

**PCR-/NAT Urogenital Panel  
 (RV 547) Mai 2026**



**Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.**

*Sample composition and expected results.*

Proben Nr.	Erwartet / expected	Probenzusammensetzung / Sample composition
547 260519 01	++ / +++	<i>Gardnerella vaginalis</i> (~ 1x10 <sup>4</sup> CFU/mL) <i>Mycoplasma hominis</i> (~ 5x10 <sup>5</sup> CFU/mL)
547 260519 02	+++ / ++	<i>Trichomonas vaginalis</i> (~ 5x10 <sup>5</sup> CFU/mL) <i>Mycoplasma hominis</i> (~ 5x10 <sup>4</sup> CFU/mL)
547 260519 03	+++ / ++ / ++++	<i>Gardnerella vaginalis</i> (~ 1x10 <sup>5</sup> CFU/mL) <i>Ureaplasma urealyticum</i> (~5x10 <sup>4</sup> CFU/mL) <i>Trichomonas vaginalis</i> (~ 2x10 <sup>6</sup> CFU/mL)
547 260519 04	+++ / +	<i>Gardnerella vaginalis</i> (~ 5x10 <sup>5</sup> CFU/mL) <i>Ureaplasma parvum</i> (~ 5x10 <sup>3</sup> 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 = 180	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	178	178	4	0	n.d.	2	2	2	2
<b>Negativ</b>	1	2	176	180	nein <i>no</i>	178	178	178	178
<b>Fraglich</b> <i>Questionable</i>	1	0	0	0	ja <i>yes</i>	0	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 *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		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)	3	100	3	100	3	100	3	100
Amplex eazyplex STD complete (n= 2)	2	100	2	100	2	100	2	100
BIORON RealLine M.hom. / M.gen. (n= 1)	1	100	1	100	1	100	1	100

BioGX for BD MAX Mycop. / Ureapl. (n= 8)	8	100	8	100	8	100	8	100
Bruker-Hain FluoroType STI (n= 5)	4 <sup>§</sup>	100	5	100	5	100	5	100
CerTest VIASURE STD (n= 4)	4	100	4	100	4	100	4	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= 3)	3	100	3	100	3	100	3	100
GeneProof M. gen. / hominis PCR Kit (n= 3)	3	100	3	100	3	100	3	100
Immundiagnostik MutaPLEX STI-2 (n= 2)	2	100	2	100	2	100	2	100
ampliCube STD Panel 2.1/2.1 LC (n= 19)	19	100	19	100	15	79	19	100
Seegene Allplex STI Essential (n= 78)	77	99	77	99	78	100	78	100
Seegene Anyplex II STI-7e (n= 2)	2	100	2	100	2	100	2	100
TIB Molbiol Modular M. hominis (n= 3)	3	100	3	100	3	100	3	100
Vitro STD Direct Flow Chip Kit (n= 1)	1	100	1	100	1	100	1	100
r-Biopharm BOSCH Vivalytic STI (n= 2)	2	100	2	100	2	100	2	100
RIDAGENE STI Mycoplasma Panel (n= 9)	9	100	9	100	9	100	9	100
In house PCR assay (n= 14)	14	100	14	100	14	100	14	100
Other commercial tests (n= 14)	14	100	13	93	14	100	14	100

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

The following tests are listed under "Other commercial tests": AmpliGnost STD 2-Panel (1x), AmpliGnost STI-Differenzierung-PCR MG/UU/MH (1x), Anatolia Geneworks Bosphore STD Combo Kit v2 (1x), AusDiagnostics STI 16-well (2x), BioeXsen STD-Panel (1x), DNA-TECHNOLOGY Androflor (1x), ELITech UroGen ELITe MGB Kit (1x), Genematrix NeoPlex STI-14 Detection kit (1x), Sacace Biotechnologies (1x), VECTOR BEST RealBest DNA M.hominis/M.genitalium (1x) and Vitassay qPCR STI (1x).

**Tabelle 4: 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> = 157	Proben Nr. (Sample no.)			
	01	02	03	04
<b>Befund</b> <i>Result</i>				
<b>Positiv</b>	0	0	1	154
<b>Negativ</b>	156	156	156	3
<b>Fraglich</b> <i>Questionable</i>	1	1	0	0

	Inhibition			
	01	02	03	04
n.d.	2	2	2	2
nein <i>no</i>	155	155	155	155
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 *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>					
	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= 3)	3	100	3	100	3	100	3	100
BIORON RealLine U. ureal. / U. parv. (n= 2)	2	100	2	100	2	100	2	100
BioGX for BD MAX Mycop. / Ureapl. (n= 8)	8	100	8	100	8	100	8	100
Bruker-Hain FluoroType STI (n= 5)	5	100	5	100	5	100	5	100
CerTest VIASURE STD (n= 4)	4	100	4	100	4	100	4	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= 3)	3	100	3	100	3	100	3	100
GeneProof Ureaplasma (UUP) PCR Kit (n= 3)	3	100	3	100	3	100	3	100
Immundiagnostik MutaPLEX UU/ UP (n= 1)	1	100	1	100	1	100	1	100
ampliCube STD Panel 2.1/2.1 LC (n= 16)	16	100	16	100	16	100	16	100
Seegene Allplex STI Essential (n= 77)	75	97	77	100	77	100	77	100
Seegene Anyplex II STI-7e (n= 2)	2	100	2	100	2	100	2	100
TIB Molbiol LightMix U. ureal. /U. parv. (n= 1)	1	100	1	100	1	100	1	100
TIB Molbiol Modular U. ureal. /U. parv. (n= 4)	4	100	4	100	4	100	4	100
In house PCR assay (n= 11)	11	100	10	91	10	91	11	100
Other commercial tests (n= 13)	12	92	13	100	13	100	12	92

The following tests are listed under "Other commercial tests": ATILA BioSystems iAMP Ureaplasma Detection Kit (1x), AusDiagnostics STI 16-well (2x), ELITechGroup UroGen ELITe MGB Kit (1x), DNA-TECHNOLOGY Androflor(1x), eSens Ureaplasma parvum/urealyticum QL PCR kit (1x), Genematrix NeoPlex STI-14 Detection kit (1x), r-Biopharm / BOSCH Vivalytic MG, MH, UP/UU (1x), Sacace Biotechnologies (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 *Ureaplasma urealyticum* dargestellt.**  
*Absolute numbers of reported individual results.*  
**Note: only the *U. urealyticum*-specific results are depicted in this table**

<i>n</i> = 168	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	1	1	163	1	n.d.	2	2	2	2
<b>Negativ</b>	166	166	5	167	nein <i>no</i>	166	166	166	166
<b>Fraglich</b> <i>Questionable</i>	1	1	0	0	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 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 <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= 3)	3	100	3	100	3	100	3	100
Amplex eazyplex STD complete (n= 2)	1	50	2	100	2	100	2	100
BIORON Realline U. ureal. / U. parv. (n= 2)	2	100	2	100	2	100	2	100
BioGX for BD MAX Mycop. / Ureapl. (n= 8)	8	100	8	100	8	100	8	100
Bruker-Hain FluoroType STI (n= 5)	5	100	5	100	5	100	5	100
CerTest VIASURE STD (n= 4)	3	75	4	100	4	100	4	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= 3)	3	100	3	100	3	100	3	100
GeneProof Ureaplasma (UUP) PCR Kit (n= 3)	3	100	3	100	3	100	3	100
Immundiagnostik MutaPLEX UU / UP (n= 1)	1	100	1	100	1	100	1	100
ampliCube STD Panel 2.1/2.1 LC (n= 19)	19	100	19	100	19	100	19	100
Seegene Allplex STI Essential (n= 76)	75	99	76	100	76	100	76	100
Seegene Anyplex II STI-7e (n= 3)	2	67	2	67	3	100	3	100
TIB Molbiol LightMix U. ureal. /U. parv. (n= 1)	1	100	1	100	1	100	1	100
TIB Molbiol Modular U. ureal. /U. parv. (n= 4)	4	100	4	100	4	100	4	100
r-Biopharm BOSCH Vivalytic STI (n= 2)	2	100	2	100	2	100	2	100

In house PCR assay (n= 13)	13	100	13	100	13	100	12	93
Other commercial tests (n= 14)	13	92	14	100	13	92	14	100

The following tests are listed under "Other commercial tests": AmpliGnost STD 2-Panel (1x), AmpliGnost STI-Differenzierung-PCR MG/UU/MH (1x), ATILA BioSystems iAMP Ureaplasma Detection Kit (1x), AusDiagnostics STI 16-well (2x), ELITechGroup STI PLUS ELITe MGB Kit (1x), ELITechGroup UroGen ELITe MGB Kit (1x), DNA-TECHNOLOGY Androflor(1x), Genematrix NeoPlex STI-14 Detection kit (1x), Biotechnologies (1x), VECTOR BEST RealBest DNA U.urealyticum/U.parvum (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.*

n = 192	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	1	192	191	3	n.d.	2	2	2	2
<b>Negativ</b>	191	0	1	189	nein <i>no</i>	190	190	190	190
<b>Fraglich</b> <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	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 <i>True positive results</i>				NAT richtig negativ <i>True negative results</i>			
	02		03		01		04	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AID RDB 2335 STI (n= 3)	3	100	3	100	3	100	3	100
Abbott Alinity m STI assay (n= 12)	12	100	12	100	12	100	12	100
BD CTGCTV2 for BD MAX System (n= 6)	6	100	6	100	6	100	6	100
BD MAX Vaginal Panel (n= 1)	1	100	1	100	1	100	1	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
VIASURE Candida alb. + G. vag. +T. vag. (n= 1)	1	100	1	100	1	100	1	100
CerTest VIASURE STD (n= 4)	4	100	4	100	4	100	4	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= 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= 17)	17	100	17	100	17	100	17	100
cobas TV/MG (for 5800/6800/8800) (n= 12)	12	100	12	100	12	100	11	92
Seegene Allplex CT/NG/MG/TV Assay (n= 10)	10	100	10	100	10	100	8	80
Seegene Allplex STI Essential (n= 76)	76	100	76	100	76	100	76	100
Seegene Anyplex II STI-7e (n= 2)	2	100	2	100	2	100	2	100
TIB Molbiol Modular T. vaginalis (n= 4)	4	100	4	100	4	100	4	100
Vitro STD Direct Flow Chip Kit (n= 1)	1	100	1	100	1	100	1	100
r-Biopharm / BOSCH Vivalytic STI (n= 3)	3	100	3	100	3	100	3	100
In house PCR assay (n= 10)	10	100	10	100	10	100	10	100
Other commercial tests (n= 15)	15	100	14	93	14	93	15	100

The following tests are listed under "Other commercial tests": AmpliGnost STD 2-Panel (1x), AmpliGnost STI Differenzierung-PCR MG/UU/MH (1x), AusDiagnostics STI 16-well (2x), BioeXsen STD-Panel (1x), DNA-TECHNOLOGY Androflor (1x), ELITechGroup STI PLUS ELITe MGB Kit (2x), Genematrix NeoPlex STI-14 Detection kit (1x), Hologic Aptima Trichomonias vaginalis assay (1x), Sacace Biotechnologies (1x), VECTOR BEST RealBest DNA Trichomonas vaginalis (1x) and Vitassay qPCR STI (1x).

**Tabelle 10: 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> = 45	Proben Nr. (Sample no.)			
	01	02	03	04
<b>Befund</b> <i>Result</i>				
<b>Positiv</b>	42	2	45	43
<b>Negativ</b>	3	43	0	2
<b>Fraglich</b> <i>Questionable</i>	0	0	0	0

	Inhibition			
	01	02	03	04
n.d.	2	2	2	2
nein <i>no</i>	43	43	43	43
ja <i>yes</i>	0	0	0	0

**Tabelle 11: 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	
	01		03		04		02	
	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. vaginalis1(n= 1)	1	100	1	100	1	100	1	100
VIASURE Candida alb.+G. vag.+T. vag. (n= 1)	1	100	1	100	1	100	1	100
VIASURE Sexual Health Panel 1 (n=2)	2	100	2	100	2	100	2	100
GeneProof G. vaginalis PCR Kit (n= 1)	1	100	1	100	1	100	1	100
Seegene Allplex Bact. Vaginosis plus (n= 12)	11	92	12	100	11	92	12	100
TIB Molbiol Modular G. vaginalis (n= 2)	2	100	2	100	2	100	2	100
In house PCR assay (n= 10)	10	100	10	100	10	100	10	100
Other commercial tests (n= 12)	10	83	12	100	11	92	10	83

The following tests are listed under "Other commercial tests": Amplex eazyplexUroGenCheck (1x), Anatolia Geneworks Bosphore STD Combo Kit v2 (1x), BioXsen STD-Panel (1x), DNA-TECHNOLOGY Androflor (1x), EUROIMMUN EUROArray STI-11 (1x), Genematrix NeoPlex STI-14 Detection kit (1x), Immundiagnostik MutaPLEX BV-1 (1x), Sacace Biotechnologies (1x), Seegene Allplex Vaginitis Screening Assay (1x) and USTAR Biotechnologies STI (1x).

**Comments:**

1. *Mycoplasma genitalium*-detection was performed by 202 laboratories. With the exception of 3 laboratories (with inhibition results in all 4 samples), all reported results were correct.
2. The following tests are listed for *Mycoplasma genitalium*: AmpliGnost STD 2-Panel (1x), AmpliGnost STI-Differenzierung-PCR MG/UU/MH (1x), AusDiagnostics STI 16-well (2x), BioXsen STD-Panel (1x), DNA-TECHNOLOGY Androflor (1x), ELITechGroup STI PLUS ELITe MGB Kit (2x), Genematrix NeoPlex STI-14 Detection kit (1x), Hologic Aptima Mycoplasma genitalium Assay (2x), Sacace Biotechnologies (1x), VECTOR BEST RealBest DNA M.hominis/M.genitalium (1x) and Vitassay qPCR STI (1x).
3. *Treponema pallidum*-detection was performed by 95 laboratories. With the exception of 3 laboratories (with Inhibition results in all 4 samples) and 1 laboratory with a false positive result, all reported results were correct.
4. The following tests are listed for *Treponema pallidum*: AusDiagnostics STI 16-well (2x), BioXsen STD-Panel (1x), CerTest VIASURE Treponema pallidum PCR Detektion Kit (2x), Genematrix NeoPlex STI-14 Detection kit (1x), and Progenie RealCycler TPHD-U Kit (1x).
5. Only *Ureaplasma* spp. detection was performed by 25 laboratories. All reported results were correct.
6. The following tests are listed for *Ureaplasma* spp.: r-Biopharm RIDAGENE STI Mycoplasma Panel (8x), DNA-TECHNOLOGY UMC Multiplex (UU+UP/MG/CT) (1x), DNA-TECHNOLOGY Ureaplasma complex Real Time PCR Detection Kit (1x) and Vitro Master Diagnostica STD Direct Flow Chip Kit (1x).