

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



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

Proben Nr.	Erwartet / expected	Probenzusammensetzung / Sample composition
547A 241015 01	++ ++ ++ (+) (+)	<i>Ureaplasma parvum</i> (~ 1x10 ⁴ CFU/mL) <i>Gardnerella vaginalis</i> (~ 2x10 ⁴ CFU/mL) <i>Trichomonas vaginalis</i> (~ 1x10 ⁴ CFU/mL) <i>Mycoplasma hominis</i> (~ 1x10 ³ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 1x10 ³ CFU/mL)
547A 241015 02	++	<i>Gardnerella vaginalis</i> (~ 5x10 ⁴ CFU/mL)
547A 241015 03	∅	<i>Escherichia coli</i> K12
547A 241015 04	+	<i>Mycoplasma hominis</i> (~ 1x10 ⁴ CFU/mL)

Tabelle 2: 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 = 147	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
Befund <i>Result</i>									
Positiv	78	0	0	144	n.d.	1	1	1	1
Negativ	66	147	147	3	nein no	146	146	146	146
Fraglich <i>Questionable</i>	3	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 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 <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= 3)	0	0	1	33	3	100	3	100
Amplex eazyplex STD complete (n= 1)	0	0	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./ gen. (n= 1)	0	0	1	100	1	100	1	100
BioGX Mycoplasma / Ureaplasma (n= 9)	5	56	9	100	9	100	9	100
Bruker-Hain FluoroType STI (n= 5)	4	80	5	100	5	100	5	100
CerTest VIASURE STD (n= 3)	1	33	3	100	3	100	3	100
EUROIMMUN EUROArray STI-11 (n= 5)	4	80	5	100	5	100	5	100
GeneProof MH/UU/UP Multiplex (n= 2)	1	50	2	100	2	100	2	100
GeneProof M.gen./ hom. PCR Kit (n= 5)	3	60	5	100	5	100	5	100
Immundiagnostik MutaPLEX STI-2 (n= 2)	0	0	2	100	2	100	2	100
KOGENE PowerChek STI Multiplex Kit II (n= 2)	0	0	2	100	2	100	2	100
ampliCube STD Panel 2.1/2.1 LC (n= 13)	6 [§]	46	13	100	13	100	13	100
Seegene Allplex STI Essential (n= 64)	42 [§]	66	64	100	64	100	64	100
Seegene Anyplex II STI-7 (n= 4)	3	75	4	100	4	100	4	100
LightMix modular M. hominis (n= 3)	1 [§]	33	3	100	3	100	3	100
aprimeo/ BOSCH Vivalytic STI (n= 1)	1	100	1	100	1	100	1	100
RIDAGENE STI Mycoplasma Panel (n= 8)	2	25	7	88	8	100	8	100
In house PCR assay (n= 10)	2	20	10	100	10	100	10	100
Other commercial tests (n= 4)	1	25	4	100	4	100	4	100

The following tests are listed under "Other commercial tests": Bioeksen Bio-Speedy Sexual transmitted infection RT-qPCR Panel (RUO) (1x), CerTest VIASURE Sexual Health Panel I Real Time PCR Detection Kit (1x), Gerbion diarellaSTI-2 (1x) and PANAGENE PANA RealTyper STD 13 (1x).

§ 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

<i>n</i> = 35	Proben Nr. (Sample no.)			
	01	02	03	04
Befund <i>Result</i>				
Positiv	33	32	0	0
Negativ	2	3	35	35
Fraglich <i>Questionable</i>	0	0	0	0

	Inhibition			
	01	02	03	04
n.d.	1	1	1	1
nein <i>no</i>	34	34	34	34
ja <i>yes</i>	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 *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			
	01		02		03		04	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
AID RDB 2335 STI (n= 3)	3	100	2	67	3	100	3	100
AmpliGnost STI Urethritis (n= 1)	1	100	1	100	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= 2)	1	50	2	100	2	100	2	100
Allplex Bacterial Vaginosis plus (n= 11)	10	91	10	91	11	100	11	100
In house PCR assay (n= 6)	6	100	6	100	6	100	6	100
Other commercial tests (n= 10)	10	100	9	90	10	100	10	100

The following tests are listed under "Other commercial tests": TIB Molbiol LightMix modular Gardnerella vaginalis (2x), Amplex eazyplexUroGenCheck (1x), Bioeksen Bio-Speedy Sexual transmitted infection RT-qPCR Panel (RUO) (1x), CerTest VIASURE Sexual Health Panel I Real Time PCR Detection Kit (1x), EUROIMMUN EUROArray STI-GV (1x), Gerbion diarellaBV-1 (1x), PANAGENE PANA RealTyper STD 13 (1x) and Seegene Allplex Vaginitis Screening Assay (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 = 131	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
Befund Result									
Positiv	128	0	1	0	n.d.	1	1	1	1
Negativ	3	131	130	131	nein no	131	131	131	131
Fraglich Questionable	0	0	0	0	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		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= 3)	2	67	3	100	3	100	3	100
BIORON RealLine U. ureal. / U. parv. (n= 1)	1	100	1	100	1	100	1	100
BioGX Mycoplasma / Ureaplasma (n= 9)	8	89	9	100	9	100	9	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
EUROIMMUN EUROArray STI-11 (n= 5)	5	100	5	100	4	80	5	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
Immundiagnostik MutaPLEX U.ur./U.pa. (n= 1)	1	100	1	100	1	100	1	100
KOGENE PowerChek STI Multiplex Kit II (n= 2)	2	100	2	100	2	100	2	100
ampliCube STD Panel 2.1/2.1 LC (n= 12)	12	100	12	100	12	100	12	100
Seegene Allplex STI Essential (n= 65)	65	100	65	100	65	100	65	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= 6)	6	100	6	100	6	100	6	100
Other commercial tests (n= 4)	4	100	4	100	4	100	4	100

The following tests are listed under "Other commercial tests": CerTest VIASURE Sexual Health Panel I Real Time PCR Detection Kit (1x), eSens Ureaplasma parvum/urealyticum QL PCR kit (1x) and PANAGENE PANA RealTyper STD 13 (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> = 157	Proben Nr. (<i>Sample no.</i>)			
	01	02	03	04
Befund <i>Result</i>				
Positiv	149	0	0	0
Negativ	8	157	157	157
Fraglich <i>Questionable</i>	0	0	0	0

	Inhibition			
	01	02	03	04
n.d.	1	1	1	1
nein <i>no</i>	156	156	156	156
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>					
	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= 4)	3	75	4	100	4	100	4	100
Abbott Alinity m STI assay (n= 11)	11	100	11	100	11	100	11	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
EUROIMMUN EUROArray STI-11 (n= 5)	5	100	5	100	5	100	5	100
GeneProof T. vaginalis (n= 4)	4	100	4	100	4	100	4	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= 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= 65)	60	92	65	100	65	100	65	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= 1)	1	100	1	100	1	100	1	100
In house PCR assay (n= 7)	7	100	7	100	7	100	7	100
Other commercial tests (n= 9)	7	78	9	100	9	100	9	100

The following tests are listed under "Other commercial tests": Immundiagnostik MutaPLEX STI-2 (2x), AmpliGnost *Trichomonas vaginalis* (1x), Bioexsen Bio-Speedy Sexual transmitted infection RT-qPCR Panel (RUO) (1x), CerTest VIASURE Sexual Health Panel I Real Time PCR Detection Kit (1x), Cepheid Xpert TV (1x), ELITech Molecular Diagnostics STI PLUS ELITe MGB Kit (1x), Gerbion diarellaSTI-2 (1x) and PANAGENE PANA RealTyper STD 13 (1x).

Comments:

2. *Mycoplasma genitalium*-detection was performed by 168 laboratories. With the exception of 1 laboratory with a false positive result for sample # 547A 241015 01, all reported results were correct.
3. The following tests are listed for *Mycoplasma genitalium*: Seegene Allplex STI Essential (65x), MIKROGEN ampliCube STD Panel 1 (11x), Abbott Alinity m STI assay (10x), BioGX Mycoplasma / Ureaplasma (9x), r-Biopharm RIDA GENE STI Mycoplasma Panel (8x), Seegene Allplex CT/NG/MG/TV Assay (7x), Bruker-Hain FluoroType STI (5x), EUROIMMUN EUROArray STI-11 (5x),

GeneProof Mycoplasma genitalium/hominis PCR Kit (5x), Roche Cobas 5800, 6800 or 8800 TV / MG (5x), TIB Molbiol LightMix modular M.genitalium (5x), AID RDB 2335 STI (3x), CerTest VIASURE STD Real Time PCR Detection Kit (3x), GeneProof CT/NG/MG Multiplex PCR Kit (3x), Seegene Anyplex II STI-7 Detection (3x), amplex eazyplex STD complete (1x), AmpliGnost M. genitalium (1x), AmpliGnost STI Urethritis (1x), BIORON diagnostics RealLine M. hominis / genitalium (1x), Immundiagnostik MutaPLEX STI-1 (1x), KOGENE BIOTECH PowerChek STI Multiplex Real-time PCR Kit I (1x), aprimeo/BOSCH Vivalytic STI (1x), AB Analytica RQ-SevenSTI (1x), Bioeksen Bio-Speedy Sexual transmitted infection RT-qPCR Panel (1x), CerTest VIASURE Sexual Health Panel I Real Time PCR Detection Kit (1x), Gerbion diarellaSTI-1 (1x), HOLOGIC Aptima Mycoplasma genitalium (1x) and PANAGENE PANA RealTyper STD 13 (1x).

4. ***Ureaplasma urealyticum***-detection was performed by 138 laboratories. With the exception of 1 laboratory with a false positive result for sample # 547A 241015 02, all reported results were correct.
5. The following tests are listed for ***Ureaplasma urealyticum***: Seegene Allplex STI Essential (63x), MIKROGEN ampliCube STD Panel 2.1 / 2.1 LC (13x), BioGX Mycoplasma / Ureaplasma (9x), TIB Molbiol LightMix modular U.urealyticum/U.parvum (6x), Bruker-Hain FluoroType STI (5x), EUROIMMUN EUROArray STI-11 (5x), GeneProof Ureaplasma (UUP) PCR Kit (4x), Seegene Anyplex II STI-7 Detection (4x), AID RDB 2335 STI (3x), CerTest VIASURE STD Real Time PCR Detection Kit (3x), AmpliGnost U. urealyt. / U. parvum (2x), GeneProof MH/UU/UP Multiplex PCR Kit (2x), KOGENE BIOTECH PowerChek STI Multiplex Real-time PCR Kit II (2x), amplex eazyplex STD complete (1x), BIORON diagnostics RealLine U.urealyt./U.parvum (1x), Immundiagnostik MutaPLEX U. urealyticum / U. parvum (1x), aprimeo/BOSCH Vivalytic STI (1x), eSens Ureaplasma parvum/urealyticum QL PCR kit (1x), PANAGENE PANA RealTyper STD 13 (1x) and CerTest VIASURE Sexual Health Panel I Real Time PCR Detection Kit (1x).
6. ***Treponema pallidum***-detection was performed by 71 laboratories. All reported results were correct.
7. The following tests are listed for ***Treponema pallidum***: Seegene Allplex Genital ulcer (31x), MIKROGEN ampliCube STD Panel 3 (8x), AID RDB 2335 STI (3x), EUROIMMUN EUROArray STI-11 (3x), TIB Molbiol LightMix modular T. pallidum (3x), amplex eazyplex STD complete (2x), KOGENE BIOTECH PowerChek STI Multiplex Real-time PCR Kit III (2x), GeneProof T. pallidum (1x), aprimeo/BOSCH Vivalytic STI (1x), PANAGENE PANA RealTyper STD 13 (1x), Bioeksen Bio-Speedy Sexual transmitted infection RT-qPCR Panel (RUO) (1x) and CerTest VIASURE Sexual Health Panel I Real Time PCR Detection Kit (1x).
8. Only ***Ureaplasma spp.*** detection was performed by 11 laboratories. With the exception of 1 laboratory with a false positive result for sample # 547A 241015 04 and a false negative result for sample # 547A 241015 01, all reported results were correct.
9. The following tests are listed for ***Ureaplasma spp.***: r-Biopharm RIDA GENE STI Mycoplasma Panel (6x), Bioeksen Bio-Speedy Sexual transmitted infection RT-qPCR Panel (RUO) (1x), Gerbion diarellaSTI-2 (1x) and Immundiagnostik MutaPLEX STI-2 (1x).