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Eliminating clot risk with the new cobas b 123 POC system

“Clotted samples, formerly the bane of a blood gas machine operator’s life...”

Price 2nd edition, (2004). p35/36.

With the ever-increasing demand for Point-of-Care (POC) testing, the laboratory has moved closer to the patient, allowing the almost immediate availability of test results.¹⁻³ Results can subsequently be acted on faster and more efficiently, and can then be used to guide drug therapy, surgical strategy and medical management, a particular benefit in emergency medicine and the operating environment.^{2,4} It is now accepted that POC testing has medical, financial and operational benefits^{5,6}, and the potential to improve patient outcome from earlier treatment.⁶

However, pre-analytic, analytic and post-analytic factors can influence the quality of POC testing leading to data errors and misinterpretation³, for example, due to sample clotting.⁷⁻⁹

In a study of over 65,000 samples assessed over a 2-year period in in-patients for routine and stat samples¹⁰, overall 14.2% were found to have clotted pre-analytically, with 63.6% of these samples being in paediatric departments. Another analysis in an out-patient clinic showed that 13.4% of samples had clotted.¹⁴

Whilst being able to run a sample immediately through a POC instrument gives the sample less time to coagulate and can help to ensure its integrity¹², blood clots can

still form and can be awkward to remove from a blood gas analyzer.¹³ For cartridge-based instruments, a clot has the potential to result in the failure of the entire cartridge long before its normal expiration time, with all the accompanying costs of this.¹

The inefficiencies caused by clotting in POC testing systems

Clotting of samples is always a concern, particularly in neonates in whom blood gases are the most common test performed.¹² Clotting can result in:

- Delayed blood gas results in critical care patients leading to subsequent delays in appropriate management
- Highly inconvenient downtime for the critical care POC analyzer user
- Increased stress and unplanned increased workload for already over-stretched hospital staff/POC analyzer users
- Unplanned significant costs for a service engineer, replacement of consumables, laboratory time, etc.
- Possible subsequent increase in time a patient remains on the critical care ward (and the associated costs)

The new POC analyzer from Roche – cobas b 123 POC system – is specifically designed to eliminate these clot blockage risks and associated costs.

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Life needs answers

“There are [now] systems ... to prevent clotted samples ... from entering key areas of the [POC] instrument.”

Point-of-care Testing, Christopher P. P., Andrew St.J., Jocelyn M.H. (2004), 2nd edition.

As an added new feature, the cobas b 123 POC system includes several methods of ensuring that blood clots do not stop it functioning, thereby allowing POC test users to get on with their everyday work, with no interruption to patient care and no costs associated with clot blockages.

Mechanisms of clot prevention with Roche’s new cobas b 123 POC system

Three key clot prevention features have been integrated into the new **cobas b 123 POC** system in response to customer needs. Although they are simple to understand, the Research and Development at Roche that allowed their inclusion was extensive and complex.

1. High quality sample collection

Whilst focus has traditionally been on the analytical phase of testing, the pre-analytical phase remains an important consideration for testing accuracy and offers room for improvement in test results and sample quality.⁷ One review of over 40,000 samples confirmed that pre-analytical errors occurred in 68.2% of samples taken in a stat laboratory.¹⁵ Another recent analysis of over 67,000 samples in a clinical laboratory over one-year found that pre-analytical errors occurred in 77.1% of cases.¹⁶

Roche has a wide range of anticoagulated syringes and capillaries. The use of suitable balanced dry-spray heparinized syringes and capillaries not only ensures high quality results with no dilution or ion bias effects, properly handled, eliminates the risk of clotting at the point of care. For total clot-free confidence combined with Roche plastic clot catchers, clots can be prevented before a sample is presented to the analyzer.

2. Clot catcher defense; pre-analytical feature

The pre-analytical New Clot Clearance feature integrated into the **cobas b 123 POC** system stops any clot that

may be present in the patient’s blood sample moving from the syringe or capillary into the analyzer.

Firstly, a sample port needle acts as a bottleneck for the whole pathway of the sample; this prevents clots entering the analyzer.

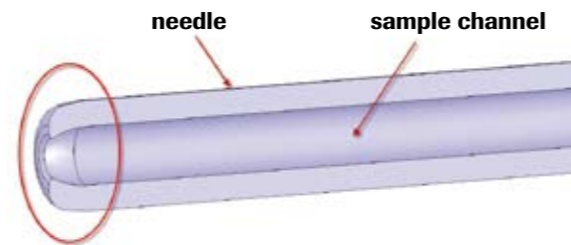


Figure 1: Bottleneck at front end of sample port needle

Secondly, there is an additional bottleneck in **cobas b 123** models with co-oximetry measuring chambers. This means that clots are collected, and can be removed by the automated default washing routine that rinses away the sample.

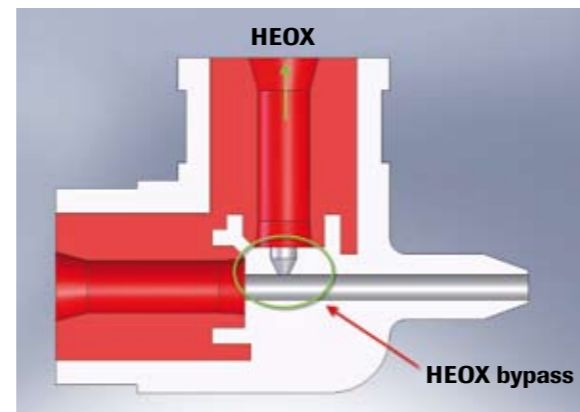


Figure 2: Bottleneck at HEOX bypass

This dual-action pre-analytical barrier prevents any clot-contaminated samples from instantly blocking the system.

3. Clot expulsion; preventative feature

Clot detection within the analysis chamber is one of the features of critical care analysers that minimises the risk of errors and contributes to ease of use.¹

In situations where blockage of the sample path does occur, the **cobas b 123 POC** system using its in-built optical sensors - detects whether the lack of fluid path flow is due to a clot. If it is, the analyzer then performs a series of automated expulsion steps to remove the clot and permit it to continue its analysis un-interrupted.

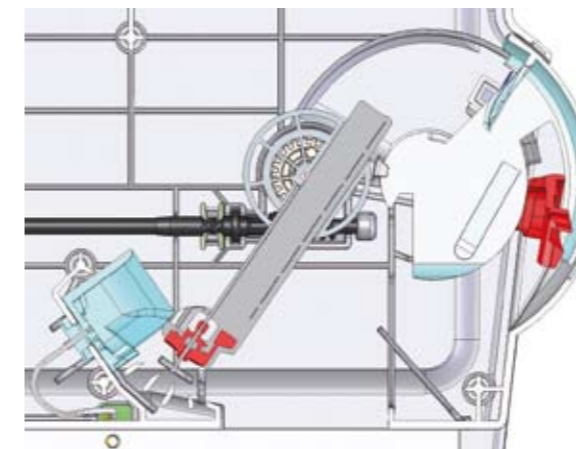


Figure 3: Needle in expulsion position

If a clot is detected:

- a) The pump within the **cobas b 123 POC** system automatically reverses and expels the clot into a spill area positioned in the fluid pack where it is absorbed.
- b) To perform this, the needle automatically turns to the expulsion position.
- c) The analyzer then automatically turns back to its ready state, with no user action necessary.

The evidence for clot prevention with Roche’s new cobas b 123 POC system

Several externally performed tests with **cobas b 123 POC** system prototypes in the clinical environment of the University Hospital in Graz, Austria, confirm the robustness of this new analyzer to prevent clot formation.

- In **2,000** samples of cord blood (umbilical whole blood), no samples showed clots or blockages. In addition, no clot expulsion was required.
- In **142** samples from non-heparinized syringes (the stress test designed to deliberately introduce clots), there were no observed clotting issues.
- In **816** whole blood and **816** plasma samples from two different laboratories with four pilot instruments, there were no observed problems regarding clotting/blockage of the sample path.
- In over **700** samples across six sites in Europe (100–120 samples/site), assessment of six instruments (one per site) also confirmed no reports of clotting/blockage of the sample path.

Overall, in both internal and external on-going evaluations, clotting has not occurred in any samples. In fact, to date, over 3,500 whole blood samples have been assessed using the cobas b 123 POC system with no clot formation reported.

Summary of clot preventative measures in new cobas b 123 POC system

- Clot formation reduces POC analyzer efficiency and increases critical care workload and costs.
- The new **cobas b 123 POC** system is a multi-parameter, flexible analyzer for use in critical care settings at the point of care. It rapidly and accurately analyzes all major blood gases needed at the bedside, with easy-to-use on-screen step-through instructions and a built-in automated quality control system.
- **Three key clot prevention features** have been integrated into the new **cobas b 123 POC system in response to customer needs.**
- **Over 3,500 whole blood samples** have been assessed using the **cobas b 123 POC** system with no clot formation reported.
- The **cobas b 123 POC** system offers an attractive, clot-free solution for POC testing, designed for maximum system up-time and simplified workload, at no cost risk to the hospital.