Online Resources for:

Evaluation of the cross-reactivity of antidrug antibodies to CT-P13 and infliximab

reference product (Remicade): an analysis using immunoassays tagged with both

agents

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## **Online resource 1.** Baseline patient characteristics for the PLANETAS safety population (patients with ankylosing spondylitis)

Characteristic*	CT-P13 5 mg/kg	RP 5 mg/kg	Total
	(n=128)	(n=122)	(N=250)
Age, years	38.0 (18–69)	38.0 (18–66)	38.0 (18–69)
Gender, no. (%)			
Male	102 (79.7)	100 (82.0)	202 (80.8)
Female	26 (20.3)	22 (18.0)	48 (19.2)
Ethnicity, no. (%)			
White	98 (76.6)	91 (74.6)	189 (75.6)
Asian	16 (12.5)	13 (10.7)	29 (11.6)
Other	14 (10.9)	18 (14.8)	32 (12.8)
Height, cm	172.0 (148–198)	171.0 (147–193)	172.0 (147–198)
Weight, kg	73.00 (45.0–120.0)	75.70 (45.5–122.7)	73.75 (45.0–122.7)
Body mass index, kg/m <sup>2</sup>	24.41 (18.0–38.7)	25.59 (17.5–42.0)	25.12 (17.5–42.0)
Baseline BASDAI score, no. (%)			
<8	94 (73.4)	93 (76.2)	187 (74.8)
≥8	34 (26.6)	29 (23.8)	63 (25.2)
Screening BASDAI score, no. (%)			
<8	99 (77.3)	95 (77.9)	194 (77.6)
≥8	29 (22.7)	27 (22.1)	56 (22.4)

<sup>\*</sup>Except where indicated otherwise, values are the median (minimum-maximum).

BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; RP, reference product.

**Online resource 2.** Agreement of immunogenicity testing between Assay ADA-A and Assay ADA-B<sup>a</sup> in PLANETAS (safety population)

Visit	Assay		ADA-A	PPAb	NPA°	Cohen's κ	
	ADA-B		ome	(%)	(%)	(95% CI)	p-value
	outcome	Pos	Neg	` '	, ,	, ,	
	_			atients (N=	250)ª	T	1
Screening	Pos	2	2	66.67	99.18	0.57 (0.12–1.00)	<0.001
	Neg	1	242			(0112 1100)	
Week 14	Pos	23	0	95.83	100.00	0.98 (0.93–1.00)	<0.001
	Neg	1	215	00.00		0.00 (0.00 1.00)	10.00
Week 30	Pos	54	1	94.74	99.42	0.95 (0.91–1.00)	<0.001
WOOK OO	Neg	3	170	54.74	00.4Z	0.00 (0.01 1.00)	<b>40.001</b>
Week 54	Pos	51	0	96.23	100.00	0.97 (0.94–1.00)	<0.001
Week 54	Neg	2	161	30.23	100.00	0.97 (0.94–1.00)	<0.001
EOS	Pos	69	1	87.34	99.36	0.89 (0.83–0.95)	<0.001
E03	Neg	10	155	07.34	99.30	0.69 (0.65–0.95)	<0.001
		C	T-P13 tre	atment gro	up (N=128)	)d	
Screening	Pos	1	1	50.00	99.20	0.49 (-0.11–1.00)	<0.001
Screening	Neg	1	124	30.00	99.20	0.49 (-0.11–1.00)	<0.001
Week 14	Pos	10	0	90.91	100.00	0.05 (0.95, 1.00)	<0.001
Week 14	Neg	1	110	90.91	100.00	0.95 (0.85–1.00)	<0.001
Week 30	Pos	30	1	93.75	98.82	0.02 (0.96.4.00)	-0.001
vveek 30	Neg	2	84	93.75	90.02	0.93 (0.86–1.00)	<0.001
Wook E4	Pos	25	0	100.00	100.00	1.00 (1.00 1.00)	-0.001
Week 54	Neg	0	84	100.00	100.00	1.00 (1.00–1.00)	<0.001
FOC	Pos	38	0	00.00	400.00	0.00 (0.00 0.00)	-0.004
EOS	Neg	6	78	86.36	100.00	0.89 (0.80–0.98)	<0.001
	1	I.	RP treati	ment group	(N=122)d		l
Caraanina	Pos	1	1	100.00	00.46	0.00 (0.04.4.00)	-0.004
Screening	Neg	0	118	100.00	99.16	0.66 (0.04–1.00)	<0.001
107 - 1 4 4	Pos	13	0	400.00	400.00	4.00 (4.00 4.00)	0.004
Week 14	Neg	0	105	100.00	100.00	1.00 (1.00–1.00)	<0.001
W1-00	Pos	24	0	00.00	400.00	0.07 (0.00 4.00)	0.004
Week 30	Neg	1	86	96.00	100.00	0.97 (0.92–1.00)	<0.001
10/	Pos	26	0	00.00	400.00	0.05 (0.00, 4.00)	0.004
Week 54	Neg	2	77	92.86	100.00	0.95 (0.88–1.00)	<0.001
500	Pos	31	1	00.57	00.70	0.00 (0.00 0.00)	0.001
EOS	Neg	4	77	88.57	98.72	0.89 (0.80–0.98)	<0.001
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<sup>a</sup>Assay ADA-A = ADA detection immunoassay with EU-approved Remicade tag; Assay ADA-B = ADA detection immunoassay with CT-P13 tag. <sup>b</sup>PPA = (number of patients with positive outcome for both Assay ADA-A and Assay ADA-B)/(number of patients with positive outcome for Assay ADA-A)\*100. <sup>c</sup>NPA = (number of patients with negative outcome for both Assay ADA-A and Assay ADA-B)/(number of patients with negative outcome for Assay ADA-A)\*100. <sup>d</sup>Concordance values will not reflect total patient numbers due to patients not being available for sampling or withdrawals throughout the study.

ADA, antidrug antibody; CI, confidence interval; EOS, end of study; EU, European Union; Neg, negative result; NPA, negative percentage agreement; Pos, positive result; PPA, positive percentage agreement; RP, reference product.

# **Online resource 3.** Agreement of immunogenicity testing between Assay NAb-A and Assay NAb-B<sup>a</sup> in PLANETAS (safety population)

Visit	Assay	A	ssay NAb	o-A	PPAb	NPAc	Cohen's κ	p-value
	NAb-B		outcome	e	(%)	(%)	(95% CI)	
	outcome	Pos	Negd	QNSe				
				All patie	ents (N=25	0) <sup>f</sup>		
	Pos	0	1	0	0.00	99.59	-0.01 (-0.01–0.00)	0.928
Screening	Neg⁴	2	244	0	0.00	33.33	-0.01 (-0.01-0.00)	0.320
	QNS	0	0	0	-	-	-	-
	Pos	22	0	1	95.65	100.00	0.98 (0.93–1.00)	<0.001
Week 14	Neg	1	215	0	33.03	100.00	0.50 (0.55 1.00)	<b>\0.001</b>
	QNS	0	0	0	-	-	-	-
	Pos	52	2	1	94.55	98.84	0.94 (0.89–0.99)	<0.001
Week 30	Neg	3	170	0	0 1.00	00.01	0.01 (0.00 0.00)	(0.001
	QNS	0	0	0	-	-	-	-
	Pos	51	0	0	96.23	100.00	0.97 (0.94–1.00)	<0.001
Week 54	Neg	2	161	0	00.20	100.00	0.07 (0.01 1.00)	(0.001
	QNS	0	0	0	-	-	-	-
	Pos	66	2	0	84.62	98.73	0.86 (0.79–0.93)	<0.001
EOS	Neg	12	155	0	0	000	(0.00 (0.00)	10.00
	QNS	0	0	0	-	-	-	-
	ı	1			ent group	(N=128) <sup>f</sup>		T
	Pos	0	1	0	0.00	99.21	-0.01 (-0.02–0.00)	0.929
Screening	Neg	1	125	0			( 0.02 0.00)	
	QNS	0	0	0	-	-	-	-
	Pos	9	0	1	90.00	100.00	0.94 (0.83–1.00)	<0.001
Week 14	Neg	1	110	0			(0.00)	
	QNS	0	0	0	-	-	-	-
	Pos	29	1	1	93.55	98.82	0.93 (0.86–1.00)	<0.001
Week 30	Neg	2	84	0			(	
	QNS	0	0	0	-	-	-	-
	Pos	25	0	0	100.00	100.00	1.00 (1.00–1.00)	<0.001
Week 54	Neg	0	84	0				
	QNS	0	0	0	-	-	-	-
<b>500</b>	Pos	35	1	0	81.40	98.73	0.83 (0.73–0.94)	<0.001
EOS	Neg	8	78	0				
	QNS	0	0	0	- ()	-	-	-
					nt group (N	l=122) <sup>r</sup>	Г	4
0	Pos	0	0	0	0.00	100.00	NE (NE-NE)	NE
Screening	Negd	1	119	0			,	
	QNS	0	0	0	-	-	-	-
Mach 44	Pos	13	0	0	100.00	100.00	1.00 (1.00–1.00)	<0.001
Week 14	Neg	0	105	0			,	
	QNS	0	0	0	-	-	-	-
Maala 00	Pos	23	1	0	95.83	98.85	0.95 (0.87–1.00)	<0.001
Week 30	Neg	1	86	0			,	
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	QNS	0	0	0	-	- 400.00		- 0.004
Week 54	Pos	26	0	0	92.86	100.00	0.95 (0.88–1.00)	<0.001

	Neg	2	77	0				
	QNS	0	0	0	-	-	-	-
	Pos	31	1	0	88.57	98.72	0.00 (0.00 0.00)	<0.001
EOS	Neg	4	77	0	00.37	90.72	0.89 (0.80–0.98)	<0.001
	QNS	0	0	0	-	-	-	-

<sup>a</sup>Assay NAb-A = NAb detection immunoassay with EU-approved Remicade tag; Assay NAb-B = NAb detection immunoassay with CT-P13 tag. <sup>b</sup>PPA = (number of patients with positive outcome for both Assay NAb-A and Assay NAb-B)/(number of patients with positive outcome for Assay NAb-A)\*100. <sup>c</sup>NPA = (number of patients with negative outcome for both Assay NAb-A and Assay NAb-B)/(number of patients with negative outcome for Assay NAb-A)\*100. <sup>d</sup>The NAb-negative population constitutes both 1) patients who were originally tested for ADA and were found to be negative (and therefore, not further tested for NAb) and 2) patients who originally tested positive for ADA but were subsequently found to be negative for NAb. <sup>e</sup>Counts of QNS are for information purposes only and not used in calculation of PPA, NPA or Cohen's κ. <sup>f</sup>Concordance values will not reflect total patient numbers due to patients not being available for sampling or withdrawals throughout the study.

ADA, antidrug antibody; CI, confidence interval; EOS, end of study; EU, European Union; NAb, neutralising antibody; NE, not estimable; Neg, negative result; NPA, negative percentage agreement; Pos, positive result; PPA, positive percentage agreement; QNS, quantity not sufficient; RP, reference product.

## **Online resource 4.** Baseline patient characteristics for the PLANETRA safety population (patients with rheumatoid arthritis)

Characteristic*	CT-P13	RP	Total
	3 mg/kg	3 mg/kg	(N=602)
	(n=302)	(n=300)	
Age, years	50 (18–75)	50 (21–74)	50 (18–75)
Gender, no. (%)			
Female	245 (81.1)	252 (84.0)	497 (82.6)
Male	57 (18.9)	48 (16.0)	105 (17.4)
Ethnicity, no. (%)			
Asian	34 (11.3)	36 (12.0)	70 (11.6)
Black	2 (0.7)	1 (0.3)	3 (0.5)
White	220 (72.8)	219 (73.0)	439 (72.9)
Other	46 (15.2)	44 (14.7)	90 (15.0)
Height (cm)	162.0	162.0	162.0
	(144.0–186.0)	(124.0–190.0)	(124.0–190.0)
Weight (kg)	69.0	68.0	68.75
	(36.5–134.0)	(36.0–136.0)	(36.0–136.0)
Body mass index (kg/m²)	26.32	25.33	25.85
	(13.9–49.8)	(15.0–53.1)	(13.9–53.1)
Baseline serum CRP concentration, no. (%)			
≤2mg/ dL	162 (53.6)	164 (54.7)	326 (54.2)
>2mg/ dL	140 (46.4)	136 (45.3)	276 (45.8)
Screening serum CRP concentration, no. (%)			
≤2mg/ dL	196 (64.9)	202 (67.3)	398 (66.1)
>2mg/ dL	105 (34.8)	98 (32.7)	203 (33.7)

<sup>\*</sup>Except where indicated otherwise, values are the median (minimum-maximum).

CRP, C-reactive protein; RP, reference product.

# **Online resource 5.** Agreement of immunogenicity testing between Assay ADA-A and Assay ADA-B<sup>a</sup> in PLANETRA (safety population)

Visit	Assay	Assa	y ADA-A o	utcome	PPAb	NPAc	Cohen's κ	p-
	ADA-B outcome	Pos	Neg	Missingd	(%)	(%)	(95% CI)	value
	00.1000		All	patients (N:	=602) <sup>e</sup>			
	Pos	15	4	0	100.00	99.32	0.88 (0.76–1.00)	<0.001
Screening	Neg	0	580	0	100.00	99.32	0.00 (0.76–1.00)	<0.001
	Missingd	0	0	0	-	-	-	-
	Pos	134	8	0	97.10	98.01	0.94 (0.91–0.97)	<0.001
Week 14	Neg	4	395	0	97.10	30.01	0.94 (0.91–0.91)	<0.001
	Missing	1	1	0	-	-	-	-
	Pos	238	8	0	97.54	96.93	0.94 (0.92–0.97)	<0.001
Week 30	Neg	6	253	0	37.54	30.33	0.94 (0.92-0.97)	<0.001
	Missing	0	0	0	-	-	-	-
	Pos	220	7	0	94.83	96.86	0.92 (0.88–0.95)	<0.001
Week 54	Neg	12	216	0	34.03	30.00	0.92 (0.00-0.93)	<0.001
	Missing	0	0	0	-	-	-	-
	Pos	292	3	1	94.50	98.69	0.92 (0.89–0.96)	<0.001
EOS	Neg	17	226	0	34.50	30.03	0.02 (0.03 0.00)	<0.001
	Missing	0	0	0	-	-	-	-
				reatment gro	oup (N=3	02) <sup>e</sup>		
	Pos	9	3	0	100.00	98.97	0.85 (0.69–1.00)	<0.001
Screening	Neg	0	289	0	100.00	30.37	0.00 (0.00 1.00)	<0.001
	Missing	0	0	0	-	-	-	-
	Pos	68	4	0	98.55	98.02	0.95 (0.91–0.99)	<0.001
Week 14	Neg	1	198	0	30.33	30.02	0.55 (0.51 0.55)	<0.001
	Missing	0	1	0	-	-	-	-
	Pos	120	6	0	98.36	95.38	0.94 (0.89–0.98)	<0.001
Week 30	Neg	2	124	0	00.00	00.00	0.01 (0.00 0.00)	10.001
	Missing	0	0	0	-	-	-	-
	Pos	120	5	0	96.77	95.58	0.92 (0.88–0.97)	<0.001
Week 54	Neg	4	108	0	00	00.00	0.02 (0.00 0.01)	10.001
	Missing	0	0	0	-	-	-	-
	Pos	150	1	1	94.94	99.10	0.93 (0.89–0.98)	<0.001
EOS	Neg	8	110	0	0 1.0 1	00.10	0.00 (0.00 0.00)	40.001
	Missing	0	0	0	-	-	-	-
	1	T		atment group	p (N=300	)e		T
	Pos	6	1	0	100.00	99.66	0.92 (0.77–1.00)	<0.001
Screening	Neg	0	291	0	100.00	00.00	0.02 (0.17 1.00)	40.001
	Missing	0	0	0	-	-	-	-
	Pos	66	4	0	95.65	98.01	0.93 (0.88–0.98)	<0.001
Week 14	Neg	3	197	0	00.00		(0.00 (0.00)	10.001
	Missing	1	0	0	-	-	-	-
	Pos	118	2	0	96.72	98.47	0.95 (0.91–0.99)	<0.001
Week 30	Neg	4	129	0	00.72	00.47	0.00 (0.01 0.00)	30.001
	Missing	0	0	0	-	-	-	-
Week 54	Pos	100	2	0	92.59	98.18	0.91 (0.85–0.96)	<0.001

	Neg	8	108	0				
	Missing	0	0	0	-	-	-	-
	Pos	142	2	0	04.04	00.24	0.02 (0.07, 0.07)	-0.001
EOS	Neg	9	116	0	94.04	98.31	0.92 (0.87–0.97)	<0.001
	Missing	0	0	0	-	-	-	-

<sup>a</sup>Assay ADA-A = ADA detection immunoassay with EU-approved Remicade tag; Assay ADA-B = ADA detection immunoassay with CT-P13 tag. <sup>b</sup>PPA = (number of patients with positive outcome for both Assay ADA-A and Assay ADA-B)/(number of patients with positive outcome for Assay ADA-A)\*100. <sup>c</sup>NPA = (number of patients with negative outcome for both Assay ADA-A and Assay ADA-B)/(number of patients with negative outcome for Assay ADA-A)\*100. <sup>d</sup>Counts of missing values are for information purposes only, are not used in calculations of PPA, NPA or κ and include patients with a QNS outcome. <sup>e</sup>Concordance values will not reflect total patient numbers due to patients not being available for sampling or withdrawals throughout the study.

ADA, antidrug antibody; CI, confidence interval; EOS, end of study; EU, European Union; Neg, negative result; NPA, negative percentage agreement; Pos, positive result; PPA, positive percentage agreement; QNS, quantity not sufficient; RP, reference product.

# **Online resource 6.** Agreement of immunogenicity testing between Assay NAb-A and Assay NAb-B<sup>a</sup> in PLANETRA (safety population)

Visit	Assay	Assa	y NAb-A o	utcome	PPAb	NPAc	Cohen's κ	p-
	NAb-B	Pos	Negd	Missinge	(%)	(%)	(95% CI)	value
	outcome	1 03						
			All	patients (N	=602) <sup>†</sup>			
	Pos	3	2	0	60.00	99.66	0.60 (0.24–0.96)	<0.001
Screening	Neg	2	592	0	00.00	33.00	0.00 (0.24-0.90)	<0.001
	Missing <sup>d</sup>	0	0	0	-	-	-	-
	Pos	130	8	2	96.30	98.02	0.94 (0.90–0.97)	<0.001
Week 14	Neg	5	396	0	00.00	00.02		10.001
	Missing	1	1	0	-	-	-	-
	Pos	234	8	0	96.30	96.95	0.93 (0.90–0.96)	<0.001
Week 30	Neg	9	254	0			(	
	Missing	0	0	0	-	-	-	-
	Pos	216	8	0	95.15	96.49	0.92 (0.88–0.95)	<0.001
Week 54	Neg	11	220	0			(0.00)	
	Missing	0	0	0	-	-	-	-
	Pos	287	5	1	94.72	97.87	0.92 (0.89–0.95)	<0.001
EOS	Neg	16	230	0			(* 11 1 1 1 1 )	
	Missing	0	0	0	- "	-	-	-
			CT-P13 t	reatment gr	oup (N=3	02)'		
	Pos	1	1	0	33.33	99.66	0.40 ( 0.15 0.04)	<0.001
Screening	Neg	2	297	0	33.33	99.00	0.40 (-0.15–0.94)	<0.001
	Missing	0	0	0	-	-	-	-
	Pos	67	4	0	97.10	98.02	0.94 (0.90–0.99)	<0.001
Week 14	Neg	2	198	0	97.10	90.02	0.94 (0.90–0.99)	<b>40.001</b>
	Missing	0	1	0	-	-	-	-
	Pos	117	6	0	96.69	95.42	0.92 (0.87–0.97)	<0.001
Week 30	Neg	4	125	0	00.00	00.12	0.02 (0.07 0.07)	40.001
	Missing	0	0	0	-	-	-	-
	Pos	120	5	0	97.56	95.61	0.93 (0.89–0.98)	<0.001
Week 54	Neg	3	109	0	0.100		(0.00 (0.00 0.00)	10.00.
	Missing	0	0	0	-	-	-	-
	Pos	148	2	1	95.48	98.25	0.93 (0.89–0.98)	<0.001
EOS	Neg	7	112	0			,	
	Missing	0	0	0	- (NI 000	- \\f	-	-
			RP trea	atment grou	p (N=300	)) <sup>1</sup>		
	Pos	2	1	0	100.00	99.66	0.90 (0.44.4.00)	-0.001
Screening	Neg	0	295	0	100.00	99.00	0.80 (0.41–1.00)	<0.001
	Missing	0	0	0			-	-
	Pos	63	4	2	05.45	08.02	0.03 (0.88 0.08)	<0.001
Week 14	Neg	3	198	0	95.45	98.02	0.93 (0.88–0.98)	<0.001
	Missing	1	0	0	-	-	-	-
	Pos	117	2	0	95.90	98.47	0.94 (0.90–0.99)	<0.001
Week 30	Neg	5	129	0	33.30	30.47	0.34 (0.30-0.33)	20.001
	Missing	0	0	0	-	-		-

	Pos	96	3	0	92.31	97.37	0.90 (0.84–0.96)	<0.001
Week 54	Neg	8	111	0	92.31	91.31	0.90 (0.64–0.96)	<0.001
	Missing	0	0	0	-	-	-	-
	Pos	139	3	0	93.92	97.52	0.91 (0.86–0.96)	<0.001
EOS	Neg	9	118	0	93.92	97.52	0.91 (0.00-0.90)	<0.001
	Missing	0	0	0	-	-	-	-

<sup>a</sup>Assay NAb-A = NAb detection immunoassay with EU-approved Remicade tag; Assay NAb-B = NAb detection immunoassay with CT-P13 tag. <sup>b</sup>PPA = (number of patients with positive outcome for both Assay NAb-A and Assay NAb-B)/(number of patients with positive outcome for Assay NAb-A)\*100. <sup>c</sup>NPA = (number of patients with negative outcome for both Assay NAb-A and Assay NAb-B)/(number of patients with negative outcome for Assay NAb-A)\*100. <sup>d</sup>The NAb-negative population constitutes both 1) patients who were originally tested for ADA and were found to be negative (and therefore, not further tested for NAb) and 2) patients who originally tested positive for ADA but were subsequently found to be negative for NAb. <sup>e</sup>Counts of missing values are for information purposes only, are not used in calculations of PPA, NPA or κ and include patients with a QNS outcome. <sup>f</sup>Concordance values will not reflect total patient numbers due to patients not being available for sampling or withdrawals throughout the study.

ADA, antidrug antibody; CI, confidence interval; EOS, end of study; EU, European Union; NAb, neutralising antibody; Neg, negative result; NPA, negative percentage agreement; Pos, positive result; PPA, positive percentage agreement; QNS, quantity not sufficient; RP, reference product.

**Online resource 7.** Agreement of immunogenicity testing between Assay ADA-A and Assay ADA-B<sup>a</sup> in pooled analysis of PLANETAS and PLANETRA (safety populations)

Visit	Assay	Assa	y ADA-A o	utcome	PPAb	NPAc	Cohen's κ	p-
	ADA-B outcome	Pos	Neg	Missingd	(%)	(%)	(95% CI)	value
	outcome		All	patients (N	 =852) <sup>e</sup>			
	Pos	17	6	0			0.00 (0.00 0.00)	2 224
Screening	Neg	1	822	0	94.44	99.28	0.83 (0.70–0.95)	<0.001
_	Missingd	0	0	0	-	-	-	-
	Pos	157	8	0	96.91	98.71	0.05 (0.02, 0.00)	-0.001
Week 14	Neg	5	610	0	96.91	96.71	0.95 (0.92–0.98)	<0.001
	Missing	1	1	0	-	-	-	-
	Pos	292	9	0	97.01	97.92	0.95 (0.93–0.97)	<0.001
Week 30	Neg	9	423	0	97.01	91.92	0.95 (0.95–0.97)	<0.001
	Missing	0	0	0	-	-	-	-
	Pos	271	7	0	95.09	98.18	0.94 (0.91–0.96)	<0.001
Week 54	Neg	14	377	0	93.09	30.10	0.94 (0.91–0.90)	<b>40.001</b>
	Missing	0	0	0	-	-	-	-
	Pos	361	4	1	93.04	98.96	0.92 (0.89–0.95)	<0.001
EOS	Neg	27	381	0	33.04	30.30	0.92 (0.09-0.93)	<0.001
	Missing	0	0	0	-	-	-	-
				P13 group (	N=430) <sup>e</sup>			
	Pos	10	4	0	90.91	99.04	0.79 (0.62–0.97)	<0.001
Screening	Neg	1	413	0	30.51	33.04	0.75 (0.02 0.07)	<b>40.001</b>
	Missing	0	0	0	-	-	-	-
	Pos	78	4	0	97.50	98.72	0.95 (0.92–0.99)	<0.001
Week 14	Neg	2	308	0	07.00	00.72	0.00 (0.02 0.00)	10.001
	Missing	0	1	0	-	-	-	-
	Pos	150	7	0	97.40	96.74	0.94 (0.90–0.97)	<0.001
Week 30	Neg	4	208	0			(0.00)	
	Missing	0	0	0	-	-	-	-
	Pos	145	5	0	97.32	97.46	0.95 (0.91–0.98)	<0.001
Week 54	Neg	4	192	0			,	
	Missing	0	0	0	-	-	-	-
	Pos	188	1	1	93.07	99.47	0.92 (0.89–0.96)	<0.001
EOS	Neg	14	188	0			,	
	Missing	0	0	0	- (1)	-	-	-
				atment grou	p (N=422	)e		I
0	Pos	7	2	0	100.00	99.51	0.87 (0.70–1.00)	<0.001
Screening	Neg	0	409	0			,	
	Missing	0	0	0	-	-	-	-
\\\\-a  44	Pos	79	4	0	96.34	98.69	0.95 (0.91–0.99)	<0.001
Week 14	Neg	3	302	0			,	
	Missing	1	0	0	-	-	-	-
Wast 00	Pos	142	2	0	96.60	99.08	0.96 (0.93-0.99)	<0.001
Week 30	Neg	5	215	0			,	
10/a al . 5.4	Missing	0	0	0	-	-	-	-
Week 54	Pos	126	2	0	92.65	98.93	0.92 (0.88–0.97)	<0.001

	Neg	10	185	0				
	Missing	0	0	0	-	-	-	-
	Pos	173	3	0	02.04	00.47	0.92 (0.88–0.96)	-0.001
EOS	Neg	13	193	0	93.01	98.47	0.92 (0.66–0.96)	<0.001
	Missing	0	0	0	-	-	-	-

<sup>a</sup>Assay ADA-A = ADA detection immunoassay with EU-approved Remicade tag; Assay ADA-B = ADA detection immunoassay with CT-P13 tag. <sup>b</sup>PPA = (number of patients with positive outcome for both Assay ADA-A and Assay ADA-B)/(number of patients with positive outcome for Assay ADA-A)\*100. <sup>c</sup>NPA = (number of patients with negative outcome for both Assay ADA-A and Assay ADA-B)/(number of patients with negative outcome for Assay ADA-A)\*100. <sup>d</sup>Counts of missing values are for information purposes only, are not used in calculations of PPA, NPA or κ and include patients with a QNS outcome. <sup>e</sup>Concordance values will not reflect total patient numbers due to patients not being available for sampling or withdrawals throughout the study.

ADA, antidrug antibody; CI, confidence interval; EOS, end of study; EU, European Union; Neg, negative result; NPA, negative percentage agreement; Pos, positive result; PPA, positive percentage agreement; QNS, quantity not sufficient; RP, reference product.

**Online resource 8.** Agreement of immunogenicity testing between Assay NAb-A and NAb-B<sup>a</sup> in pooled analysis of PLANETAS and PLANETRA (safety populations)

Visit	Assay	Assa	y NAb-A	outcome	PPAb	NPAc	Cohen's κ	p-value
	NAb-B outcome	Pos	Neg <sup>d</sup>	Missinge	(%)	(%)	(95% CI)	
			A	Il patients (	N=852) <sup>f</sup>	l	I	
	Pos	3	3	0	42.86	99.64	0.46 (0.12–0.80)	<0.001
Screening	Neg	4	836	0	42.00	33.04	0.40 (0.12 0.00)	<b>\0.001</b>
	Missinge	0	0	0	-	-	-	-
	Pos	152	8	3	96.20	98.71	0.94 (0.92–0.97)	<0.001
Week 14	Neg	6	611	0	00.20	00.7	0.01 (0.02 0.01)	10.001
	Missing	1	1	0	-	-	-	-
	Pos	286	10	1	95.97	97.70	0.94 (0.91–0.96)	<0.001
Week 30	Neg	12	424	0	00.07	01110	0.01 (0.01 0.00)	10.001
	Missing	0	0	0	-	-	-	-
	Pos	267	8	0	95.36	97.94	0.94 (0.91–0.96)	<0.001
Week 54	Neg	13	381	0	00.00	07.01	0.01 (0.01 0.00)	(0.001
	Missing	0	0	0	-	-	-	-
	Pos	353	7	1	92.65	98.21	0.91 (0.88–0.94)	<0.001
EOS	Neg	28	385	0	32.00	30.21	0.51 (0.55 0.54)	<b>VO.001</b>
	Missing	0	0	0	-	-		-
			CT-P13	treatment g	group (N=	430) <sup>f</sup>		
	Pos	1	2	0	25.00	99.53	0.28 (-0.16–0.72)	<0.001
Screening	Neg	3	422	0	25.00	33.33	0.20 ( 0.10 0.72)	<b>\0.001</b>
	Missing	0	0	0	-	-	-	-
	Pos	76	4	1	96.20	98.72	0.94 (0.90–0.99)	<0.001
Week 14	Neg	3	308	0	00.20	00.72	0.01 (0.00 0.00)	40.001
	Missing	0	1	0	-	-	-	-
	Pos	146	7	1	96.05	96.76	0.93 (0.89–0.97)	<0.001
Week 30	Neg	6	209	0	00.00	00.70	0.00 (0.00 0.01)	10.001
	Missing	0	0	0	-	-	-	-
	Pos	145	5	0	97.97	97.47	0.95 (0.92–0.99)	<0.001
Week 54	Neg	3	193	0	01.01		0.00 (0.02 0.00)	10.001
	Missing	0	0	0	-	-	-	-
	Pos	183	3	1	92.42	98.45	0.91 (0.87–0.95)	<0.001
EOS	Neg	15	190	0	02.12	00.10	0.01 (0.01 0.00)	10.001
	Missing	0	0	0	-	-	-	-
			RP tre	eatment gro	oup (N=42	2) <sup>f</sup>		
	Pos	2	1	0	66.67	99.76	0.66 (0.23–1.00)	<0.001
Screening	Neg	1	414	0	00.07	99.70	0.00 (0.23-1.00)	<0.001
	Missing	0	0	0	-	-	-	-
	Pos	76	4	2	06.20	00.70	0.04 (0.00, 0.00)	-0.001
Week 14	Neg	3	303	0	96.20	98.70	0.94 (0.90–0.99)	<0.001
	Missing	1	0	0	-	-	-	-
Mook 20	Pos	140	3	0	05.00	00.60	0.05 (0.02.0.00)	-0.001
Week 30	Neg	6	215	0	95.89	98.62	0.95 (0.92–0.98)	<0.001

	Missing	0	0	0	-	-	-	-
Week 54	Pos	122	3	0	92.42	98.43	0.92 (0.87–0.96)	<0.001
	Neg	10	188	0				
	Missing	0	0	0	-	-	-	-
EOS	Pos	170	4	0	92.90	97.99	0.91 (0.87–0.95)	<0.001
	Neg	13	195	0				
	Missing	0	0	0				-

<sup>a</sup>Assay NAb-A = NAb detection immunoassay with EU-approved Remicade tag; Assay NAb-B = NAb detection immunoassay with CT-P13 tag. <sup>b</sup>PPA = (number of patients with positive outcome for both Assay NAb-A and Assay NAb-B)/(number of patients with positive outcome for Assay NAb-A)\*100. <sup>c</sup>NPA = (number of patients with negative outcome for both Assay NAb-A and Assay NAb-B)/(number of patients with negative outcome for Assay NAb-A)\*100. <sup>d</sup>The NAb-negative population constitutes both 1) patients who were originally tested for ADA and were found to be negative (and therefore, not further tested for NAb) and 2) patients who originally tested positive for ADA but were subsequently found negative for NAb. <sup>e</sup>Counts of missing values are for information purposes only, are not used in calculations of PPA, NPA or κ and include patients with a QNS. <sup>f</sup>Concordance values will not reflect total patient numbers due to patients not being available for sampling or withdrawals throughout the study.

ADA, antidrug antibody; CI, confidence interval; EOS, end of study; EU, European Union; NAb, neutralising antibody; Neg, negative result; NPA, negative percentage agreement; Pos, positive result; PPA, positive percentage agreement; QNS, quantity not sufficient; RP, reference product.