



# e-Network Forum

## CALIFORNIA BLOOD BANK SOCIETY

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### ***Switching from glass tubes to plastic tubes for blood bank laboratory testing***

A member asked what others in the e-Network have done (or plan to do) before switching from glass tubes to plastic tubes for blood bank laboratory testing, to document that the plastic tubes will perform as expected. She was told that some (but not all) transfusion services were validating plastic tubes before placing them into service in the blood bank lab.

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The following replies were submitted in response to the above.

1. In the **Editor's opinion**, one cannot overemphasize the importance of verifying that a new procedure, a new piece of equipment, a new reagent, or a new sample collection or testing tube will perform as expected in one's own laboratory environment prior to implementation.
2. A **blood banker in the Northwest US** commented that there have been several discussions among ABC members as to how to deal with a change from glass to plastic specimen tubes. Of primary concern to the responding blood banker is **any impact on NAT testing**, which is under an IND and includes specifications for type of tube and anticoagulant. He says that Chiron and Roche will validate both plastic and an alternative glass tube with respect to the sensitivity of NAT as well as to the function of pooling equipment. There is also **concern over a change from K<sub>3</sub> to K<sub>2</sub> EDTA** as the anticoagulant that is loaded in some collection tubes. The responding blood banker said he had knowledge of at least one blood center that made a change to plastic tubes without validation. The responding member lamented that the phase-in of new tubes was being done in response to an announced change by tube manufacturers. Apparently, the tube manufacturer did not consult with the blood bank before deciding on making the change, which has made the transition more difficult. As a result, he states that there is a fair amount of antagonism towards a particular tube manufacturer, since, in his experience, this is not the first time this manufacturer has made a change that has had an impact on the transfusion industry without prior discussion or consultation.
3. A **blood banker in California** commented that when her facility investigated switching to plastic tubes for blood bank testing, they contacted the tube manufacturer and were told that the 10ml plastic red top vacutainer tubes were NOT yet-FDA approved for blood bank testing. Consequently, she states that her facility continues to use glass red top vacutainer tubes for blood bank testing **until such time as the plastic tubes are FDA-approved**, or until her lab switches from testing serum to plasma. She is interested to learn if other e-Network members have been told the same thing about FDA non-approval of plastic 10ml red top vacutainer tubes.

**Editor's NOTE:** It would seem prudent for a blood bank lab to verify with FDA that a specimen tube has been approved for blood bank testing before switching to that tube, and if it is not approved, to ask FDA what they expect the lab to do (if anything) in terms of validation studies to avoid being cited for using the tube.

4. **Another blood banker** commented that her facility switched to plastic microtainers several years ago as part of their implementation of gel technology, as EDTA plasma is the preferred specimen in this methodology. Because this blood banker works in a pediatric institution, most of their specimens are received in those tubes. She says that they validated these tubes by default, as part of the implementation of gel column methodology. They **did not perform a separate validation** with a specific focus on the utilization of these tubes. She supposes that, if one is not changing a methodology but is simply changing a specimen requirement, you could do some parallel studies. But she asks the question "do you have to get patient consent for drawing an extra tube of blood?"
5. **Yet another blood banker** said that her facility is planning to switch to plastic tubes soon, but not until after they validate these tubes by **parallel testing** of samples collected in glass EDTA and in the new plastic tubes.
6. A **blood banker in Texas** said that her facility changed from 10ml lavender top glass tubes to 6ml pink top plastic tubes in August of 2001, and that they have observed no differences in the way specimens react. They report picking up the same number of antibodies as before. The EDTA in the

pink top tubes is K<sub>2</sub> while the EDTA in the lavender top tubes is K<sub>3</sub>. Their validation consisted of performing routine blood bank testing (including tests with weakly reacting antibodies positive antibodies) **in parallel** using both tubes.

7. **The manager of a large transfusion service** at a teaching institution where they perform about 2,000 type and antibody screens per month reported that they use the gel method for antibody screening and the tube method for ABO/Rh. They were using glass tubes (EDTA) and decided to switch to plastic (EDTA). Their validation plan was to perform duplicate testing for at least 100 samples. However, after 20 paired tests the storeroom informed them that they had run out of glass EDTA tubes, and asked for permission to order only the new plastic tubes. Of the 20 samples that were tested, 3 had positive antibody screens and the others were negative. **All 20 paired sets of test results were concordant.** Based on the abbreviated validation data, they switched to plastic tubes and had no problems since switching. In addition, they contacted another large teaching institution that informed them that they had made the same switch from glass to plastic tubes without having done a validation study.
8. **A blood banker in Central California** wrote that his biggest concern is whether the **viral marker test** manufacturers have validated the use of plastic tubes for testing. They have very specific requirements as to what types of plastic are acceptable for use. This blood banker contacted his account representative and posed this question. He is still waiting for a response! The responding blood banker says that he has heard rumors that glass tubes may be discontinued at the end of the year.
9. **A blood banker in Virginia** wrote that her facility **considers extra validation to be overkill.** She says that the validation of plastic tubes is a moot issue, since she has heard that we will all have to switch anyway, since glass tubes will no longer be available in the not to distant future.

**Editor's NOTE:** Even if glass tubes are history, it is my opinion that it is good laboratory practice to validate a new kind of collection or testing tube, just to verify that they work well in your institution. Reply #10 could serve as a practical approach.

10. **A blood banker in Los Angeles** wrote that a change from glass clot tubes to plastic EDTA tubes **probably only requires verification (as opposed to a full validation) provided the tubes are FDA-approved for blood bank testing.** He would verify that the new tube functions as expected in his laboratory's environment, but with only a few patient samples in parallel comparing the performance of the new and old tubes. He does not think that such verification would require more than 20 samples, including two samples with positive antibody screens. Verification should include a look at how the new tubes affect critical processes such as collection and labeling of blood samples if the vendor applied label is ever used for writing the patient's identification. A **questionnaire** could be used to ask phlebotomists and clinical laboratory scientists to comment as follows:

- Is the tube easy to use?
- Is the tube easy to use with current computer generated labels?
- Is it easy to hand-write patient identification on the tube?
- Is the tube label easy to read throughout the testing process?
- Did using the new tube take more or less time than using the old tube?
- Were any problems encountered using this tube?

The questionnaire would have a space for **comments**, perhaps after each question.

11. **A chief technologist** working at the same facility as the blood banker responding in **item #10** wondered if it was really necessary to validate a new tube before placing it into service in the blood bank, **if the tube had been FDA-approved for blood bank testing.** However, since she could not find a definitive answer to this question, she authorized validation of new plastic tubes before allowing the tubes to be used in official blood bank laboratory testing. She reasoned it was important to validate the new tubes because the laboratory was changing several aspects of testing. The lab was switching from testing serum to plasma while at the same time introducing plastic pink top EDTA tubes. The new tubes contain a different concentration of EDTA than what they had been using before (i.e., K<sub>2</sub> EDTA versus K<sub>3</sub> EDTA). She was not too worried about the outcome of validating these tubes for blood bank testing, and the validation studies proved that the plastic pink top EDTA tubes functioned well in the blood bank. She is concerned about how switching to pink top EDTA tubes might make a difference for hematology (CBC) studies, however. She also commented that at least one tube manufacturer is going to discontinue K<sub>3</sub> EDTA (liquid) lavender tubes which are commonly used for Hematology, etc and replacing them with K<sub>2</sub> EDTA formulation exclusively. She concluded by saying that before she approves switching to K<sub>2</sub> EDTA tubes for Hematology, a study will be done to see the effects of a different concentration on the CBC parameters.

**ADDENDA** Oct. 5, 2001

12. **A facility in California** reports that they recently changed from glass to plastic EDTA tubes for blood bank testing. **They verified with the manufacturer that the tubes had been licensed for transfusion use and then did a brief side by side trial using both types of tubes.** After

comparing the reactivity on 20 specimens, with no significant differences in test results, they adopted the new tubes for use. They kept a record of the reactivity using both tubes and the appearance of the plasma in each tube. The only difference that was noted was that the plasma, in most instances, had a **more yellow** appearance.

13. **A blood banker** wanted follow-up in response to the question raised in [response # 4](#), above. He is curious about the proportion of **transfusion services that are validating methods as part of an institutional review board proposal (IRB)**. At his facility, they are obtaining informed consent to draw another tube as part of a general laboratory IRB proposal, that would include activities such as implementing plastic tubes.

**ADDENDA** Dec. 17, 2001

14. **Editor's Note:** According to the AABB (source: PulsePoints No. 499 December 13, 2001) the **AABB/FDA liaison committee** recently meet at the AABB National Office, and one of the agenda items at that meeting addressed this issue. According to the AABB report the renewed OSHA emphasis on the need for safer products has stimulated some tube manufacturers to start phasing out glass tubes in favor of plastic tubes. The committee asked for information on options for the use of plastic vs. glass tubes in blood banking procedures, and what validation or parallel testing the FDA would expect to see. FDA Devices Review Branch, Division of Blood Application, OBRR discussed the difficulty of investigating this issue. Collection tubes are classified as medical devices and are approved by the [Center for Devices & Radiological Health \(CDRH\)](#). CBER is involved only when the manufacturer makes a specific claim for blood bank testing. Although CBER does not have specific guidance, some quality control will be necessary and only validated systems should be used. It was suggested that the following **CFR references** might be helpful: 21 CFR 606.65(e), 606.100(b)(14), and 606.140(b). It is not clear why the package insert of at least one collection tube manufacturer states in general terms, that these tubes are not suitable for blood bank procedures. It may be that because chemistry and hematology testing were specifically included in labeling, the manufacturers were questioned about the lack of a statement for blood banking procedures. If they did not have data to support blood banking use, the manufacturer may have added a statement rather than pursue testing that would allow the blood banking label claim. It is also not clear what the definition of blood banking procedures is, although the type of tube used is especially critical in performing NAT. Adding to the complexity of the problem is that there are two manufacturers involved, the collection tube manufacturer and the reagent or kit manufacturer. Because there are a smaller number of kit or reagent manufacturers, it may be more practical to pursue that avenue than to get collection tube manufacturers to provide validation information. FDA has limited information about the multiple brands of tubes in use, or about the tubes to which blood banks may be planning to switch. FDA needs to take a closer look at what testing should be performed by the manufacturers or by the end user, or both. FDA suggested that manufacturers may be more responsive to customer contact and concerns than to agency contacts. FDA said it may be beneficial for AABB to enlist the assistance of [AdvaMed](#) (the device manufacturers' association).

**ADDENDA** Feb. 8, 2003

15. Please see the new e-Network Forum discussion: [Use of plastic tubes for collection of patient samples as well as for testing \(ABO/Rh determination, unexpected antibody detection and identification, and crossmatching\)](#).

Please submit comments to the [e-Network Forum](#).



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**Posted:** October 4, 2001

**Addenda:** Oct. 5 & Dec. 17, 2001; Feb. 8, 2003