

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

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## **Risk to Health**

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.
- 3. 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.
- 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.

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Calibration Overview	Create Calibratio	n Orders	Calibration Res	ults Calibrator	Definitions	IMT Calibration						
ters	<b>X</b>											
alyzer	Assay	Analyzer	Cal Lot	Result Date <b>v</b>	Cal Status	Cal Exp	Туре	Reagent Lot	Pack/Well	Flags		
say	✓ Xtc30	0 CM00295	M2	7/17/2019 9:57:09 AM	Valid	8/6/2019 9:48:05 AM	Pack	190020	00936:Well 1		1	
agent Lot		0 CM00295		7/17/2019 9:30:27 AM	Valid			190020	00936:Well 1			
	• × XtC30	0 CM00295	MZ	//1//2019 9:30:27 AM	Valid	9/15/2019 9:21:35 AM	Lot	190020	00936.Well 1			
agent Pack	•											
e From												
e To												
I/DD/YYYY												
ributes Pending												
Expired												
Invalid												
Rejected												
Extended												
Canceled												
Ordered												
Measuring Interval Verif	cation											
Calibration												
Active												
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## Figure 1. Calibration Results Screen

# 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.

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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 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.

	ers Atell		N Version 1.1	9.2.3357001		libration	↓ A		HT Orders	Worklist	A Maintenance	තිලි Setup
Reage	nt Overview	Reagen	t Loader	Reagent Needs	Suppli	es Overview	Reagent Lot Comparison	Cal-QC Sto	rage Inventory	Cal-QC Needs		
С-Р	2-20										All	C-P2-20
agents										Reage	nt Details	C-P2-20 IA-P1-28
	Reagent	Inventory	Onboard Stability	Sequence	Calibration Status	Calibration Interval	Cal Type In QC Use Status	Lot	Cal Eligibility		85215	02021
	ALT	413	10 d 3 h	07333 / 06878	Z	10 d 3 h	Lot	280715	Pack		Name Lot ID	RF 123456
	ALT	850	39 d 13 h	07473 / 06876		17 d 18 h	Lot	280715	Lot and Pack		Pack Location Position	CH Reagent Compartment 46
	CO2_c	729	4 d 3 h	01053		0 d 0 h		190003	Pack		Status	40 Idle
7	Mg	391	39 d 13 h	03631 / 00342		0 d 0 h		280678	Lot and Pack		Sequence Number Paired Pack	85215 02021
_ _	RF	180	89 d 23 h	85215 / 02021				123456	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				190016			Calibration Expiration Well	
	TP	1850	8 d 13 h	03441 / 02627		8 d 13 h	Lot	280568	Lot and Pack	Те	st Count 90 Time Punctured	Ready 07/24/2019 10:17:18 AM
	WBA	276	142 d 19 h	01017		1777.1		190011			Calibrate Lot	Calibrate Pack
	Xtc	100	89 d 23 h	00936 / 01024		-		190020	Lot and Pack	Те	Well st Count 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
- 2. 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.

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	System Samples		Ci					ient Orders Worklist						
Reagen	t Overview	Reagen	t Loader	Reagent Needs	Suppli	es Overview	Reagent Lot	Comparison	Cal-QC Stor	age Inventory	Cal-QC Needs			
C-P2	-20											۲		6
gents											Rea	AI Igent Details	C-P2-20	IA-P1-28
] ÷	Reagent	Inventory	Onboard Stability	Sequence	Calibration Status	Calibration	Cal Type In Use	QC Status	Lot	Cal Eligibility		85215	0	2021
	ALT	413	10 d 3 h	07333 / 06878	Ľ	10 d 3 h	Lot		280715	Pack			ame RF	
	ALI	415	100.511	07333700076	-	100.511	LOC		200710	FOLK			ot ID 12345	
	ALT	850	39 d 13 h	07473 / 06876		17 d 18 h	Lot		280715	Lot and Pack		Pack Loca		agent Compartment
	000	729	4d3h			0 d 0 h			190003	Pack			ition 46 atus Idle	
	CO2_c	129	4031	01053		0001			190003	Pack		Sequence Nur		
	Mg	391	39 d 13 h	03631 / 00342		0 d 0 h			280678	Lot and Pack		Paired I		
	RF	180	89 d 23 h	85215 / 02021					123456	Lot and Pack		Count Remai	ning 180	
	RF	180	89 d 23 h	85215 / 02021					123456	Lot and Pack		Onboard Stat	bility 10/22/	2019 10:14:43 AM
	RPC1	418	56 d 13 h	00686 / 00690					190029			Lot Expira		2020 11:59:59 PM
												Calibration Expira	ation	
	RPC2	418	49 d 13 h	03900 / 03853					190016				Well 1	
	TP	1850	8 d 13 h	03441 / 02627		8 d 13 h	Lot		280568	Lot and Pack		Test Count 90	Ready	
												Time Punct		2019 10:17:18 AM
	WBA	276	142 d 19 h	01017					190011			Calibrate Lot		Calibrate Pack
	Xtc	100	89 d 23 h	00936 / 01024					190020	Lot and Pack		Test Count 90	Well 2 Seale	d
												Calibrate Lot	C	Calibrate Pack
					_									
Group t	y reagent			Disable Well 1	Disabl	e Reagent Pack	D	isable Reagen	t Lot	Unload				

## Figure 3. Reagent Overview Screen

- 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<sup>®</sup> 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.

I have read and understood the UFSN instructions provided in Yes I No I this letter.

#### Name of person completing questionnaire:

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

Please send a scanned copy of the completed form via email to: xxxx@siemens-healthineers.com.

Or to fax this completed form to the Customer Care Center at: (xxx) xxx-xxxx

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