CFU/mL) <i>Mycoplasma genitalium</i> (~ 1x10 ³ CFU/mL) <i>Ureaplasma urealyticum</i> (~ 1x10 ³ CFU/mL) <i>Ureaplasma parvum</i> (~ 5x10 ² CFU/mL) <i>Gardnerella vaginalis</i> (~ 2x10 ³ 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> = 37	Proben Nr. (Sample no.)				Inhibition			
Befund Result	01	02	03	04	01	02	03	04
Positiv	1	36	0	36	n.d.	1	1	1
Negativ	36	1	37	1	nein no	36	36	36
Fraglich Questionable	0	0	0	0	ja yes	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 *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 True positive results				NAT richtig negativ True negative results			
	02		04		01		03	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
AID RDB 2335 STI (n= 2)	2	100	2	100	2	100	2	100
AmpliGnost STI Urethritis (n= 1)	1	100	1	100	1	100	1	100
CerTest VIASURE Sexual Health Panel 1 (n= 1)	1	100	1	100	1	100	1	100
GeneProof G. vaginalis PCR Kit (n= 4)	3	100	3	100	3	100	3	100

Seegene Allplex Bact. Vaginosis plus (n= 13)	12	92	12	92	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= 7)	7	100	7	100	7	100	7	100
Other commercial tests (n= 8)	8	100	8	100	7	88	8	100

The following tests are listed under "Other commercial tests": Bioeksen Bio-Speedy Sexual transmitted infection RT-qPCR Panel (1x), Genematrix NeoPlex STI-14 Detection kit (1x), GeneProof G. vaginalis MC PCR Kit (1x), Gerbion diarellaBV-1 (1x), PANAGENE PANA RealTyper STD (1x) and VISION STI Kit (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

n = 146	Proben Nr. (Sample no.)				Inhibition			
Befund Result	01	02	03	04	01	02	03	04
Positiv	1	0	0	137	n.d.	1	1	1
Negativ	145	146	146	9	nein no	145	145	145
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 *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					
	04		01		02		03	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
AID RDB 2335 STI (n= 2)	1	50	2	100	2	100	2	100
Amplex eazypex STD complete (n= 1)	0	0	1	100	1	100	1	100
AmpliGnost U. urealyticum / U.parvum (n= 2)	2	100	2	100	2	100	2	100
BIORON RealLine U. ureal. / U. parv. (n= 1)	1	100	1	100	1	100	1	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= 2)	2	100	2	100	2	100	2	100
CerTest VIASURE Sexual Health Panel I (n= 1)	1	100	1	100	1	100	1	100
EUROIMMUN EUROArray STI-11 (n= 4)	4	100	4	100	4	100	4	100

GeneProof MH/UU/UP Multiplex PCR Kit (n= 2)	2	100	2	100	2	100	2	100
GeneProof Ureaplasma (UUP) PCR Kit (n= 4)	4	100	4	100	4	100	4	100
ampliCube STD Panel 2.1/2.1 LC (n= 18)	18	100	18	100	18	100	18	100
Seegene Allplex STI Essential (n= 69)	63	91	69	100	69	100	69	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	6	100	6	100
In house PCR assay (n= 10)	10	100	10	100	10	100	10	100
Other commercial tests (n= 8)	7	88	7	88	8	100	8	100

The following tests are listed under "Other commercial tests": Altona diagnostics (1x), AusDiagnostics STI 16-well (2x), Genematrix NeoPlex STI-14 Detection kit (1x), GeneProof Ureaplasma urealyticum MC PCR Kit (1x), PANAGENE PANA RealTyper STD (1x), VISION STI Kit (1x) and Vitassay qPCR STI (1x).

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*

n = 138	Proben Nr. (Sample no.)					Inhibition			
Befund <i>Result</i>	01	02	03	04		01	02	03	04
Positiv	137	0	1	92	n.d.	1	1	1	1
Negativ	0	138	137	42	nein no	137	137	137	137
Fraglich <i>Questionable</i>	1	0	0	4	ja yes	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 <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 RDB 2335 STI (n= 2)	2	100	0	0	2	100	2	100
BIORON RealLine U. ureal. / U. parv. (n= 1)	0^s	100	0	0	1	100	1	100
BioGX Mycoplasma / Ureaplasma (n= 9)	9	100	5^s	71	9	100	9	100
Bruker-Hain FluoroType STI (n= 5)	5	100	2^s	50	5	100	5	100
CerTest VIASURE STD (n= 2)	2	100	2	100	2	100	2	100
CerTest VIASURE Sexual Health Panel I (n= 1)	1	100	1	100	1	100	1	100

EUROIMMUN EUROArray STI-11 (n= 4)	4	100	3	75	4	100	4	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	0	0	3	100	3	100
ampliCube STD Panel 2.1/2.1 LC (n= 15)	15	100	15	100	15	100	15	100
Seegene Allplex STI Essential (n= 70)	70	100	52	74	70	100	69	99
Seegene Anyplex II STI-7e (n= 2)	2	100	1	50	2	100	2	100
TIB Molbiol modular U. ureal. /U.parv. (n= 6)	6	100	1	17	6	100	6	100
In house PCR assay (n= 9)	9	100	5	56	9	100	9	100
Other commercial tests (n= 8)	8	100	3 [§]	42	8	100	8	100

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

The following tests are listed under "Other commercial tests": AusDiagnostics STI 16-well (2x), eSens Ureaplasma parvum/urealyticum QL PCR kit (1x), Genematrix NeoPlex STI-14 Detection kit (1x), GeneProof Ureaplasma parvum MC PCR Kit (1x), PANAGENE PANA RealTyper STD (1x), VISION STI Kit (1x) and Vitassay qPCR STI (1x).

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</i> = 181	Proben Nr. (Sample no.)				Inhibition				
Befund Result	01	02	03	04		01	02	03	04
Positiv	180	0	0	2	n.d.	1	1	1	1
Negativ	1	181	181	179	nein no	180	180	180	180
Fraglich Questionable	0	0	0	0	ja yes	0	0	0	0

Tabelle 9: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwenden 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 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
Abbott Alinity m STI assay (n= 14)	14	100	14	100	14	100	14	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= 1)	1	100	1	100	1	100	1	100
Bruker-Hain FluoroType STI (n= 5)	5	100	5	100	5	100	5	100
CerTest VIASURE STD (n= 3)	3	100	3	100	3	100	3	100
DNA-TECHNOLOGY T. vaginalis RT PCR (n= 1)	1	100	1	100	1	100	1	100
EUROIMMUN EUROArray STI-11 (n= 4)	4	100	4	100	4	100	4	100
GeneProof T. vaginalis (n= 4)	4	100	4	100	4	100	4	100
Immundiagnostik MutaPLEX STI-2 (n= 1)	1	100	1	100	1	100	1	100
ampliCube STD Panel 2.1/2.1 LC (n= 17)	16	94	17	100	17	100	16	94
cobas 5800, 6800, 8800 TV/ MG (n= 9)	9	100	9	100	9	100	9	100
Seegene Allplex CT/NG/MG/TV Assay (n= 11)	11	100	11	100	11	100	11	100
Seegene Allplex STI Essential (n= 68)	68	100	68	100	68	100	68	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	4	80
In house PCR assay (n= 8)	8	100	8	100	8	100	8	100
Other commercial tests (n= 16)	16	100	16	100	16	100	16	100

The following tests are listed under "Other commercial tests": Altona diagnostics (1x), AmpliGnost Trichomonas vaginalis (1x), AusDiagnostics STI 16-well (2x), Bioexen Bio-Speedy Sexual transmitted infection RT-qPCR Panel (1x), Cepheid Xpert TV (2x), ELITech Molecular Diagnostics STI PLUS ELITe MGB Kit (1x), Genematrix NeoPlex STI-14 Detection kit (1x), GeneProof T. vaginalis MC PCR Kit (1x), Gerbion diarellaSTI-2 (1x), HOLOGIC Aptima Trichomonias vaginalis assay (1x), PANAGENE PANA RealTyper STD (1x), VISION STI Kit (1x) and Vitassay qPCR STI (1x).

Tabelle 10: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Mycoplasma hominis* dargestellt.

Absolute numbers of reported individual results.

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

n = 162	Proben Nr. (Sample no.)			
Befund Result	01	02	03	04
Positiv	2	1	0	159
Negativ	160	161	162	2
Fraglich Questionable	0	0	0	1

	Inhibition			
	01	02	03	04
n.d.	1	1	1	1
nein no	161	161	161	161
ja yes	0	0	0	0

Tabelle 11: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwenden verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Mycoplasma hominis* dargestellt.

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

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

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ <i>True negative results</i>					
	04		01		02		03	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AID RDB 2335 STI (n= 2)	1	50	2	100	2	100	2	100
Amplex eazypex STD complete (n= 1)	1	100	1	100	1	100	1	100
AmpliGnost M. hominis (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 M.hom./ M.gen. (n= 1)	1	100	1	100	1	100	1	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= 2)	2	100	2	100	2	100	2	100
CerTest VIASURE Sexual Health Panel I (n= 1)	1	100	1	100	1	100	1	100
DNA-TECHNOLOGY M. hominis RT PCR (n= 1)	1	100	1	100	1	100	1	100
EUROIMMUN EUROArray STI-11 (n= 4)	4	100	4	100	4	100	4	100
GeneProof MH/UU/UP Multiplex (n= 1)	1	100	1	100	1	100	1	100
GeneProof M. gen. / hominis PCR Kit (n= 5)	5	100	5	100	5	100	5	100
Immundiagnostik MutaPLEX STI-2 (n= 1)	1	100	1	100	1	100	1	100
ampliCube STD Panel 2.1/2.1 LC (n= 18)	18	100	18	100	18	100	18	100
Seegene Allplex STI Essential (n= 70)	70	100	70	100	70	100	70	100
Seegene Anyplex II STI-7 (n= 2)	2	100	2	100	2	100	2	100
TIB Molbiol modular M. hominis (n= 4)	4	100	3	75	4	100	4	100
RIDAGENE STI Mycoplasma Panel (n= 11)	10	91	11	100	11	100	11	100
In house PCR assay (n= 12)	11 [§]	100	12	100	12	100	12	100
Other commercial tests (n= 10)	10	100	9	90	9	90	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": AusDiagnostics STI 16-well (2x), Bioeksen Bio-Speedy Sexual transmitted infection RT-qPCR Panel (RUO) (1x), Genematrix NeoPlex STI-14 Detection kit (1x), GeneProof Mycoplasma hominis MC PCR Kit (1x), Gerbion diarellaSTI-2 (1x), PANAGENE PANA RealTyper STD (1x), VISION STI Kit (1x) and Vitassay qPCR STI (1x).

Tabelle 12: 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*

<i>n</i> = 191	Proben Nr. (Sample no.)				Inhibition			
Befund Result	01	02	03	04	01	02	03	04
Positiv	0	0	0	183	n.d.	1	1	1
Negativ	191	191	191	6	nein no	190	190	190
Fraglich Questionable	0	0	0	2	ja yes	0	0	0

Tabelle 13: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwenden 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 True negative results					
	04		01		02		03	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
AID RDB 2335 STI (n= 2)	2	100	2	100	2	100	2	100
Abbott Alinity m STI assay (n= 13)	13	100	13	100	13	100	13	100
Amplex eazypex STD complete (n= 1)	1	100	1	100	1	100	1	100
AmpliGnost M. genitalium (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 M. hom./ M. gen. (n= 1)	1	100	1	100	1	100	1	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= 2)	2	100	2	100	2	100	2	100
CerTest VIASURE Sexual Health Panel I (n= 1)	1	100	1	100	1	100	1	100
DNA-TECHNOLOGY UMC Multiplex (n= 1)	1	100	1	100	1	100	1	100
EUROIMMUN EUROArray STI-11 (n= 4)	4	100	4	100	4	100	4	100
GeneProof CT/NG/MG Multiplex (n= 3)	3	100	3	100	3	100	3	100
GeneProof M. gen. / hominis PCR Kit (n= 5)	5	100	5	100	5	100	5	100
ampliCube STD Panel 1 (n= 16)	16	100	16	100	16	100	16	100
cobas 5800, 6800, 8800 TV / MG (n= 9)	8§	100	9	100	9	100	9	100

Seegene Allplex CT/NG/MG/TV Assay (n= 10)	10	100	10	100	10	100	10	100
Seegene Allplex STI Essential (n= 69)	64 [§]	94	69	100	69	100	69	100
Seegene Anyplex II STI-7 (n= 2)	2	100	2	100	2	100	2	100
TIB Molbiol modular M. genitalium (n= 5)	5	100	5	100	5	100	5	100
RIDAGENE STI Mycopl. Panel (n= 9)	8	89	9	100	9	100	9	100
In house PCR assay (n= 9)	8	89	9	100	9	100	9	100
Other commercial tests (n= 13)	13	100	13	100	13	100	13	100

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

The following tests are listed under "Other commercial tests": Altona diagnostics (1x), AmpliSens M. genitalium FRT PCR kit (1x), AusDiagnostics STI 16-well (2x), Bioeksens Bio-Speedy Sexual transmitted infection RT-qPCR Panel (RUO) (1x), Genematrix NeoPlex STI-14 Detection kit (1x), GeneProof Mycoplasma genitalium MC PCR Kit (1x), Gerbion diarellaSTI-1 (1x), HOLOGIC Aptima Mycoplasma genitalium Assay (2x), PANAGENE PANA RealTyper STD (1x), VISION STI Kit (1x) and Vitassay qPCR STI (1x).

Comments:

1. *Treponema pallidum*-detection was performed by 84 laboratories. With the exception of 1 laboratory (with one false positive result), all reported results were correct.
2. The following tests are listed for *Treponema pallidum*: AID RDB 2335 STI (2x), Amplex eazyplex STD complete (2x), AusDiagnostics STI 16-well (2x), Bioeksens Bio-Speedy Sexual transmitted infection RT-qPCR Panel (1x), CerTest VIASURE Sexual Health Panel I Real Time PCR Detection Kit (1x), CerTest Viasure Treponema Pallidum PCR Detektion Kit (1x), EUROIMMUN EUROArray STI-11 (4x), Genematrix NeoPlex STI-14 Detection kit (1x), GeneProof T. pallidum (6x), MIKROGEN ampliCube STD Panel 3 (9x), PANAGENE PANA RealTyper STD (1x), Seegene Allplex Genital ulcer (39x), TIB Molbiol modular T. pallidum (3x) and VISION STI Kit.
3. Only *Ureaplasma* spp. detection was performed by 17 laboratories. With the exception of 1 laboratory (with one false positive result), all reported results were correct.
4. The following tests are listed for *Ureaplasma* spp.: r-Biopharm RIDAGENE STI Mycoplasma Panel (10x), DNA-TECHNOLOGY U.urealyticum+parvum/M.genitalium/C.trachomatis Multiplex REAL-TIME PCR Detection Kit (UMC Multiplex) (1x), Amplisens (1x), Bioeksens Bio-Speedy Sexual transmitted infection RT-qPCR Panel (1x), Gerbion diarellaSTI-2 (1x), Immundiagnostik MutaPLEX STI-2 (1x) and TIB Molbiol Modular U.urealyticum/parvum (1x).