

**PCR-/NAT Gastrointestinal Panel
 (RV 548) November 2024**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

Proben Nr.	Erwartet / expected	Probenzusammensetzung / Sample composition
548A 241015 01	+++ / +	<i>Yersinia enterocolitica</i> ETEC (ST positive)
548A 241015 02	++ / ++ / ++	<i>Aeromonas hydrophila</i> EPEC <i>Salmonella enteritidis</i>
548A 241015 03	++	<i>Campylobacter jejuni</i>
548A 241015 04	++	<i>Shigella sonnei</i>

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

Absolute numbers of reported individual results.

Note: only the *Aeromonas*-specific results are depicted in this table

<i>n</i> = 18	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
Befund <i>Result</i>									
Positiv	0	18	0	1	n.d.	0	0	0	0
Negativ	18	0	18	17	nein <i>no</i>	18	18	18	18
Fraglich <i>Questionable</i>	0	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 *Aeromonas* dargestellt.

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

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

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ <i>True negative results</i>					
	02		01		03		04	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
CerTest VIASURE Gastroint. Panel II (n= 1)	1	100	1	100	1	100	1	100
Seegene Allplex GI-Bacteria (I) Assay (n= 17)	17	100	17	100	17	100	16	94

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

Absolute numbers of reported individual results.

*Note: only the *Campylobacter*-specific results are depicted in this table*

<i>n</i> = 61	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
Befund <i>Result</i>									
Positiv	0	0	60	1	n.d.	0	0	0	0
Negativ	61	61	1	60	nein <i>no</i>	61	61	61	61
Fraglich <i>Questionable</i>	0	0	0	0	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 *Campylobacter* dargestellt.

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

*Note: only the *Campylobacter*-specific results depicted.*

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>	%
BD MAX Enteric Bacterial Panel (n= 9)	9	100	9	100	9	100	9	100
Bruker-Hain LiquidArray Gastroint. (n= 1)	1	100	1	100	1	100	1	100
CerTest VIASURE Gastroint. Panel II (n= 1)	1	100	1	100	1	100	1	100
Luminex NxTAG Gastroint. Pathogen Panel (n= 1)	1	100	1	100	1	100	1	100
QIAstat-Dx Gastrointestinal Panel (n= 1)	1	100	1	100	1	100	1	100
RIDAGENE Bacterial Stool Panel I (n= 6)	6	100	6	100	6	100	5	83
RIDAUNITY Bacterial Stool Panel (n= 1)	1	100	1	100	1	100	1	100
Roche UC-TIB-Gastro-BAC (n= 2)	2	100	2	100	2	100	2	100
Seegene Allplex GI-Bacteria (I) (n= 17)	16	94	17	100	17	100	17	100
Seegene Allplex GI-EB Screening (n= 16)	16	100	16	100	16	100	16	100
In house PCR assay (n= 1)	1	100	1	100	1	100	1	100
Other commercial tests (n= 5)	5	100	5	100	5	100	5	100

The following tests are listed under "Other commercial tests": BioMerieux BioFire FILMARRAY Gastrointestinal (GI) Panel (3x), AmpliGnost Bakterielle Gastroenteritis Panel 1 (1x) and AmpliGnost Bakterielle Gastroenteritis B1 -qPCR.

Tabelle 6: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Enterotoxische E. coli* dargestellt.

Absolute numbers of reported individual results.

*Note: only the *Enterotoxische E. coli* specific results are depicted in this table*

<i>n</i> = 42	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
Befund <i>Result</i>									
Positiv	33	0	0	0	n.d.	0	0	0	0
Negativ	9	42	42	42	nein <i>no</i>	42	42	42	42
Fraglich <i>Questionable</i>	0	0	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 *Enterotoxische E. coli* dargestellt.

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

*Note: only the *Enterotoxische E. coli*-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>	%
BD MAX Extended Enteric Bacterial Panel (n= 9)	4	44	9	100	9	100	9	100
Bruker-Hain LiquidArray Gastroint. (n= 1)	1	100	1	100	1	100	1	100
CerTest VIASURE Gastroint. Panel II (n= 1)	1	100	1	100	1	100	1	100
Luminex NxTAG Gastroint. Pathogen Panel (n= 1)	0	0	1	100	1	100	1	100
QIAstat-Dx Gastrointestinal Panel (n= 1)	1	100	1	100	1	100	1	100
Seegene Allplex GI-Bacteria (II) (n= 22)	22	100	22	100	22	100	22	100
Other commercial tests (n= 7)	4	57	7	100	7	100	7	100

The following tests are listed under "Other commercial tests": r-Biopharm RIDAGENE ETEC/EIEC (4x) and BioMerieux BioFire FILMARRAY Gastrointestinal (GI) Panel (3x).

Tabelle 8: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Enteropathogene E. coli* dargestellt.
Absolute numbers of reported individual results.
Note: only the *Enteropathogene E. coli*-specific results are depicted in this table

n = 42	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
Befund <i>Result</i>									
Positiv	0	40	0	1	n.d.	0	0	0	0
Negativ	42	2	42	41	nein <i>no</i>	42	42	42	42
Fraglich <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 Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Enteropathogene E. coli* dargestellt.
Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.
Note: only the *Enteropathogene E. coli*-specific results are depicted in this table.

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ <i>True negative results</i>					
	02		01		03		04	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Bruker-Hain LiquidArray Gastroint. (n= 1)	1	100	1	100	1	100	1	100
CerTest VIASURE Gastroint. Panel II (n= 1)	0	0	1	100	1	100	1	100
QIAstat-Dx Gastrointestinal Panel (n= 1)	1	100	1	100	1	100	1	100
RIDAUNITY EHEC/EPEC (n= 1)	1	100	1	100	1	100	1	100
Roche UC-TIB-EHEC/C.diff (n= 1)	1	100	1	100	1	100	1	100
Seegene Allplex GI-Bacteria (II) (n= 22)	22	100	22	100	22	100	22	100
In house PCR assay (n= 1)	1	100	1	100	1	100	1	100
Other commercial tests (n= 13)	12	92	13	100	13	100	12	92

The following tests are listed under "Other commercial tests": r-Biopharm RIDAGENE EHEC/EPEC (6x), r-Biopharm RIDAGENE E.coli Stool Panel 1 (4x) and BioMerieux BioFire FILMARRAY Gastrointestinal (GI) Panel (1x).

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

Absolute numbers of reported individual results.

*Note: only the *Salmonella*-specific results are depicted in this table*

<i>n</i> = 61	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
Befund <i>Result</i>									
Positiv	0	58	0	0	n.d.	0	0	0	0
Negativ	61	3	61	61	nein <i>no</i>	61	61	61	61
Fraglich <i>Questionable</i>	0	0	0	0	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 *Salmonella* dargestellt.

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

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

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ <i>True negative results</i>					
	02		01		03		04	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
BD MAX Enteric Bacterial Panel (n= 9)	9	100	9	100	9	100	9	100
FILMARRAY Gastrointestinal Panel (n= 3)	3	100	3	100	3	100	3	100
Bruker-Hain LiquidArray Gastroint. (n= 1)	1	100	1	100	1	100	1	100
CerTest VIASURE Gastroint. Panel II (n= 1)	1	100	1	100	1	100	1	100
Luminex NxTAG Gastroint. Pathogen Panel (n= 1)	1	100	1	100	1	100	1	100
QIAstat-Dx Gastrointestinal Panel (n= 1)	1	100	1	100	1	100	1	100
RIDAGENE Bacterial Stool Panel I (n= 5)	4	80	5	100	5	100	5	100
RIDAUNITY Bacterial Stool Panel (n= 1)	1	100	1	100	1	100	1	100
Roche UC-TIB-Gastro-BAC (n= 2)	2	100	2	100	2	100	2	100
Seegene Allplex GI-Bacteria (I) (n= 17)	15	88	17	100	17	100	17	100
Seegene Allplex GI-EB Screening (n= 16)	16	100	16	100	16	100	16	100
In house PCR assay (n= 1)	1	100	1	100	1	100	1	100
Other commercial tests (n= 3)	3	100	3	100	3	100	3	100

The following tests are listed under "Other commercial tests": AmpliGnost Bakterielle Gastroenteritis Panel 1 (1x), AmpliGnost Bakterielle Gastroenteritis B1 -qPCR (1x) and r-Biopharm RIDA GENE Bacterial Stool Panel (1x).

Tabelle 12: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Enteroinvasive E. coli* dargestellt.

Absolute numbers of reported individual results.

*Note: only the *Enteroinvasive E. coli*-specific results are depicted in this table*

<i>n</i> = 50	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
Befund <i>Result</i>									
Positiv	0	0	0	45	n.d.	0	0	0	0
Negativ	50	50	50	1	nein <i>no</i>	50	50	50	50
Fraglich <i>Questionable</i>	0	0	0	4	ja <i>yes</i>	0	0	0	0

Tabelle 13: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Enteroinvasive E. coli* dargestellt.

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

*Note: only the *Enteroinvasive E. coli*-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>	%
BD MAX Enteric Bacterial Panel (n= 6)	5 [§]	83	6	100	6	100	6	100
Bruker-Hain LiquidArray Gastroint. (n= 1)	1	100	1	100	1	100	1	100
RIDAUNITY EHEC/EPEC (n= 1)	1	100	1	100	1	100	1	100
Seegene Allplex GI-Bacteria (I) (n= 15)	14 [§]	93	15	100	15	100	15	100
Seegene Allplex GI-EB Screening (n= 14)	12 [§]	86	14	100	14	100	14	100
Other commercial tests (n= 13)	12	92	13	100	13	100	13	100

The following tests are listed under "Other commercial tests": r-Biopharm RIDAGENE EHEC/EPEC (4x), r-Biopharm RIDAGENE ETEC/EIEC (4x), BioMerieux BioFire FILMARRAY Gastrointestinal (GI) Panel (3x), CerTest VIASURE Gastrointestinal Panel II (1x) and Qiagen QIAstat-Dx Gastrointestinal Panel (1x).

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

Tabelle 14: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Shigella* dargestellt.

Absolute numbers of reported individual results.

*Note: only the *Shigella*-specific results are depicted in this table*

<i>n</i> = 50	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
Befund <i>Result</i>									
Positiv	0	0	0	46	n.d.	0	0	0	0
Negativ	50	50	50	0	nein <i>no</i>	50	50	50	50
Fraglich <i>Questionable</i>	0	0	0	4	ja <i>yes</i>	0	0	0	0

Tabelle 15: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Shigella* dargestellt.

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

*Note: only the *Shigella*-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>	%
Bruker-Hain LiquidArray Gastroint. (n= 1)	1	100	1	100	1	100	1	100
CerTest VIASURE Gastroint. Panel II (n= 1)	1	100	1	100	1	100	1	100
Luminex NxTAG Gastroint. Pathogen Panel (n= 1)	1	100	1	100	1	100	1	100
RIDAGENE Bacterial Stool Panel I (n= 2)	2	100	2	100	2	100	2	100
RIDAUNITY EHEC/EPEC (n= 1)	1	100	1	100	1	100	1	100
Roche UC-TIB-Gastro-BAC (n= 2)	2	100	2	100	2	100	2	100
In house PCR assay (n= 1)	1	100	1	100	1	100	1	100
Other commercial tests (n= 41)	37 [§]	90	41	100	41	100	41	100

The following tests are listed under "Other commercial tests": Seegene Allplex GI-Bacteria (I) Assay (14x), Seegene Allplex GI-EB Screening Assay (11x), BD MAX Enteric Bacterial Panel (7x), BioMerieux BioFire FILMARRAY Gastrointestinal (GI) Panel (3x), AmpliGnost Bakterielle Gastroenteritis Panel 1 (1x), AmpliGnost Bakterielle Gastroenteritis B1 -qPCR (1x), Qiagen QIAstat-Dx Gastrointestinal Panel (1x) and r-Biopharm RIDA GENE EHEC/EPEC (1x).

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

Tabelle 16: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Yersinia enterocolitica* dargestellt.

Absolute numbers of reported individual results.

*Note: only the *Y. enterocolitica*-specific results are depicted in this table*

n = 59	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
Befund <i>Result</i>									
Positiv	59	1	0	0	n.d.	0	0	0	0
Negativ	0	58	59	59	nein <i>no</i>	59	59	59	59
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 17: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Yersinia enterocolitica* dargestellt.

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

*Note: only the *Y. enterocolitica*-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>	%
BD MAX Enteric Bacterial Panel (n= 7)	7	100	7	100	7	100	7	100
Bruker-Hain LiquidArray Gastroint. (n= 1)	1	100	1	100	1	100	1	100
CerTest VIASURE Gastroint. Panel II (n= 1)	1	100	1	100	1	100	1	100
Luminex NxTAG Gastroint. Pathogen Panel (n= 1)	1	100	1	100	1	100	1	100
QIAstat-Dx Gastrointestinal Panel (n= 1)	1	100	1	100	1	100	1	100
RIDAUNITY Bacterial Stool Panel (n= 2)	2	100	2	100	2	100	2	100
Roche UC-TIB-Gastro-BAC (n= 2)	2	100	2	100	2	100	2	100
Seegene Allplex GI-Bacteria (I) (n= 17)	17	100	17	100	17	100	17	100
Seegene Allplex GI-EB Screening (n= 16)	16	100	16	100	16	100	16	100
In house PCR assay (n= 1)	1	100	1	100	1	100	1	100
Other commercial tests (n= 10)	10	100	9	90	10	100	10	100

The following tests are listed under "Other commercial tests": r-Biopharm RIDA GENE Bacterial Stool Panel (4x), BioMerieux BioFire FILMARRAY Gastrointestinal (GI) Panel (3x), AmpliGnost Bakterielle Gastroenteritis Panel 1 (1x) and AmpliGnost Bakterielle Gastroenteritis B1 -qPCR (1x).

Comments:

1. ***Clostridium difficile***-detection was performed by 46 laboratories. All reported results were correct.
2. The following tests are listed for ***Clostridium difficile***: Seegene Allplex GI-Bacteria (I) Assay (17x), Seegene Allplex GI-EB Screening Assay (14x), BioMerieux BioFire FILMARRAY Gastrointestinal (GI) Panel (3x), r-Biopharm RIDA GENE C.difficile (3x), Altona diagnostics RealStar C. difficile (2x), Amplex eazyplex C. difficile complete (1x), Bruker-Hain Lifescience LiquidArray Gastrointestinal (1x), CerTest VIASURE Gastrointestinal Panel II (1x), Luminex NxTAG Gastrointestinal Pathogen Panel (1x), Qiagen QIAstat-Dx Gastrointestinal Panel (1x) and Roche UC-TIB-EHEC/C.diff (1x).
3. ***Enterohaemorrhagische E. coli***-detection was performed by 57 laboratories. All reported results were correct.
4. The following tests are listed for ***Enterohaemorrhagische E. coli***: Seegene Allplex GI-Bacteria (II) Assay (17x), Seegene Allplex GI-EB Screening Assay (11x), BD MAX Enteric Bacterial Panel (9x), r-Biopharm RIDA GENE EHEC/EPEC (5x), BioMerieux BioFire FILMARRAY Gastrointestinal (GI) Panel (3x), r-Biopharm RIDA GENE E. coli Stool Panel 1 (3x), Bruker-Hain Lifescience LiquidArray Gastrointestinal (1x), CerTest VIASURE Gastrointestinal Panel II (1x), Luminex NxTAG Gastrointestinal Pathogen Panel (1x), Qiagen QIAstat-Dx Gastrointestinal Panel (1x), r-Biopharm RIDAGENE Bacterial Stool Panel I (1x), r-Biopharm RIDA UNITY EHEC/EPEC (1x) and Roche UC-TIB-EHEC/C.diff (1x).
5. ***Escherichia coli O157***-detection was performed by 35 laboratories. All reported results were correct.
6. The following tests are listed for ***Escherichia coli O157***: Seegene Allplex GI-Bacteria II Assay (17x), Seegene Allplex GI-EB Screening Assay (13x), BioMerieux BioFire FILMARRAY Gastrointestinal (GI) Panel (2x), Bruker-Hain Lifescience LiquidArray Gastrointestinal (1x) and Qiagen QIAstat-Dx Gastrointestinal Panel (1x).
7. ***Vibrio spp.***-detection was performed by 32 laboratories. With the exception of 2 laboratories (with false positive results for sample # 548A 241015 02), all reported results were correct.
8. The following tests are listed for ***Vibrio spp.***: Seegene Allplex GI-Bacteria (I) Assay (17x), BD MAX Extended Enteric Bacterial Panel (7x), BioMerieux BioFire FILMARRAY Gastrointestinal (GI) Panel (3x), Bruker-Hain Lifescience LiquidArray Gastrointestinal (1x), Luminex NxTAG Gastrointestinal Pathogen Panel (1x) and Qiagen QIAstat-Dx Gastrointestinal Panel (1x).