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INSTITUTE OF HAEMATOLOGY AND TRANSFUSION MEDICINE

**A test of the DIVA system for
archiving samples of biological
materials**

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Warsaw, September 21, 2009

1. INTRODUCTORY INFORMATION

Name of the product: DIVA archiving system

Name of the manufacturer: Cryo Bio System, IMV Technologies

Name of the supplier: Proplasma Sp. z o.o.

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Product purpose: a system for archiving samples of biological materials

Evaluating unit: Institute of Haematology and Transfusion Medicine

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2. A TEST OF THE DIVA ARCHIVING SYSTEM

According to the Commission Directive 2005/61/EC of 30.09.2005 implementing the Directive 2002/98/EC of the European Parliament and of the Council with respect to the requirements of monitoring the history of blood and its components and of reporting severe adverse effects and events, as well as according to the Regulation of the Minister of Health of 19.09.2005 regarding the manner and organization of blood therapy in clinics hospitalizing patients with indications for therapy with blood and its components ((Dz.U. [Official Journal], No. 191, item 1607) and according to the medical rules of blood drawing, separating its components, and its distributing in organizational units of the public blood service, a possibility of future examination of the biological material taken from a donor must be provided. Therefore, samples from blood donors must be archived. At present, the Polish blood service observes the rule of storing the samples for 10 years in freezing. Similar rules govern the storage of cells, tissues, and organs. It is also advisable to archive patients' blood samples at health service units, particularly at laboratories of clinical analyses.

The DIVA system for automatic archiving has been designed to prepare samples of biological material with the purpose of their archiving and long-term storage. It offers the possibility of automatic collecting and marking of the material with both electronic and traditional documentation. The samples may be from 0.3 to 0.5 ml in volume. The system has been tested at the Institute of Haematology and Transfusion Medicine with respect to its application in archiving plasma samples.

The aim of the test was to evaluate the system's usability for archiving, as determined by, e.g.: thorough and safe filling of the microtubes, called straws, with the archived biological material, safe and correct welding of the straws in order to protect the material from contamination or loss due to its release from the straw, an evaluation of the straws before and after placing them in nitrogen vapor.

Safe archiving of biological material is an indispensable component of correct performance of numerous procedures.

2.1. *Description of the equipment*

The archiving system consists of: a drum containing straws, a stand for tubes, a bar code scanner, an apparatus for filling the straws, welders for sealing the ends of the straws, a receiver, a band for moving the straws, and an arm for transporting the components of the system. It is also possible to install a printer for bar codes placed on the straws and a printer for reports. If a bar code printer is used, it is necessary to provide an adequate room for the DIVA archiving system. In the room, the printer should be connected to the ventilation (with a pipe of 6 cm in diameter) so that the substances released during the printer's routine operation are carried away outside the building.

The material for the DIVA system may be drawn from test tubes of the size of 13 x 100 mm. The manufacturer is preparing stands and software for an application of other test tube sizes.

The straws (available in 7 colors) with the biological material inside are placed in visotube containers (available in 12 colors). Each visotube container may hold 14 straws. The visotube containers are placed in goblet containers, each of the latter holding 12 visotube containers.

One goblet container may hold 168 straws. The goblet containers are put into special tubes, canisters, and then placed in refrigerators.

In the routine operation of the system the following expendable elements are used: straws to be filled with the biological material, special tips for filling and pipette tips for drawing the material from base tubes. The sequence of the procedures performed by the operator in the course of the routine operation of the system is fairly complicated but, nevertheless, clear and understandable thanks to the list of consecutive stages displayed on the monitor screen, with an indication of the current stage. The progress from one stage to the other has to be accepted by the operator. It is possible to preset the number of tubes for archiving. The system enables the operator to control the process at any given stage. Any incorrect or not performed action is signaled with a sound alarm and, additionally, with information on the monitor screen, stating at which stage of the process the problem occurred.

2.2. Testing the correctness of the DIVA system operation during a routine archiving of biological material

Full blood was drawn into test tubes of 5 ml of volume and the size of 13 x 100 mm, containing the EDTA gel, and then gyrated in a horizontal centrifuge in order to separate the plasma.

The straws were coded before the beginning of the procedure. The system ensures automatic filling of the straws and welding of their ends in order to protect the material. Throughout the process there is no possibility of contamination of the content of both the base tubes and the straws. The plasma was archived in the amount of 1 ml in two straws of 0.5 ml of volume each. After the process had been completed, the correctness of the straw filling and welding was checked as well as was the correspondence of the sample to the original material, according to the protocol generated by the software of the system. All the straws for storing biological material and their weldings were found to be tight. The system offers a quick archiving procedure: it is possible to fill ca. 160-170 straws in an hour. After 300 samples had been prepared by the DIVA system, they were placed in cryostats in nitrogen vapor. No errors in the procedure were discovered.

None of the straws used in the process was damaged either before being placed in the cryostats with nitrogen vapor or after defrosting them.

2.3. Operation of the system

Before starting the procedure the expendable accessories used in the archiving process, such as straws, pipette tips or special tips, should be replenished. Otherwise, visual information appears on the monitor, accompanied by a sound signal. Similarly, the visual and sound information appears when any of the equipment elements have been placed incorrectly.

All the stages of the archiving process are monitored on the screen. During the system's operation, the monitor displays clear and detailed information on the current stage of the process, on the particular straw containing the archived material and on the samples which have already been archived. The system allows identifying each sample by means of a bar code label placed on the straw. The system uses a clear and easy process of sample tracing by the colors of the straws and the containers in which they are placed. It is possible to print overall protocols containing the data of all the samples archived by the system. The process is controlled by one person only.

There is a possibility of setting the menu in Polish if the request has been submitted to the supplier.

2.4. Sample tracing

Separate software is applied for sample tracing. The system provides a detailed description of a sample's location by means of the identification of the room, storage apparatus, tube, main container, inner container and the straw itself. In order to find a sample, its identification number must be entered. After the function of searching has been activated, the system supplies the information concerning its storage location as well as additional information regarding the number of archived samples, the type of biological material in the straw, the date and hour of the archiving procedure, the personal data of the operator performing the process, and possibly additional remarks. When the straws have been removed from cryostats or freezers, the system allows recording the action in a manual way or automatically, by reading the bar code with a scanner.

It is possible to find particular groups of samples according to preset parameters, such as the centre being the source of the samples, the date of sample archiving etc.

In the course of the tests at the Institute there was no possibility to check the correspondence of the codes assigned to the straws with the codes on the test tubes, due to the lack of a printer.

The correctness of protocols and of assigning codes was checked on an apparatus being in routine operation at a centre indicated by the system's supplier.

The Institute's representative participated in a demonstration of the operation of the system equipped with all its elements. Printing of both the codes and the protocols was correct and did not raise any objections.

3. CONCLUSIONS

The DIVA archiving system ensures quick, automatic and safe straw archiving of biological material from test tubes with the EDTA gel, of 5 ml of volume and 13 x 100 mm of size. The system of colored straws and containers is clear, which makes it easy to locate the samples properly and find them quickly. The application of straws allows defrosting only one particular sample at a time for examination purposes. Thanks to the design of the storage containers the space in refrigerators is used in a rational and economical way. The DIVA system employs modern solutions, not available on the Polish market before.

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