

Urgent Field Safety Notice SBN-CPS-2017-012

CPS / Serum Work Area Version 1 21-June-2017

Mixed sample results in immunochemistry modules

MODULAR
MODULAR ANALYTICS EVO <e170> (GMMI 04998642001)</e170>
cobas e 601 module (GMMI 04745922001)
cobas e 602 module (GMMI 05990378001)
MODULAR ANALYTICS <e170> (GMMI 03617505001)</e170>
MODULAR ANALYTICS EVO <e170> (GMMI 04998642001)</e170>
cobas e 601 module (GMMI 04745922001)
cobas e 602 module (GMMI 05990378001)
MODULAR ANALYTICS <e170> (GMMI 03617505001)</e170>
MODULAR ANALYTICS EVO <e170> (GMMI 04998642001)</e170>
cobas e 601 module (GMMI 04745922001)
cobas e 602 module (GMMI 05990378001)
MODULAR ANALYTICS
MODULAR ANALYTICS EVO
cobas 6000 analyzer series
cobas 8000 modular analyzer series
All of the software versions
Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We regret to inform you that a sample mismatch may occur in the immunochemistry modules (**cobas e** 602, **cobas e** 601 and E170 modules) due to a software limitation.

<u>The sample mismatch is caused by a software limitation and only occurs if the following conditions are</u> <u>simultaneously met (i.e. very rare occurrence):</u>

- Immunochemistry module (cobas e 602, cobas e 601 and E170 modules) is included in its respective system (cobas 8000 modular analyzer series, cobas 6000 analyzer series, MODULAR ANALYTICS, MODULAR ANALYTICS EVO).
- The **"Module Rack Buffer setting"** ≠"1" **à** Two or more sample racks stay in the idling/processing line (L-Line) consecutively during operation.



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- · One rack (Rack A) is undergoing sampling and the following rack (Rack B) is waiting for measurement.
- The Gripper (T/V Carrier) fails to pick up the last vessel (cup) on Rack A. As a consequence, the measurement for the sample in the last vessel which 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.

cobas e 801 module, **cobas e** 411 and all of the clinical chemistry modules (**cobas c** 501, **cobas c** 502, **cobas c** 701 and **cobas c** 702 modules, P 800, D 2400) are not affected by this software limitation.

<u>The software limitation occurs only when all of the above mentioned conditions are met simultaneously</u> (i.e. very rare occurrence):

The sample orders are shifted by one position; the immunochemistry module performs the test order requested for the sample in the 2nd rack position of Rack B with the sample material in the 1st position of Rack B. After processing the 4th sample position (with the test order requested for the sample in the 5th position) the rack is moved in the L-line to the rack output position. At that time, the module will recognize (as no signal from the rack position sensor) the wrong rack position and issue the Sampling Stop alarm **"Abnormal L2-Line Movement"**. With the occurrence of that alarm, no further samples will be pipetted but the measurement for the samples already in process/pipetted (before the alarm occurred) will be completed.

<u>The software limitation described above and the sample mismatch caused by that limitation can be</u> <u>detected as follows:</u>

The two alarms below must occur within a few minutes time difference in between both alarms

- "Tip/Cup pick up error" (Caution Level)
 Alarm code for cobas 8000 is 301-000002 or 301-000015
 Alram 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

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

Meanwhile and until the new software version is available, your local Roche Diagnostics service organization will contact you and change the setting for the **"Module Rack Buffer setting"** to 1, this setting

- is only required for the immunochemistry modules (cobas e 602, cobas e 601 and E170 modules).
- will ensure that only one rack will go in the idling/processing line (L-Line).



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Note:

• The throughput of the system maybe impacted by that setting change. The impact is dependent on the configuration and workload used.

When the new software version is available it will be installed as a mandatory update to the system.

Actions to be taken by the customer/user

Use the following interim solution until your local Roche Diagnostics service organization changes the setting for the **"Module Rack Buffer setting"** to 1:

Whenever an **"Abnormal L2-line Movement"** (S.Stop Level) is issued by the system and the immunochemistry module (**cobas e** 602, **cobas e** 601 and E170 module) goes in "Sampling Stop," perform the following steps to determine if a sample result mismatch occurred (provided that the alarm **"Tip/Cup pick up error"** occurred a few minutes before the alarm **"Abnormal L2-line Movement"**).

1) Collect the remaining racks in the system.

Standalone systems:

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

Lab automation connected systems:

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

2) Identify the wrong software behavior and locate the rack and mismatched samples

Att 1 "How to identify and deal with potential mixed sample results on cobas e602"

Att 2 "How to identify and deal with potential mixed sample results on cobas e601"

Att 3 "How to identify and deal with potential mixed sample results on E170"

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

4) Run measurements for the identified samples again.



Mixed sample results in immunochemistry modules

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied.

Please transfer this notice to other organizations/individuals on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

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

Best regards,

Contact Details

To be completed locally:

Name Title Company Name Address Tel. +xx-xxx-xxxx xxxx Email name@roche.com Attachment 1 FSN-CPS-2017-012 "How to identify and deal with potential mixed sample results on cobas e602"

Target

How to identify and deal with potential mixed sample results on **cobas** e602 if the two alarms below occur within a short time.

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

Alarm 301-000002 or 301-000015 Alarm 104-000005

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 301-00002 and / or 301-000015 (Caution Level) is issued in advance shortly, by the Alarm screen and Daily Alarm Trace.

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

Alarm						
Alarm List						
Code	Module	Level	Alarm		Date/Time	· •
104-000005	AU1	S.Stop	Abnormal L2-line Mo	vement	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	r	2017/06/16 12:00	
						$\mathbf{\vee}$
Alarm : At	onormal L2-line Moveme	nt				
Code : 10	4-000005		n	Nodule : AU1	Level	: S.Stop
Description L2-line rack trar	nsfer mechanism does n	ot reach at Out-Bu	ffer when L2-line rack	transfer mechanism moving	from sampling position.	
						\sim
						\sim
Pemedy						
(1) Execute < <r< th=""><th>ack Reset>> on the [Ma</th><th>intenance] screen</th><th>of [Utility] job.</th><th></th><th></th><th></th></r<>	ack Reset>> on the [Ma	intenance] screen	of [Utility] job.			
Resume operation	ion; if the alarm recurs,	contact Service Re	epresentative.			\sim
						\sim
	Main	tenance	Delete	New Alarm	Sound	Close

- 2. Collect the remained racks in the corresponded **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 for measuring samples output.
 - 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. Printout "Daily Alarm Trace" and check the alarm "301-000002 Tip/Cup pick up error" or "301-000015 Tip/Cup pick up error" occurs in short time from the occurrence time of "104-000005 Abnormal L2-line Movement".

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

If two alarms below occur in a short time, the failure could happen.

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

If you identified that the software failed follow the next procedure!

2. Handling of potential 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 by performing "Reset or Rack Reset" to Unloader.

Follow 1 through 4 in the Figure 1 below.

Stand	і Ву						2017/04/27	7 18:16	Help
w	orkplace	Reagent	Calibration		QC	Utility		Overview	
Te	est Selection	Data Review	Calib. Review				(1)		Stop
Data:	Routine View	Filter:	ON	OF	F	Filter	Search	Sample Count: 4870	
DM C.	St. S. ID	Rack No Pos.	S. Type Coi Date/Time	· ^		(2)	Searcl	n Sample	
н	1736340381	50068-1	Ser/PI 04/07 10:06:5		Find:	Sample ID	Comment- 001		S.Stop
н	1736359811	5006	Ser/PI 04/07 10:06:5	;	(3)				
н	1736362831	50068-5	Ser/PI 04/07 10:06:5	5	1736340381			\sim	
н	1736379531	50082-2	Ser/PI 04/07 10:07:24	•					
н	1736553111	50025-5	Ser/PI 04/07 10:26:4	•	Search Option	: 🗌 Match	Case		
н	1736372391	50062-1	Ser/PI 04/07 10:44:2						\land
н	I 1736489941	50062-2	Ser/PI 04/07 10:44:20			1 15			Alarm
н	I 1736520561	50006-4	Ser/PI 04/07 10:47:4		Searched S	ample ID			
н	I 1736377501	50016-1	Ser/PI 04/07 10:48:3) L	snows on t	ne screen.			
н	I 1736525401	50079-2	Ser/PI 04/07 10:50:4	•					Monitor
н	I 1736542811	50079-4	Ser/PI 04/07 10:50:5						
H	1 1736527771	50049-5	Ser/PI 04/07 10:51:2						
н	1 1/36566351	50094-4	Ser/Pl 04/07 11:15:20				4		Print
	1736354151	50024-1	Ser/Pl 04/07 11:22:23		Focus Move:		Jp V	Down	
H H	1736367411	50024-1	Ser/Pl 04/07 13:40:1			L			
н	0 1736368391	50039-2	Ser/Pl 04/07 13:40:3						
н	1736359641	50039-5	Ser/PI 04/07 13:40:3	\sim				Close	
Sa Infor	mple Ur mation F	change ckack Priority	Send to DM	elete Recor	d Delete All	Backup D	ata Test Rev	riew Reaction Monitor	Start Start

Figure 1. Data Review screen

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

t Review Sample	: Rou	tine							Г	Rad	k No F	9 05 . :	50	068-1	1				
S. Type Status	: Ser/ : Com	PI Iplete		Sample Carryov	ID ver Ev	asion	: 1736 :	34038	1		Rac	k and	pos	ition	-		Pre-dil	ution	
			1st Res	ult							i		•]
Select Result	Test	Unit	Result	Alarm	R. M.	Dil. A. U.	Time	C. E.	DM	St.	Result	Alarm	R. M.	DII. U	Time	C. E.	DM	St.	~
1st	анвз					📕 A1-1													
1st	A-HCV II	соі	0.038		N	📕 A1-1	10:35:10		н										
1st	HBSAGII	COI	0.335		N	A1-2	10:34:49		н										
1st	ніхсо	соі	0.226		٩	📕 A2-1	11:29:07		н										
		Verif	y corre	spond	led e	2602 mo	odule an	d san	nplin	g tir	ne.								~
			Sample II	nformati	ion	Re	agent Deta	il		Oriç	jinal Dat	a		All F	Results		R	eactio Ionito	n r
Del	lete Test		Up	date			Cancel			P	revious			١	lext			Close	

Figure 2. Test Review screen

Note:

Corresponded **cobas** e602 means that the module which has alarm "Abnormal L2-line Movement (S.Stop Level). Please check the alarm from Alarm screen or Daily Alarm Trace.

- 2.1.3. Repeat step 2.1.1. and 2.1.2. above for all samples on the collected racks.
- 2.1.4. The rack concerned sample mismatching can be identified by the sample which sampling time is the latest.

2.2. Rack position number mode

2.2.1. Go to Workplace> Data Review screen, search racks collected by performing "Reset or Rack Reset" to Unloader.

Note: If the same rack is repeatedly using, the newest "Date/Time" is the latest used.

Stand By		bn	iserv			2017/06/13	16:47	Help
Workplace	Reagent	Calibration		QC	Utility		Overview	\square
Test Selection	Data Review	Calib. Review						Stop
Data: Routine View	Filter:	O N	OFF		Filter	Search	Sample Count: 50	द्न्⊖ Logoff
DM C. st. Seq. E. St. No.	S. ID Rack S. No Type Pos	Comment Date/Time	^	C. Dil. Test	Result Unit	Alarm A. U.	Rg. St. 3rd ٨	
O 000203	50037-3 Ser/PI	06/13 15:28:41		📕 TSH	0.275 IU/mL	A1-1		S.Stop
H O 000204	50037-4 Ser/PI	06/13 15:28:41						
H O 000205	50037-5 Ser/PI	06/13 15:28:41						
O 000206	Ser/PI							
O 000207	50102-2 Ser/PI	06/13 15:28:49						
O 000208	50102-3 Ser/PI	06/13 15:28:49						\neg
Н 000209	50102-4 Ser/PI	06/13 15:28:50						Alarm
H 000210	50102-5 Ser/PI	06/13 15:28:50					_	
H 000211	50037-1 Ser/PI	06/13 16:16:50					=	
H 000212	50037-2 Ser/PI	06/13 16:16:50						L <u>⊢</u> Q Monitor
O 000213	50037-3 Ser/PI	06/13 16:16:51						
O 000214	50037-4 Ser/Pi	06/13 16:16:51						
O 000215	50037-5 Ser/Pi	06/13 16:16:51						C_(Print
O 000216	Ser/Pi		=					
H 000217	50102-2 Ser/PI	06/13 16:16:59						
H 000218	50102-3 Ser/PI	06/13 16:16:59						
H 000219	50102-4 Ser/PI	06/13 16:17:00	\mathbf{v}				\sim	
H 000220	50102-5 Ser/PI	06/13 16:17:00	•					
Sample Information	Jnload Change Rack Priority	Send to DM Dele	te Record	Delete All	Backup Da	ta Test Revi	ew Reaction Monitor	Start

Figure 3. Data Review screen

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

Stand By		bms	13 16:50	R? Help		
Workplace	Reagent	Calibration	QC	Utility	Overview	
Test Selection	Data Review	Calib. Review				Stop
Test Review Sample : Routine S. Type : Ser/Pi Status : Comple	e Sequence Sample IE ete Carryove	e No. : 000211) : r Evasion :	Rack No Pos.	: 50037-1	Pre-dilution	
Select Test L Result TSH IL	Jnit Result Alarm	R. Dil. A. Time C. M. Dil. U. Time E.	DM St. Result Ala	rm R. Dil. A. Time	C. DM St.	S.Stop
	Verify correspo	onded e602 module a	and sampling time	<u>.</u>		Alarm
						Monitor
						Print
					~	
	Sample Information	n Reagent Detail	Original Data	All Results	Reaction Monitor	
Delete Test	Update	Cancel	Previous	Next	Close	Start

Figure 4. Test Review screen

Note:

Corresponded **cobas** e602 means that the module which has alarm "Abnormal L2-line Movement (S.Stop Level). Please check the alarm from Alarm screen or Daily Alarm Trace.

- 2.2.3. Repeat step 2.2.1. and 2.2.2. above for all samples on the collected racks.
- 2.2.4. The rack concerned sample mismatching can be identified by the sample with the latest sampling time.

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Attachment 2 FSN-CPS-2017-012 "How to identify and deal with potential mixed sample results on cobas e601"

Target

How to identify and deal with potential mixed sample results on **cobas** e601 if the two alarms below occur within a short time.

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

Alarm 301-0002 or 301-0015 Alarm 104-0005

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 issued in advance shortly, by the Alarm screen and Daily Alarm Trace.

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

Core Core	Stand By		bmserv	13/06/17	13:55	USB
			Alarm			
Code	Module	Level	Alarm	Da	te/Time	Stop
104-0005	e601	Sample Stop	Abnormal L2-line Movement	13/06/	17 13:34	
402-0401	e601	Caution	Sample Short	13/06/	17 13:33	Shut
315-0015	e601	Caution	Solid Waste	13/06/	17 13:33	Down
301-0015	e601	Caution	Tip/Cup pick up error	13/06/	17 13:32	
301-0002	e601	Caution	Tip/Cup pick up error	13/06/	17 13:32	
						S. Stop
Description	and Remedy		л			Alarm
Description	and Kennedy					
Code :10	4-0005					
Description:	L2-line rack transfe	r mechanism doe	s not reach at Out-Buffer when L2-line rack transfer			
mechanism	moving from sampli	ng position.				
Remedy :(1)) Execute < <rack re<="" td=""><td>eset>> on the [Mai</td><td>intenance] screen of [Utility] job.</td><td></td><td></td><td></td></rack>	eset>> on the [Mai	intenance] screen of [Utility] job.			
Resume ope	eration; if the alarm	recurs, contact se	ervice Representative.			Print
					T	
Delete	New Alarn	n Sound	Maint.		Close	
L						
						Start
? Sel	ect the alarm from t	he list box.			NØ	
Help					628	J

- 2. Collect the remained racks in the corresponded **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 for measuring samples output.
 - 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. Printout "Daily Alarm Trace" and check the alarm "301-000002 Tip/Cup pick up error" or "301-000015 Tip/Cup pick up error" occurs in short time from the occurrence time of "104-000005 Abnormal L2-line Movement".

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	62	2 A 02-113-0006-281	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	

If two alarms below occur in a short time, the failure could happen.

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

If you identified that the software failed follow the next procedure!

2. Handling of potential 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 by performing "Reset or Rack Reset" to Unloader.

c		Stand By				bmserv	13/06/17 14:43	USB
	Workp	lace Re	agen	t	Calibration	QC	Utility	Stop
Те	st Selectio	Data Review		ta		Search	ı Sample	Shut
L	⊙ OFF C	ON	F	Routine Viev	w _	Fir 2		Down
St.	Rack	Sample ID	Туре	Comment-	001 Date/Time	Sample ID		
	N0013-1	00000	1 Ser/Pl		13/06 14:13	C Comment-001 (3)		S. Stop
0	N0050-3	10000	3 Ser/Pl	-	13/06 14:15	200004	-	
0	N0050-4	10000	5 Ser/Pl		13/06 14:15	L <u>I</u>		
0	N0401-2	20000	2 Ser/Pl		13/06 14:16		~	
	N0401-3	20000	3 Ser/Pl	<u> </u>	13/06 14:16	Search Option	Search 4	Alarm
	N0401-4	20000	4 Ser/Pl		13/06 14:16			
P	N0401-5	20000	5 Ser/Pi		13/06 14:16	🗖 Match Case		
	N0401-5	20000	5 Ser/Pi		13/06 14:16	🗖 Match Case	Down Up	
	N0401-5	20000	5 Sen Pi		13/06 14:16	☐ Match Case	Down Up	(((
	N0401-5	20000	5 Ser/FI			Match Case Comment-001	Down Up	
			5 Set/P1			Comment-001	Down Up	Print
			Ser/P1		13:06 14:16	Comment-001	Down Up	Print
			5 Ser/P1		Searched shows on	Comment-001	Down Up	Print
					Searched shows on	Comment-001 Sample ID the screen.	Down Up	Print
	Demogra-	1 Search Fi	5 Sen/Pri	Send To Host	Searched shows on Delete Record	Comment-001	Down Up Close	Print
	Demogra- phics	20000 1 Search Fi	5 Senfri	Send To Host	Searched shows on Delete Record	Comment-001	Down Up Close	Print
	NU401-5	1 Search Fi	s Sen Pri	Send To Host	Searched shows on Delete Record	Comment-001	Down Up	Print
	Demogra- phics	1 Search Fi	Iter the mouse	Send To Host	Searched shows on Delete Record D	Comment-001	Down Up Close	Print

Follow 1 through 4 in the Figure 1 below.

Figure 1. Data Review screen

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

Core Core	l S	tand By									bmserv	1	3/06/17	14:4	14	USB
Worl	kplac	ce Data	Re	ager	nt b. Revie	C	alib	atio	on		QC		l	Utility		Stop
Test selet	ction	Data	Review	Call	b. Revi		Test R	eview	7	_						
Sample : Type :	Routi Ser/P	ine 'I		Sample	e ID :		200004	ŧ			Ra	ack No	Pos. :	N0401-	4 n	Shut Down
Status :	Com	olete		Carryo	ver Eva	ision:						Ra	ck and	positio	n	
Test		Data	Alarm	1st Re	sult	A 11	Time	St		ata Al	Rerun	Re	AII	Time	St	S. Stop
TOXIGG		.00		N.III.		E -1	14:18		_				A.U.	Time	-	
									_						_	Alarm
												<u> </u>	-	ii	_	
			Verif	y corre	espond	led e6	01 mo	dule	and sa	ampling	; time.					CCC
								Ē	_				-		_	
									_					<u> </u>	_	Print
									_						_	· · · · ·
1																
Cancel		emogra	- Sh	ow	Del	ete	Upd	ate	M	anual	Previous		lext	Clos	se	
		pines				5.				lest						
? Help	Type the	e result	data from	-999999	9 to 999	9999, tř	nen pres	s <er< td=""><td>nter>.</td><td></td><td></td><td></td><td></td><td></td><td>\$?</td><td>Start</td></er<>	nter>.						\$?	Start

Figure 2. Test Review screen

Note:

Corresponded **cobas** e601 means that the module which has alarm "Abnormal L2-line Movement (S.Stop Level). Please check the alarm from Alarm screen or Daily Alarm Trace.

- 2.1.3. Repeat step 2.1.1. and 2.1.2. above for all samples on the collected racks.
- 2.1.4. The rack concerned sample mismatching can be identified by the sample which sampling time is the latest.

2.2. Rack position number mode

2.2.1. Go to Workplace> Data Review screen, search racks collected by performing "Reset or Rack Reset" to Unloader.

Note: If the same rack is repeatedly using, the newest "Date/Time" is the latest used.

C	ore (**) ese I	Stand B	у						t	omserv	13/0	06/17	13:55	(USB
	Workp	blace	Re	agent	t Ca	alibratio	n		Q	C		Uti	lity		Stop
Те	st Selecti	on Dat	a Review	Calib.	Review										Stop
	Filter —	O ON		Dat	a outine View	•			Sample	Count: 70)				Shut Down
St.	Seq. No.	Rack	ID	Туре	Comment-001	Date/Time			Test	Result	R.M.	Alarm	Unit		
0	N001015	N0050-5		Ser/Pl		08/06 11:34			TOXIGG	1.00			IU/mL		S. Stop
0	N001016	N0401-1		Ser/Pl		08/06 11:35									•
0	N001017	N0401-2		Ser/Pl		08/06 11:35									
0	N001018	N0401-3		Ser/Pl		08/06 11:35									
0	N001019	N0401-4		Ser/Pl		08/06 11:35									
0	N001020	N0401-5		Ser/Pl		08/06 11:35									Alarm
0	N001021	Ν		Ser/Pl											
0	N001022	Ν		Ser/Pl										ΙL	<u> (((</u>
0	N001023	N0050-3		Ser/Pl		13/06 13:31									
0	N001024	N0050-4		Ser/Pl	<u> </u>	13/06 13:31				_					
0	N001025	N0050-5		Ser/Pl	<u> </u>	13/06 13:31				_					
0	N001026	N		Ser/PI	<u> </u>										
0	N001027	N0401-2		Ser/Pl	<u> </u>	13/06 13:31				_					Print
	N001028	N0401-3		Ser/Pl		13/06 13:31				_	<u> </u>	<u> </u>			
	N001029	N0401-4		Ser/Pl		13/06 13:31	-			_	<u> </u>		<u> </u>		
0	N001030	N0401-5		Ser/PI		13/06 13:31	•								
	Demogra- phics	Searc	h Fil	ter	Send To Host	Delete Record	De	elete	AII Ba	ckup Data	Tes Revi	ew	Reaction Monitor		
He	? elp												\		Start

Figure 3. Data Review screen

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

Core (X1 e60 I	:	Stand By							b	mserv	13/06/17	13:55	
Work	pla tion	ce Data	Review	eager	nt b. Review	Calib	ratio	n	Q	C	l	Jtility	s
Sample :	Rou	tine	-	Seque	nce No. :	Test R 00102	leview 9			Rac	k No Pos. :	N0401-4	S
Type : Status :	Ser/ Com	Pl Iplete		Sample Carryo	e ID : ver Evasio	n:				Perun P	Rack and p	e-dilution osition	
Test		Data	Alarm	R.M.	A	U. Time	St	Data	Alarm	R.M.	A.U.	Time St	
													AI
		Verify	corresp	onded	e601 mo	dule and	sampli	ing time					
													P
Cancel		Demogra phics	a- Sh De	now etail	Delete Test	Upd	ate	Manu Test	al Pr	evious	Next	Close	
? Ti Help	ype th	ie result	data from	-999999	9 to 999999	9, then pre	ss <ent< td=""><td>er>.</td><td></td><td></td><td></td><td></td><td></td></ent<>	er>.					

Figure 4. Test Review screen

Note:

Corresponded **cobas** e601 means that the module which has alarm "Abnormal L2-line Movement (S.Stop Level). Please check the alarm from Alarm screen or Daily Alarm Trace.

- 2.2.3. Repeat step 2.2.1. and 2.2.2. above for all samples on the collected racks.
- 2.2.4. The rack concerned sample mismatching can be identified by the sample with the latest sampling time.

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Attachment 3 FSN-CPS-2017-012 "How to identify and deal with potential mixed sample results on E170"

Target

How to identify and deal with potential mixed sample results on cobas e601 if the two alarms below occur within a short time.

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

Alarm 301-0002 or 301-0015 Alarm 104-0005

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 issued in advance shortly, by the Alarm screen and Daily Alarm Trace.

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

Host <mark>Core</mark> ls€00.091 <mark>E1</mark> Stand By		BMSERV	17/06/14 (Wed)	12:20							
Alarm											
Code Module Level	Alarm	Dateл	ime	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								
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 Remedy Code :104-0005 Level :S. STOP Description L2-line rack transfer mechanism does not reach at Out-Buffer when L2-line rack transfer mechanism moving from											
Remedy											
Delete New Alarm	Sound Maint.		Close								
Select the alarm from the list box Help			\?	Start							
				NIM							

- 2. Collect the remained racks in the corresponded 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 for measuring samples output.
 - 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. Printout "Daily Alarm Trace" and check the alarm "301-000002 Tip/Cup pick up error" or "301-000015 Tip/Cup pick up error" occurs in short time from the occurrence time of "104-000005 Abnormal L2-line Movement".

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

If two alarms below occur in a short time, the failure could happen.

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

If you identified that the software failed follow the next procedure!

2. Handling of potential 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 by performing "Reset or Rack Reset" to Unloader.

Follow 1 through 4 in the Figure 1 below.

Ho	ost <mark>Core</mark> l se in Pi E1 S	tand By			BMSER	√ 17/06/14 (We	d) 13:35
	Workplace	R	leagent	Calibration	QC	Utility	Ston
	Test Selection	Data Rev	iew				Stop
	Filter • OFF • O	N	Data Hard Disk		Searc	ch Sample	Logoff
	St. Rack No.	Sample ID	Type	nent-0 Arrived Date/Time	Find 2	3	
	C0003-2	cont01	Ser/PI	08/29 10:22	200004	-	S. Stop
	C0003-2	cont01	Ser/PI	08/29 10:22	C Comment-00		
	C0003-3	cont01	Ser/PI	08/29 10:22	Commente	·	
	C0003-3	cont01	Ser/PI	08/29 10:22			
	C0003-4	cont01	Ser/Pl	08/29 10:22	Search Ontion	Search 4	
	C0003-4	cont01	Ser/Pl	08/29 10:22	Search Option-		
	C0003-5	contu'i	Ser/Pl	08/29 10:22	🗆 Match Case	╄ ♠	Alarm
	N0039 1	000001	Ser/Pl	06/29 10:22			
	0 N0210-3	100003	Ser/Pl	06/14 13:01			
	0 N0210-0	100000	Ser/Pl	06/14 Searched Sa	mple ID 01		
	0 N0210-5	100005	Ser/Pl	shows on th	ne screen		
	0 N0317-2	200002	Ser/Pl	06/14 13:01			
	N0317-3	200003	Ser/Pl	06/14 13:01			Print
	N0317-4	200004	Ser/PI	06/14 13:01			
	O N0317-5	200005	Ser/Pi	06/14 13:01	-		
	Demo- graphics Se	arch	Filter Send Hos	To Delete Delete	e All	Close	
	? Help	he screen, cl	lick the mouse, p	ress the space bar or <ent< th=""><th>ter>.</th><th>k?</th><th>Start</th></ent<>	ter>.	k ?	Start
							NUM

Figure 1. Data Review screen

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

Host <mark>Core</mark> lst D4 P1 E1	Stand By	/						BMSER	V 17/	06/14 (We	d) 13:35
Workplace	Workplace Reagent		Calibration			QC	Uti	lity	Stop		
Test Selection	Data R	eview									
				T€	est Review						Logoff
Sample : Ro	utine	Seque	nce No.	:				Rack No	Pos.: N03'	17-4	Logon
Type : Se	r/PI	Sampl	e ID	: 2000	04				🗖 Pre-c	lilution	
Sample Status	s : Com	plete						Rack and	d position		S. Stop
Test	1st Resu Data	ilt Alarm F	RMDil	AU	Time St	Г	Rerun Res	sult Alarm R M [Time St	
TOXIGG	7.00	¥		E1-2	13:04						
						Í					
											Alorm
	Veri	fy corre	sponded E	170 mo	dule and	samp	ling time				Alarm
	<u> </u>										Print
]										
Cancel	emo - aphics	Detail	Delete Test	<u>`</u> [u	Jpdate	Man Te	ual st	Previous	Next	Close	
? To sele Help	ect from the	e test iter	m: touch th	e screer	ı, click the	mous	e or use t	he arrow keys]	Start
											NUM

Figure 2. Test Review screen

Note:

Corresponded E170 means that the module which has alarm "Abnormal L2-line Movement (S.Stop Level). Please check the alarm from Alarm screen or Daily Alarm Trace.

- 2.1.3. Repeat step 2.1.1. and 2.1.2. above for all samples on the collected racks.
- 2.1.4. The rack concerned sample mismatching can be identified by the sample which sampling time is the latest.

2.2. Rack position number mode

2.2.1. Go to Workplace> Data Review screen, search racks collected by performing "Reset or Rack Reset" to Unloader.

Note: If the same rack is repeatedly using, the newest "Date/Time" is the latest used.

ŀ	lost <mark>Core</mark>	September 1	Stand By				BMSEF	V 17/	/06/14 (We	d) 12 21
	W	orkplace	Э	Reagent	Calibration		QC	Uti	ility	Ston
ĺ	Test	Selection	Data Re	view						Stop
	Filte	r DFF OC	DN	Data Hard Disk	_		Sample Cour	nt: 159		Logoff
	St.	S. No.	Rack	Sample Type	nment- Arrived		Test 1	st	Rerun	
	0	N000166	N	Ser/PI	Dater		TOXIGG 4	.00 ¥		S. Stop
	0	N000167	N0317-2	Ser/PI	06/14 10:39	,	-			
		N000168	N0317-3	Ser/PI	06/14 10:39)				
	0	N000169	N0317-4	Ser/PI	06/14 10:39	1				
		N000170	N0317-5	Ser/PI	06/14 10:39)				
		N000171	N0038-1	Ser/PI	06/14 11:55	i				
	0	N000176	N	Ser/Pl						Alarm
	0	N000177	N	Ser/PI						
		N000178	N0210-3	Ser/PI	06/14 11:56	i –				
	0	N000179	N0210-4	Ser/PI	06/14 11:56	;				
	0	N000180	N0210-5	Ser/PI	06/14 11:56	i				
	0	N000181	N	Ser/PI						
	0	N000182	N0317-2	Ser/PI	06/14 11:56	i				Print
		N000183	N0317-3	Ser/Pl	06/14 11:56	; 				
		N000184	N0317-4	Ser/PI	06/14 11:56					
	0	N000185	N0317-5	Ser/PI	06/14 11:56				~	
Demo- graphics Search Filter Send To Delete Record All Data Test Reaction Monitor										
	? Hel	p Select 1	the sample	from the list box.				\ ?		Start
										NIM

Figure 3. Data Review screen

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

Host <mark>Core</mark> lSE D4 P4 E1	Stand By			BMSER	V 17/06/14 (Wed	i) 12 21			
Workplace	Workplace Reagent		Calibration	QC	Utility	Stop			
Test Selection	Data Rev	iew							
			Test Review			Logoff			
Sample : Ro	utine S	equence No.	: 000184	Rack No F	os.: N0317-4				
Type : Sei	r/PI S	ample ID	:		Pre-dilution				
Sample Status	1st Result	te		Raci	k and position	S. Stop			
Test	Data Al	larm R.M. Dil.	A.U. Time St.	Data Alarm R.M. D	il. A.U. Time St.				
TOXIGG	4.00 ¥		E1-1 11:59						
						Alarm			
	Verif	y corresponde	d E170 module and sa	mpling time.					
				<u> </u>					
				<u> </u>		Print			
	emo - N	Delete							
Cancel	aphics	Detail Test		st Previous	Next				
? To select from the test item: touch the screen, click the mouse or use the arrow keys. Help									
						NUM			

Figure 4. Test Review screen

Note:

Corresponded E170 means that the module which has alarm "Abnormal L2-line Movement (S.Stop Level). Please check the alarm from Alarm screen or Daily Alarm Trace.

- 2.2.3. Repeat step 2.2.1. and 2.2.2. above for all samples on the collected racks.
- 2.2.4. The rack concerned sample mismatching can be identified by the sample with the latest sampling time.

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