

Field Safety Notice SBN-CPS-2017-012

CPS / Serum Work Area Version 1 05-Ju1-2017

Mixed-up sample results in immunochemistry modules

Product Name / Device Identifier	MODULAR <i>ANALYTICS</i> <e170> (GMMI 03617505001) MODULAR <i>ANALYTICS</i> EVO <e170> (GMMI 04998642001) cobas e 601 module (GMMI 04745922001) cobas e 602 module (GMMI 05990378001)</e170></e170>
Product Description	MODULAR ANALYTICS <e170> (GMMI 03617505001) MODULAR ANALYTICS EVO <e170> (GMMI 04998642001) cobas e 601 module (GMMI 04745922001) cobas e 602 module (GMMI 05990378001)</e170></e170>
Production Identifier (Lot No./Serial No.)	Not applicable
SW Version	All SW versions
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Due to a software limitation, sample mismatch may occur in the immunochemistry modules (**cobas e** 602, **cobas** e 601 and E170 modules). All of the clinical chemistry modules (**cobas** c 501, **cobas** c 502, **cobas** c 701 and cobas c 702 modules, P 800) are not affected by this software limitation.

The sample mismatch occurs when the following conditions are simultaneously met:

- The **"Module Rack Buffer setting"** ≠"1" → Two or more sample racks stay in the idling/processing line (L-Line) consecutively during operation.
- One rack (Rack A) is undergoing sampling and the following rack (Rack B) is waiting for its turn.
- The Gripper (T/V Carrier) fails to pick up the last vessel (cup) on Rack A. Consequently, the test measurement of the cup that failed to be picked up is canceled and the warning "**Tip/Cup pick up error**" (Caution Level) is issued.
- Sample position 1 of the following rack (Rack B) is empty or has no test order for the immunochemistry module.



Mixed-up sample results in immunochemistry modules

When all of the above mentioned conditions are met, the sample orders in Rack B are mixed up in the following way:

- Test (or tests) requested for the sample in the 2nd rack position will be run with the sample in the 1st position.
- After sample in 4th rack position is processed (with the test order requested for the sample in the 5th position), the rack is moved to the L-line's rack output position. At this time, the module will recognize (through a no signal from the rack position sensor) the wrong rack position and issue the Sampling Stop alarm "Abnormal L2-Line Movement". With this alarm, no further samples will be pipetted but the measurement for the samples already in process/pipetted (before the alarm occurred) will be completed.

The detection of the software limitation and the sample results mismatch is by the generation of two alarms within a few minutes of each other:

- "Tip/Cup pick up error" (Caution Level)
 Alarm code for cobas 8000 is 301-00002 or 301-000015
 Alarm code for cobas 6000 and MODULAR ANALYTICS is 301-0002 or 301-0015
- "Abnormal L2-line Movement" (S.Stop Level)
 Alarm code for cobas 8000 is 104-000005
 Alarm code for cobas 6000 and MODULAR ANALYTICS is 104-0005

Risk Assessment

Frequency of Occurrence

The failure has been reported one time out of 17982 modules (Installed capacity base year end 2016) installations.

Detectability

The failure may happen if the two alarms below occur within a few minutes:

- · Tip/Cup pick up error (Caution Level)
- · Abnormal L2-line Movement (S.Stop Level)

Severity (HHE Summary)

The issue described above can lead to result mismatch (wrong test order and wrong result reporting). All tests that are run on the affected systems are potentially affected whereas the extent of the bias cannot be predicted. Both erroneous increased/positive and decreased/negative results are possible. From a medical point of view, the most relevant immediate impact is related to results which are triggering directly medical therapy such as cardiac markers. Also, in case of false negative results for infectious diseases a spread of infection cannot be excluded. Considering the poor detectability of the issue and unknown extent of erroneous results, relevant medical risk cannot be entirely excluded.



Mixed-up sample results in immunochemistry modules

Actions taken by Roche Diagnostics

The root cause has been clearly identified and a new software version fixing that issue will be released by November 2017. The new software version will be installed as a mandatory update to the system.

Actions to be taken by the customer

Until the new software version is available, you must change the **"Module Rack Buffer setting"** to **1**. The change in setting

- Is only required for the immunochemistry modules (cobas e 602, cobas e 601 and E170 modules) and
- Will ensure that only one rack will go in the idling/processing line (L-Line)
- May impact the throughput of the system. The impact is dependent on the configuration and workload of the system.

Please see

- Attachment A for the step by step instructions for e602 module
- Attachment B for the step by step instructions for e601 moodule
- Attachment C for the step by step instructions for E170 modules.

Should the lab encounter the two alarms, **"Abnormal L2-line Movement"** (S.Stop Level) and **"Tip/Cup pick up error"**, within a few minutes of each other before the change in the **"Module Rack Buffer setting"**, please do the following steps:

1) Collect the remaining racks in the system.

For Standalone systems:

- a) Wait until system status turns to Stand-By.
- b) Perform "Reset or Rack Reset" to collect racks to Unloader.

For Lab automation connected systems:

- a) Stop sending racks from the lab automation, then wait until all results are out.
- b) Press "Stop" button to make system status turns to Stand-By.
- c) Perform "Reset or Rack Reset" to collect racks to Unloader.

2) Locate the rack and mismatched samples

- a) See Attachment 1 "How to identify and deal with potential mixed sample results on cobas e602"
- b) See Attachment 2 "How to identify and deal with potential mixed sample results on cobas e601"
- c) See Attachment 3 "How to identify and deal with potential mixed sample results on E170"

3) Delete sample results that were identified as mismatched from Workplace > Data Review screen.

4) Run measurements for the identified samples again.



Mixed-up sample results in immunochemistry modules

Communication of this Field Safety Notice

This notice must be passed on to all those who need to be aware within your organization or to any other organization/individual where the potentially affected devices have been distributed/supplied. Please pass on this notice to the Chairman Medical Board and Head of Department as well, as required by HSA. Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action

We apologize for any inconvenience this may cause and thank you for your understanding and support.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd Email: sg.regulatory@roche.com

ATTACHMENT A

e602 Module Rack Buffer Setting

This screen can be accessed by an operator with administrator level password only.

Step 1: Select Utility > System Configuration > Module Configuration

Stand By		bn	iserv	2017	/06/28 16:51	R? Help
Workplace	Reagent	Calibration	QC	Utility	Overview	
System	Maintenance	Application	Special Wash	System Configuration		Stop
Test Assignme	ant	Module Settings	Clas Setting	• • •		रू⊖ Logoff
Module Config	juration					S.Stop
						Alarm
						Monitor
						Print

ATTACHMENT A

N SE 1	Module T	ype				
SE 1			Module Name	Short Name	Serial No.	Module Rack Buffer
	ISE	\sim	ISE1	11	0800-40	
SE 2	Inactive	\mathbf{v}				
Buffer 1			MSB1	B1	1129-09	
Module 1 o	c 702	\sim	AU1	A1	1129-09	3
Buffer 2			MSB2	B2	0800-39	5
Module 2	c 701	$\mathbf{\vee}$	AU2	A2	0800-39	3
Buffer 3			MSB3	B3	0907-01	
Module 3 o	c 502	$\mathbf{\vee}$	AU3	A3	0907-01	
Buffer 4			MSB4	B4	2254-08	
Module 4	e 602	\sim	AU4	A4	2254-08	1
					Module Type	Setting OK Cancel

Step 2: For Module Type e602 only, change the number under "Module Rack Buffer" to 1 and click OK.

ATTACHMENT B

e601 Module Rack Buffer Setting

This screen can be accessed by an operator with administrator level password only.

Step 1: Select Utility > Module Set > Module Configuration

Host Core 61	C2 +1 Stand B	У			bm	iserv	28/06/17	16:30	USB
Wo	rkplace	Re	agent	Calibration	QC	:		Utility	Stop
Sys	tem Mai	ntenance	Application	Calculated Test	Special Wash	Report F	ormat	Module Set	
									Shut Down
									S. Stop
									Alarm
									Print
Con	Aodule figuration	Te Assig	st nment	Module Setting					
									Start
? Help	Touch the scr	een, click th	e mouse, press	<enter>.</enter>				8	

Step 2: For Module Type e601 only, change the field under "Module Rack Buffer" to 1 and click OK.

HostCore c1 c2 e1	Stand By	l.				bm	serv 28/06	6/17 16:32	USB
Workpla	ace	Rea	igent	Calibr	ration	QC	:	Utility	Stop
System	Mair	itenance	Application	Calculat	ed Test Spe	cial Wash	Report Format	Module Set	
	Modul	е Туре	M	Module Co odule Name	nfiguration Short Name	Serial Ne	o. Modu	le Rack Buffer	Shut Down
Module 1	c501			c1	c1	1155-20		1	
Module 2	c501			c2	c2	1156-01		1	S. Stop
Module 3	e601			e1	E	2298-13		1	
									Alarm
									Print
Cancel ? Help	he serial	number with	n up to 12 char	acters, then p	press <enter>.</enter>			ок	Start

ATTACHMENT C

E170 Module Rack Buffer Setting

This screen can be accessed by an operator with administrator level password only.

Step 1: Select Utility > Module Set > Module Configuration



ATTACHMENT C

ŀ	lost <mark>Core</mark> El E2 Sta	and By				I	bmserv	17/06/28 (W	ed) 17
	Workpla	ce	Reagent		Calibration	QC	:	Utility	Ĺ
	System	Maintena	nce Applicati	on	Calc. Test	Special Wash	Report Forma	t Module Set	
				Mo	odule Configurati	on			
		Module Typ	e Module N	lame	Short Name	Serial No.	Modu	lle Rack Buffer	
	Module 1	E	E-1		E1			1	
	Module 2	E	E-2		E2			1	
	Module 3	Inactive							
	Module 4	Inactive							
	ISE 1	Inactive							
	ISE 2	Inactive							
	Cancel		Nodule Type Settin	ng				ок	
	? Type Help	the module	name with up to 4	chara	acters, then press	⊧ <enter>.</enter>		\?	

Step 2: For Module Type E only, change the number under "Module Rack Buffer" to 1 and click OK.

1. Identification of the software malfunction

Whenever an Abnormal L2-line Movement 104-000005 (S.Stop Level) is issued by the system, check whether Tip/Cup pick up error 301-000002 and / or 301-000015 (Caution Level) is also issued earlier on the Alarm screen.

1. Check Alarm screen and make sure the alarm "104-000005 Abnormal L2-line Movement (S.Stop Level)" occurs.

arm					
Alarm List					
Code	Module	Level	Alarm	Date/Time	- 🔨
104-000005	AU1	S.Stop	Abnormal L2-line Movement	2017/06/16 12:03	
402-050102	AU1	Caution	Sample Short	2017/06/16 12:02	
316-000006	AU1	Caution	Tip/AssayCup Short	2017/06/16 12:01	
315-000015	AU1	Caution	Solid Waste	2017/06/16 12:01	=
301-000015	AU1	Caution	Tip/Cup pick up error	2017/06/16 12:01	
301-000002	AU1	Caution	Tip/Cup pick up error	2017/06/16 12:00	
Alarm : A	\bnormal L2-line Mo	vement	Madula - Alla		· ·
Alarm : A Code : 1 Description L2-line rack tra	Abnormal L2-line Mc 104-000005 Insfer mechanism d	ovement loes not reach at Out	Module : AU1 t-Buffer when L2-line rack transfer mechanism mo	Level : S.Stop	
Alarm : A Code : 1 Description L2-line rack tra Remedy	Abnormal L2-line Mc 104-000005 Insfer mechanism d	ovement	Module : AU1 t-Buffer when L2-line rack transfer mechanism mo	Level : S.Stop	
Alarm : A Code : 1 Description L2-line rack tra Remedy (1) Execute < <f Resume operat</f 	Abnormal L2-line Mc 104-000005 ansfer mechanism d Rack Reset>> on th Rack Reset>> on th tion; if the alarm re	ovement loes not reach at Out e [Maintenance] scre curs, contact Service	Module : AU1 t-Buffer when L2-line rack transfer mechanism mo een of [Utility] job. e Representative.	Level : S.Stop	

- 2. Collect the remained racks in the **cobas** e602 module.
 - Standalone system:
 - 2-1) Wait until system status turns to Stand-By.
 - 2-2) Perform "Reset or Rack Reset" to collect racks to Unloader.
 - CLAS connected system:
 - 2-1) Stop sending racks from CLAS, then wait until all results are out.
 - 2-2) Press "Stop" button to make system status turns to Stand-By.
 - 2-3) Perform "Reset or Rack Reset" to collect racks to Unloader.

 Print "Daily Alarm Trace" and check if the alarm "301-000002 Tip/Cup pick up error" or "301-000015 Tip/Cup pick up error" occurs within a short time from time alarm "104-000005 Abnormal L2-line Movement". If yes, go to the next procedure for identifying of rack with potential mixed sample results.

2017/06/16	12:03:23	10	1 E	PC	0013-000001	Rack Collect End
2017/06/16	12:03:23	13	2 E	SU	0741-000002	Rack Collect Complete
2017/06/16	12:03:19	5	1A	A1	104-000005-342	Abnormal L2-line Movement
2017/06/16	12:02:12	5	1 A	A1	402-050102-276	Sample Short
2017/06/16	12:01:42	5	1A	A1	316-000006-091	Tip/AssayCup Short
2017/06/16	12:01:42	5	1A	A1	315-000015-091	Solid Waste
2017/06/16	12:01:11	5	1A	A1	301-000015-315	Tip/Cup pick up error
2017/06/16	12:00:50	5	2A	A1	301-000002-315	Tip/Cup pick up error
2017/06/16	11:59:35	8	1 E	PC	0011-000001	Rack Supply End
2017/06/16	11:58:33	7	1 E	PC	0010-000001	Operation
2017/06/16	11:58:33	11	1 E	SU	0510-000001	Change to Operation Request

2. Identification of rack with mixed sample results on cobas e602

2.1. Sample Barcode mode

2.1.1. Go to Workplace > Data Review screen, search Sample ID of the samples on the racks collected at Unloader after "Reset or Rack Reset" is completed.

Follow 1 through 4 in the Figure 1 below.

W	orkplace	Reagent	C	alibration	QC	Utility	Overview
Те	st Selection	Data Review		Calib. Review			
Data:	Routine View	Filter:	() c	N		Filter Sea	Irch Sample Count: 4870
DM C.	St. S. ID	Rack No	S. Type	Col Date/Time	~		Search Sample
H.	1736340381	50068-1	Ser/Pl	04/07 10:06:	Eind	Sample ID Cor	nment-
н	1736359811	50068-4	Ser/Pl	04/07 10:06:55		00	
н	1736362831	50068-5	Ser/Pl	04/07 10:06:55	1736340381		\sim
н	1736379531	50082-2	Serrel	04/07 10:07:24			
н	1736553111	50025-5	Ser/PI	04/07 10:26:40	Annut Outlin		
н	1736372391	50062-1	Ser/Pl	04/07 10	search Option	n: Match Case	
н	I 1736489941	50062-2	Ser/Pl	04/07 10 Sea	rched Sample ID		
н	I 1736520561	50006-4	Ser/Pl	04/07 10	ws on the screen.		
н	I 1736377501	50016-1	Ser/Pl	04/07 10:48:30			
н	I 1736525401	50079-2	Ser/PI	04/07 10:50:49			
н	I 1736542811	50079-4	Ser/Pl	04/07 10:50:51		\bigcirc	
н	I 1736527771	50049-5	Ser/Pl	04/07 10:51:28		(4)	
н	I 1736566351	50094-4	Ser/Pl	04/07 11:15:20			
н	I 1736400601	50001-4	Ser/Pl	04/07 11:22:29	Focus Move:		Down
н	1736354151	50024-1	Ser/Pl	04/07 13:40:19		- op	
н	1736367411	50024-3	Ser/Pl	04/07 13:40:21			
н	O 1736368391	50039-2	Ser/PI	04/07 13:40:31			Close
н	1736359641	50039-5	Ser/PI	04/07 13:40:33			

Figure 1. Data Review screen

2.1.2. Select the searched Sample ID and then, open "Test Review" screen. Verify corresponding **cobas** e602 module and sampling time.

Status	: Com	plete	Carry	over E	vasion	:				Rac	k and	pos	ition		Ļ	ener i		
Select			1st Result	R.	A.	1_	С.					R.		A				
Result	lest	Unit	Result Alari	^п М.	UII. U.	lime	E.	DIM	51.	Result	Alarm	М.	DII.	U. ""	e e		n st.	1
1st	AHBS	IU/L	118.0		A1-1	10:34:28		н										
1st	A-HCV II	COI	0.038	N	A1-1	10:35:10		Н										
1st	HBSAGII	COI	0.335	N	📕 A1-2	2 10:34:49		н										
1st	HIVCO	COI	0.226	٧	A2-1	11:29:07	1	н										
																		-

Figure 2. Test Review screen

- 2.1.3. Repeat step 2.1.1. and 2.1.2. for all samples on the collected racks.
- 2.1.4. The rack with the samples that are mismatched can be identified by the sample with sampling time that is the closest to the Tip/Cup pick up error alarm generation time.

2.2. Rack position number mode

2.2.1. Go to Workplace > Data Review screen, search by "Rack No." Note: If the rack is used repeatedly used, search by "Date/Time".

Stand	B	y				bn	iserv				2017/06/	13 16:4	47	(k? Help
w	ork	place		Reagent		Calibration		QC		Utility		Ove	rview		
Te	st S	election		Data Review		Calib. Review									Stop
Data:	Ro	outine View	4	✓ Filt	er:		OFI	•	Filte	er	Search	Sa	mple Co	ount: 50	द्रु⊖ Logoff
	St.	Seq. No.	S. ID	Rack No Pos	s. Type	Comment Date/Time	^	C. Dil. Test	Result	Unit	Alarm A.	U. Rg. 9	it. 3rd	^	6
	0	000203		50037-3	er/PI	06/13 15:28:41		📕 ТЅН	0.275	IU/mL	A1-	-1			S.Stop
н	0	000204		50037-4	er/Pi	06/13 15:28:41									
н	0	000205		50037-5	er/Pi	06/13 15:28:41									
	0	000206			er/Pi										
	o	000207		50102-2	er/Pi	06/13 15:28:49									
	0	000208		50102-3	er/Pi	06/13 15:28:49									\square
н		000209		50102-4	er/Pl	06/13 15:28:50									
н		000210		50102-5	er/Pl	06/13 15:28:50									
н		000211		50037-1	er/Pl	06/13 16:16:50								11	
н		000212		50037-2	er/Pl	06/13 16:16:50									L_Q Monitor
	0	000213		50037-3	er/Pl	06/13 16:16:51									Monitor
	0	000214		50037-4	er/Pi	06/13 16:16:51									
	0	000215		50037-5	er/Pl	06/13 16:16:51									
	0	000216			er/Pl										Print
н		000217		50102-2	er/Pl	06/13 16:16:59									
н		000218		50102-3	er/Pl	06/13 16:16:59									
н		000219		50102-4	er/Pi	06/13 16:17:00	-								
н		000220		50102-5	er/Pl	06/13 16:17:00	$\mathbf{\vee}$							$\mathbf{\mathbf{v}}$	
Sa Infor	nple nati	e I	Unioad Rack	Cha Pric	nge ority	Send to DM Dele	te Recor	d Delete /	All Ba	ckup Dat	Test R	eview	Read Mor	tion nitor	Start

Figure 3. Data Review screen

2.2.2. Select the sample on the searched racks, then open "Test Review" screen. Verify corresponding **cobas** e602 module and sampling time.

						br	mserv						2017/	06/13	16:5	50		
Workpla	ace		Reagent		Calibra	tion		QC			U	tility			Over	rview	/	
Test Selec	ction		Data Review		Calib. Re	eview												Stop
Review Sample S. Type Status	: Rou : Ser : Cor	utine /PI mplete	Sequer Sample Carryov	ce No. ID 'er Eva	ision	: 00021 : :	1	Rad	ck No Po	s. : Racl	5003 k and	a7-1 l posi	tion		Pre-dilu	ution		₽ Logoff
Select Result	Test TSH	Unit IU/mL	Result Alarm	R. 1 M.	Dii. A. U. A1-1 1	Time E	р. DN	1 St.	Result A	Alarm	R. M.	Dil. <mark>A.</mark> U.	Time	C. E.	DM	St.	^	S.Stop
	1.02012		Service of the servic													_		
		Ve	rify corresp	ondi	ing e60:	2 modu	le and	l samj	pling tii	me.								Alarm
		Ve	erify corresp	oondi	ing e602	2 modu	le and	l samj	pling tir	me.								Alarm Monitor Print
		Ve	erify corresp Sample Informat	on	ing e602	2 modu	le and	l samj	pling tin	me.		All Res	uits		Re M	eaction	=	Alarm Monitor

Figure 4. Test Review screen

- 2.2.3. Repeat step 2.2.1. and 2.2.2. for all samples on the collected racks.
- 2.2.4. The rack with the samples that are mismatched can be identified by the sample with sampling time that is the closest to the Tip/Cup pick up error alarm generation time.

1. Identification of the software malfunction

Whenever an Abnormal L2-line Movement 104-000005 (S.Stop Level) is issued by the system, check whether Tip/Cup pick up error 301-000002 and / or 301-000015 (Caution Level) is also issued earlier on the Alarm screen.

1. Check Alarm screen and make sure the alarm "104-000005 Abnormal L2-line Movement (S.Stop Level)" occurs.

C019 001 960 1	Stand By		bmserv	13/06/17	13:55	USB
	Madula		Alarm	De	- Time -	Stop
Code	Wodule	Level	Alarm	Da	te/lime	
104-0005 e	601	Sample Stop	Abnormal L2-line Movement	13/06/	17 13:34	(
402-0401 e	601	Caution	Sample Short	13/06/	17 13:33	Shut
315-0015 e	601	Caution	Solid Waste	13/06/	17 13:33	
301-0015 e	601	Caution	TIP/Cup pick up error	13/06/	17 13:32	
301-0002 e	601	Caution	Tip/Cup pick up error	13/06/	17 13:32	C. Cham
						S. Stop
Description an	d Remedy					Alarm
Level Samp	uuus ale Stan					
Description:L2	line rack transfer	mechanism doe	s not reach at Out-Buffer when L2-line rack transfer			
mechanism mo	oving from samplin	ng position.				
Remedy :(1) E	xecute < <rack re<="" td=""><td>set>> on the [Ma</td><td>ntenance] screen of [Utility] job.</td><td></td><td></td><td></td></rack>	set>> on the [Ma	ntenance] screen of [Utility] job.			
Resume opera	ition; if the alarm r	ecurs, contact Se	rvice Representative.			Print
						FILL
					-	
	-		-	_		
Delete	New Alarm	Sound	Maint		Cloco	
Delete	New Alarm	Sound	Manit.		CIUSE	
				100		1
Select	t the alarm from th	Construction and the second				Start
2		ne list box.				Start
Halp		ie list box.				Start

- 2. Collect the remained racks in the **cobas** e601 module.
 - Standalone system:
 - 2-1) Wait until system status turns to Stand-By.
 - 2-2) Perform "Reset or Rack Reset" to collect racks to Unloader.
 - CLAS connected system:
 - 2-1) Stop sending racks from CLAS, then wait until all results are out.
 - 2-2) Press "Stop" button to make system status turns to Stand-By.
 - 2-3) Perform "Reset or Rack Reset" to collect racks to Unloader.

3. Print "Daily Alarm Trace" and check the alarm "301-000002 Tip/Cup pick up error" or "301-000015 Tip/Cup pick up error" occurs within a short time from time alarm "104-000005 Abnormal L2-line Movement". If yes, go to the next procedure for identifying of rack with potential mixed sample results.

13/06 13:35	2	2 A 01-029-0001-065	Inc. Water Level Too Low
13/06 13:35	2	2 A 01-113-0009-063	Abnormal Temp Control
13/06 13:34	2	1 A 01-029-0001-065	Inc. Water Level Too Low
13/06 13:34	2	1 A 01-113-0009-063	Abnormal Temp Control
13/06 13:34	62	1 A 02-104-0005-342	Abnormal L2-line Movement
13/06 13:34	bΖ	Z A UZ-113-0006-281	Abnormal Temp Control
13/06 13:34	4	3 A 02-329-0003-271	Pressure Sensor Error
13/06 13:33	4	1 A 02-402-0401-276	Sample Short
13/06 13:33	4	1 A 02-315-0015-091	Solid Waste
13/06 13:32	4	1 A 02-301-0015-315	Tip/Cup pick up error
13/06 13:32	2	23 A 01-113-0009-063	Abnormal Temp Control
13/06 13:32	4	2 A 02-301-0002-315	Tip/Cup pick up error
13/06 13:31	2	30 A 01-029-0001-065	Inc. Water Level Too Low
13/06 13:31	2	7 A 01-113-0010-063	Abnormal Temp Control
13/06 13:31	4	25 A 02-113-0006-141	Abnormal Temp Control

2. Identification of rack with mixed sample results on cobas e601

2.1. Sample Barcode mode

2.1.1. Go to Workplace> Data Review screen, search Sample ID of the samples on the racks collected by performing "Reset or Rack Reset" to Unloader.

Follow 1 through 4 in the Figure 1 below.

q	019 0 1 1 0 0 1	Stand By	/				bmserv	13/06/17	14:43	USB
	Workp	lace	Rea	gen	t C	Calibration	QC	U	tility	Stop
Te	st Selectio	n Data	Review	Calib.	Review					$\left \bigcup \right $
St.	Filter • OFF • Rack	ON Sam	ple ID	Type	ta Routine View Comment-00	D1 Date/Time	Fip 2	earch Sample		Shut Down
	N0013-1		000001	Ser/Pl		13/06 14:13	C Comment-001	3		S. Stop
0	N0050-3		100003	Ser/Pl		13/06 14:15	200004			
0	N0050-4		100004	Ser/Pl		13/06 14:15	L.			
0	N0401-2		200002	Ser/PI		13/06 14:15				
È	N0401-3		200003	Ser/Pl		13/06 14:16	- Search Option	Search 4)	Alarm
	N0401-4		200004	Ser/PI		13/06 14:16				- Ial III
0	NU4UT-5		200005	Ser/PI		13/06 14:16	Comment-001	Down	Up	
						Searched shows on	Sample ID the screen.			Print
L (Demogra- phics ? alp	Searcl	h Filte	mouse	Send To Host	Delete Record D				Start

Figure 1. Data Review screen





2.1.2. Select the searched Sample ID, then open "Test Review" screen. Verify corresponding **cobas** e601 module and sampling time.

Work	plac	e	Re	agei	nt	C	alib	ratio	n	Q	C	L	tility	Sto
est Selec	tion	Data	Review	Cali	b. Revi	ew								
							Test F	leview					_	Chu
ample :	Routi	ine									Rack	No Pos. :	N0401-4	Dow
ype:	Ser/P	'l Nete		Sampl	e ID : wer Ev	scion:	20000	4				📕 📕 Pre	-dilution	
tatus.	comp	here		Carryo	ver Ev							Rack and p	osition	
Test		Data	Alarm	1ST RE	suit	AU	Time	St	Data	Alarm	Rerun Re	AU	Time St	5. St
oxigg	1	00		14,000		E -1	14.18		- Deale		1			
					-	-		┿┛─┼─						
														Alai
		_	Vorifi	Loorry		lingof	01 m	dulor	nd com	ling tim				all
		_	vern		spon	ing eu	01 110	Juule	inu samj	Jing thi	IC.			
		_												
	_		· · · · · ·						-		<u> </u>			Ph
			-						-					
			- -			<u> </u>			-					
Cancel		emogra phics	- Sh De	ow tail	Del	ete st	Upd	ate	Manua	ai Pr	evious	Next	Close	
					-				~				-	
	-								1990 Alexandre				_	Sta

Figure 2. Test Review screen

- 2.1.3. Repeat step 2.1.1. and 2.1.2. for all samples on the collected racks.
- 2.1.4. The rack with the samples that are mismatched can be identified by the sample with sampling time that is the closest to the Tip/Cup pick up error alarm generation time.

2.2. Rack position number mode

2.2.1. Go to Workplace> Data Review screen, search by "Rack No." Note: If the rack is used repeatedly, search by "Date/Time".

0	078 JAN 1 850 1	Stand B	У						b	mserv	13/0	06/17	13:55	Us
	Work	blace	Rea	agent	t Ca	libratio	n		Q	С	1	Uti	lity	Sto
те	st Selecti	on Dat	a Review	Calib.	Review									310
	Filters	hannan												
	• OFF	O ON			a Ioutine View	•		Sample Count: 700					Shu	
-	ľ., .,				1	()	1	_	1	1	(<u> </u>			
St.	Seq. No.	Rack	ID	Туре	Comment-001	Date/Time	<u> </u>		Test	Result	R.M.	Alarm	Unit	
0	N001015	N0050-5		Ser/Pl		08/06 11:34			TOXIGG	1.00			IU/mL	S. St
0	N001016	N0401-1		Ser/Pl		08/06 11:35						Ĩ.		
0	N001017	N0401-2		Ser/PI	<u> </u>	08/06 11:35	_							
0	N001018	N0401-3		Ser/PI	ļ	08/06 11:35	_	_						
0	N001019	N0401-4		Ser/Pl		08/06 11:35			<u> </u>					
0	N001020	N0401-5		Ser/Pl		08/06 11:35								Alar
0	N001021	N		Ser/Pl										1.00
0	N001022	N		Ser/Pl								[
0	N001023	N0050-3		Ser/Pl		13/06 13:31						Į.		
0	N001024	N0050-4		Ser/Pl		13/06 13:31								
0	N001025	N0050-5		Ser/Pl		13/06 13:31			<u> </u>			<u></u>		
0	N001026	N		Ser/PI			_						<u> </u>	
0	N001027	N0401-2		Ser/Pl	-	13/06 13:31								Prin
	N001028	N0401-3		Ser/Pl		13/06 13:31								
	N001029	N0401-4		Ser/PI		13/06 13:31								
0	N001030	N0401-5		Ser/PI		13/06 13:31	-							
	Demogra- phics	Searc	h Fill	ter	Send To Host	Delete Record	De	elete	All Bac	kup Data	Tes Revi	ew	Reaction Monitor	
							-	_			_			Sta
Не	? elp												8	

Figure 3. Data Review screen

2.2.2. Select the sample on the searched racks, then open "Test Review" screen. Verify corresponding **cobas** e601 module and sampling time.

Core Core	Stand By							bms	erv	13/06/17	13:55	USE
Work	place	Review	agent Calib. Re	view	Calibr	atior	1	QC		U	tility	Sto
Sample : Type :	Routine Ser/Pl		Sequence I Sample ID :	lo. :	Test R 001029	eview)			Rack	No Pos. :	N0401-4 -dilution	Shu Dow
Test	Data	Alarm	1st Result R.M.	A.U.	Time	St	Data	Rer Alarm R	un R .M.	Rack and po	Time St	S. St
OXIGG	1.00			E -2	13:34							
	Verify	correspo	onding e60	1 modu	ile and	sampli	ng time.					Alar
												Pri
	Demogr			elete			Manua					
Cancel	phics	data from	-9999999 to 9	9999999, t	Upd:	ss <ente< td=""><td>Test</td><td>Previo</td><td>ous</td><td>Next</td><td></td><td>Sta</td></ente<>	Test	Previo	ous	Next		Sta

Figure 4. Test Review screen

- 2.2.3. Repeat step 2.2.1. and 2.2.2. for all samples on the collected racks.
- 2.2.4. The rack with the samples that are mismatched can be identified by the sample with sampling time that is the closest to the Tip/Cup pick up error alarm generation time.

1. Identification of the software malfunction

Whenever an Abnormal L2-line Movement 104-000005 (S.Stop Level) is issued by the system, check whether Tip/Cup pick up error 301-000002 and / or 301-000015 (Caution Level) is also earlier on the Alarm screen.

1. Check Alarm screen and make sure the alarm "104-000005 Abnormal L2-line Movement (S.Stop Level)" occurs.

Host Core ISE DY PART Stand I	Зу		BMSERV	17/06/14 (We	d) 12:20
		Alarm			
Code Module	Level	Alarm	Date/T	ïme	Stop
104-0005 E1	S. STOP	Abnormal L2-line Movement	17/06/14	11:59	
028-0001 Core	Caution	Execute Rack Collect	17/06/14	12:00	Logoff
402-0317 E1	Caution	Sample Short	17/06/14	11:58	Logon
315-0015 E1	Caution	Solid Waste	17/06/14	11:58	\geq
301-0015 E1	Caution	Tip/Cup pick up error	17/06/14	11:57	
301-0002 E1	Caution	Tip/Cup pick up error	17/06/14	11:57	S. Stop
Description and Remed	У				Alarm
Code :104-0005 Level :S. STOP Description L2-line rack transfer med sampling position. Remedy	hanism does not	t reach at Out-Buffer when L2-line rack t	ransfer mechanism n	noving from	Print
Delete M ? Select the alarm	New Alarm	Sound Maint.		Close	Start
					NUM

- 2. Collect the remained racks in the E170 module.
 - Standalone system:
 - 2-1) Wait until system status turns to Stand-By.
 - 2-2) Perform "Reset or Rack Reset" to collect racks to Unloader.
 - CLAS connected system:
 - 2-1) Stop sending racks from CLAS, then wait until all results are out.
 - 2-2) Press "Stop" button to make system status turns to Stand-By.
 - 2-3) Perform "Reset or Rack Reset" to collect racks to Unloader.

3. Print "Daily Alarm Trace" and check the alarm "301-000002 Tip/Cup pick up error" or "301-000015 Tip/Cup pick up error" occurs within a short time from the time alarm time "104-000005 Abnormal L2-line Movement". If yes, go to the next procedure for identifying of rack with potential mixed sample results.

06/14 11:59 7	1 E 15-005-0001-000 Rack Supply Complete
06/14 11:59 11	1 E 99-016-0001-000 Restart Disable (All Module)
06/14 11:59 5	1 A 03-104-0005-342 Abnormal L2-line Movement
06/14 11:59 62	1 E 03-007-0001-000 Rack Supply Complete
06/14 11:58 5	1 A 03-402-0317-276 Sample Short
06/14 11:58 5	1 A 03-316-0006-091 Tip/AssayCup Short
06/14 11:58 5	1 A 03-315-0015-091 Solid Waste
06/14 11:57 5	1 A 03-301-0015-315 Tip/Cup pick up error
06/14 11:57 5	1 A 03-301-0002-315 Tip/Cup pick up error
06/14 11:57 6	1 E 15-005-0001-000 Rack Supply Complete
06/14 11:57 43	1 E 99-017-0001-000 Barcode Read Complete
06/14 11:56 10	1 E 99-013-0001-000 Rack Supply Complete
06/14 11:56 6	1 R 15-001-0001-006 Water Reservoir Level Too Low
13/06 13:31 628	1 E 11-502-0000-000 Restart

2. Identification of rack with mixed sample results on E170

2.1. Sample Barcode mode

2.1.1. Go to Workplace > Data Review screen, search Sample ID of the samples on the racks collected at Unloader after "Reset or Rack Reset" is completed.

Follow 1 through 4 in the Figure 1 below.

H	ost <mark>Core</mark> l	stor en s	tand By			BMSER	V 17/06/14 (We	d) 13:35
	W	orkplace	R	eagent	Calibration	QC	Utility	Stop
	Test	Selection	Data Revi	ew				
	Filte	r		Data		Sear	ch Sample	
	• • •	DFF 00	N	Hard Disk				Logon
	St.	Rack No.	Sample ID	Type m	ment-0 Arrived	Find 2	3	
	-	C0003-2	cont01	Ser/PI	08/29 10:22	• Sample ID		S. Stop
		C0003-2	cont01	Ser/PI	08/29 10:22	200004		
		C0003-3	cont01	Ser/Pl	08/29 10:22	C Comment-00	1	
		C0003-3	cont01	Ser/PI	08/29 10:22		<u> </u>	
		C0003-4	cont01	Ser/PI	08/29 10:22			
		C0003-4	cont01	Ser/PI	08/29 10:22	Search Option	Search	
		C0003-5	cont01	Ser/PI	08/29 10:22	☐ Match Case		Alarm
		C0003-5	cont01	Ser/PI	08/29 10:22			
		N0038-1	000001	Ser/PI	06/14 13:01		Down Up	
	0	N0210-3	100003	Ser/PI	06/14 13:01			
	0	N0210-4	100004	Ser/PI	06/1 Searched S	ample ID		
	0	N0210-5	100005	Ser/PI	06/1 shows on th	he screen.		
	0	N0317-2	200002	Ser/PI	06/14 13:01			Print
		N0317-3	200003	Ser/Pl	06/14 13:01			
		N0317-4	200004	Ser/PI	06/14 13:01			
	0	NU317-5	200005	Ser/PI	06/14 13:01			
	Demo	hics Se	arch	ilter Send	st Delete Delet	te All	Close	
	? Helj	p Touch t	he screen, cl	ick the mouse,	press the space bar or <en< td=""><td>iter>.</td><td>k?</td><td>Start</td></en<>	iter>.	k ?	Start

Figure 1. Data Review screen

2.1.2. Select the searched Sample ID, then open "Test Review" screen. Verify corresponding E170 module and sampling time.

Host Core Reference BMSERV 17/06/14 (Wed) 13												
Workplace Reagent	Calibration	QC	Utility	Stop								
Test Selection Data Review												
	Test Review			Logoff								
Sample : Routine Sequence No.	2	Rack No Pos. :	N0317-4	Logon								
Type : Ser/PI Sample ID	: 200004		Pre-dilution									
Sample Status : Complete		Rack and posit	tion	S. Stop								
Test 1st Result	Rerun I	Result										
	E1-2 13:04		A.U. TIME St.									
				Alarm								
Verify corresponding I	£170 module and sampling t	ime.										
				Print								
Cancel graphics Detail Delete	Update Test	Previous	t Close									
? Help	e screen, click the mouse or us	e the arrow keys.	k?	Start								
				NUM								

Figure 2. Test Review screen

- 2.1.3. Repeat step 2.1.1. and 2.1.2. for all samples on the collected racks.
- 2.1.4. The rack with the samples that are mismatched can be identified by the sample with sampling time that is the closest to the Tip/Cup pick up error alarm generation time.

2.2. Rack position number mode

2.2.1. Go to Workplace> Data Review screen, search by "Rack No." Note: If the rack is used repeatedly, search by "Date/Time".

ŀ	ost <mark>Core</mark> l	sedan (Men S	Stand By				BMSE	RV 17	//06/14 (We	d) 12 21	
	W	orkplace	э 📃	Reagent	Calil	bration		QC	Ut	ility	Stop
ľ	Test 9	Selection	Data Re	wiew							Stop
ľ	Filter	r	Butu Itt	Data							
	• •	OFF CC	N	Hard Disk	<u>.</u>			Sample Cou	nt: 159		Logoff
	St.	S. No.	Rack	Sample Type	nment-	Arrived Date/Time		Test	lst	Rerun	
	0	N000166	N	Ser/PI			•	TOXIGG 4	1.00 ¥	<u>.</u>	S. Stop
I	0	N000167	N0317-2	Ser/PI	0	06/14 10:39		_			
I		N000168	N0317-3	Ser/PI	0	06/14 10:39					
	0	N000169	N0317-4	Ser/PI	0	06/14 10:39					
		N000170	N0317-5	Ser/PI	0	06/14 10:39					
		N000171	N0038-1	Ser/PI	0	06/14 11:55					
	0	N000176	N	Ser/PI							Alarm
	0	N000177	N	Ser/PI							
		N000178	N0210-3	Ser/PI	0	06/14 11:56					
	0	N000179	N0210-4	Ser/PI	0	06/14 11:56					
	0	N000180	N0210-5	Ser/PI	0	06/14 11:56					
	0	N000181	N	Ser/PI							
	0	N000182	N0317-2	Ser/PI	٥	06/14 11:56	_				Print
		N000183	N0317-3	Ser/PI	0	06/14 11:56					
		N000184	N0317-4	Ser/PI	0	06/14 11:56					
	0	N000185	N0317-5	Ser/Pl	0	06/14 11:56	-			*	
	Demo grap	hics Se	arch	Filter Send Hos	t Del	lete D	elete All	Backup Data	Test Review	Reaction Monitor	
	? Helj	Select	he sample	from the list box.							Start
											NUM

Figure 3. Data Review screen

2.2.2. Select the sample on the searched racks, then open "Test Review" screen. Verify corresponding E170 module and sampling time.

Host Core St D4 P1 E1	Stand By							BM	SERV	17/06/14 ((Wed) 12 21
Workplace	e	Reage	nt	Ca	libra	tion		QC		Utility		Stop
Test Selection	Data Re	view										
				Ť	est Re	view						Logoff
Sample : Ro	utine	Sequenc	e No.	: 0001	84			Rack	No Po	s.: N0317-4		
Type : Sei	r/PI	Sample I	D	:					Ť	Pre-dilution		
Sample Status	s : Comp	olete	_	_	_		Dorup D	ooult	Rack	and position		S. Stop
Test	Data	L Alarm R.N	1. Dil.	A.U.	Time	St.	Data	Alarm R.N	A. Dil.	A.U. Time St.		
TOXIGG	4.00	¥		E1-1	<u>11:59</u>							
												Alarm
	Vei	rify corre	spondin	g E170	modu	le and :	ampling	time.				
			-						_			
									_			
			-		4 ¹							Print
			-		-							
											1	
Cancel	aphics	Detail	Delete		Update		est	Previou	IS	Next		
? To sele Help	ect from the	test item:	touch th	e scree	n, click	the mo	use or use	the arrow	keys.	k ?		Start
												NUM

Figure 4. Test Review screen

- 2.2.3. Repeat step 2.2.1. and 2.2.2. for all samples on the collected racks.
- 2.2.4. The rack with the samples that are mismatched can be identified by the sample with sampling time that is the closest to the Tip/Cup pick up error alarm generation time.