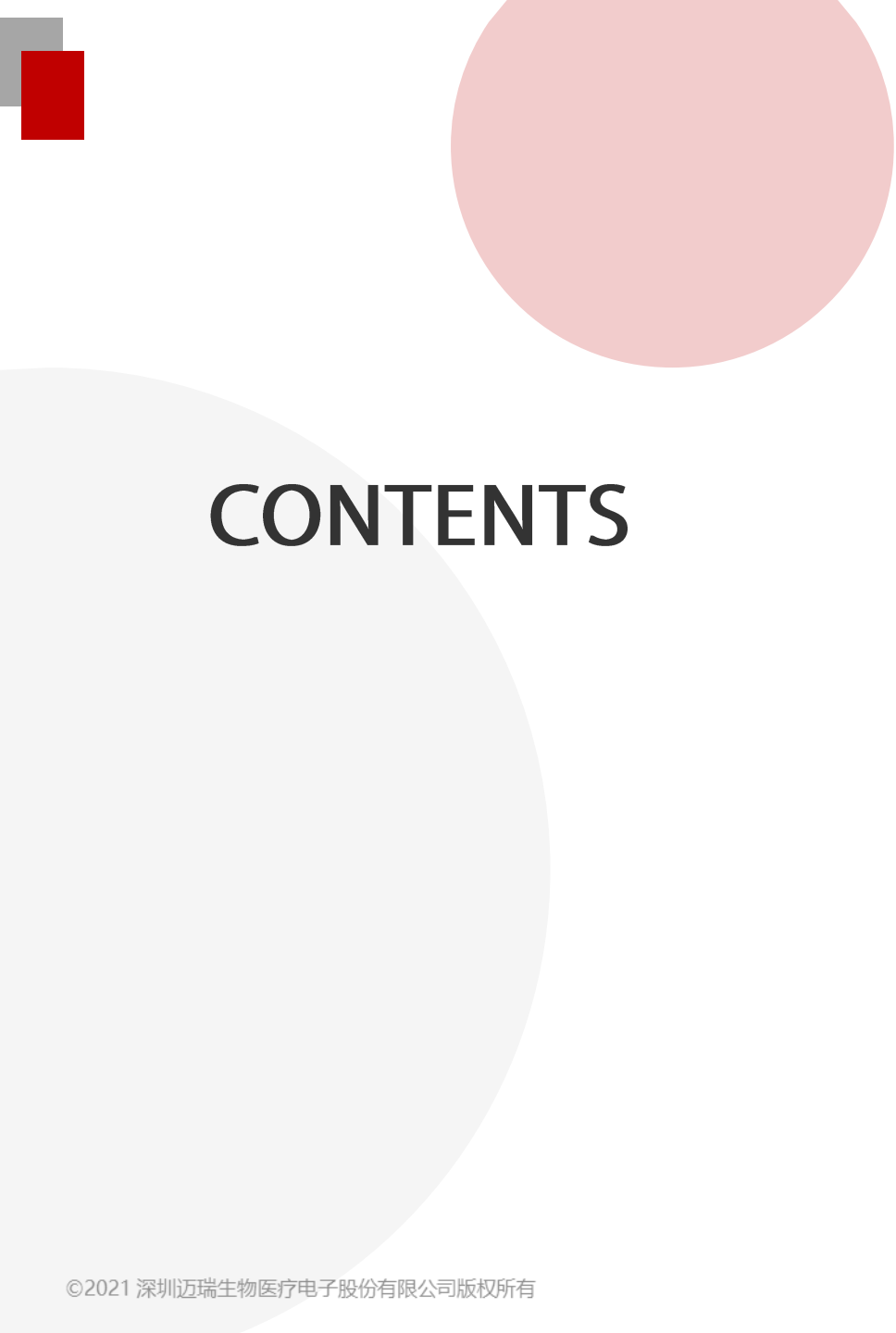


Urgent Alert PII Result Corruption from Roche Acid Wash on BS-2000

IVD International Clinical Application Department

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2025/7/10



CONTENTS

01. Case Background



02. Case Analysis



03. Case Solution



04. Case Summary



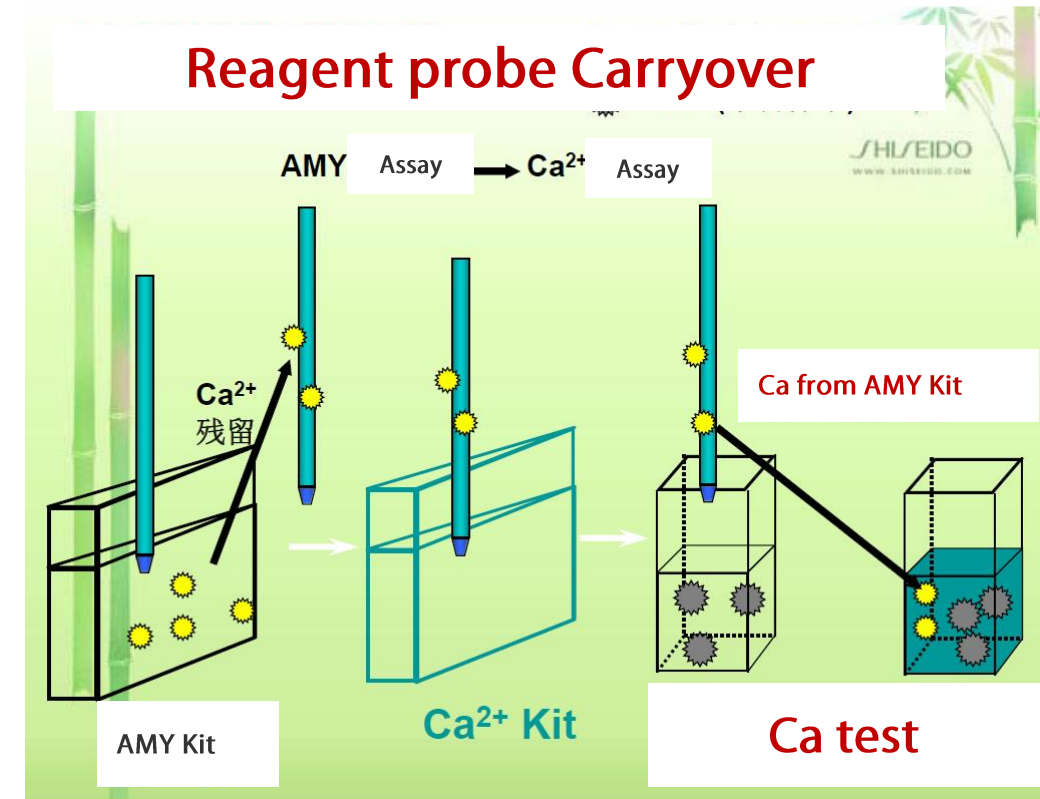
How to understand carryover?

What are the factors that can influence carryover?

Carryover refers to residual material from a previous sample or reagent that contaminates the next sample being tested; can causes false results by introducing traces of a previous reaction into a new one.

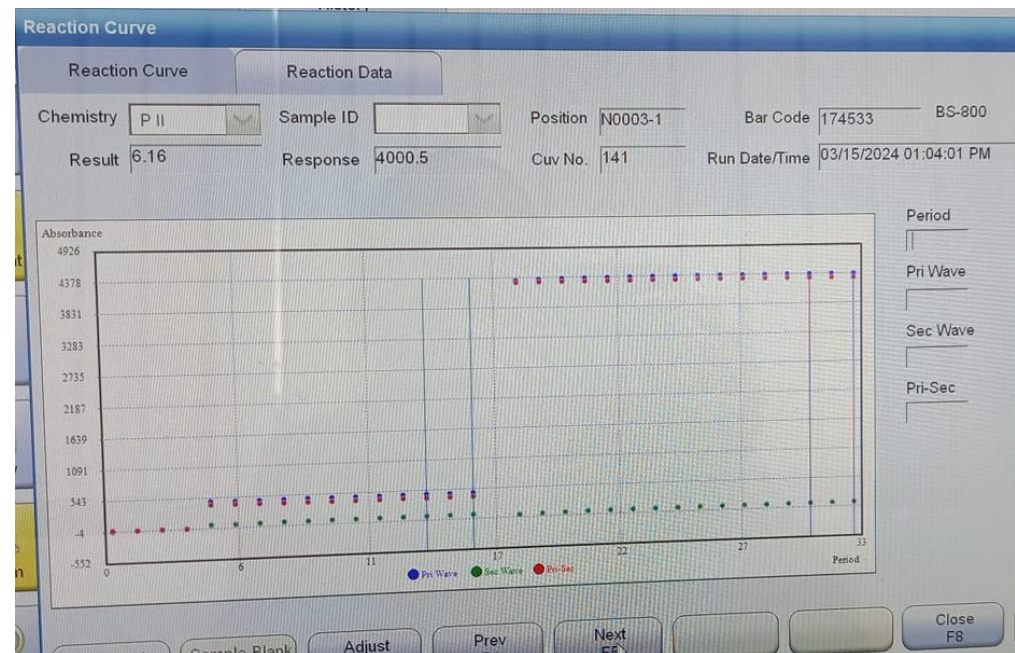
Factors that contribute to carryover issues:

- poor condition of the analyzer
- improper usage of analyzer
- lack of routine maintenance
- accumulation of debris inside the analyzer
- improper test order



Context:

- A sample result issue was observed during routine testing of PII on an BS-2000 analyzer (SAL6000).
- The issue occurred when the patient sample had elevated TP levels, when PII results within the same run showed doubled values.
- When PII was tested as a single parameter the results were accurate and repeatable.



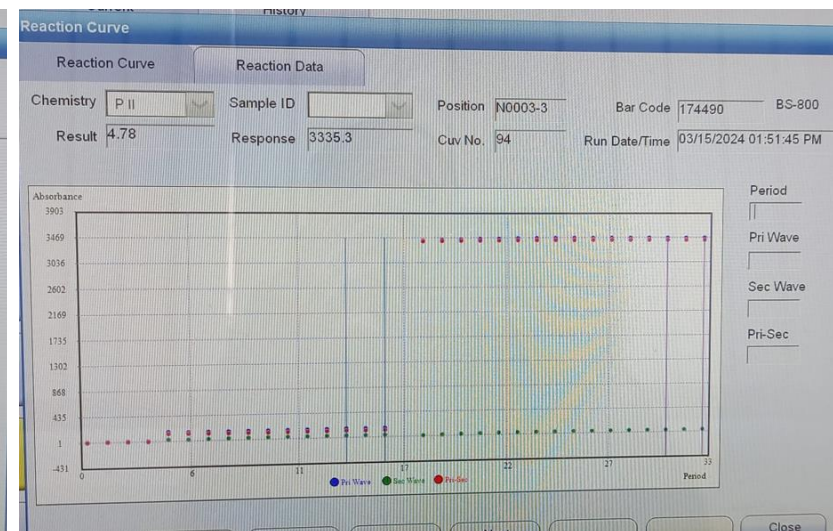
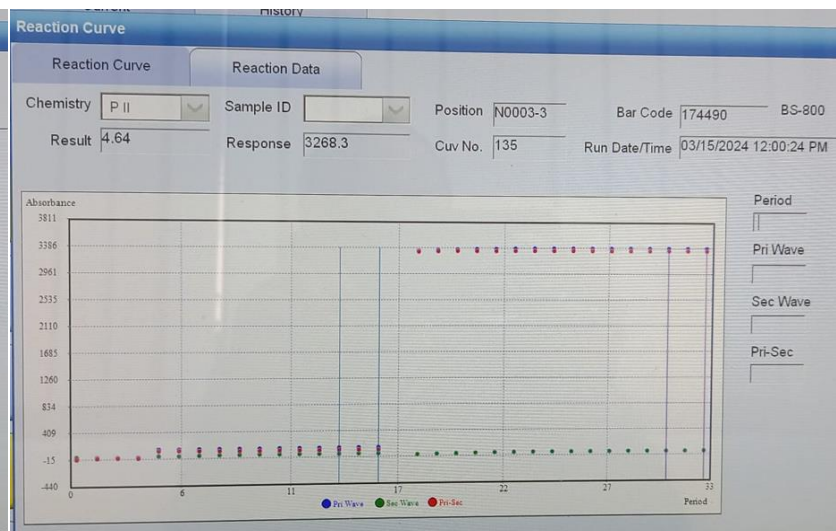
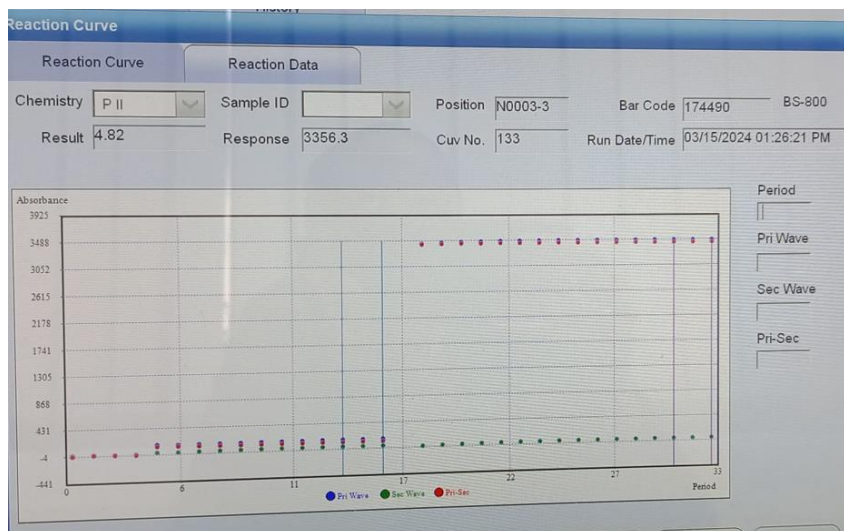
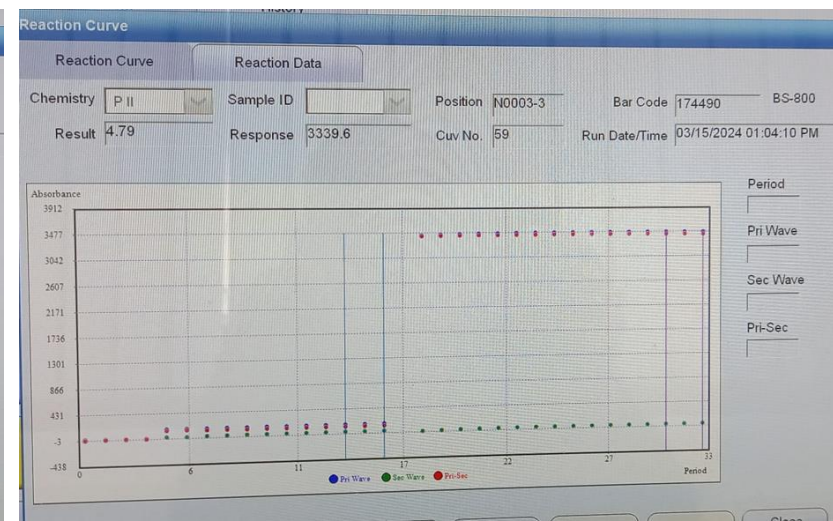
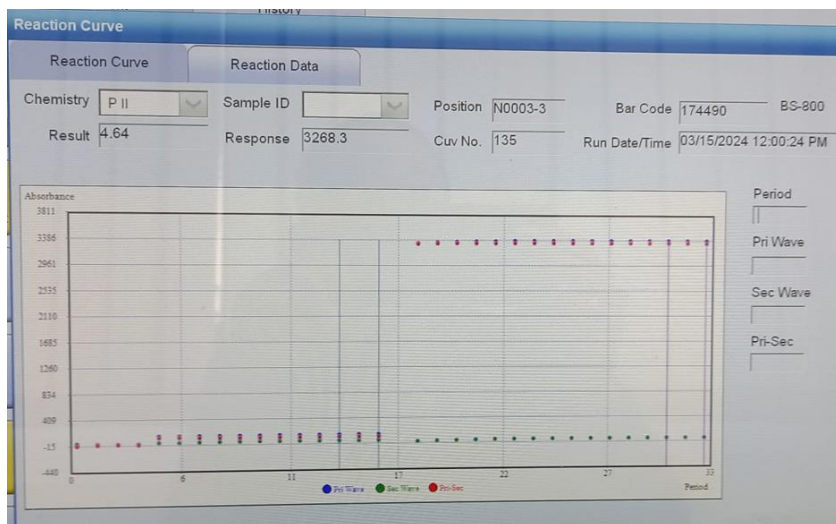
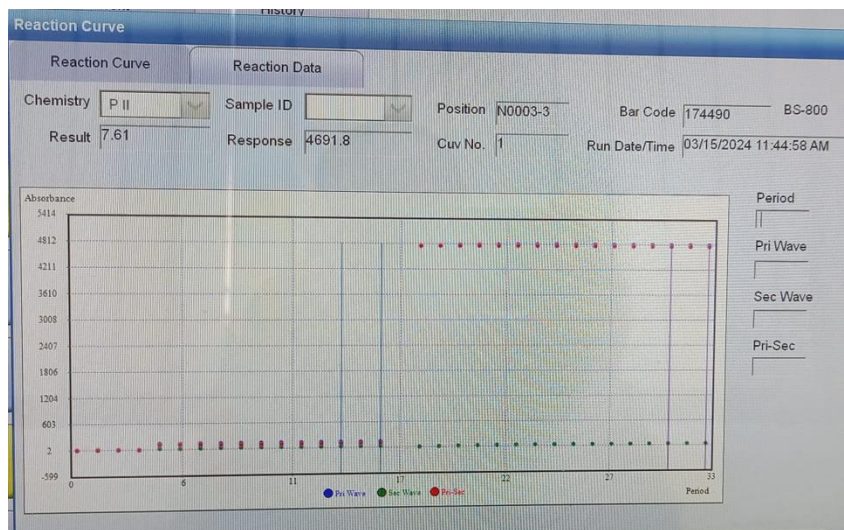
Case Analysis – PII repeatability

Background

Analysis

Solution

Summary



Case Analysis

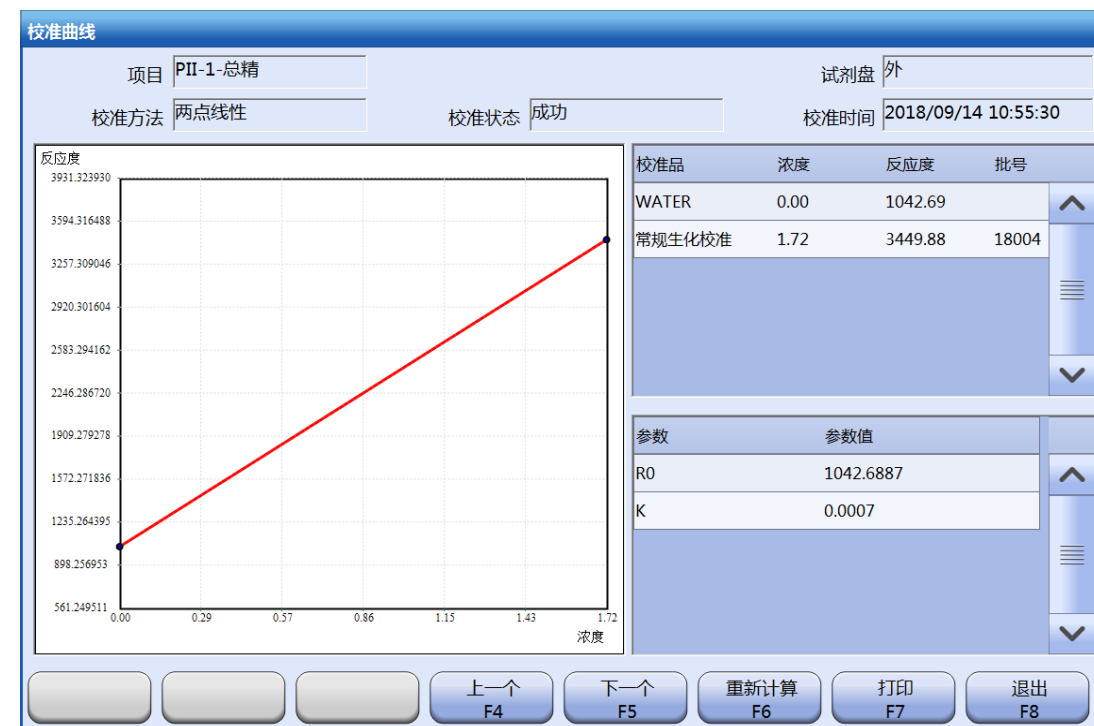
Background

Analysis

Solution

Summary

The calibration curves obtained from the system for PII show a highly consistent linear relationship between theoretical and actual values.



=> we exclude the following scenarios as potential causes:

- Reagent stability issues
- Calibrator inconsistencies
- Instrument malfunctions
- Parameter configuration

W response: 1050.8

Cal response: 3668.4

R0: 1050.8356

K: 0.0020

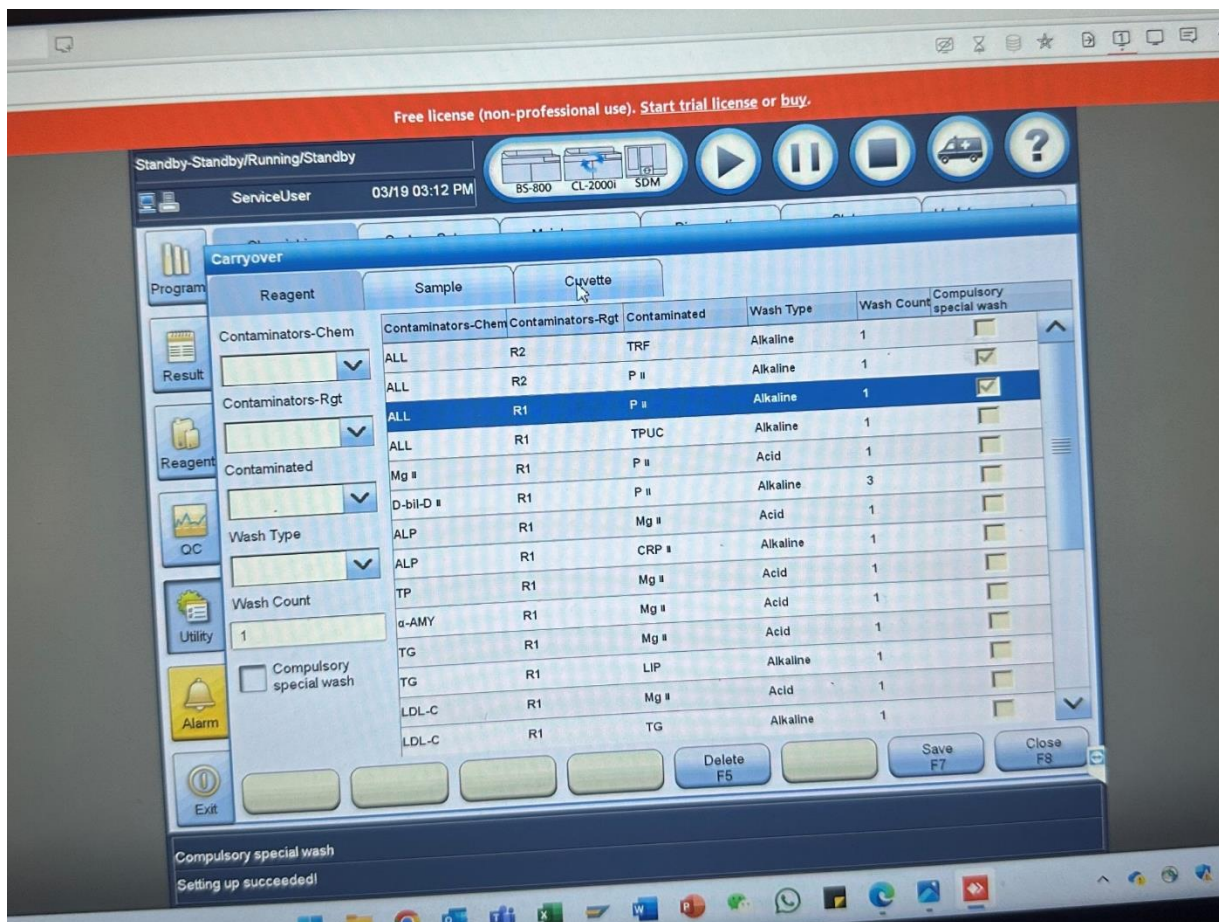
Case Analysis

Background

Analysis

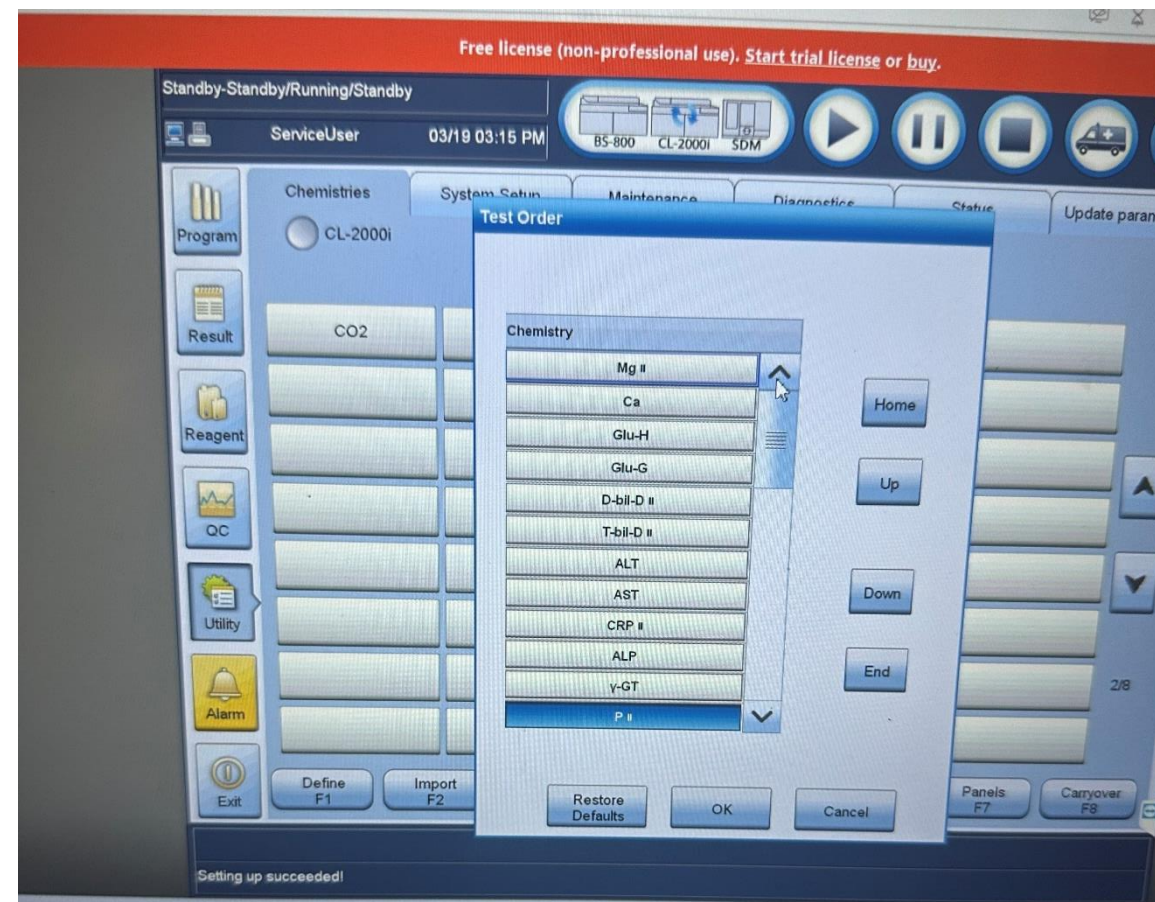
Solution

Summary



The end-user added extra wash steps for both R1 and R2 of PII prior to performing the PII analysis to minimize potential carryover contamination.

They also adjusted the test order for both scenarios: as recommended by Mindray and also the scenario where PII was the first test run on each sample.



Carryover context

Background

Analysis

Solution

Summary

Sample/ Reagent probe carryover contamination

Investigated potential contamination from the sample probe, especially when switching between high TP and PII tests.

Mixer carryover contamination

Evaluated whether residual reagent or sample left in the mixer could cause interference.

Cuvette carryover contamination

Examined whether residual components from previous reactions remained in the cuvette, affecting subsequent PII measurements.

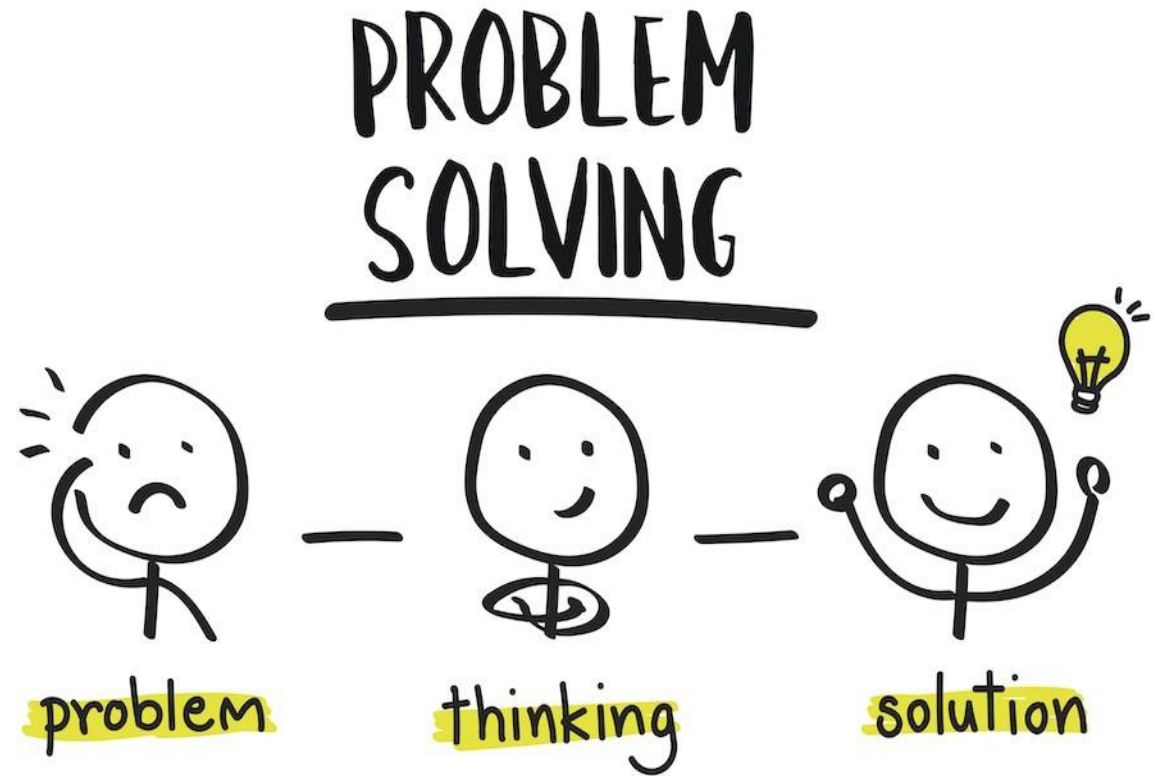
Washing system carryover contamination

Investigated the washing system efficiency, particularly the use of acid wash from Roche, which was linked to the contamination. Extra wash steps for both R1 and R2 of PII were added to minimize the risk.

Reagent carryover contamination

Analyzed reagent purity and compatibility, as well as the test sequence to ensure PII was the first test run. Adjusted the test order as recommended by Mindray to minimize cross-contamination.

- The carryover issue in PII analysis was linked to the use of Roche's Cell Wash Solution II used as Acid Wash. The formulation of this wash solution, contains formic acid, citric acid, Nikkol BT-9 and was not suitable for Mindray BS series analyzers.
- To resolve the carryover issue, we replaced the Roche acid wash with the Mindray Acid Wash as recommended.
- After implementing the recommended Mindray wash solution, the carryover issue in PII analysis was resolved, demonstrating the importance of using manufacturer-specific cleaning solutions.



Case Summary

Background

Analysis

Solution

Summary

EU-GJLA202311240011

mindray

November 27, 2023

DECLARATION

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, (“Mindray”) manufacturer of Mindray BS series chemistry analyzers and chemistry reagent, hereby announce 24mmol/L hydrochloric acid or 50mmol/L citric acid can be used as the DA wash solution to clean sample and reagent probes, mixers and cuvettes of the chemistry analyzer. It’s effective for removing proteins, lipids, ions and other chemistry reaction residues on probe, mixer or cuvette surfaces.


Zhou Chun
Marketing Manager of In-Vitro Diagnostic Division, Europe
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.



- The issue was reported by the end-user after observing higher PII values when high TP samples were tested in the same run.

- Verification tests were conducted by adjusting the test order, running PII as the first test and adding extra wash steps for both R1 and R2 of PII.

- Carryover issue in PII analysis linked to the use of Roche’s Cell Wash Solution II instead of Mindray’s recommended acid wash.

- Issue was solved with consistent and accurate PII results after implementing the recommended cleaning protocol.

Summary

- PII results were affected when run after high TP samples.
- Suspected carryover contamination from probes, mixer, cuvette or washing system.

To avoid and resolve carryover contamination, follow Mindray's carryover workflow and use recommended consumables, including:

- Define recommended carryover pairs
- Approved acid wash solution
- Proper test order (e.g. run PII before high TP)
- Extra wash steps for sensitive assays

Mixing consumables or protocols from other manufacturers (e.g., Roche acid wash) may lead to insufficient cleaning and contamination.

Carryover solutions



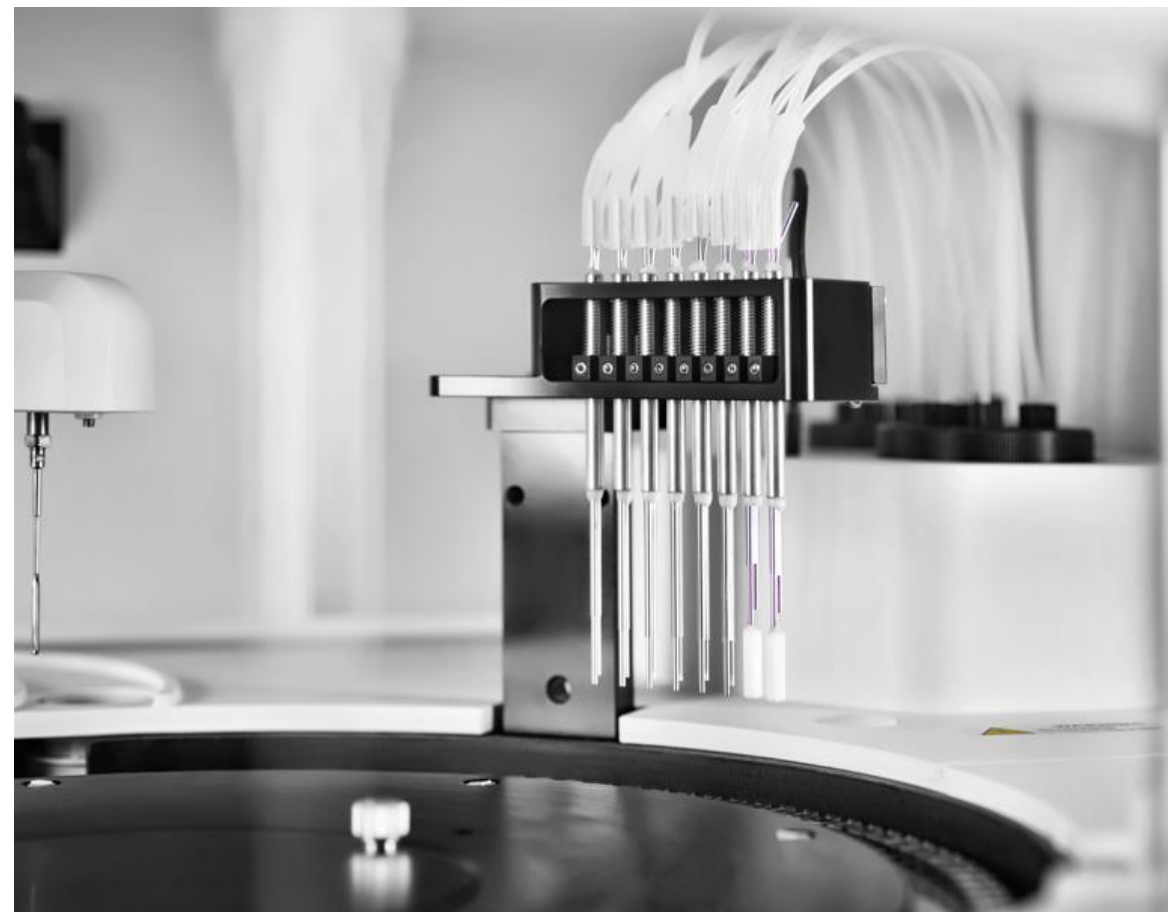
Carryover pairs



Test Order



Maintenance



Thanks!

mindray迈瑞