

	<p>RELATÓRIO DE VALIDAÇÃO DE PROCESSOS CRÍTICOS</p>	<p><b>FORM. GER 110</b></p>
		<p><b>REV: 00</b></p>
		<p><b>FL 1 de 19</b></p>

## 1. PROCESSO

Transporte de concentrado de hemácias (CH) em caixa térmica PP

## 2. OBJETIVO

Relatar os resultados do processo de validação de caixas térmicas para o transporte de concentrados de hemácias, atestando a adequabilidade do processo para o transporte.

## 3. SIGLAS E ABREVIATURA

CH - Concentrado de Hemácias.

## 4. EQUIPAMENTOS E MATERIAIS UTILIZADOS

- Concentrados de hemácias separados para descarte
- Caixa térmica entre 9 e 10 litros Adarve, colerman e Rubbermaid (Caixa PP)
- Logger Tempmate® de monitoramento de temperatura
- Gelo reciclável (gelox)
- Sacos plásticos de acondicionamento de bolsas quádruplas (isolantes térmicos)
- Fita adesiva
- Computador

## 5. DOCUMENTAÇÃO COMPLEMENTAR

- Relatórios de calibração dos registradores (logger) utilizados.
- Portaria de Consolidação número 5 do Ministério da Saúde

## 6. CONSIDERAÇÕES INICIAIS

Todos os dados descritos no presente relatório são oriundos apenas das formas adequadas de transporte em condições ideais de temperatura quando essas se mostraram reprodutíveis. Para cada forma de transporte (combinação de caixa, quantidade de gelo e

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bolsas) foram feitas várias combinações objetivando encontrar a forma mais adequada, ou seja, aquela onde a temperatura das unidades não ultrapassasse os valores de 1 e 10°C. A metodologia de refrigeração das caixas térmicas para transporte de componentes eritrocitários foi feita com gelo reciclável de dimensões 17,5 x 9 x 3 cm e volume 500mL (Figura 1). O armazenamento do gelo reciclável deve ser feito sempre por pelo menos 72 horas em temperatura inferior a -20°C, como forma de garantir a capacidade térmica do gelox e a estabilidade da temperatura observada durante o transporte. É de extrema relevância que sejam seguidas as orientações não apenas sobre o quantitativo de material refrigerante como também a configuração que estes ocupam no interior da caixa e em relação ao empilhamento das bolsas.



**Figura 1.** Padrão de gelo reciclável utilizado refrigeração das caixas térmicas para transporte de hemocomponentes eritrocitários.

Para isolar os hemocomponentes do contato direto com o gelox, reutilizou-se o plástico das embalagens primárias de bolsas para coleta de sangue total (bolsa quádrupla). Esse material está prontamente disponível, sendo de fácil acesso e sem custo para toda a hemorrede. Todos os hemocomponentes utilizados no presente estudo são de unidades destinadas ao descarte por motivos vários.

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## 7. CRITÉRIOS DE ACEITAÇÃO

Durante todo o período considerado, as temperaturas dos hemocomponentes monitorados devem estar entre 1 e 10°C.

## 8. PROCEDIMENTO/PROTOCOLO

### 8.1 Descrição

- Caixa com capacidade para isolamento térmico.
- Fabricante: Adarve, colerman e rubbermaid
- Capacidade estimada: 10
- Tempo validado de transporte: 10 horas

### 8.2 Procedimento para preparo da caixa (Figura 2)

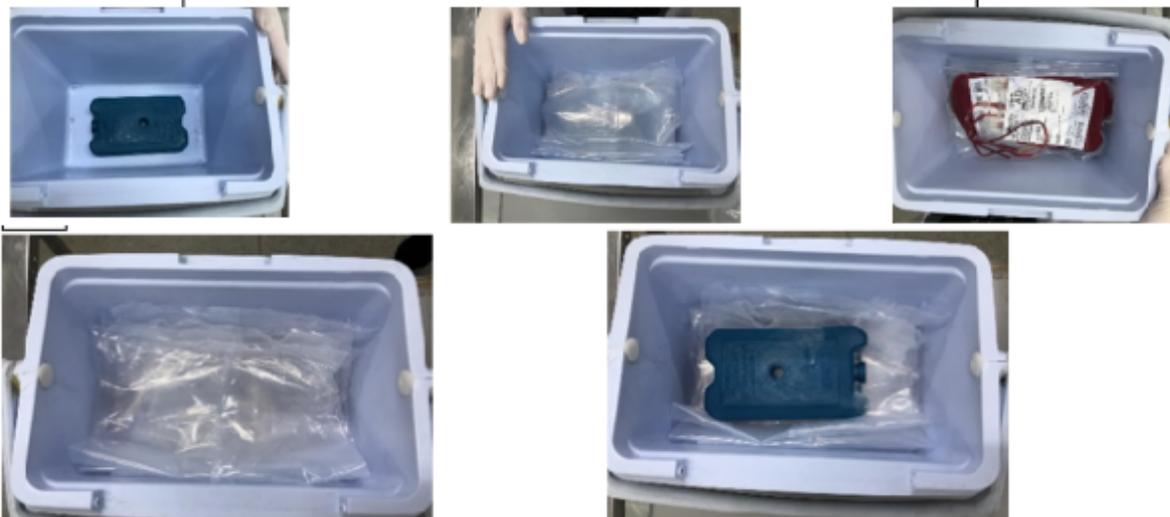
1. Posicionar um gelox de 500 mL no fundo da caixa térmica.
2. Colocar três isolantes térmicos acima do gelox, dobrados ao meio, formando 6 camadas de plástico.
3. Posicionar a(s) unidade(s) de CH acima dos isolantes, com o bulbo do termômetro ou logger entre o CH e os isolantes abaixo.
4. Colocar mais três isolantes térmicos acima do CH, dobrados ao meio, formando 6 camadas de plástico.
5. Posicionar um gelox de 500 mL acima dos isolantes.
6. Fechar a caixa e passar fita adesiva para evitar sua abertura acidental.

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**Figura 2.** Passo a passo do preparo da caixa térmica PP para transporte de aliquotas a 5 concentrado de hemácias.

## 9. RESULTADOS

Abaixo estão os gráficos com a evolução das temperaturas nas caixas térmicas com uma alíquota, um e cinco CH.

a.

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b.

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**Figura 3.** Evolução das temperaturas na caixa térmica com alíquotas de concentrado de hemácias. Legenda: a. Temperatura acima do concentrado de hemácias; b. Temperatura abaixo do concentrado de hemácias.

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08:15:34 6.9 °C  
08:20:34 6.9 °C  
08:25:34 6.9 °C  
08:30:34 7.0 °C  
08:35:34 7.0 °C  
08:40:34 7.0 °C  
08:45:34 7.0 °C  
08:50:34 7.0 °C  
08:55:34 7.0 °C  
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09:05:34 7.1 °C  
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09:15:34 7.1 °C  
09:20:34 7.1 °C  
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09:30:34 7.2 °C  
09:35:34 7.2 °C  
09:40:34 7.2 °C  
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a.

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b.

**Figura 4.** Evolução das temperaturas na caixa térmica com 5 concentrados de hemácias. Legenda: a. Temperatura acima do concentrado de hemácias; b. Temperatura abaixo do concentrado de hemácias.

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	<p>RELATÓRIO DE VALIDAÇÃO DE PROCESSOS CRÍTICOS</p>	<p><b>FORM. GER 110</b></p>
		<p><b>REV: 00</b></p>
		<p><b>FL 1 de 19</b></p>

## 10. CONSIDERAÇÕES FINAIS

Uma vez que as temperaturas observadas para as circunstâncias registradas acima atendem aos critérios de aceitação, pode-se concluir que o transporte de alíquotas e 5 concentrados de hemácias em caixas PP encontra-se validado por um período de até 10 horas, desde que observadas todas as disposições durante o processo de montagem das caixas.

## 11. APROVAÇÕES

***Maria Isaaquielle Andrade de Oliveira***

Coordenadora da Distribuição

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isaaquielle.oliveira@hemoce.ce.gov.br

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