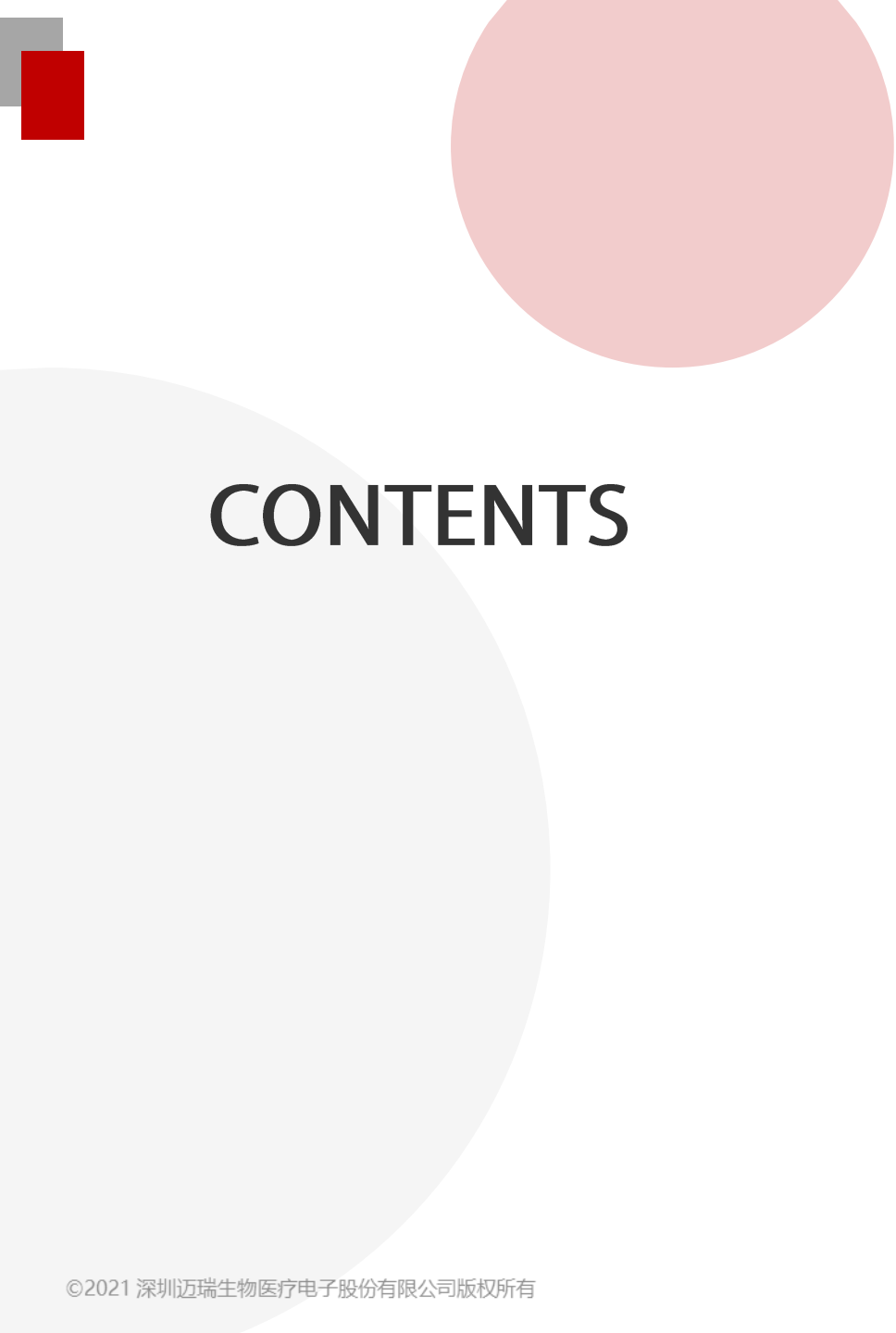


HCG Calibration falure

IVD International Clinical Application Department

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2024/9/4



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Case Background

Background

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Summary

Require:

- Customer use HCG reagent lot 230201 (exp. Date 27.03.2024) on CL-1200i;
- Calibrate current lot of reagent with new lot of calibrator (lot number 230901, expiration date 6.10.2024, open 1.02.2024);
- Calibration failure with flag SLO, DEV

Выв. 00 : 25 06.02 17:31

Реагент/калибровка Управление расх.материалами Рез-т калибровки Обзор реагента Настр. Позиция кал.

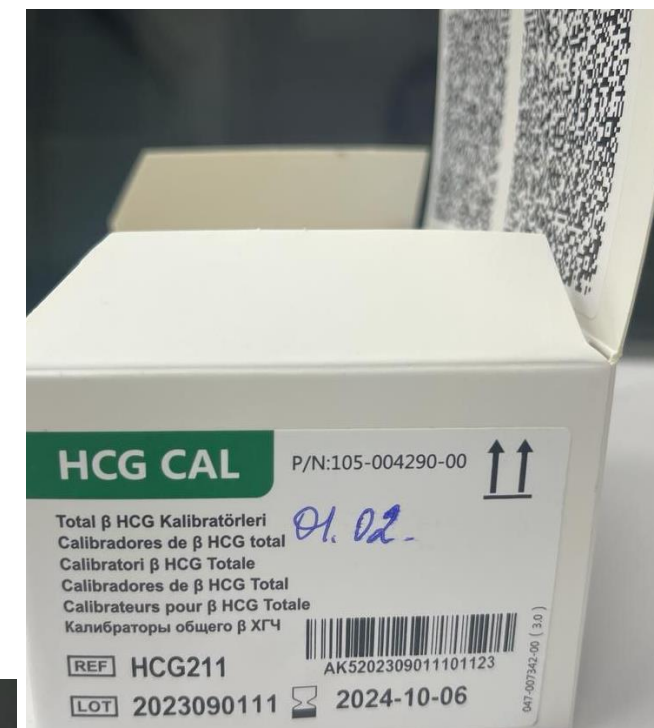
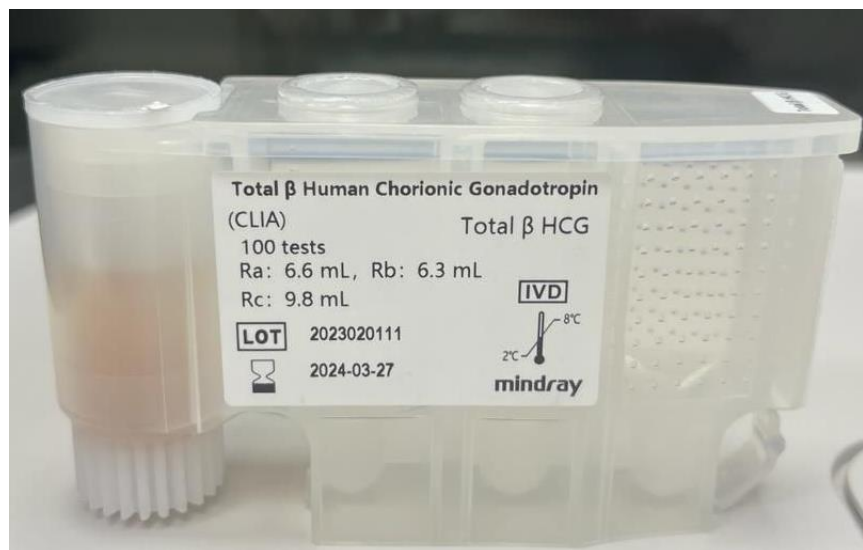
Хим. ALL Статус ALL Текущий История Дата кал. 22.12.2023 - 22.12.2023

Хим.	№ парт	Сер.№	Флаг	Мат.модель	Сост.калиб	Дата/врем.кал
FT3	230401	001718		4PLC	Продлено	03.01.2024 14:46:08
TSH	230501	041626		4PLC	Откалибр.	11.01.2024 09:32:25
FT4	221005	004924		4PLC	Откалибр.	11.01.2024 09:23:45
FSH	230201	000748		4PLC	Откалибр.	13.01.2024 15:47:07
LH	221101	51295		4PLC	Откалибр.	13.01.2024 15:46:07
Anti-TPO	230601	006935		4PLC	Откалибр.	18.01.2024 15:31:50
E2	230101	00260		4PLC	Откалибр.	05.02.2024 12:24:26
PROG	230101	062649	R.Exp	4PLC	Откалибр.	05.02.2024 12:34:06
PRL	230201	005422		4PLC	Откалибр.	06.02.2024 12:17:35
Total βHCG	230201	001286	SLO,DEV	4PLC	Сбоев кал.	06.02.2024 17:20:31

Поиск F1 Кал.данные F2 Архив F5 Тренд F6 Печать F7

Follow :

- Ask about any problem with other tests;
- Ask about system errors and performance system check;
- Ask about procedure of calibrator and reagent maintenance, like time of warming ets:
- Ask calibration results
- Ask QC results for this test;



Calibration results :

- RLU of calibrators C1 and C2 significantly decreased from target

Рез-т калибровки

Отобр. реагента

Настр.

Позиция кал.

Данные калибровки

Хим. Total βHCG

№ парт.реаг. 230201

Сер№реа 001286

Мат.модель 4PLC

Сост.калиб Сбоев кал.

Дата кал. 08.02.2024 15:44:13

№ парт 230901

Уровень	Конц	OCE	Флаг	№ прт.субстр.	Сер.№ субстрата	Дата/врем. кал
C0	0	3981.159		20230903	07707	08.02.2024 15:42:13
C0	0	3993.609		20230903	07707	08.02.2024 15:42:33
C0	0	4001.271		20230903	07707	08.02.2024 15:42:53
C1	54.16	103517.793		20230903	07707	08.02.2024 15:43:13
C1	54.16	104780.999		20230903	07707	08.02.2024 15:43:33
C2	4541.98	8597224.057		20230903	07707	08.02.2024 15:43:53
C2	4541.98	8468024.581		20230903	07707	08.02.2024 15:44:13

Пред F4

След F5

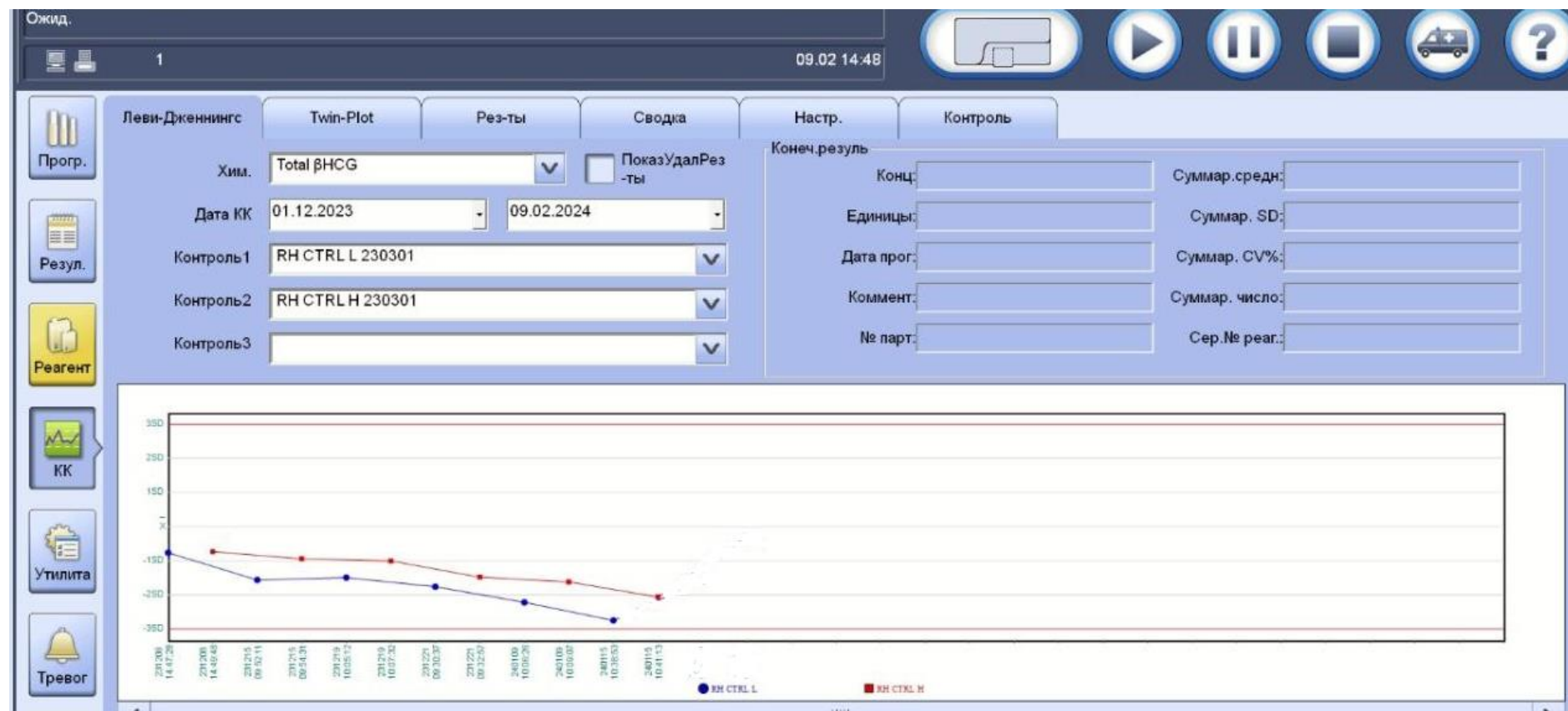
Печать F7

Закреть F8

HCG Catalog		
Calibrator	Cal point	Lot20230901
Reagent Lot230201	C0	4236
	C1	181706
	C2	13082306
Reagent Lot230501	C0	4309
	C1	222879
	C2	14981741

QC results :

- QC results display trend to decrease results of rests;
- There is last reagent bottle if this lot at customer laboratory

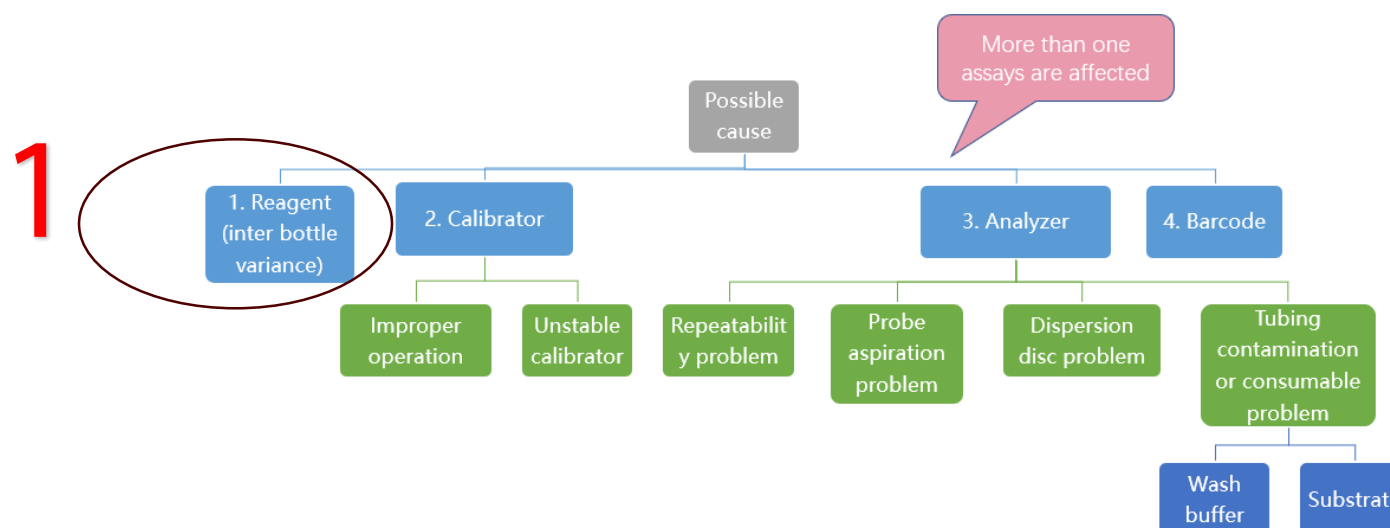


Case analysis:

- No problem with other tests;
- System status of analyzer is ok: no error message, no alarms;
- Effect check is ok;
- Expiration date of reagent is Ok;
- QC results display trend to decrease results of rests;
- Calibration RLU decrease;
- Consumables status is Ok;
- QC lot is the same, do not change;
- Last reagent bottle of this lot on customer side

Case ideas:

- CAL Failure with SLO and DEV flag, which means
DEV: "Calibrator RLU deviation out of range. Check failed"
- SLO: "Calibration slope check failed"
- First suspect the reagent problem



Take new reagents :

- Customer use new fresh lot of reagents and re-calibrate with the same lot of calibrator;
- Calibration successfully complete;
-

Данные калибровки

Хим. Total βHCG № парт.реар. 230501 Сер.№реа 001191

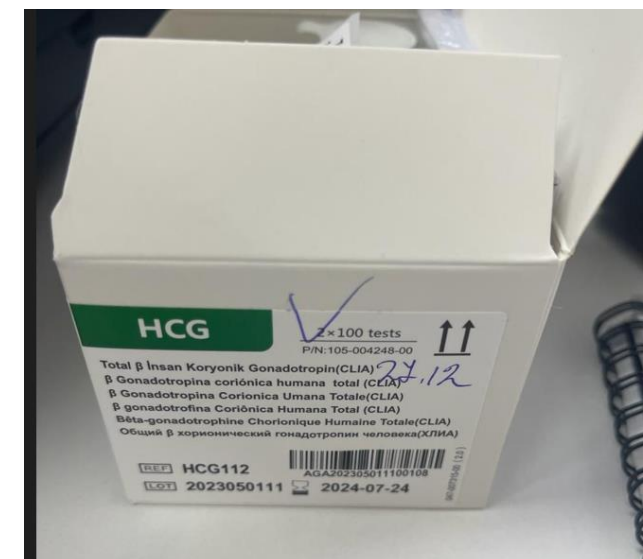
Мат.модель 4PLC Сост.калиб Откалибр. Дата кал. 06.02.2024 19:15:54

№ парт 230901

Уровень	Конц	OCE	Флаг	№ прт.субстр.	Сер.№ субстрата	Дата/врем.кал
C0	0	3975.314		20230903	07707	06.02.2024 19:13:54
C0	0	4118.146		20230903	07707	06.02.2024 19:14:14
C0	0	4066.381		20230903	07707	06.02.2024 19:14:34
C1	54.73	148639.557		20230903	07707	06.02.2024 19:14:54
C1	54.73	153074.041		20230903	07707	06.02.2024 19:15:14
C2	4516.55	10776915.751		20230903	07707	06.02.2024 19:15:34
C2	4516.55	11214646.062		20230903	07707	06.02.2024 19:15:54

Пред F4 След F5 Печать F7 Закреть F8

	HCG	Catalog	
1	Calibrator	Cal point	Lot20230901
2			
3	Reagent	C0	4236
4	Lot230201	C1	181706
5		C2	13082306
6			
7	Reagent	C0	4309
8	Lot230501	C1	222879
9		C2	14981741
10			



QC results display more convenient results:



Result:

- Customer successfully calibrate test;
- Pay attention to reagent maintenance. Reasons to decrease RLU could be:
 - Out of reagent expiration date
 - Out of on-board stability reagent
 - Repeatedly put on and off reagent of analyzer could lead to reagent deterioration
 - Reagent storage should be in appropriate temperature (+2+8)

Thanks !

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