

Test Definition Enhancements

In an ongoing effort to keep our customers informed, Siemens Healthineers is providing this supplement describing updates to the Atellica® CH Analyzer test definitions. The new test definition enhancements are available in software version 1.27.

The CH Analyzer, some assays, and some features are not available for use in all countries. Product availability varies from country to country based on regulatory requirements. Contact the local regulatory representative for CH Analyzer and assay availability.

NOTE: The operator should review CH Analyzer Test Definition Enhancements for every software update, as operator-modified test definitions may not update with the newest test definition information. If test definitions do not update after software installation, select **Restore Defaults** and then select **Save**.

For questions about this information, contact the local technical support provider.

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Mitigation Updates

Atellica Solution software versions 1.25.1 and higher improve carryover mitigations to the following assays to address Urgent Medical Device Correction (UMDC) ACHC21-14.A.US and Urgent Field Safety Notices (UFSN) ACHC21-14.A.OUS:

- UCFP

Atellica Solution software versions 1.25.2 and higher improve carryover mitigations to the following assays to address UMDC ACHC22-02.A.US and UFSN ACHC22-02.A.OUS:

- A1c_E/A1c_H
- CA_2
- Fruc
- LITH_2

Atellica Solution software versions 1.25.4 and higher improve carryover mitigations to the following assays to address UMDC ACHC22-06.A.US and UFSN ACHC22-06.A.OUS:

- Iron_2

Atellica Solution software versions 1.27 and higher improve carryover mitigations to the following assays to address UMDC ACHC23-01.A.US and UFSN ACHC23-01.A.OUS:

- DLDL
- TP

- Trig
- Trig_2

New Test Definition Enhancements

The following table contains the new test definition changes to available assays:

Assay	Test definition version	Enhancement
ALT	1.91	Updates the substrate depletion flag
ALTPLc	1.5	Updates the substrate depletion flag
AST	1.91	Updates the substrate depletion flag
ASTPLc	1.5	Updates the substrate depletion flag
JALT ¹	1.1	Adds C0-adjust auto-acceptance criteria
JAST ¹	1.1	Adds C0-adjust auto-acceptance criteria
Lac_2	1.2	Supports measuring interval adjustment
LITH_2	1.1	Supports an updated LITH_2 reagent pack
Mtx	1.5	Supports measuring interval adjustment

¹ Japan only.

New Test Definition Releases

The following table contains the new test definitions:

Assay	Test definition version
CHE_2	1.0
Gbp	1.0
Hapt_2	1.0
Iron3	1.0
JKL-6 ¹	1.0

Assay	Test definition version
Lac_3	1.0
TP_2	1.0

¹ Japan only.

Test Definition Record

The following table contains a record of the latest test definition changes for available assays and new test definition enhancements:

Assay	Test definition version	Enhancement	Notification document
μALB_2	1.5	Allows measuring interval extension	11472896 Rev. 07
6AM	1.2	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
A1c_3	1.7	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
A1c_E	1.2	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
A1c_H	1.0	—	11472896 Rev. 06
AAG	1.5	Allows measuring interval extension	11472896 Rev. 07
AAT	1.3	Allows measuring interval extension	11472896 Rev. 07
ACE	1.0	—	11472896 Rev. 04
Acet	1.2	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
Alb	1.2	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
AlbP	1.2	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
Aldo	1.2	Updates the Extended Measuring Interval from 10x to 2x	11472896 Rev. 07

Assay	Test definition version	Enhancement	Notification document
ALP_2c	1.1	Allows Open Channel cloning	Atellica Solution 1.17 Release Notes (11316897)
ALT	1.91	Updates the substrate depletion flag	11472896 Rev. 09
ALTPLc	1.5	Updates the substrate depletion flag	11472896 Rev. 09
Amik	1.3	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
Amm	1.6	Changes Lot Calibration to 30 days	11472896 Rev. 05
Amp1K	1.4	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
Amp300	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
Amp500	1.4	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
AMY_2	1.1	Allows Open Channel cloning	Atellica Solution 1.17 Release Notes (11316897)
Amylas	1.2	Allows Open Channel cloning	Atellica Solution 1.17 Release Notes (11316897)
APO A1	1.4	Allows measuring interval extension	11472896 Rev. 07
APO B	1.4	Allows measuring interval extension	11472896 Rev. 07
ASO_2	1.1	Allows Open Channel cloning	Atellica Solution 1.17 Release Notes (11316897)
AST	1.91	Updates the substrate depletion flag	11472896 Rev. 09
ASTPLc	1.5	Updates the substrate depletion flag	11472896 Rev. 09

Assay	Test definition version	Enhancement	Notification document
B2M	1.3	Updates Pack Calibration and OBS	11472896 Rev. 01
Bnz200	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
Bnz300	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
Brb200	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
Brb300	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
Bupn	1.2	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
C3	1.4	Allows measuring interval extension	11472896 Rev. 07
C4	1.5	Allows measuring interval extension	11472896 Rev. 07
Ca	1.3	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
CA_2	1.3	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
Caff	1.3	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
Carb	1.4	Allows measuring interval extension	11472896 Rev. 07
Che	1.1	Allows Open Channel cloning	Atellica Solution 1.17 Release Notes (11316897)
CHE_2	1.0	—	11472896 Rev. 09
Chol_2	1.2	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04

Assay	Test definition version	Enhancement	Notification document
Cerul	1.3	Updates Test Count and Fill Volume	11472896 Rev. 03
CK_L	1.2	Updates the Extended Measuring Interval from 6x to 30x	11472896 Rev. 07
CK-MB	1.0	—	11472896 Rev. 03
Cl	1.4	Updates the analyte scale factor	11472896 Rev. 07
CO2_c	1.2	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
Coc150	1.5	Updates Pack Calibration	11472896 Rev. 01
Coc300	1.5	Updates Pack Calibration	11472896 Rev. 01
Cop	1.0	—	11472896 Rev. 02
Crea_2	1.5	Updates mix speeds and adds an error flag	11472896 Rev. 07
CRP_2	1.4	Allows measuring interval extension	11472896 Rev. 07
CYSC_2	1.3	Allows measuring interval extension	11472896 Rev. 07
D_HDL	1.3	Updates OBS to 89 days	11472896 Rev. 05
DBil_2	1.3	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
Dgn	1.4	Allows measuring interval extension	11472896 Rev. 07
DLDL	1.2	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
eCKMB	1.0	—	Atellica Solution 1.19 Release Notes (11470124)
ECre_2	1.5	Updates an error flag.	11472896 Rev. 07
ECre3	1.1	Corrects urine measuring interval	11472896 Rev. 08

Assay	Test definition version	Enhancement	Notification document
ETG1K ¹	1.4	Changes Lot Calibration from 161 days to 150 days	11472896 Rev. 03
ETG500 ¹	1.4	Changes Lot Calibration from 161 days to 150 days	11472896 Rev. 03
ETOH	1.3	Updates Pack Calibration to 1 day (C0 adjust)	11472896 Rev. 05
Fen	1.0	—	Atellica Solution 1.19 Release Notes (11470124)
Fen2	1.0	—	11472896 Rev. 05
FLCK	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
FLCL	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
Fruc	1.2	Updates serum and plasma expected ranges and adds C0 correlation factor	11472896 Rev. 05
G6PDH	1.2	Updates Lot Cal to 180 days and OBS to 90 days	11472896 Rev. 07
Gbp	1.0	—	11472896 Rev. 09
Gent	1.5	Allows measuring interval extension	11472896 Rev. 07
GGT	1.2	Updates OBS to 6 days	11472896 Rev. 08
GluH_3	1.4	Optimizes mix speeds and adds Abnormal Assay flag	11472896 Rev. 06
GluO	1.3	Updates OBS to 51 days	11472896 Rev. 05
Hapt	1.5	Allows measuring interval extension	11472896 Rev. 07
Hapt_2	1.0	—	11472896 Rev. 09
HDLC	1.0	—	11472896 Rev. 07

Assay	Test definition version	Enhancement	Notification document
HFABP	1.1	Changes P1 and P2 fill volumes to 20.12 mL	11472896 Rev. 05
HIL	1.7	Updates HIL donor assay syntax	11472896 Rev. 04
hsCRP	1.3	Allows measuring interval extension	11472896 Rev. 07
IgA_2	1.5	Updates the Extended Measuring Interval from 10x to 15x and allows measuring interval extension	11472896 Rev. 07
IgG_2	1.4	Allows measuring interval extension	11472896 Rev. 07
IgM_2	1.6	Modifies the extended range to 10x	11472896 Rev. 08
IP	1.4	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
Iron_2	1.3	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
Iron3	1.0	—	11472896 Rev. 09
K	1.5	Updates the analyte scale factor	11472896 Rev. 07
Lac	1.3	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
Lac_2	1.2	Supports measuring interval adjustment	11472896 Rev. 09
Lac_3	1.0	—	11472896 Rev. 09
LDLC	1.0	—	11472896 Rev. 07
LDLP	1.8	Updates HIL donor assay syntax	11472896 Rev. 04
LEV	1.1	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04

Assay	Test definition version	Enhancement	Notification document
Li	1.1	Allows Open Channel cloning	Atellica Solution 1.17 Release Notes (11316897)
LIDO	1.4	Allows measuring interval extension	11472896 Rev. 07
Lip	1.2	Allows Open Channel cloning	Atellica Solution 1.17 Release Notes (11316897)
LITH_2	1.1	Supports an updated LITH_2 reagent pack	11472896 Rev. 09
Lp(a)	1.4	Allows measuring interval extension	11472896 Rev. 07
LSD	1.3	Extends Lot Calibration to 180 days	11472896 Rev. 02
LTG	1.2	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
Mdn150	1.5	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
Mdn300	1.5	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
MetMtb	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
Mg	1.3	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
MPA	1.2	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
Mthaq	1.3	Extends Lot Calibration to 180 days	11472896 Rev. 02
Mtx	1.5	Supports measuring interval adjustment	11472896 Rev. 09
Na	1.3	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04

Assay	Test definition version	Enhancement	Notification document
NAPA	1.4	Allows measuring interval extension	11472896 Rev. 07
Op2000	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
Op300	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
OXY100	1.2	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
OXY300	1.2	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
PAmy	1.2	Allows Open Channel cloning	Atellica Solution 1.17 Release Notes (11316897)
PAMY_2	1.2	Adds plasma claim	11472896 Rev. 04
Pcp25	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
Phnb	1.4	Allows measuring interval extension	11472896 Rev. 07
Phny	1.5	Allows measuring interval extension	11472896 Rev. 07
Ppx300	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
PreAlb	1.4	Allows measuring interval extension	11472896 Rev. 07
PROC	1.4	Allows measuring interval extension	11472896 Rev. 07
q1EDDP	1.0	—	11472896 Rev. 03
q3EDDP	1.0	—	11472896 Rev. 03
qTRAM	1.0	—	11472896 Rev. 05
RF	1.5	Allows measuring interval extension	11472896 Rev. 07

Assay	Test definition version	Enhancement	Notification document
s1EDDP	1.0	—	11472896 Rev. 03
s3EDDP	1.0	—	11472896 Rev. 03
Sal	1.3	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
sBnz	1.3	Adds HIL thresholds	11472896 Rev. 04
sBrb	1.2	Adds HIL thresholds	11472896 Rev. 04
STFR	1.7	Converts to LOGIT calibration	11472896 Rev. 08
sTRAM	1.0	—	11472896 Rev. 05
SVTCR	1.3	Extends Lot Calibration to 180 days	11472896 Rev. 02
SVTNT	1.3	Extends Lot Calibration to 180 days	11472896 Rev. 02
SVTOX	1.3	Extends Lot Calibration to 180 days	11472896 Rev. 02
SVTPH	1.3	Extends Lot Calibration to 180 days	11472896 Rev. 02
SVTSG	1.4	Extends Lot Calibration to 180 days	11472896 Rev. 02
TACR	1.2	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
TBA	1.0	—	Atellica Solution 1.19 Release Notes (11470124)
TBil_2	1.4	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
TCA	1.3	Adds HIL thresholds	11472896 Rev. 04
Thc100	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
Thc20	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)

Assay	Test definition version	Enhancement	Notification document
Thc50	1.3	Restricts the extension of measuring interval	Atellica Solution 1.18 Release Notes (11469756)
Theo	1.4	Allows measuring interval extension.	11472896 Rev. 07
TIBC	1.3	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
Tob	1.5	Allows measuring interval extension	11472896 Rev. 07
TP	1.7	Updates OBS to 90 days	11472896 Rev. 05
TP_2	1.0	—	11472896 Rev. 09
Trf	1.4	Allows measuring interval extension	11472896 Rev. 07
Trig	1.2	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
Trig_2	1.1	Allows Open Channel cloning	Atellica Solution 1.17 Release Notes (11316897)
UA	1.3	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
UCFP	1.2	Update the number of tests and allows measuring interval extension	11472896 Rev. 07
UN	1.0	—	Atellica Solution 1.13 Release Notes (11314713)
UN_c	1.9	Updates OBS to 90 days	11472896 Rev. 05
UPro	1.4	Adds common/SI unit syntax and conversion factor	11472896 Rev. 04
Vanc	1.5	Allows measuring interval extension	11472896 Rev. 07
VPA	1.5	Allows measuring interval extension	11472896 Rev. 07

Assay	Test definition version	Enhancement	Notification document
wrCRP	1.4	Allows measuring interval extension	11472896 Rev. 07
Xtc300	1.5	Updates Pack Calibration	11472896 Rev. 01
Xtc500	1.6	Updates Pack Calibration	11472896 Rev. 01
Zn	1.0	—	11472896 Rev. 02

¹ Not available in US

Japan Only Test Definitions

The following table contains a record of the latest test definition changes for assays available only in Japan:

Assay	Test definition version	Enhancement	Notification document
ALTJ	1.4		11472896 Rev. 07
AMYJ	1.1	Adds the region code	Atellica Solution 1.17 Release Notes (11316897)
ASTJ	1.4	Updates mix speeds	11472896 Rev. 07
CKJ_L	1.1	Adds the region code	Atellica Solution 1.17 Release Notes (11316897)
EcreJ	1.4	Updates an error flag	11472896 Rev. 07
GGTJ	1.1	Adds the region code	Atellica Solution 1.17 Release Notes (11316897)
JALB	1.2	Adds onboard SH storage values for the calibrator	Atellica Solution 1.18 Release Notes (11469756)
JALT	1.1	Adds C0-adjust auto-acceptance criteria	11472896 Rev. 09
JALP	1.2	Adds onboard SH storage values for the calibrator	Atellica Solution 1.18 Release Notes (11469756)
JAST	1.1	Adds C0-adjust auto-acceptance criteria	11472896 Rev. 09
JBUN	1.2	Adds substrate depletion check	11472896 Rev. 07

Assay	Test definition version	Enhancement	Notification document
JCHE	1.2	Adds onboard SH storage values for the calibrator	Atellica Solution 1.18 Release Notes (11469756)
JCK_L	1.0	—	11472896 Rev. 01
JCRP	1.1	Adds above range auto-dilution, restricts assay range modification, and updates the calibration scheme to use onboard saline	Atellica Solution 1.19 Release Notes (11470124)
JEcre	1.0	—	11472896 Rev. 08
JFE	1.0	—	11472896 Rev. 03
JGGT	1.0	—	11472896 Rev. 07
JHDL	1.0	—	11472896 Rev. 05
JIP	1.2	Adds onboard SH storage values for the calibrator	Atellica Solution 1.18 Release Notes (11469756)
JKL-6	1.0	—	11472896 Rev. 09
JLAP	1.1	Adds the region code	Atellica Solution 1.17 Release Notes (11316897)
JLDL	1.0	—	11472896 Rev. 05
JPL	1.3	Adds onboard SH storage values for the calibrator	Atellica Solution 1.18 Release Notes (11469756)
JTCHO	1.0	—	11472896 Rev. 05
JTG	1.2	Adds onboard SH storage values for the calibrator	Atellica Solution 1.18 Release Notes (11469756)
LDLPJ	1.1	Adds the region code	Atellica Solution 1.17 Release Notes (11316897)
PAMYJ	1.2	Adds plasma claim	11472896 Rev. 04

China Only Test Definitions

The following table contains a record of the latest test definition changes for assays available only in China:

Assay	Test definition version	Enhancement	Notification document
5NT	1.0	—	11472896 Rev. 03
ADA	1.0	—	11472896 Rev. 03
AFU	1.0	—	11472896 Rev. 03
ALBCN	1.0	—	11472896 Rev. 03
CG	1.0	—	11472896 Rev. 03
CK-MB	1.0	—	11472896 Rev. 03
FHCY	1.0	—	11472896 Rev. 05
FTBA	1.0	—	11472896 Rev. 03
GSP	1.0	—	11472896 Rev. 03
HBDH	1.0	—	11472896 Rev. 03
HFABP	1.0	—	11472896 Rev. 03
NEFA	1.0	—	11472896 Rev. 03
NGAL	1.0	—	11472896 Rev. 03
TBA_C	1.0	—	11472896 Rev. 03

Trademark Information

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