

NaOHD - SMS - SmpCln1+2 - SCCS cobas®

Special Wash Requirements Method Sheet

CONTENT	REF	Analyzer(s) on which kit(s) can be used
NaOHD* (old: 50 mL, new: 66 mL)	04489241 190	System-ID 07 6871 5 cobas c 501/311
SMS* (50 mL)	04489225 190	System-ID 07 6872 3 cobas c 501/311
SCCS (Special Cell Cleaning Solution)* (50 mL)	04880994 190	System-ID 07 6973 8 cobas c 501/311
Sample Cleaner 1 (59 mL)	04708725 190	cobas c 501/311
Sample Cleaner 2 (68 mL)	05958024 190	cobas c 501/311

* The value encoded in the instrument settings is 41.2 mL (NAOHD old, SMS, SCCS) / 58.7 mL (NAOHD new) to account for the dead volume of the bottles.

English

System information

NAOHD (D1):	ACN 947
SMS (D2):	ACN 948
Special Cell Cleaning Solution (D3):	ACN 949

Intended use

NaOHD, Cat. No. 04489241190 and SMS, Cat. No. 04489225190:
Wash solution for reagent probes and reaction cells on Roche/Hitachi **cobas c** systems.
SCCS, Cat. No. 04880994190:
Wash solution for reaction cells on Roche/Hitachi **cobas c** systems.
Sample Cleaner 1, Cat. No. 04708725190 and Sample Cleaner 2, Cat. No. 05958024190:
Wash solution for sample probes on Roche/Hitachi **cobas c** systems.

Summary

Reagent and sample probe or cell washes may be required due to potential interference from other reagents or samples. These special washes maintain reagent and sample integrity.

Reagent probe carry over

Extra wash cycles are required with specific reagent combinations, e.g. if a preceding test interferes with an assay through carry over by the reagent probe.

Sample probe carry over

Extra wash cycles are required with specific sample type combinations, e.g. if a preceding test interferes with an assay through carry over by the sample probe.

Reaction cell carry over

Extra wash cycles are required with specific reagent combinations, e.g. if a preceding test interferes with an assay through carry over via the cuvette.

Reagents - working solutions

NaOHD: NaOH 1 mol/L (approx. 4 %); detergent

SMS: HCl 200 mmol/L

SmpCln1: NaOH 1 mol/L

SmpCln2: buffer; detergent

Special Cell Cleaning Solution: NaOH 3 mol/L (approx. 12 %); sodium hypochlorite solution (< 2 % active chlorine); additive

Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines.

Safety data sheet available for professional user on request.

For USA: For prescription use only.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:



Danger

H290 May be corrosive to metals.**

**does not apply to Sample Cleaner 2

H314 Causes severe skin burns and eye damage.

Prevention:

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Product safety labeling primarily follows EU GHS guidance.

Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336

Reagent handling

Ready for use

Note for NaOHD

Over time, a slight discoloration or small particles may be observed on the bottom of the bottle. The discoloration or particles do not affect reagent performance.

Storage and stability

NaOHD

Shelf life at 15-25 °C: See expiration date on **cobas c** pack label.

On-board in use and refrigerated on the analyzer: 12 weeks

SMS

Shelf life at 15-25 °C: See expiration date on **cobas c** pack label.

On-board in use and refrigerated on the analyzer: 12 weeks

SmpCln1

Shelf life at 15-25 °C: See expiration date on reagent.

On-board in use on the analyzer: 4 weeks

SmpCln2

Shelf life at 15-25 °C: See expiration date on reagent.

On-board in use on the analyzer: 4 weeks

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Special Cell Cleaning Solution

Shelf life at 2-8 °C: See expiration date on
cobas c pack label.

On-board in use and refrigerated on the
analyzer: 7 days

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

See "Order information" section

Assay

The definition and configuration of extra wash cycles is described in detail in the appropriate chapter of the **cobas 6000** and **cobas c 311** operator's manual.

For optimal performance of the wash solutions, follow the directions given in this document for the analyzer concerned.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Carry-over evasion list

1. Reagent probe carry-over:

The table on the following pages lists all tests that require extra wash cycles under certain circumstances.

2. Reaction cell carry-over:

The table on the following pages lists all tests that require extra wash cycles under certain circumstances.

3. Sample probe carry-over:

The table on the following pages lists all tests that require extra wash cycles under certain circumstances.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

	Contents of kit
	Volume after reconstitution or mixing
	Global Trade Item Number

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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Additions, deletions or changes are indicated by a change bar in the margin.

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US Customer Technical Support 1-800-428-2336



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1. Reagent probe carry-over on cobas c 501 analyzer

In case more than one application is installed for a reagent, make sure that evasion is programmed for all applications.

Please note that the individual wash steps must be programmed before the "all tests" wash steps.

Probe	From Test Reagent [Applications]	From	To Test Reagent [Applications]	To	Wash Type	Wash Vol (µL)
1	AMIK2 [456]	R1	ALBT2 [128*, 253*, 412*, 628, 153, 407]	R1	D1	180
1	AMPS2 [787, 814, 815, 816, 817, 818, 819]	R1	GGT2 [220, 480]	R1	D2	110
1	BILT3 [712*, 711*, 297, 296]	R1	STFR [665]	R1	D1	140
1	BILT3 [712*, 711*, 297, 296]	R1	B2MG [222]	R1	D1	140
1	CARB2 [124]	R1	GGT2 [220, 480]	R1	D2	120
1	CHOL2 [798, 433]	R1	CREP2 [452]	R1	D2	180
2	CKL [057]	R2	ACET2 [172]	R2	D1	80
2	CKL [057]	R2	CREP2 [452]	R3	D1	60
2	CKL [057]	R2	NAPA2 [618]	R2	D1	80
2	CKL [057]	R2	OXY [568, 569, 621, 622]	R3	D1	80
2	CKL [057]	R2	PROC2 [619]	R2	D1	80
2	CKL [057]	R2	VALP2 [207]	R2	D1	80
2	CKL [057]	R2	VANC2 [624]	R2	D1	80
2	CKMBL [060]	R2	ACET2 [172]	R2	D1	80
2	CKMBL [060]	R2	CREP2 [452]	R3	D1	60
2	CKMBL [060]	R2	NAPA2 [618]	R2	D1	80
2	CKMBL [060]	R2	OXY [568, 569, 621, 622]	R3	D1	80
2	CKMBL [060]	R2	PROC2 [619]	R2	D1	80
2	CKMBL [060]	R2	VALP2 [207]	R2	D1	80
2	CKMBL [060]	R2	VANC2 [624]	R2	D1	80
1	CRPHS [217]	R1	CA2 [698, 699]	R1	D2	150
1	CRPL3 [210]	R1	CA2 [698, 699]	R1	D2	170
1	CRPLX [019]	R1	CA2 [698, 699]	R1	D2	150
1	CYSC [431]	R1	CA2 [698, 699]	R1	D2	180
1	CYSC2 [109]	R1	CA2 [698, 699]	R1	D2	180
2	D-DI2* [102, 403]	R3	MG2 [701, 688]	R2	D2	180
1	DIG [081]	R1	ALBT2 [253*, 153]	R1	D1	120
1	DIGIT* [430]	R1	ALBT2 [253*, 153]	R1	D1	145
1	FRA [667]	R1	AMPS2 [787, 814, 815, 816, 817, 818, 819]	R1	D2	180
2	FRA [667]	R2	AMPS2 [787, 814, 815, 816, 817, 818, 819]	R2	D2	180
1	FRA [667]	R1	CHE* [725]	R1	D2	100
1	FRA [667]	R1	CHE2 [510]	R1	D2	100
1	FRA [667]	R1	CHED2* [534, 434]	R1	D2	100
1	FRA [667]	R1	SVTNI [511]	R1	D1	120
1	FRA [667]	R1	RPR2* [453]	R1	D1	80
1	GENT2 [416]	R1	GGT2 [220, 480]	R1	D2	120
2	HCYS [778]	R2	GLDH3* [588]	R2	D1	50
2	HCYS [778]	R2	HBDH2* [567]	R2	D1	50
2	HCYS [778]	R2	LDHI2 [080, 147]	R2	D1	50
2	HCYS [778]	R2	LDHL [672]	R2	D1	50

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Probe	From Test Reagent [Applications]	From	To Test Reagent [Applications]	To	Wash Type	Wash Vol (µL)
2	LDL_C [059]	R2	LIPC [731, 733]	R2	D2	90
2	LDL_C [059]	R2	MPA [623]	R2	D1	90
1	LIPC [731, 733]	R1	CA2 [698, 699]	R1	D2	130
1	MDN2 [447, 448, 792]	R1	GGT2 [220, 480]	R1	D2	120
1	PHNY2 [772]	R1	GGT2 [220, 480]	R1	D2	120
1	PHNY2 [772]	R1	GLDH3* [588]	R1	D1	120
2	PREA [710]	R2	RPR2* [453]	R2	D1	110
1	QUIN2 [437]	R1	ALBT2 [253*, 153]	R1	D1	180
2	QUIN2 [437]	R2	ALBT2 [253*, 153]	R2	D1	120
1	RF-II [017]	R1	CA2 [698, 699]	R1	D2	110
1	THEO2 [415]	R1	GGT2 [220, 480]	R1	D2	120
2	TP2 [678, 679]	R2	SVTOX [512]	R2	D2	60
1	TPLA* [192]	R1	CRPHS [217]	R1	D1	180
1	TPLA* [192]	R1	CRPLX [019]	R1	D1	180
1	TPLA2* [507]	R1	CRPHS [217]	R1	D1	160
1	TPLA2* [507]	R1	CRPLX [019]	R1	D1	160
2	TPUC3 [708*, 402*, 058, 471]	R2	CHE* [725]	R2	D1	60
2	TPUC3 [708*, 402*, 058, 471]	R2	CHE2 [510]	R3	D1	80
2	TPUC3 [708*, 402*, 058, 471]	R2	CHED2* [434, 534]	R3	D1	80
1	TRIGL [781]	R1	LIPC [731, 733]	R1	D2	170
1	ALL	R1	A1MG2* [614]	R1	D1	180
2	ALL	R2	A1MG2* [614]	R2	D1	120
2	ALL	R3	A1MG2* [614]	R2	D1	120
1	ALL	R1	MG2 [701, 688, 704, 689]	R1	D2	180
2	ALL	R2	MG2 [701, 688, 704, 689]	R2	D2	180
1	ALL	R1	TPUC3 [708*, 402*, 058, 471]	R1	D1	180
2	ALL	R2	TPUC3 [708*, 402*, 058, 471]	R2	D1	120
2	ALL	R3	TPUC3 [708*, 402*, 058, 471]	R2	D1	120
2	ALL	R2	TOBR2 [607]	R2	Water	160
2	ALL	R3	TOBR2 [607]	R2	Water	160
2	ALL	R2	TOBR2 [607]	R3	Water	160
2	ALL	R3	TOBR2 [607]	R3	Water	160

D1 = NaOHD; D2 = SMS; D3 = SCCS

*Not available in the US.

2. Reaction cell carry-over on cobas c 501 analyzer

Test	R1 Type	R1 Vol. (µL)	R2 Type	R2 Vol. (µL)	Comment
A1C-3 [881, 851]	D3	130	D3	30	Only required when more than 100 HbA1c samples are processed per day.

D1 = NaOHD; D2 = SMS; D3 = SCCS

*Not available in the US.

3. Sample probe carry-over on cobas c 501 analyzer

Reagent [Applications]	Detergent Type
ALBT2 [412*, 407]	SmpCln1
ALBT2 [253*, 153]	Water

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Reagent [Applications]	Detergent Type
ALBT2 [128*, 628]	Water only required if DIG [081] is used on the same module
AMIK2 [456]	SmpCln1
IGA-C [436]	Water
IGG-2 [673, 625*]	SmpCln1
IGM-C [484]	Water
RPR2* [453]	Water only required if A1C-3 [881, 851] is used on the same module
TOBR2 [607]	Water
TPUC3 [708*, 402*, 058, 471]	Water

*Not available in the US.

Amphetamines II and Tina-quant Hemoglobin A1c Gen.3 assay

When you are running Amphetamines II or Tina-quant Hemoglobin A1c Gen.3 assay on a cobas 6000 system having more than one cobas c 501 analyzer, please follow the below instructions:

It is advisable to install the tests in Column 1 on one module and the tests in Column 2 on another module. In this case no special calibration handling or special wash programming would be required.

Column 1	Column 2
Amphetamines II (AMPS2 300/500/1000 Qualitative and Semi-quantitative); Cat. Number 04939425190 AM3Q2: ACN 814 AM5Q2: ACN 815 AM1Q2: ACN 816 AM3S2: ACN 817 AM5S2: ACN 818 AM1S2: ACN 819 AM5QC: ACN 787	Tina-quant Hemoglobin A1c – Whole Blood Application (A1C-3); Cat. Number 05336163190 Hemolyzing Reagent Gen.2; Cat. Number 04528182190 HB-W3: ACN 871 A1-W3: ACN 881 A1CD2: ACN 952

When you are running Amphetamines II or Tina-quant Hemoglobin A1c Gen.3 assay on a cobas 6000 system having only one cobas c 501 analyzer, please follow the below instructions:

The special calibration procedures below must be followed when any test listed in Column 1 and any test listed in Column 2 are processed in the same routine run on the same **cobas c 501** module. Avoid processing Amphetamines II as the first test from standby status. If no other testing is pending then a dummy test sample should be processed to prevent the Amphetamines II from being the first test from standby (Dummy test order any test having an R1 (not HbA1c)).

SPECIAL CALIBRATION AND SAMPLE HANDLING: Amphetamines II: The Amphetamines II assay must not be calibrated or assayed immediately after the processing of any calibration, control, or routine HbA1c test order. If the Amphetamines II must be assayed, or calibrated in Operation, Rack Supply Complete, or Rack Collect End, then run one serum sample or dummy serum sample for any serum assay between the last HbA1c test processed and the first Amphetamines Calibrator, control or sample.

TPLA* (Mediace TPLA (Treponema pallidum latex agglutination test)), TPLA2* (Mediace TPLA Gen.2) and RPR2* (Mediace RPR Gen.2) assays:

When you are running TPLA assay on a cobas 6000 system, please follow the below instructions:

Samples which are to be analyzed for other infectious diseases should first be measured on the Elecsys system.

*Not available in the US.

Please note that non-Roche reagents may cause carry-over interference. Roche is not responsible for any carry-over interference caused by non-Roche reagents.

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1. Reagent probe carry-over on cobas c 311 analyzer

In case more than one application is installed for a reagent, make sure that evasion is programmed for all applications.

Please note that the individual wash steps must be programmed before the "all tests" wash steps.

From Test Reagent [Applications]	From	To Test Reagent [Applications]	To	Wash Type	Wash Vol (µL)
COC2 [189, 267, 268, 477, 791]	R1	COC2 [189, 267, 268, 477, 791]	R2	Water	100
CRPHS [217]	R1	CA2 [698, 699]	R1	D2	150
CRPL3 [210]	R1	CA2 [698, 699]	R1	D2	170
CRPLX [019]	R1	CA2 [698, 699]	R1	D2	150
CYSC [431]	R1	CA2 [698, 699]	R1	D2	180
CYSC2 [109]	R1	CA2 [698, 699]	R1	D2	180
FRA [667]	R1	HAPT2 [228]	R2	D1	100
HCYS [778]	R2	GLDH3* [588]	R1	D1	50
HCYS [778]	R2	GLDH3* [588]	R2	D1	50
LDLC3* [552]	R2	CA2 [698, 699]	R1	D2	180
LIPC [731, 733]	R1	CA2 [698, 699]	R1	D2	130
QUIN2 [437]	R1	PREA [710]	R2	D1	120
QUIN2 [437]	R2	PREA [710]	R1	D1	120
RF-II [017]	R1	CA2 [698, 699]	R1	D2	110
ALL	R1	AMPS2 [787, 814, 815, 816, 817, 818, 819] ^{a)}	R1	D2	180
ALL	R2	AMPS2 [787, 814, 815, 816, 817, 818, 819] ^{a)}	R1	D2	180
ALL	R3	AMPS2 [787, 814, 815, 816, 817, 818, 819] ^{a)}	R1	D2	180
ALL	R1	AMPS2 [787, 814, 815, 816, 817, 818, 819] ^{a)}	R2	D2	150
ALL	R2	AMPS2 [787, 814, 815, 816, 817, 818, 819] ^{a)}	R2	D2	150
ALL	R3	AMPS2 [787, 814, 815, 816, 817, 818, 819] ^{a)}	R2	D2	150
ALL	R1	A1MG2* [614]	R1	D1	180
ALL	R2	A1MG2* [614]	R1	D1	180
ALL	R3	A1MG2* [614]	R1	D1	180
ALL	R1	A1MG2* [614]	R2	D1	120
ALL	R2	A1MG2* [614]	R2	D1	120
ALL	R3	A1MG2* [614]	R2	D1	120
ALL	R1	ALBT2 [253*, 153**] ^{b)}	R1	D1	180
ALL	R2	ALBT2 [253*, 153**] ^{b)}	R1	D1	180
ALL	R3	ALBT2 [253*, 153**] ^{b)}	R1	D1	180
ALL	R2	CA2 [698, 699]	R2	D2	180
ALL	R3	CA2 [698, 699]	R2	D2	180
ALL	R1	CHE* [725] ^{c)}	R1	D2	150
ALL	R1	CHE* [725] ^{c)}	R2	D2	150
ALL	R2	CHE* [725] ^{c)}	R1	D2	150
ALL	R2	CHE* [725] ^{c)}	R2	D2	150
ALL	R3	CHE* [725] ^{c)}	R1	D2	150
ALL	R3	CHE* [725] ^{c)}	R2	D2	150
ALL	R1	CHE2 [510] ^{c)}	R1	D2	100

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From Test Reagent [Applications]	From	To Test Reagent [Applications]	To	Wash Type	Wash Vol (µL)
ALL	R1	CHE2 [510] ^{c)}	R3	D2	100
ALL	R2	CHE2 [510] ^{c)}	R1	D2	100
ALL	R2	CHE2 [510] ^{c)}	R3	D2	100
ALL	R3	CHE2 [510] ^{c)}	R1	D2	100
ALL	R3	CHE2 [510] ^{c)}	R3	D2	100
ALL	R1	CHED2* [434, 534] ^{c)}	R1	D2	100
ALL	R1	CHED2* [434] ^{c)}	R2	D2	100
ALL	R1	CHED2* [434, 534] ^{c)}	R3	D2	100
ALL	R2	CHED2* [434, 534] ^{c)}	R1	D2	100
ALL	R2	CHED2* [434] ^{c)}	R2	D2	100
ALL	R2	CHED2* [434, 534] ^{c)}	R3	D2	100
ALL	R3	CHED2* [434, 534] ^{c)}	R1	D2	100
ALL	R3	CHED2* [434] ^{c)}	R2	D2	100
ALL	R3	CHED2* [434, 534] ^{c)}	R3	D2	100
ALL	R1	DIGIT* [430] ^{d)}	R1	D1	180
ALL	R2	DIGIT* [430] ^{d)}	R2	D1	40
ALL	R3	DIGIT* [430] ^{d)}	R2	D1	40
ALL	R2	HBDH2* [567] ^{e)}	R2	D1	50
ALL	R3	HBDH2* [567] ^{e)}	R2	D1	50
ALL	R2	LDHI2 [080, 147] ^{e)}	R2	D1	50
ALL	R3	LDHI2 [080, 147] ^{e)}	R2	D1	50
ALL	R2	LDHL [672] ^{e)}	R2	D1	50
ALL	R3	LDHL [672] ^{e)}	R2	D1	50
ALL	R1	LIPC [731, 733] ^{f)}	R1	D1	120
ALL	R2	LIPC [731, 733] ^{f)}	R1	D1	120
ALL	R3	LIPC [731, 733] ^{f)}	R1	D1	120
ALL	R1	MG2 [701, 688, 704, 689]	R1	D2	180
ALL	R2	MG2 [701, 688, 704, 689]	R1	D2	180
ALL	R3	MG2 [701, 688, 704, 689]	R1	D2	180
ALL	R1	MG2 [701, 688, 704, 689]	R2	D2	180
ALL	R2	MG2 [701, 688, 704, 689]	R2	D2	180
ALL	R3	MG2 [701, 688, 704, 689]	R2	D2	180
ALL	R2	MPA [623] ^{f)}	R1	D1	70
ALL	R3	MPA [623] ^{g)}	R1	D1	70
ALL	R1	TOBR2 [607]	R2	Water	160
ALL	R1	TOBR2 [607]	R3	Water	160
ALL	R2	TOBR2 [607]	R2	Water	160
ALL	R2	TOBR2 [607]	R3	Water	160
ALL	R3	TOBR2 [607]	R2	Water	160
ALL	R3	TOBR2 [607]	R3	Water	160
ALL	R1	TPUC3 [402*, 708*, 058, 471]	R1	D1	180
ALL	R2	TPUC3 [402*, 708*, 058, 471]	R1	D1	180
ALL	R3	TPUC3 [402*, 708*, 058, 471]	R1	D1	180
ALL	R1	TPUC3 [402*, 708*, 058, 471]	R2	D1	180
ALL	R2	TPUC3 [402*, 708*, 058, 471]	R2	D1	180
ALL	R3	TPUC3 [402*, 708*, 058, 471]	R2	D1	180

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- a) only required if **FRA** [667] is run on the same instrument
- b) only required if **DIG** [081] or **AMIK2** [456] are run on the same instrument
- c) only required if **FRA** [667] or **TPUC3** [708*, 402*, 058, 471] are run on the same instrument
- d) only required if **ALBT2** [128, 253*, 153**, 412] is run on the same instrument
- e) only required if **HCYS** [778] is run on the same instrument
- f) only required if **LDL_C** [059], **LDLC3*** [552] or **TRIGB** [783] are run on the same instrument
- g) only required if **LDL_C** [059] is run on the same instrument

D1 = NaOHD; D2 = SMS; D3 = SCCS

*Not available in the US.

** Only available in the US.

2. Reaction cell carry-over on cobas c 311 analyzer

Test	R1 Type	R1 Vol. (µL)	R2 Type	R2 Vol. (µL)	Comment
A1C-3 [881, 851]	D3	130	D3	30	Only required in long HbA1c batches. Please contact your local Roche affiliate for details of the procedure.
TPUC3 [708*, 402*, 058, 471]	D1	150	D1	50	only required if CREJ2 [690, 691, 773, 774] is run on the same instrument

D1 = NaOHD; D2 = SMS; D3 = SCCS

*Not available in the US.

3. Sample probe carry-over on cobas c 311 analyzer

Reagent [Applications]	Detergent Type
TPUC3 [708*, 402*, 058, 471]	SmpCln1
IGA-C [436]	Water
IGG-2 [673, 625*]	SmpCln1
IGM-C [484]	Water
AMIK2 [456]	SmpCln1
TOBR2 [607]	SmpCln1

Please note: **AMPS2** [787, 814, 815, 816, 817, 818, 819] must not be run at the same time as **A1C-3** [881, 851]. After running **A1C-3**, it is necessary to perform a 'wash reaction parts' cycle prior to running **AMPS2**.

*Not available in the US.