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. Sto
Description	and Remedy		л			Alarm
-						
	4-0005 mple Stop				A	
		r mechanism doe	s not reach at Out-Buffer when L2-line rack transfer			
	moving from sampli					
			intenance] screen of [Utility] job.			
Resume ope	eration, il trie alarm	recurs, contact se	ervice Representative.			Print
Delete	New Alarn	n Sound	Maint.		Close	
L						
						Start
?	ect the alarm from t	he list box.			NO	
Help					628	5

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

[Core Carl e60 I	Stand By					bmserv	13/06/17	14:43	USB
Т	Workp		i	agent Calib.	Review	alibration	QC	Ut	ility	Stop
St		ON Sample		Туре	a outine View Comment-00		Fin_2 © Sample ID	rch Sample		Shut Down
0	N0013-1 N0050-3 N0050-4			Ser/PI Ser/PI Ser/PI		13/06 14:13 13/06 14:15 13/06 14:15	C Comment-001 3)	_	S. Stop
0	N0050-4 N0050-5 N0401-2 N0401-3		100005 200002	Ser/PI Ser/PI Ser/PI		13/06 14:15 13/06 14:15 13/06 14:16	Search Option	Search 4		
Ļ	N0401-3			Ser/Pl		13/06 14:16 13/06 14:16	T Match Case			Alarm
							Comment-001	Down	Up	
							Sample ID the screen.			Print
	Demogra- phics	Search	Filt	er	Send To Host	Delete Record D		c	lose	

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.

Work	plac	ce	Re	agei	nt	C	alibr	atic	n		QC		L L	Jtility		Sto
st Select	tion	Data	Review	Cali	b. Revie	w										
							Test R	eview								
ample :	Rout	ine									Ra	ck No	Pos.:	N0401-4		Shi Dov
pe:	Ser/F	-		Sampl			200004	ļ					F Pr	e-dilutior		
atus :	Com	plete			ver Eva	sion:							k and	positior		
Test		D-t-		1st Re	sult			a t		-	Rerun R	le.				. St
		Data	Alarm	R.M.		A.U. E -1	Time	St	Dat	ta Ala	rm R.M.		A.U.	Time	st 📃	
DXIGG		1.00				E -1	14:18	┛╌┝	_						-	
									_							
	i i															Ala
			Marci C				0.1	1.1.				L				
	_	_	vering	corre	espona	ea eo	UI moo	iule a	ina sa	mpling	time.				_ •	
									_						-	
	1-1-														_	
	_								_						_	Pri
	_								_						-	
									_						- `	
				_				_								
Cancel		emogra phics		ow 🔪	Dele Tes		Upda	ate		est	Previous		ext	Clos	e _	

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.

С	ore c x1 e60 I	Stand B	y						b	mserv	13/0	06/17	13:55	USE	в
	Workp	blace	Re	agent	t Ca	alibratio	า		Q	С		Uti	lity	Sto	n
Те	st Selecti	on Dat	a Review	Calib.	Review									510	٢
	Filter —			Dat	a coutine View	•			Sample C	ount: 700)			Shu Dow	
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. St	ор
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								Alar	m
0	N001021			Ser/Pl											
0	N001022			Ser/Pl											(
0	N001023			Ser/Pl		13/06 13:31									
0	N001024	!		Ser/Pl	<u> </u>	13/06 13:31				_ <u> </u>					
0	N001025			Ser/Pl	<u> </u>	13/06 13:31									
0	N001026			Ser/Pl	<u> </u>										
0	N001027			Ser/Pl	<u> </u>	13/06 13:31								Prin	nt
	N001028			Ser/Pl		13/06 13:31				<u> </u>		<u> </u>			
	N001029			Ser/Pl		13/06 13:31									
0	N001030	N0401-5		Ser/Pl		13/06 13:31	▼								
	Demogra- phics	Searc	h Fil	ter	Send To Host	Delete Record	De	elete		kup Jata	Tes Revi		Reaction Monitor		
	? elp												\	stai	rt

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 CX1 e60 1	s	tand By							I	bmserv	13/06/17	13:55	
Work		1		eager		Calil	oratio	n	G	QC	l	Jtility	s
est Select	lon	Data	Review		ib. Review	Test	Review						
ample : ype :	Rout Ser/F			Seque Sample	nce No. : e ID :	0010	929			Rac	k No Pos. :	N0401-4	S D
tatus :	Com	plete			ver Evasio	n:				1	Rack and p	e-dilution	
Test			1	1st Re				_		Rerun R			s.
		Data	Alarm	R.M.		.U. Tim		Data	Alarm	R.M.	A.U.	Time St	
OXIGG		1.00			E E	2 13:3	4						
					├─── ↑			-	-	-			
													AI
	╌┝╌┏┷	Vorifu	corrosp	ondod	e601 mo	dulo and	d campl	ingtime		-			
		verny	corresp	onueu	2001 110	uule all	i sampi	ing time	•				
	- -						_						
								_	_	-			P
Cancel		emogra		now	Delete	U	date	Manu		revious	Next	Close	
		phics		etail	Test			Tes					
	ne th	e recult	data from	_999999	9 to 999999	9 then n	acc - En	tars					- s
		e e sull	unta nom			o, then pl						R	

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.

<end of the document>