J Bras Patol Med Lab. 2018 Oct; 54(5): 306-309.

10.5935/1676-2444.20180051

Sample transport validation: experience of a medium-sized laboratory

Validação do transporte de amostras: experiência de um laboratório de médio porte

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ABSTRACT

Introduction: The adequacy of biological samples is a critical and important item in the clinical laboratory, so that reliable results can be obtained for patients. **Objective:** To ensure integrity and stability of biological samples during the transport process. **Method:** Concurrent validation was carried out – in parallel with the production process and distribution of the product, from January to March 2017. The blood samples were packaged primarily in tube racks, and those of urine, feces and microbiological materials were packed in plastic bags. Materials were wrapped in a blanket of absorbent material to ensure temperature integrity and to avoid possible material losses. Thermal bags were the containers used to carry the samples. There were five transport routes, with two daily routes for each collection unit. A recommendation of the number of ice packs, predefined by the laboratory, was followed. **Results and conclusion:** In the first month, the pre-established temperatures (blood: 10°C to 22°C/urine-feces: 2°C to 8°C) were not reached until arrival at the central laboratory, and the amount of ice in each bag was gradually increased, daily, until reaching the ideal temperature, in all collection units and the central. Transport routes were changed three times in the most distant units. Materials that arrived outside specifications were processed with restrictions, and results were evaluated by the professional responsible for the release. After these modifications, the temperature records of the biological materials were in accordance with the current legislation and the defined specifications, thus validating the process.

Key words: specimen handling; validation studies; clinical laboratory techniques; substances, products and materials transportation.

INTRODUCTION

Clinical laboratories are part of the health care chain, playing a key role in disease diagnosis and prognosis, adequate treatments and evaluations of response to different therapeutical modalities, thus contributing to more than 70% of medical decisions[1, 2].

Laboratory routine comprises three phases: pre-analytical, analytical, and post-analytical. Pre-analytical phase includes test order, obtainment of patients' relevant data, collection, identification, storage, transportation, and receipt of biological specimens[3, 4]. It is the phase with the highest frequency of errors, especially human error, and major risks to professionals' health[3]. Several works published in the latest years, related to laboratory errors, verified that approximately 60%-90% of laboratory errors are consequence of lack of standardization in the pre-analytical phase[3, 5-8]. Thus, adequacy of biological specimens is a critical important item for reliability of results released to patients.

An adequate biological sample is that obtained in a sufficient amount, in a suitable container, well identified and transported so as to maintain integrity of the material to be investigated. Meeting the requirements established by the norms aims to reduce the possibility of sample contamination – as a result of exposure to infectious microorganisms that can escape from packages due to breakage, leakage or inadequate conditioning during transportation process – besides ensuring integrity and stability of the transported biological material[9]. For this reason, transport temperature monitoring is essential to ensure conservation of biological materials.

First submission on 04/30/18; last submission on 05/02/18; accepted for publication on 08/06/18; published on 10/20/18

OBJECTIVE

Ensure integrity and stability of biological samples during their transportation process.

MATERIALS

• Thermal bags;

• foam ice packs (Gelo Ice Foam® – Polar Técnica), models (length × width × thickness):

- large size: IF 2500 (320 × 180 × 45 mm);

- medium size: IF 1500 (255 × 155 × 40 mm);

- small size: IF 500 (200 × 90 × 30 mm);

• rigid ice packs (Gelotech): slim model:

- rigid ice 1000 (size: 270 × 120 × 40 mm);

• absorbing blankets;

• tube racks;

• plastic bags;

• infrared thermometer.

METHOD

Concurrent validation: conducted in parallel with the productive process and product distribution.

Temperature validation was carried out from January to March, 2017. In order to initiate the process, the recommendation of quantity of ice packs previously defined by the laboratory was followed: large thermal bags (four large ice packs), medium bags (three large packs for urine/three large packs for blood), and small bags (two small ice packs), sized according to the volume of laboratory samples. This initial specification was used to base the new specification, which would be defined according to the progress and the result of the validation process. There were five transport routes, with two daily paths for each collection unit.

Blood samples were primarily packaged in tube racks; and samples of urine, feces, and biological materials, in plastic bags. Next, materials were wrapped in a blanket of absorbent material to ensure temperature integrity and avoid possible material losses. The insulated shipping containers are thermal bags, characterized as tertiary packaging. Inside the thermal bags, ice packs were put according to the bag size and type of material to be transported.

Thermal bags (tertiary containers) were identified with the labels and information required by the current legislation[9]:

• name, address, and contact of sender and recipient;

• correct classification of material to be transported: "biological substance, category B";

• numeric code of United Nations Organization (UNO) (UN 3373).

Biological samples also follow recommendations of the current legislation for transport aimed at clinical diagnosis, according to their category[9, 10].

Statistical analysis

The statistical data are expressed in mean ± standard deviation (SD).

RESULTS

The laboratory transportation process is carried out by cars and motorcycles, in its 18 collection units, and organized in five routes. The most distant ones – around, at most, 16 km from the central unit – are managed by motorcycle, and the closest – around, at most, 9 km from the central unit –, by car.

During the first month, sample temperatures were not kept until arrival at the central, so the amount of ice in each thermal bag was slowly increased, and the temperature record was evaluated everyday until the ideal temperature range was reached, in all collection units as far as the central. Then, we observed that even with the increase of ice packs, appropriate temperature had not been reached in some of the most distant collection units. With this in mind, transportation routes were retraced so that each one was taken three times per day, except Saturdays, with two routes being followed in the morning and one in the afternoon; the quantity of ice packs was also adjusted per thermal bag, as shown in **Table 1**. After this last change, transportation temperatures were kept within the established range for each material type[11], according to **Tables 2** and **3**.

DISCUSSION

The transport temperature of biological specimens in a laboratory is essential for quality and reliability of exam results.

TABLE 1 – Specification of the quantity of ice by size of thermal bag

Size of thermal bag	Material	Quantity of ice packs
Large (45 l to 57 l)	Blood	At least seven ice packs, with at least: three L, two M, and two SL
	Urine/feces	At least eight ice packs, with at least: two L, four M, and two SL
Medium (32 l to 34 l)	Blood	At least five ice packs, with at least: two L, one M, and two S
	Urine/feces	At least five ice packs, with at least: two L, one M, and two S
Small (12 l to 15 l)	Blood	At least four ice packs, with at least: one M, and three S
	Urine/feces	At least four ice packs, with at least: one M, and three S
Extra-small (5 l to 9 l)	Blood	At least three S packs
	Urine/feces	At least four S packs

L: large; M: medium; SL: slim; S: small.

TABLE 2 – Biological materials transported under refrigeration* (2°C-8°C)

Routes	Mean temperatures	SD
1	6.2°C	± 1.4
2	5.5°C	± 1.45
3	6.42°C	± 1.26
4	6.12°C	± 1.38
5	6.56°C	± 1.43

**Urine and feces; SD: standard deviation.*

TABLE 3 – Biological materials transported under other temperatures* (10°C-22°C)

Routes	Mean temperatures	SD
1	16.67°C	± 2.83
2	17.31°C	± 2.9
3	14.98°C	± 2.55
4	15.62°C	± 2.56
5	16.02°C	± 2.97

**Total blood, serum, plasma, and biological materials; SD: standard deviation.*

To this end, quality assurance of transportation has a key role in avoiding possible errors arising from material stability because of false rejections of samples that may affect quality, delay release results and increase enterprise costs[12, 13]. We do not know other national accounts on validation of biological specimen transport temperature by clinical laboratories, what reflects a great difficulty of many laboratories in this issue. Therefore, we believe this work can offer a contribution to the international scientific community.

In international publications, we observed some divergences regarding the techniques used to refrigerate biological specimens during the transportation process, in which dry ice, principally, is used[14, 15]. However, the techniques of labelling and identification of biological materials are the same adopted in Brazil, as the latest change in our legislation achieved the international standards[9].

In the beginning of the validation process, the materials that did not reach the adequate temperatures were processed with restrictions, and the results of analyses were evaluated by the pharmaceutical biochemist/biomedical scientist responsible for the release. In case deviations were observed in transport temperatures, after validation, a non-conformity and preventive action report would be prepared for investigation of cause, and corrective measures would be taken for problem resolution.

At the end of the process, the average temperatures recorded for the five transportation routes, considering the calculated SD, delivered a satisfactory performance, according to the established ranges (Tables 2 and 3).

The laboratory decided the revalidation process should take place annually, or when variations in daily control are observed.

CONCLUSION

Transport temperatures of all biological materials received in the laboratory, as well as the transportation process, are in accordance with the current legislation. The process, therefore, is validated.

RESUMO

Introdução: *A adequação das amostras biológicas é um item crítico e importante no laboratório clínico, para que possamos oferecer resultados confiáveis aos pacientes.* ***Objetivo:*** *Garantir a integridade e a estabilidade das amostras biológicas durante o processo de transporte.* ***Método:*** *Foi realizada validação concorrente – concomitantemente ao processo produtivo e à distribuição do produto, no período de janeiro a março de 2017. As amostras de sangue foram acondicionadas primariamente em galerias; as de urina, fezes e materiais microbiológicos, em sacos plásticos. Os materiais foram envoltos por uma manta de material absorvente para garantir a integridade da temperatura e evitar possíveis perdas de material. Maletas térmicas foram os recipientes utilizados para transportar as amostras. Havia cinco rotas de transporte, com dois percursos diários para cada unidade de coleta. Foi seguida a recomendação da quantidade de barras de gelo predefinida pelo laboratório.* ***Resultados e conclusão:*** *No primeiro mês, as*

temperaturas preestabelecidas (sangue: 10°C a 22°C/urina e fezes: 2°C a 8°C) não foram atingidas até a chegada à matriz, e aumentou-se gradativamente a quantidade de gelo em cada maleta, com avaliações diárias, até se atingir a temperatura ideal, em todas as unidades de coleta e na matriz. Foi realizada mudança nas rotas de transporte com frequência de três vezes nas unidades mais distantes. Os materiais que chegaram fora das especificações foram processados com restrição; e os resultados, avaliados pelo profissional responsável pela liberação. Após essas modificações, os registros de temperatura dos materiais biológicos estavam de acordo com a legislação vigente e as especificações definidas, validando, portanto, o processo.

Unitermos: *manejo de espécimes; estudos de validação; técnicas de laboratório clínico; transporte de substâncias, produtos e materiais.*

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