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Expiration Date of Plasma Frozen within 24 Hours?

We use Frozen Plasma separated within 24 hours after collection as opposed to FFP which is separated within 8 hours of collection. AABB Standards states that thawed plasma may be used for up to 5 days so long as it's not being used for Factor VIII replacement. How do other hospitals assign the expiration date for this product?

1. Do you assign 24 hours, then change it to 5 days if not used?
2. Do you assign a 5 day date right from the time of thawing?
3. Do you use only 24 hour dating and not change to 5 days?

Are there any AABB inspectors out there that could tell me if we would be noncompliant if we were to assign the 5 day date right at the time of thawing?

To which the following replies were received:

1. I am not an inspector currently, but **there is a conflict** between the Standards and the Circular of Information versus the Technical Manual about this topic. The 8/2000 Circular of Information (p. 24) says thawed plasma stored for 5 days is made from FFP. The XXth Standards do not define thawed plasma, but in the same table (p 99) has Plasma, Frozen Within 24 Hours, Thawed, with an outdate of 24 hr. The 13th Technical Manual says Thawed Plasma is made from FFP, but on the next page (p 171) says that plasma frozen within 24 hr of collection can be kept thawed up to 5 days. My take is that facilities wanting to store 24-hr plasma for 5 days should have data available on its content and should have a local Circular addendum to define it and its use. Inspectors and Manual writers, what do you think?
2. Due to our software (Sunquest), we found it most convenient to assign the expiration date of thawed plasma as 5 days from the time of thawing.
3. Our transfusion service is the largest in our state and it serves a busy level I trauma center. While we do not use Frozen Plasma, we do have a procedure for conversion (re-labeling) of thawed FFP into "Thawed Plasma" if it is not used within 24 hours. Since implementation of this procedure, we have cut FFP wastage by about 80%. The protocol is conservative and stipulates that the 5 day "plasma" not be used in pediatric patients or in patients with known factor deficiencies. The expiration is set 5 days after original thawing of the FFP.
4. There is little difference in the levels of labile coagulation factors (i.e., Factor V and Factor VIII) between FFP and Plasma (Frozen Within 24 Hours). Factor V levels studied were essentially the same in plasma frozen at 8 hours and at 24 hours after collection (REFERENCES: O'Neill EM et al. Transfusion 1999;39 (5):488-91; Smith JF et al. Vox Sang 2000;78 (1):28-30). On average, the major difference between the two components is a reduction of Factor VIII. In the previous version of the Circular of Information, it said there was a 25% reduction {for some reason, this was not included in the current Circular}. Factor VIII measured in plasma held at 4 C for 8 hours after collection was 84% +/- 16% versus plasma held at 4 C for 24 hours after collection which was 64% +/- 13% (see O'Neill reference above). In the Smith reference above, it showed the percentage of Factor VIII:C at 8 hours holding time was 89.8% +/- 1.0% versus 75.9 +/- 2.4% at 24 hours. Since there is little difference in the level of coagulation factors between FFP and Plasma (Frozen within 24 hours), for most therapeutic uses the two components are comparable (see O'Neill and Smith references). For patients with isolated Factor VIII deficiency, more potent sources of Factor VIII are available. In addition to the above, according to the 20th edition of Standards - see pages 65-66, Item #27, Plasma Frozen w/in 24 hrs (I'll abbreviate it as FP24 here), has a 12-month expiration date from collection. Once you thaw it, it becomes Item #28, Plasma, Frozen Within 24 Hours, Thawed, which has a 24 hr expiration. If you do not use the thawed FP24 within 24 hrs after thawing, it becomes Item #30, Thawed Plasma, which you can use up to 5 days after thawing. (If you used it within the first 24 hrs. of thawing, it would be #28). That is equivalent to what happens to FFP. FFP has a 12 month expiration while frozen (item # 23), then when thawed, it becomes item #24 with a 24 hr expiration. If you don't use it thawed, it becomes item #30, Thawed plasma. (If

you use it within the first 24 hrs after thawing, it would be item #24). This information was obtained from the Standards. The Circular of Information is NOT clear on expiration periods regarding FP24. I would suggest posing this question to the AABB's Circular of Information committee (Kay Gregory, perhaps?).

5. The questioner seems to assume that 24-hour refrigerated storage after thawing is acceptable for Factor VIII replacement. This is not medically correct. The product has already had its 24-hour refrigerated storage at the front end, prior to freezing, and has already lost a significant percentage of VIII (I believe this is about 20% loss). To my knowledge, the blood suppliers that produce this product make no claims as to how long the product can be stored after thawing if being used for Factor VIII replacement. In my opinion, if Transfusion Services want to have a full 24 hours of refrigerated storage available to them after thawing, they should start off with FFP, not Frozen Plasma. The following is an article that might be of interest:

O'Neill EM, Rowley J, Hansson-Wicher M, McCarter S, Ragno G, Valeri CR American Red Cross Blood Services, New England Region, Dedham, Massachusetts 02026, USA. oneillm@crossnet.org.

BACKGROUND: The current requirements for the preparation of fresh frozen plasma within 8 hours of whole blood collection were designed to maintain clotting factor activities. These requirements, however, limit the production of fresh frozen plasma in a large blood center. There are few data on the effect of the extension of CPD whole blood storage to 24 hours on clotting factor activity.

STUDY DESIGN AND METHODS: A 500 ml unit of whole blood was collected from 10 volunteer donors. At 1 hour after collection, a plasma sample was separated by centrifugation, and each unit was equally divided into 2 half units, with 1 half unit stored at 4 degrees C (range, 1-6 degrees C) and 1 half unit stored at 22 degrees C (range, 20-24 degrees C) for 8 hours after collection. Each half unit was then placed at 4 degrees C for further storage for 16 hours. At 8 and 24 hours after collection, plasma samples were separated from each half unit. All plasma samples were frozen at -18 degrees C. Factors V, VII, VIII, and X; fibrinogen; antithrombin III; protein C; and protein S were measured.

RESULTS: No significant changes were noted in factors V, VII, and X; fibrinogen; antithrombin III; protein C; and protein S over the 24 hour storage period. Factor VIII in both half units was significantly reduced, by 13 percent, from the baseline sample as compared to the level in the 8 hour storage sample ($p < 0.05$). Factor VIII was further reduced by 15 to 20 percent after the 24 hour storage period ($p < 0.05$).

CONCLUSION: The coagulation factor activity for all factors measured, with the exception of factor VIII, showed no significant change over the 24 hour storage period. Factor VIII was significantly decreased by 13 percent in 8 hour storage and by an additional 15 to 20 percent in 24 hour storage. ***For clinical situations not requiring the replacement of factor VIII only, 24 hour frozen plasma has properties comparable to those of fresh frozen plasma.***

ADDENDUM: Jan. 31, 2001

6. **Kay Gregory**, Director of Regulatory Affairs at the **AABB** national office was asked to comment on this discussion, and she has graciously provided the following feedback:

The section on Plasma Components in the current **Circular of Information** for the Use of Human Blood and Blood Components was **completely reorganized** as compared to the previous version of the Circular. There are now **two** major sections relating to this issue: (1) Fresh Frozen Plasma and Plasma Components Containing Functional Factors V and VIII (Labile Coagulation Factors) and (2) Plasma Components Containing Reduced Amount of Labile Coagulation Factors.

Thawed Plasma, Plasma Frozen within 24 Hours after Phlebotomy, and Plasma; Liquid Plasma are all listed as equivalent products to be used as a source of defective or deficient plasma proteins except for Factors V and VIII.

The definition of Thawed Plasma does say that it is derived from FFP. However, I have checked with the FDA and they see no reason why Thawed Plasma could not be derived from Plasma Frozen within 24 Hours. From a practical standpoint, if Plasma Frozen within 24 Hours after Phlebotomy were to be relabeled after it was thawed, it could then be labeled as Thawed Plasma. However since the Plasma Frozen within 24 Hours accurately describes the content of this product, it will probably not be relabeled when it is thawed out. On the other hand, FFP **must** be relabeled as Thawed Plasma, ***if it is not used within 24 hours***, so that the label will accurately reflect the content of the product.

Both the Circular of Information and the Standards are currently undergoing review for the next addition, and I will bring this issue to the attention of those committees.

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Posted: January 18, 2001

Addenda: Jan. 31, 2001