

Cc to Chairman Medical Board and relevant Head of Departments

Atellica[®] Solution

Atellica CH 930 Analyzer – Three issues identified in Atellica Solution Software V 1.19.2 and below

Our records indicate that your facility may have received the following product:

Table 1. Atellica[®] Solution Affected Product:

Product	Siemens Material Number (SMN)
Atellica CH 930 Analyzer	11067000

Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of issues with the Atellica CH 930 Analyzer listed in Table 1 above, installed with Atellica Solution software (SW) versions V1.19.2 or lower and to provide instructions on actions that your laboratory must take. These issues will be fixed in software version 1.20.

Siemens Healthcare Diagnostics Inc. has confirmed three issues:

Assays	Issue observed
	The test definitions allow for 20 day pack calibration interval instead of
	15 days. Based on Siemens Healthineers' investigation, there is no
Issue #1: Ecstasy (SMN#	impact to the performance of the Ecstasy assay due to the extended
11097518)	pack calibration.
	The test definition allows for a 185 day lot calibration interval instead of
	181 days. Based on Siemens Healthineers' investigation, there is no
Issue #2: Total Protein	impact to the performance of the Total Protein assay due to the
(SMN# 11097604)	extended lot calibration.
	The test definition allows for a 30 days Onboard Stability (OBS) interval
	instead of 21 days. Based on Siemens Healthineers' investigation, there
	is no impact to performance of the Rheumatoid Factor (RF) assay
	concentrations of approximately 7 IU/mL and 45 IU/mL due to the
Issue #3: Rheumatoid Factor	extended OBS. At a RF concentration of 75 IU/mL, a maximum
(SMN# 11097618)	decrease in recovery of 9% was observed due to the extended OBS.

Risk to Health

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Ecstasy and Total Protein	The risk to health due to this issue is negligible. There is no impact to assay performance for Ecstasy and Total Protein.
Rheumatoid Factor	The risk to health due to this issue is negligible. Patient samples with results above the reference interval for Rheumatoid Factor would have similar clinical interpretation. Mitigations include correlation to clinical history and presentation as well as to other laboratory diagnostic evaluation. Siemens Healthineers' is not recommending a review of previously generated results.

Actions to be Taken by the Customer

Issue #1: Atellica CH 930 Ecstasy (Xtc300 & Xtc500) Pack Calibration Workaround

- 1. Load Atellica CH Ecstasy (Xtc300/500) reagent packs onto the CH Analyzer. Refer to the Atellica Solution Online Help Section *Loading CH Reagents* for instructions.
- 2. Immediately perform a lot calibration. Refer to the Atellica Solution Online Help Section *Creating Assay Reagent Lot Calibration Orders* for instructions.
- Upon completion and acceptance of the lot calibration, record the date and time the calibration was performed by navigating to Calibration > Calibration Results and filtering on the appropriate assay and analyzer. (Reference Figure 1. Calibration Results Screen)
- 4. If the test count in the well reaches zero before the 15 days elapses no additional action is required.
- If the test count in the well does not reach zero before 15 days elapses, 15 days after the lot calibration was performed, a pack calibration must be performed. Refer to the Atellica Solution Online Help Section *Creating Assay Reagent Pack Calibration Orders* for instructions.
- 6. Upon completion and acceptance of the pack calibration, record the date and time the pack calibration was performed by navigating to **Calibration > Calibration Results** and filtering on the appropriate assay.
- 7. Perform steps 5 6 until either the well has zero tests left or has insufficient tests to perform another pack calibration upon expiration.
- 8. When the system switches wells, the already established lot calibration will be applied to the newly punctured well. When this happens, Navigate to **Inventory > Reagent Overview** select the onboard Xtc pack and under Reagent Details record the date and time that the second well was punctured. Fifteen days after the second well is punctured, a pack calibration must be performed. This process must be repeated until the well test count reaches zero.

Figure 1. Calibration Results Screen

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₽ A System		HHH Samples		inventory		Calibrat	ion	ac 🔺	Patient Or	ders	¥. Worklist		Maintenance	G Setup	
Calibration Overview	Create	e Calibration	Orders	Calibration Res	ults	Calibrator De	finitions	IMT Calibration							
Filters	• 7/2														
Analyzer	•	Assay	Analyzer	Cal Lot	Result	Date 🔻	Cal Status	Cal Exp	Туре	Reagent Lot	Pack/Well	Flags			
Assay		✓ Xtc300	CM00295	M2	7/17/20	19 9 57 09 AM	Valid	8/6/2019 9 48 05 AM	Pack	190020	00936 Well 1				
Reagent Lot		✓ Xtc300	CM00295	M2	7/17/20	19 9:30:27 AM	Valid	9/15/2019 9:21:35 AM	Lot	190020	00936:Well 1				
Reagent Pack	•	_													
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Issue #2: Atellica CH 930 Total Protein (TP) Lot Calibration Workaround

- 1. Navigate to **Calibration > Calibration Results** and select the TP Assay. (Reference Figure 1. Calibration Results Screen)
- 2. Record the date and time of the TP Lot calibration. A lot calibration will need to be performed 181 days from the recorded date.

Issue #3: Atellica CH 930 Rheumatoid Factor (RF) Onboard Stability Workaround

Reagent loading and Onboard Stability Recording

- 1. Load Atellica CH Rheumatoid Factor (RF) reagent packs onto the CH Analyzer. Refer to the Atellica Solution Online Help Section *Loading CH Reagents* for instructions.
- 2. Navigate to **Inventory > Reagent Overview** and select RF to view the Reagent Details. (Reference Figure 2. Reagent Overview Screen)
- 3. Record the date and time the reagent pack well(s) is opened. Please check status of each well in "Reagent Details".
 - a. Condition #1: If both wells are punctured upon loading the reagent pack and/or the Atellica Software Version is <1.19, the entire pack must be unloaded after 21 days. Refer to the Atellica Solution Online Help Section *Unloading Reagents* for instructions.
 - b. Condition #2: If only the first well is punctured upon loading the reagent pack and the Atellica software version is 1.19 and greater, please follow steps below for

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manually disabling a reagent pack well to utilize the second well. Once the second well is open for 21 days the entire pack must be unloaded from the CH analyzer.

c. **NOTE:** If either Well 1 or Well 2 test count reaches zero before the 21 onboard stability expires, no additional action is required.

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Rea	gent Overview	Reager	nt Loader	Reagent Needs	Supplier	s Overview	Reagent Lot Comparison	Cal-QC Sto	rage Inventory	Cal-QC Needs				
0 c.	P2-20										•	3		
Reagen	5									Reagent [AI Details	C-P2-20 (A-P1-28		
	Reagent	Inventory	Onboard Stability	Sequence	Calibration Status	Calibration	Cal Type In QC Use Status	Lot	Cal Eligibility		85215	02021		
	ALT	413	10 d 3 h	07333 / 06678		10 d 3 h	Lot	260715	Pack		Name Lot ID	RF 123456		
	ALT	850	39 d 13 h	07473 / 06876		17 d 18 h	Lot	260715	Lot and Pack		Pack Location	CH Reagent Compartment 1		
	C02_c	729	4d3h	01053		0 d 0 h		190003	Pack		Position Status	46 idle		
	Mg	391	39 d 13 h	03631/00342		0 d 0 h		280678	Lot and Pack		Sequence Number Paired Pack	85215		
	RF	180	89 d 23 h	85215 / 02021		-		123458	Lot and Pack		Count Remaining Onboard Stability	180 10/22/2019 10:14:43 AM		
	RPC1	418	56 d 13 h	00686 / 00690				190029			Lot Expiration	01/31/2020 11:59:59 PM		
	RPC2	418	49 d 13 h	03900 / 03853		(44)		190016			alibration Expiration			
	710	1050	04*35	02441 (02627		0.4.13.5	1.00	100520	Let and Dauk	Test C	ount 90	Ready		
	19	1850	80.131	03441702627	-	80131	LOL	280668	Lot and Pack		Time Punctured	07/24/2019 10:17:18 AM		
	WBA	276	142 d 19 h	01017		155		190011			Calibrate Lot	Calibrate Pack		
	Xttc	100	89 d 23 h	00936 / 01024		-		190020	Lot and Pack	Test C	ount 90	2 Sealed		
											Calibrate Lot	Calibrate Pack		

Figure 2. Reagent Overview Screen

Manually Disabling a Reagent Pack Well or Unloading a Reagent Pack from the CH Analyzer

For Atellica software versions 1.19 and greater:

- 1. Log in as Lab Manager
- Navigate to Inventory > Reagent Overview (Reference Figure 3. Reagent Overview Screen)
- 3. Locate and select the RF reagent.
- 4. Select the P1 Reagent Pack in Reagent Details
- 5. Select Disable Well 1

For Atellica Software Versions <1.19:

- 1. Remove the Reagent Pack from the CH Analyzer. Refer to the Atellica Solution Online Help Section *Unloading Reagents* for instructions.
- 2. Discard the reagent pack.

Figure 3. Reagent Overview Screen

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C-P2	-20										Passa	Al Notella	01220	() A-P1-20
i i	Reagent	Inventory	Onboard Stability	Sequence	Calibration Status	Calibration	Cal Type In Use	QC Status	Lot	Cal Eligibility	, integr	85215	02021	1
	ALT	413	10 d 3 h	07333 / 06878		10 d 3 h	Lot		280715	Pack		Name	RF	
	ALT	850	39 d 13 h	07473 / 06876		17 d 18 h	Lot		280715	Lot and Pack		Pack Location Position	CH Reagent Compa 46	rtmen
	CO2_c	729	4d3h	01053		0 d 0 h			190003	Pack		Status	Idle	
	Mg	391	39 d 13 h	03631/00342		OdOh			280678	Lot and Pack		Sequence Number Paired Pack	85215 02021	
	RF	180	89 d 23 h	85215 / 02021		- 11-1			123456	Lot and Pack		Count Remaining Onboard Stability	180 10/22/2019 10:14:43	АМ
	RPC1	418	56 d 13 h	00686 / 00690					190029			Lot Expiration	01/31/2020 11 59:59	PM
	RPC2	418	49 d 13 h	03900 / 03853		# 2			190016			Well		
	TP	1850	8d13h	03441/02627		8 d 13 h	Lot		280568	Lot and Pack	Te	st Count 🖗	Ready	
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	VIDA	270	142 0 19 0	01017		-			190011			Well	2	
	Mic	100	89 d 23 h	00936 / 01024		223			190020	Lot and Pack	Te	st Count 60	Sealed	
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iroup I	by reagent			Disable Well 1	Disable	Reagent Pack	Dis	able Reagen	Lot	Unload			Satura	
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- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse health events associated with the product listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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FIELD CORRECTION EFFECTIVENESS CHECK

Atellica® CH 930 Analyzer

Multiple issues identified in Atellica Solution Software V 1.19.2 and below

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) ASI19-04.A.OUS, dated August 2019 regarding "Atellica[®] CH 930 Analyzer Three issues identified in Atellica Solution Software V 1.19.2 and below".

Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

Name of person completing questionnaire:

Title:	
Institution:	Instrument Serial Number:
Street:	
City:	State:
Phone:	Country:

If you have any questions, contact your local Siemens technical support representative.