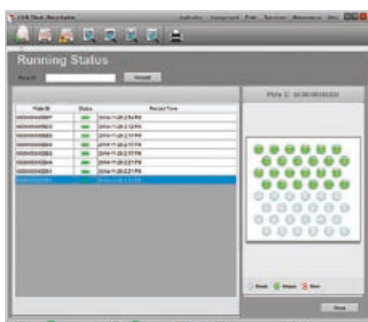


INTELLIGENT SAMPLE BANK

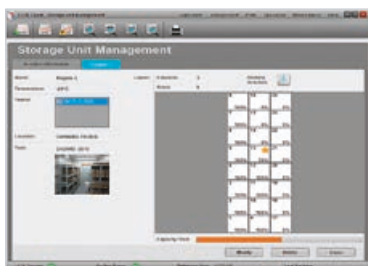


ISB - Main window interface

The requirement of the ISO 15189 Standard for medical biological laboratories has an impact on all sample analysis steps, from sampling to results.

Pre-analytics is one of the most critical steps because of the assignment of the patient's identification and sample's traceability.

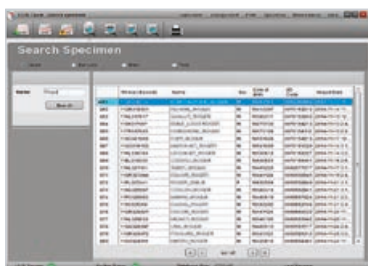
However, the traceability of patient identity does not end once the laboratory has the results on the sample. Many biological liquids are required to be kept in a sample bank (mandatory in some countries) i.e. the conservation of an aliquot of the sample for a specific period and temperature according to prescribed analysis (1).



Storage unit settings

The benefit of a sample bank is to have samples with known results that can be used for confirmation, additional research and method validation (2).

Sample bank processing can highlight a wide variety of potential errors listed by the ISO 15189 standard: identification, traceability, data archiving, etc. For laboratories also considering the ISO 14001 standard, the sample bank can have an impact on waste reduction, management costs and energy savings.



Sample retrieval window

Setting-up a sample bank not only requires modifications to the laboratory organization, but also a dedicated budget. On the contrary, feedback tells us that only approximately 3% of the samples stored are re-tested.

To address these issues, Beckman Coulter has developed ISB (Intelligent Sample Bank) software. Linked to the AutoMate 2500 Family, ISB is an innovative, user-friendly application able to build a sample bank using microtube racks during automated sample sorting (pre or post analytics).

There are many advantages to combining AutoMate and ISB :

- > Solution is integrated into peri-analytics (no additional instruments)
- > Capability to aliquot samples in intelligent mode into different microtube racks (depending on the test orders and disciplines involved)
- > Use of racks with 2D Datamatrix coded microtubes (secure sample identity)
- > Long-term traceability and data security
- > Greatly reduced operator time (no manual processing, fast sample retrieval)
- > Total management of storage units
- > Reduction of space needed for storage
- > Reduction of biological waste
- > Total cost savings for the sample bank



Currently, technical and data archiving recommendations for sample banks are not defined in every country. In France for example, the appendix C for good laboratory practice (GBEA – Guide de Bonne Execution des Analyses) lists the time periods and temperatures for serum sample storage.

During the development of this software, special attention was paid to addressing all requirements of data safety and traceability (patient data, events on samples, user actions...).

Ease of use was also an ongoing issue for Beckman Coulter. For users, implementation of the sample bank requires only two operations: recording the microtube rack in the system using a barcode reader and confirming the storage unit (freezer) proposed by ISB.

The software is available in many languages and also touch-screen compatible, offering optimal ergonomics.

1. GBEA – Appendix C – Biological samples storage recommendations
2. SH-GTA-04. §9. Validation of method performance. The criteria of specificity and sensitivity is to be evaluated, for example based on samples (serum bank) ... with known characteristics.



TESTIMONIAL

Jean-François Gayrel, Biologist and laboratory Manager.

Eric Viala, Manager of Hub laboratory.

Interlab 81 – Val de Caussels, Albi (Tarn – France)

Interlab 81 includes 1 hub and 7 spoke laboratories and processes more than 950 patients per day.

“Thanks to the ISB Software, we have started to build our sample bank very quickly on the AutoMate 2500 Family instrument in our laboratory without any worries. We have put the sample bank as a major component of peri-analytics on AutoMate, which has enabled us to optimize workflow and ensure this mandatory task is completed. The system provided by Beckman Coulter is not operator dependent. Risks associated with aliquoting and patient demographics are eliminated because the processing and data transfer is fully automated.

ISB is designed similarly to the AutoMate software: customizable and upgradeable. Organizational criteria for the sample bank answer our needs: volume of aliquots based on tests, aliquots dispensed into microtube racks according to the legal retention period...

The level of traceability is established beyond reproach. Throughout all processes, it's possible to get information on specimens. After this, it is very simple to retrieve a specimen and we have several search settings. Storage units can be managed comprehensively with a user-friendly interface.

Financially, this Beckman Coulter sample bank solution is more economic than a serum bank based on 5 ml tubes. To estimate the overall cost, it's important to take into account all items required for a sample bank: consumables, operator time, maintenance, space (storage and disposal of biological waste). For example, in our laboratory we have reduced the number of freezers from 6 to 2. This is an important advantage, significantly decreasing the number of storage condition controls as well as energy costs.

ISB software was accepted very quickly by all users at Interlab 81.”

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