SIEMENS

Customer Notification

11219558, Rev. A

February 2015

ADVIA® Chemistry Systems

ADVIA Chemistry 1200, 1800/1650, and 2400 Instructions For Use (IFU) Updates

Reason for Customer Notification

Siemens Healthcare Diagnostics has determined through an internal investigation that the assays listed in Table 1 do not align with the representative data published in the Instructions For Use (IFU) for On-board Stability, Calibration Frequency, and/or Interference. Refer to Tables 2 and 3 for revised On-board Stability, Calibration Frequency, and/or Interference IFU claims.

NOTE: Blank fields in Table 3 indicate that there was no change to the IFU claims.

Risk to Health

ADVIA Chemistry Systems IFU updates do not impact the clinical utility for the assays listed in Table 1. The risk to health is negligible to nonexistent. Siemens is not recommending a review of previously generated results due to this update.

Actions to be Taken by the Customer

- Verify that the current IFU version for methods in use in the laboratory is being followed. Navigate to the Siemens Document Library for the current version of the IFU: https://www.healthcare.siemens.com/doclib.
- For on-board stability and calibration frequency changes, ensure that the ADVIA Chemistry system is programmed to reflect the changes indicated in the IFU. For assistance in implementing these changes, please contact your local Siemens Customer Care Center.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

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Additional Information

Table 1. ADVIA Chemistry Systems IFU Information

Assay	IFU Siemens Material Number (SMN)	IFU Current Revision	Interferences
ALT	10493941	F	Table 2
ALP (AMP)	10493939	F	Table 2
Ammonia	10493945	H*	Table 2
CO2 Liquid	10493973	F	Table 2
GGT	10493990	E	Table 2
hsCRP	10493998	D	Table 2
IP	10494002	F	Table 2
IP_c	10494003	D	Table 2
Lactate	10494006	G*	Table 2
Lithium	10494010	G*	Table 2
Myoglobin	10697501	B	Table 2
Uric Acid_c	10494052	C	Table 2
wrCRP	10494060	F	Table 2
Assay	**IFU Siemens Material Number (SMN)**	**IFU Current Revision**	**Onboard Stability Calibration Frequency**
Acetaminophen	10493934	F	Table 3
ALP (AMP)	10493939	F	Table 3
ALP (DEA)	10493940	F	Table 3
ALT P5P	10493944	G	Table 3
Creatinine_2	10493978	J	Table 3
IGG_2	10494000	E	Table 3
Lithium	10494010	G*	Table 3
Magnesium	10494014	G	Table 3
Magnesium_c	10494015	D	Table 3
Total Bilirubin_2	10494037	F*	Table 3
Total Protein II	10494044	H	Table 3
Transferrin	10494046	F	Table 3
Microalbumin_2	10494053	F	Table 3

* These IFUs are being updated and will be available on the Siemens Document Library once complete.

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Table 2. ADVIA Chemistry Systems IFU Interference Changes

Assay	System	Interferent	Current Claims			New/Revised Claims		
			Interferent Level (mg/dL)	Analyte Concentration	Interference (NSI*=<10%)	Interferent Level (mg/dL)	Analyte Concentration	Interference (NSI=<10%)
Alanine Aminotransferase (without P5P) (ALT)	1200	Hemoglobin	500	25 U/L	NSI	450 (4.5 g/L)	49 U/L	NSI
	1200					500 (5.0 g/L)	516 U/L	NSI
	1800/1650		520	29 U/L	16%	450 (4.5 g/L)	50 U/L	NSI
	1800/1650		520	107 U/L	NSI	500 (5.0 g/L)	534 U/L	NSI
	2400		500	49 U/L	NSI	375 (3.75 g/L)	49 U/L	NSI
	2400					500 (5.0 g/L)	509 U/L	NSI
Alkaline Phosphatase (AMP)	1200	Hemoglobin	125	62 U/L	NSI	125 (1.25 g/L)	62 U/L	-10.2%
	1200					125 (1.25 g/L)	275 U/L	NSI
	1200		250	62 U/L 243 U/L	-19% NSI	250 (2.50 g/L)	62 U/L	-24.6%
	1200					250 (2.50 g/L)	275 U/L	NSI
	1200		375		-23% NSI	250 (2.50 g/L)	62 U/L	-24.6%
	1200					250 (2.50 g/L)	275 U/L	NSI
	1200		500		-35% NSI	250 (2.50 g/L)	62 U/L	-24.6%
	1200					250 (2.50 g/L)	275 U/L	NSI
	1800/1650		250	63 U/L	-11%	125 (1.25 g/L)	69 U/L	-12.1%
	1800/1650					125 (1.25 g/L)	308 U/L	NSI
	1800/1650		525	63 U/L	-27%	250 (2.50 g/L)	69 U/L	-25.7%
	1800/1650					250 (2.50 g/L)	308 U/L	NSI
	2400		500	113 U/L	NSI	125 (1.25 g/L)	71 U/L	-11.3%
	2400					125 (1.25 g/L)	119 U/L	NSI
	2400					250 (2.50 g/L)	71 U/L	-23.1%
	2400					250 (2.50 g/L)	119 U/L	-15.7%

*NSI stands for Non-Significant Interference

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Assay	System	Interferent	Current Claims			New/Revised Claims		
			Interferent Level (mg/dL)	Analyte Concentration	Interference (NSI=<10%)	Interferent Level (mg/dL)	Analyte Concentration	Interferent Level (mg/dL)
Ammonia	1200	Hemoglobin	250	65 ug/dL	-11.0%	375 (3.75g/L)	74.1 ug/dL (43.5 umol/L)	NSI
	1200					500 (5.0 g/L)	120.1 ug/dL (70.5 umol/L)	NSI
	1800/1650		250	60 ug/dL	15.8%	375 (3.75 g/L)	84.6 ug/dL (49.7 umol/L)	NSI
	1800/1650					500 (5.0 g/L)	133.4 ug/dL (78.3 umol/L)	NSI
	2400		500	117.2 ug/dL	NSI	125 (1.25 g/L)	83.6 ug/dL (49.1 umol/L)	NSI
	2400		500	117.2 ug/dL	NSI	125 (1.25 g/L)	123.6 ug/dL (72.6 umol/L)	NSI
Carbon Dioxide Liquid	1200	Conj. Bili	40	18.2 mmol/L	NSI	21.8 (373 µmol/L)	23 mmol/L (23 mEq/L)	NSI
	1200					29 (496 µmol/L)	36 mmol/L (36 mEq/L)	NSI
	1800/1650		40	17.6 mmol/L	NSI	14.5 (248 µmol/L)	22 mmol/L (22 mEq/L)	NSI
	1800/1650					29 (496 µmol/L)	35 mmol/L (35 mEq/L)	NSI
	2400		40	18.3 mmol/L	NSI	14.5 (248 µmol/L)	22 mmol/L (22 mEq/L)	NSI
	2400					22 (376 µmol/L)	36 mmol/L (36 mEq/L)	NSI
Gamma-Glutamyl Transferase (GGT)	1200	Unconj. Bili	25	27 U/L	NSI	10 (171 umol/L)	41 U/L	NSI
	1200					40 (684 µmol/L)	118 U/L	NSI
	1800/1650		30	25 U/L	NSI	10 (171 umol/L)	44 U/L	NSI
	1800/1650					20 (342 µmol/L)	131 U/L	NSI
	2400		25	52 U/L	NSI	13 (222 umol/L)	57 U/L	NSI
	2400					30 (513 umol/L)	140 U/L	NSI

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			Interferent Level (mg/dL)	Analyte Concentration	Interference (NSI=<10%)	Interferent Level (mg/dL)	Analyte Concentration	Interferent Level (mg/dL)
CardioPhase High Sensitivity C-Reactive Protein (hsCRP)	1200	Hemoglobin	500	0.49 mg/L	NSI	500 (5.0 g/L)	0.55 mg/L	NSI
	1200					500 (5.0 g/L)	3.04 mg/L	NSI
	1800/1650		500	0.56 mg/L	NSI	500 (5.0 g/L)	0.57 mg/L	NSI
	1800/1650					500 (5.0 g/L)	2.87 mg/L	NSI
	2400		500	0.57 mg/L	NSI	125 (1.25 g/L)	0.53 mg/L	-10%
	2400					500 (5.0 g/L)	2.92 mg/L	NSI
Inorganic Phosphorus (IP)	1200	Hemoglobin	1000	2.8 mg/dL	NSI	250 (2.5 g/L)	2.8 mg/dL (0.89 mmol/L)	NSI
	1200					1000 (10.0 g/L)	6.4 mg/dL (2.08 mmol/L)	NSI
	1800/1650		1000	2.8 mg/dL	NSI	500 (5.0 g/L)	2.7 mg/dL (0.88 mmol/L)	NSI
	1800/1650					1000 (10.0 g/L)	6.4 mg/dL (2.07 mmol/L)	NSI
	2400		1000	2.8 mg/dL	NSI	250 (2.5 g/L)	2.5 mg/dL (0.81 mmol/L)	NSI
	2400					250 (2.5 g/L)	4.2 mg/dL (1.36 mmol/L)	NSI
Inorganic Phosphorus, Concentrated Reagents (IP_c)	1200	Hemoglobin	250	3.6 mg/dL	NSI	250 (2.5 g/L)	3.6 mg/dL (1.16 mmol/L)	NSI
	1800/1650		250	3.4 mg/dL	NSI	250 (2.5 g/L)	3.4 mg/dL (1.10 mmol/L)	NSI
	2400		500	3.7 mg/dL	NSI	250 (2.5 g/L)	2.6 mg/dL (0.84 mmol/L)	NSI
	2400					250 (2.5 g/L)	4.4 mg/dL (1.42 mmol/L)	NSI

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			Interferent Level (mg/dL)	Analyte Concentration	Interference (NSI=<10%)	Interferent Level (mg/dL)	Analyte Concentration	Interferent Level (mg/dL)
Lactate	1200	Conj. Bili	25	14 mg/dL	NSI	9.2 (157.4 umol/L)	12.39 mg/dL (1.4mmol/L)	NSI
	1200					9.2 (157.4 umol/L)	24.29 mg/dL (2.7 mmol/L)	NSI
	1200	Unconj. Bili	18.75	14 mg/dL	NSI	3.75 (64.1 umol/L)	12.59 mg/dL (1.4mmol/L)	NSI
	1200					7.5 (128.3 umol/L)	24.49 mg/dL (2.7 mmol/L)	NSI
	1800/1650	Conj. Bili	25	45 mg/dL	NSI	6.9 (118.0 umol/L)	12.43 mg/dL (1.4 mmol/L)	NSI
	1800/1650					9.2 (157.4 umol/L)	24.17 mg/dL (2.7 mmol/L)	NSI
	1800/1650	Unconj. Bili	25	45 mg/dL	NSI	3.75 (64.1 umol/L)	12.4 mg/dL (1.4 mmol/L)	NSI
	1800/1650					7.5 (128.3 umol/L)	24.27 mg/dL (2.7 mmol/L)	NSI
	2400	Conj. Bili	25	12 mg/dL	NSI	6.9 (118.0 umol/L)	12.23 mg/dL (1.4 mmol/L)	NSI
	2400					9.2 (157.4 umol/L)	24.13 mg/dL (2.7 mmol/L)	NSI
	2400	Unconj. Bili	25	12 mg/dL	NSI	3.75 (64.1 umol/L)	12.27 mg/dL (1.4 mmol/L)	NSI
	2400					7.5 (128.3 umol/L)	24.1 mg/dL (2.7 mmol/L)	NSI
Lithium	1200	TRIG	1000	1 mmol/L	NSI	1000 (11.3 mmol/L)	~1 mmol/L	NSI
	1800/1650		500	1 mmol/L	NSI	500 (5.65 mmol/L)	~1 mmol/L	NSI
	2400		1000	1 mmol/L	NSI	250 (2.83 mmol/L)	~1 mmol/L	NSI
	2400	Hemoglobin	500 (50.0 g/L)	1 mmol/L	NSI	500 (5.0 g/L)	~1 mmol/L	NSI
Myoglobin	2400	Intralipid	750	51.8 ng/mL	NSI	562.5 (6.4 mmol/L)	51.8 ng/mL (µg/L)	NSI
	2400		1000	51.8 ng/mL	13.5%	750 (8.4 mmol/L)	51.8 ng/mL (µg/L)	13.5%

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			Interferent Level (mg/dL)	Analyte Concentration	Interference (NSI=<10%)	Interferent Level (mg/dL)	Analyte Concentration	Interferent Level (mg/dL)
Uric Acid, Concentrated Reagents	1200	Conj. Bili	30	3.03 mg/dL	NSI	6.25 (107 µmol/L)	3.5 mg/dL (205 µmol/L)	NSI
	1200					6.25 (107 µmol/L)	10.3 mg/dL (615 µmol/L)	NSI
	1800/1650		30	3.03 mg/dL	NSI	6.25 (107 µmol/L)	3.4 mg/dL (202 µmol/L)	NSI
	1800/1650					6.2 (107 µmol/L)	10.2 mg/dL (608 µmol/L)	NSI
	2400		30	3.11 mg/dL	NSI	6.25 (107 µmol/L)	3.4 mg/dL (202 µmol/L)	NSI
	2400					6.25 (107 µmol/L)	10.2 mg/dL (606 µmol/L)	NSI
Wide Range C-Reactive Protein (wrCRP)	1200	Hemoglobin	1000	10 mg/L	NSI	500 (5.0 g/L)	0.093 mg/dL (0.93 mg/L)	-10.8%
	1200					500 (5.0 g/L)	1.083 mg/dL (10.8 mg/L)	NSI
	1800/1650		694	0.68 mg/L	NSI	500 (5.0 g/L)	0.11mg/dL (1.1 mg/L)	NSI
	1800/1650					500 (5.0 g/L)	1.097 mg/dL (10.97 mg/L)	NSI
	2400		1000	1.02 mg/L	NSI	250 (2.5g/L)	0.089 mg/dL (0.89 mg/L)	NSI
	2400					500 (5.0 g/L)	1.087 mg/dL (10.87 mg/L)	NSI

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Table 3. ADVIA Chemistry Systems IFU Onboard Stability Changes

Assay	System	Reagent Container Insert	Current Claims		New/Revised Claims	
			Onboard Stability	Calibration Frequency	Onboard Stability	Calibration Frequency
Acetaminophen	1200	Without RCI	42 days	7 days	14 days	7 days
	1800/1650		14 days	7 days	10 days	7 days
	2400		14 days	7 days	10 days	5 days
Alanine Aminotransferase (with P5P)	1200	Without RCI	20 days		20 days	
	1800/1650		30 days		30 days	
	2400		30 days		12 days	
Alkaline Phosphatase (ALPDEA)	1200	With RCI	None		30 days	None
	1800/1650				40 days	
	2400				40 days	
	1200	Without RCI	30 days		11 days	
	1800/1650		40 days		8 days	
	2400		40 days		10 days	
Alkaline Phosphatase (AMP)	1200	With RCI	None		6 days	None
	1800/1650				9 days	
	2400				8 days	
	1200	Without RCI	7 days		4 days	
	1800/1650		10 days		4 days	
	2400		10 days		4 days	
Creatinine or Creatinine_2 (Jaffe)	1200	With RCI	20 days	3 days	20 days	3 days
	1800/1650		45 days	7 days	20 days	3 days
	2400		45 days	7 days	12 days	3 days
	1200	Without RCI	12 days	3 days	9 days	3 days
	1800/1650		12 days	3 days	9 days	3 days
	2400		12 days	3 days	6 days	3 days
Immunoglobulin G_2	1200	Without RCI	60 days	60 days	60 days	60 days
	1800/1650		60 days	60 days	60 days	60 days
	2400		60 days	60 days	30 days	30 days
Lithium	1200	With RCI	45 days	7 days	30 days	7 days
	1800/1650		60 days	7 days	21 days	4 days
	2400		60 days	7 days	20 days	7 days
	1200	Without RCI	30 days	7 days	30 days	6 days
	1800/1650		30 days	7 days	30 days	6 days
	2400		30 days	7 days	27 days	3 days

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Assay	System	Reagent Container Insert	Current Claims		New/Revised Claims	
			Onboard Stability	Calibration Frequency	Onboard Stability	Calibration Frequency
Magnesium	1200	With RCI	10 days	10 days	7 days	4 days
	1800/1650		21 days	21 days	7 days	4 days
	2400		21 days	21 days	10 days	7 days
Magnesium, Concentrated Reagents	1200	With RCI	10 days	10 days	7 days	7 days
	1800/1650		21 days	21 days	10 days	10 days
	2400		21 days	21 days	14 days	14 days
Total Bilirubin_2	1200	Without RCI	60 days	60 days	30 days	30 days
Total Protein II	1200	With RCI	60 days	30 days	60 days	30 days
	1800/1650		60 days	30 days	60 days	30 days
	2400		60 days	30 days	45 days	30 days
	1200	Without RCI	21 days	21 days	21 days	12 days
	1800/1650		30 days	21 days	21 days	21 days
	2400		30 days	30 days	17 days	17 days
Transferrin	1200	Without RCI	14 days	14 days	14 days	14 days
	1800/1650		30 days	14 days	30 days	14 days
	2400		40 days	40 days	21 days	21 days
Microalbumin_2 (µALB_2)	1200	With RCI	60 days	30 days	60 days	30 days
	1800/1650		60 days	60 days	60 days	60 days
	2400		60 days	60 days	45 days	45 days
	1200	Without RCI	60 days	20 days	60 days	19 days
	1800/1650		60 days	60 days	60 days	60 days
	2400		60 days	20 days	40 days	14 days

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