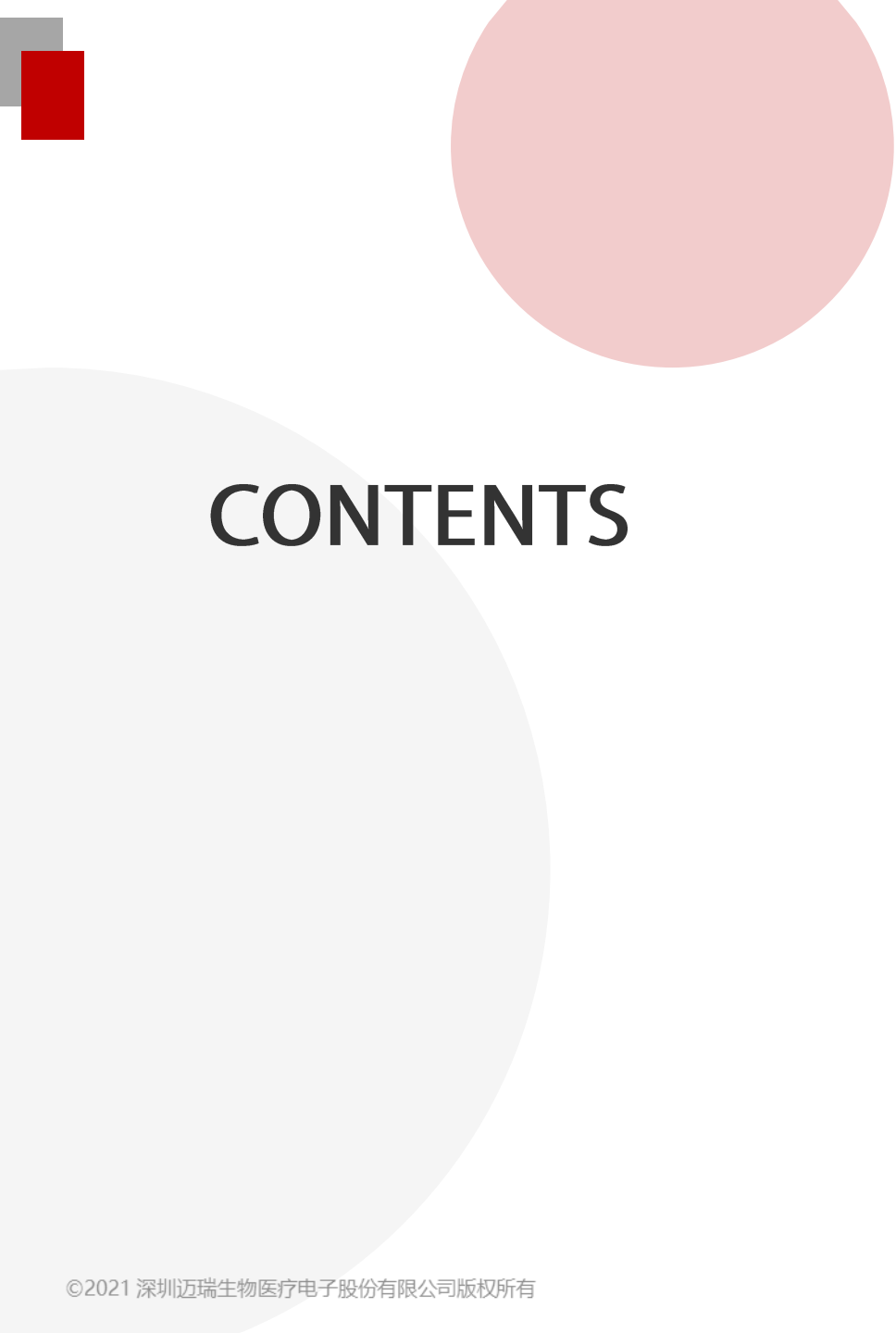


International BA Case Enzymes LIN

IVD International Clinical Application Department Russia, Saint-Petersburg

2024/10/16



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Require:

- Customer ask about become non-usual enzyme results on Biochemistry analyser;
- This customer about half year work with Mindray BA analyser and get quite experienced;
- Few times a day analyser BS-800 get negative results, on enzymes, like ALT, AST, a-AMY;
- After re-exam ion this analyzer results become normal.
- LIN fLag on results within refence ranges
- ...

Химанализ	Резул.	Флаг
Fe	5.2	
TP	77.1	
α-AMY	90.5	
AST	19.4	
ALT	40.3	LIN
T-bil-D II	6.89	
D-bil-D II	2.48	
CRP II	91.0	EXT
CREA-S	65.5	

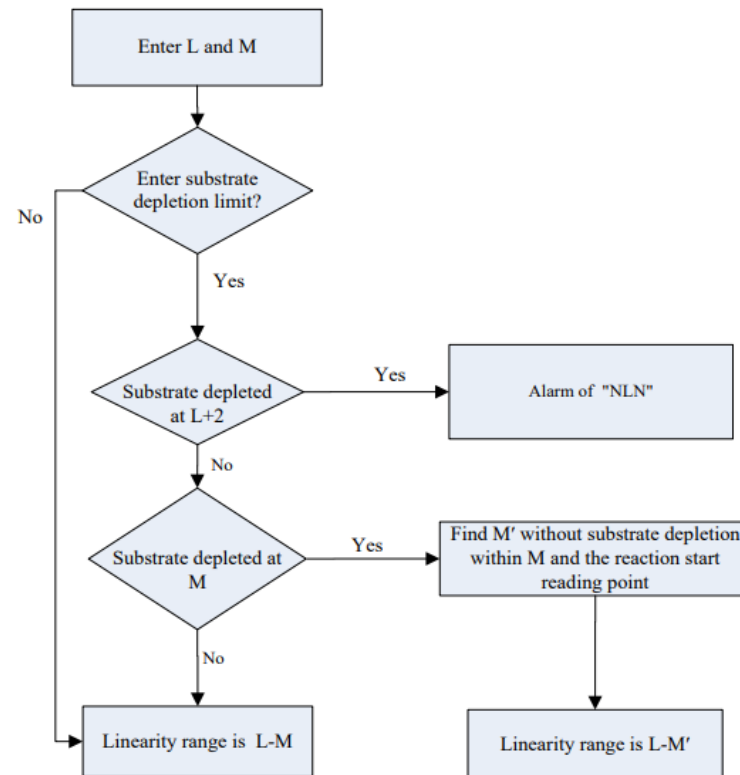
LIN alarm meaning:

- The measuring points for result calculation are nonlinear, because the sample concentration is too high, or the substrate depletion limit is not specified or unreasonable. The lamp is aged.



?

Figure 4.3 Determination of linearity range for **Kinetic** measurement:



Fact	Idea
Different tests affected	Not related with reagents
No issue with non-enzyme tests	Not related with Multisera Calibrator
No issue with non-enzyme tests	Not related with quality of water supply

- First: as have LIN flag: **ask photo of reaction curve**
- Second: ask about sample condition and pre-analytics requirement;
- Third: check recent alarms and system status;
-

Case Ideas: check reaction curve

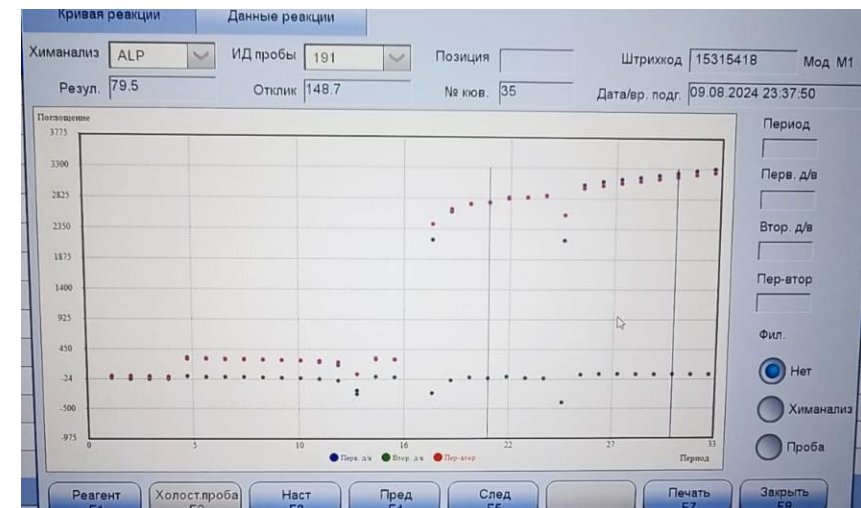
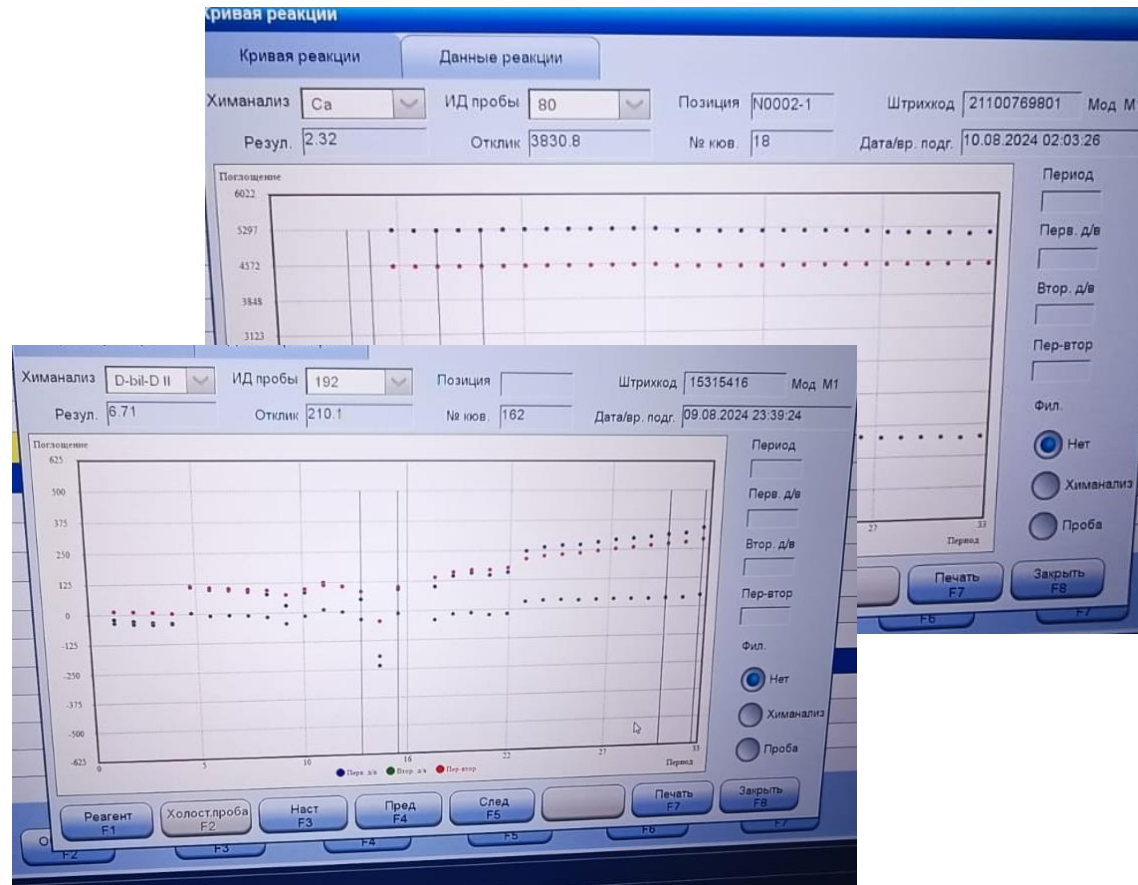
Background

Ideas

Solution

Summary

Reaction curve reveal abnormalities: on enzyme tests and non-enzyme tests



Case Ideas: ask sample condition and pre-analytics requirement

Background

Ideas

Solution

Summary

- Reagent storage condition is ok
- Centrifugation condition is 3000 rpm 10 min
- Sample test type and type tube is ok



Case Ideas: check recent alarms and system status

- Reveal error 10x: water blank out-of-limit
- Highlights in maintenance: Lamp need to be replaced

[illegible]

ИТ	Дата/время	Описание
	10.08 04:11:31	SDM : В блоке подачи нет штативов для проб Часть: Лоток блока подачи штативов
9	10.08 04:08:06	M1 : Холостая проба с водой вне диапазона (10X)
5	10.08 03:38:28	M1 : Предел линейности вне диапазона.ИД/штрихкод пробы: 81/21100770501; позиция: N0011-6; химанализ: ALP
03	10.08 01:27:55	SDM : В штативе установлены лишние

Case Ideas

Background

Ideas

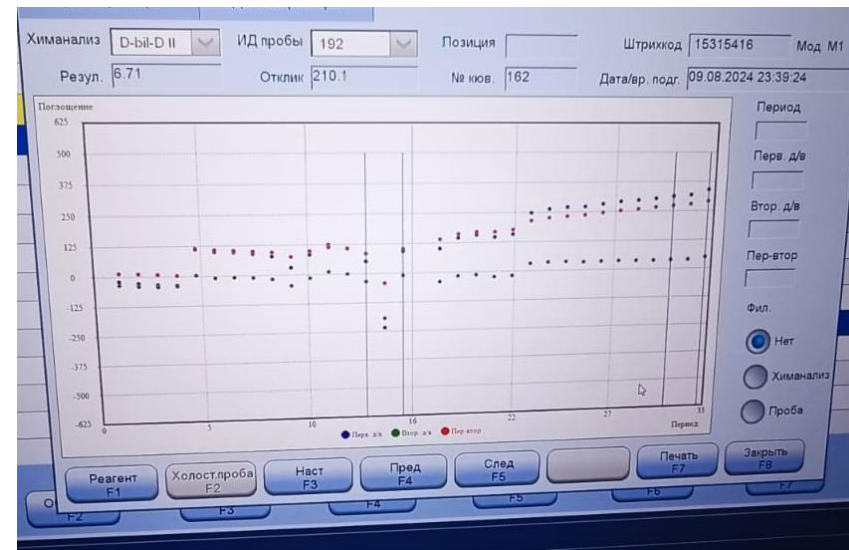
Solution

Summary

Reaction curve reveal abnormalities: on enzyme tests and non-enzyme tests

Possible reason:

- Lamp aging
- Mixer do not perform well
- Mixer hitting cuvette
- Bubbles in reaction cuvette

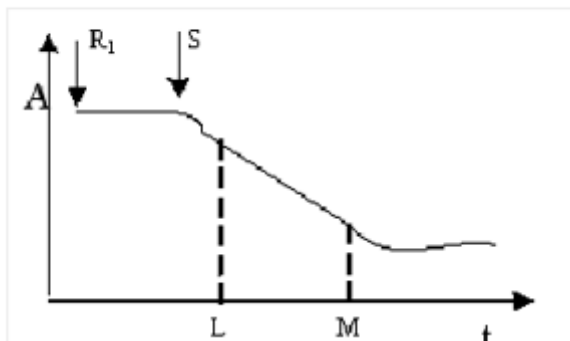


Reaction curve reveal abnormalities: on enzyme tests and non-enzyme tests

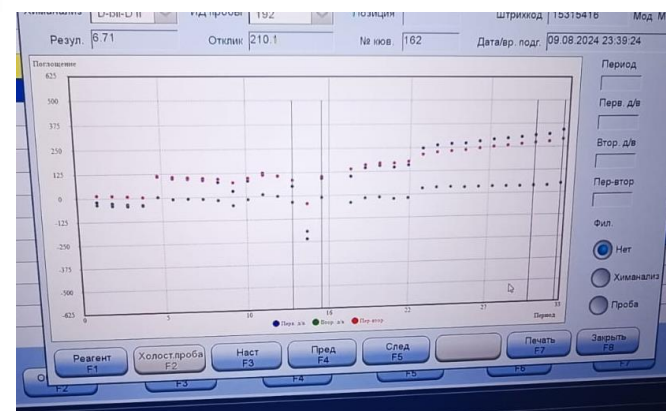
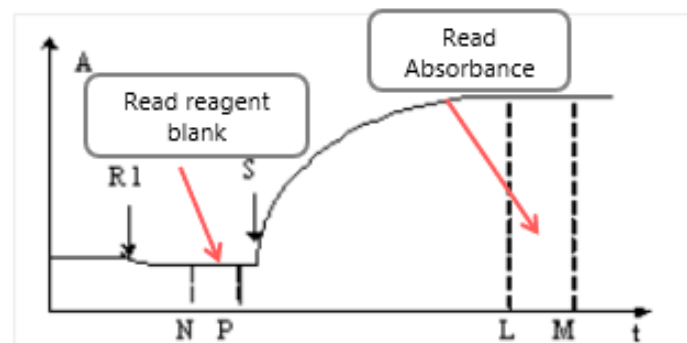
For enzymes tests user kinetic methods and end-point methods for other tests.

This two methods difference with time of measurement, so flick on absorbance more affect kinetic reading than end-point

Single-reagent Kinetic Reaction



Single-reagent End Point Reaction



Case Solution

Reaction curve reveal abnormalities: on enzyme tests and non-enzyme tests

Possible reason:

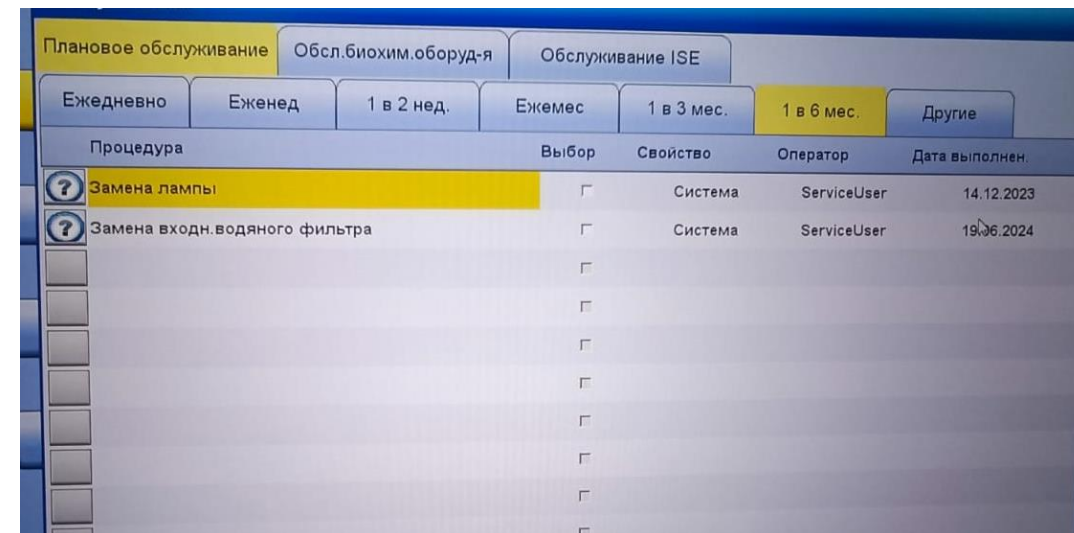
- Lamp aging – there is system highlights +10X error reveal
- Mixer do not perform well – not confirmed
- Mixer hitting cuvette – not confirmed
- Bubbles in reaction cuvette – no alarms and no obvious evidence

Background

Ideas

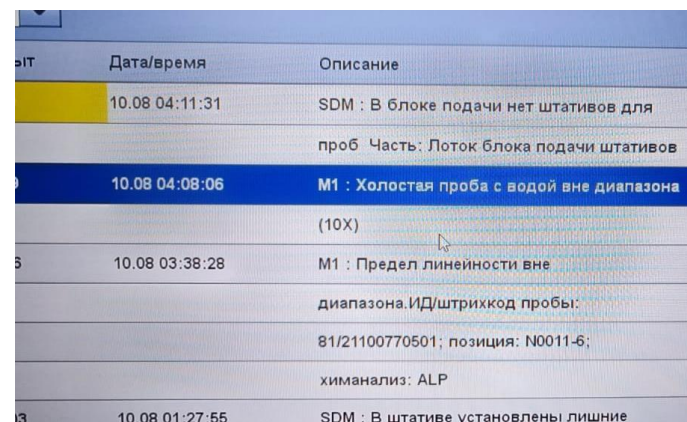
Solution

Summary

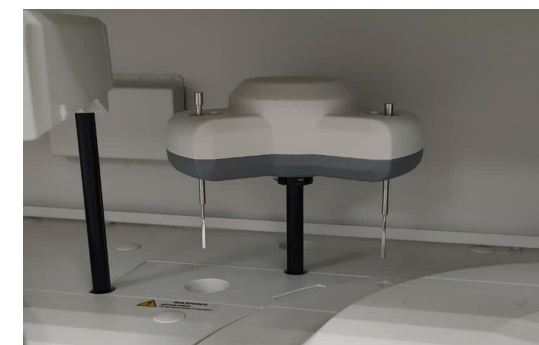


Плановое обслуживание						
Обсл.биохим.оборуд-я						
Обслуживание ISE						
Ежедневно	Еженед	1 в 2 нед.	Ежемес	1 в 3 мес.	1 в 6 мес.	Другие
Процедура		Выбор	Свойство	Оператор	Дата выполнен.	
Замена лампы		☐	Система	ServiceUser	14.12.2023	
Замена входн.водяного фильтра		☐	Система	ServiceUser	19.06.2024	
		☐				
		☐				
		☐				
		☐				
		☐				
		☐				
		☐				
		☐				
		☐				

Solution: replace lamp (half-year PM)



ИТ	Дата/время	Описание
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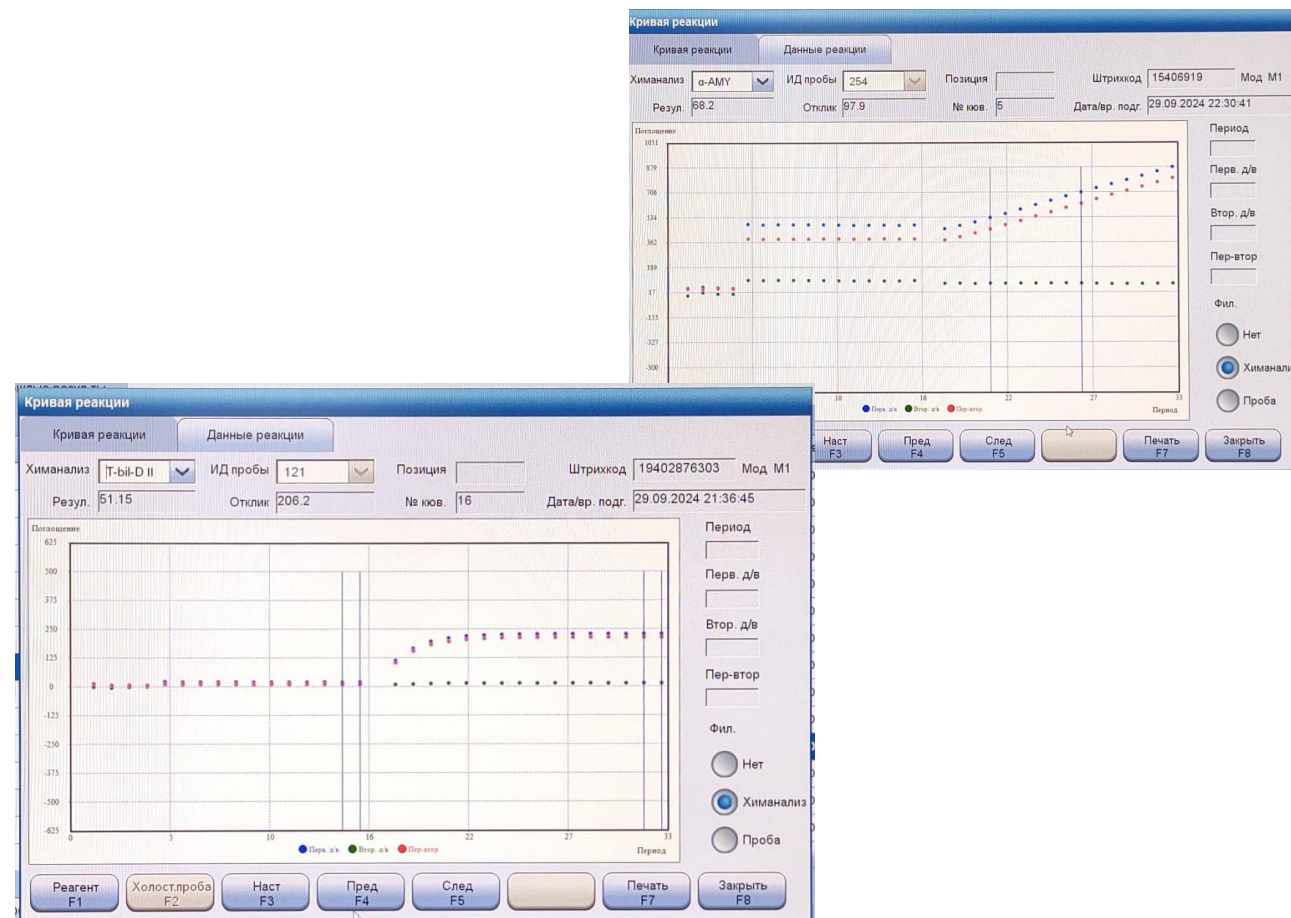
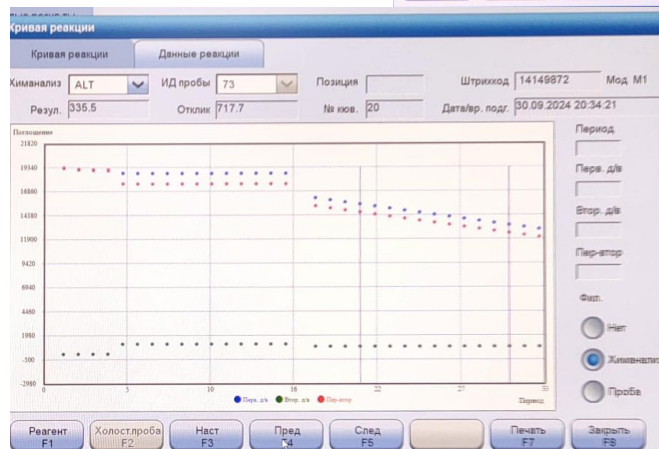
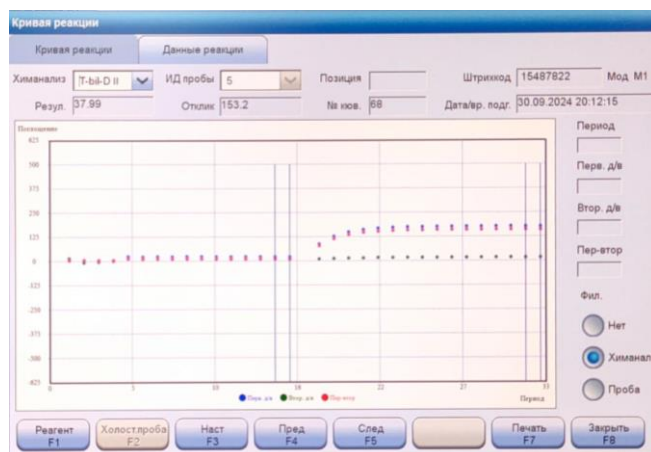
- there is system highlights +10X error reveal
- **Casuse:** last 10 measurements of water blank cuvettes after wash station if exceed 10 last measurements.
- **Possible solutions:**1. Check if the cuvette is overflowing. 2. Check if the Replace Lamp command is executed during lamp replacement. 3. Check if the Cuvette Check command is executed after maintenance.



Solution: replace lamp (half-year PM)

Reaction curve after lamp replacement:

After replacement lamp reaction curve is ok



Main points:

- Ask customer about their experience and how long they used instrument – in this case half-year is important information;
- Ask about data last PM is obligatory information
- Even if customer complain specific kind of tests check other tests also
- Good understanding of reaction curve reading is obligatory

Thanks!

mindray迈瑞