

FREQUENTLY ASKED QUESTIONS (FAQ) - Biologics

1. When is a California Biologics license required?

Any time blood, blood components, including cord blood, stem cells (peripheral blood progenitor cells), or apheresis products are collected, processed, stored, or distributed. Also if you are collecting, processing, storing, or distributing cord blood products from California patients or donors, then you will need a California Biologics license. This includes facilities that contract for these services, but who also register “clients”, obtain “informed consent” documents, and are responsible for distribution of the cord blood products when necessary.

2. Do I need a Biologics license for cord blood if I am collecting menstrual blood?

Cord blood sources include blood from the umbilical cord, placental, or menstrual blood which is or was present in peripheral circulation.

3. I want to collect stem cells – what kind of a license should I apply for?

Stem cells or hematopoietic progenitor cells can be found from many sources. If the source is or was from circulating blood, then a Biologics license would be required. If the stem cells are from sources other than circulating blood (FAQ #1), embryonic, adipose, mesenchymal, for example, then a Tissue Bank license would be needed.

4. I work in a hospital blood bank, but we do not collect blood from donors. Do we need a Biologics license?

Even though your facility may not actually collect blood from donors, there are a number of other functions which would require a Biologics license, such as blood irradiation, separating whole blood into red cells and plasma, repackaging into new bags and labeling with ISBT 128 labels, reconstituting red blood cells, or re-packaging red cells from an intra-operative blood salvage for later patient use. Also, and very importantly, ALL blood banks and transfusion services in California must follow the current version of AABB Standards for Blood Banks and Transfusion Services. The requirement for a California Clinical Laboratory license and CLIA certificate does not replace this process, and every blood bank and transfusion service should have the current version of these Standards, an AABB technical manual, and associated Standard Source documents to guide their practices. Please consult with your individual Medical Director and our office if you have further inquiries.

5. How do I apply for a Biologics license?

The process is started with form LAB 114, which may be found on the [LFS forms page](https://www.cdph.ca.gov/Programs/PSB/Pages/LaboratoryFieldServices.aspx) – (<https://www.cdph.ca.gov/Programs/PSB/Pages/LaboratoryFieldServices.aspx>)

There is another link to general requirements for blood banks, cord blood and plasma collection facilities under [guidelines for initial application and routine inspection](http://www.cdph.ca.gov/programs/lfs/Pages/BloodBanksandBiologics.aspx): (<http://www.cdph.ca.gov/programs/lfs/Pages/BloodBanksandBiologics.aspx>)

The timeframe for this process generally is 60 days or less and scheduling a time for the initial inspection is required. Application fees are non-refundable and may be found on the [LFS fee information page](https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/Fees.aspx) (<https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/Fees.aspx>).

6. How is the Biologics license renewal process handled?

During the application process, you are asked for two valid email addresses of responsible individuals in your organization. Approximately two months prior to the expiration date of your license, an email will be sent with read and delivery receipts. The email will contain your specific license renewal form, a Biologics personnel form, and general instructions. Renewal fees are the same as application fees – see #6 above. Please note that the renewal must be filed ten days prior to the license expiration date – failure to do so will result in termination of the license on the expiration date – there is no grace period. If for any reason, the license renewal email has not been received, please contact our department and we will gladly assist you, or refer to our [LFS forms page](#) (LAB 175) for the personnel form LAB (118) and Biologics license renewal (<https://www.cdph.ca.gov/Programs/PSB/Pages/LaboratoryFieldServices.aspx>)

7. How do we handle changes to our license information?

Any time the Medical Director, location, or ownership change, the Biologics license is automatically revoked. A new license may be obtained (#6 above) after re-evaluation of continued compliance with applicable laws and regulations. If directorship is shared, and fifty percent or more of the directors remain, a new license need not be obtained, as long as the remaining directors meet director qualification requirements. Please check with our department for more detailed explanation if required.

8. Our blood center operates many mobile blood drives. Do we always need an RN?

Yes – by regulation (17 CCR§1002), if there is no M.D. on site there must always be an RN on site, while blood is being collected.

9. I work in a plasma center and they are always asking questions about the “Total Protein” refractometer testing. Who can do these tests?

Typically in a plasma center, testing personnel could include a registered nurse (RN), a clinical laboratory scientist (CLS), an M.D., a Family Nurse Practitioner (FNP), or a Physician’s Assistant (PA). While other license categories may be permitted, in this setting, an LVN or EMT would not qualify – please review [Business and Professions Code 1206.5](#).

10. I work in a surgeon’s office and we have heard about the Paul Gann blood act. How can we get a copy of the information for patients?

Here is a link to both the English and Spanish versions of the information:

[A Patient's Guide to Blood Transfusion](http://www.mbc.ca.gov/Publications/Brochures/Blood_Transfusions.aspx) (http://www.mbc.ca.gov/Publications/Brochures/Blood_Transfusions.aspx)

11. I am the quality manager of a large blood center. We compete with other centers for blood donors and have an incentive program in place to help acquire and retain donors. We have tried to ensure that our programs are in compliance, but see that others may appear to be violating the requirements for volunteer donations in California. What should we do?

The first step would be to review the [FDA website for donor incentive guidance](#) and subsequently ask the FDA for guidance.

If your program does not fall easily into the FDA categories, please forward all the incentive program information to our office for review. Please be sure to include all aspects of the program and how it clearly defines how the incentives are given and applied to donors. If you still feel that a complete picture of your (or that of a competitor) program is not being presented, you may file a complaint with our department – we will forward a complaint form to you. We would then review the documentation, and evaluate it for the necessity to initiate an on-site investigation.

12. I work for a blood collection facility. If I feel we are doing something wrong, how can I file a complaint or find out more about our situation and the laws and regulations?

We would be happy to discuss the situation with you at any time. You may [view a list of LFS program contacts](#) on our website.

If you would prefer to file an anonymous complaint, please use the contact information provided and we will send you a complaint form. Please be as thorough as possible, including dates of services or other information that will allow us to follow the thread of your information.

13. I am a quality assurance manager for a blood center. Our policies and procedures are proprietary and they cannot be copied without appropriate permission and documentation. What should I do if an inspector requires copies?

A mechanism should be in place to copy the document(s) in question, have the inspector sign the copy to assure that the document in use at the time will be the one actually obtained. Then use your internal process to acquire the permissions and documentation required to release these to the inspector. If you have further questions regarding the process, please do not hesitate to contact our office for clarification.

14. How can I obtain the actual license number of a blood bank, plasma center, cord blood facility, or verify information about them?

Please contact our department and we can provide license numbers and license verification.

15. I work in a hospital blood bank and we prepare crossmatch products for home health agencies, convalescent homes, and surgicenters which include pedipacks and aliquots specimens. Do we need a Biologics license?

This is a complicated question. In general, if the crossmatched products are not modified or relabeled, they may be issued following your facility protocols for tracking and traceability. You are required to confirm that the facilities where you are transporting products, meet all applicable laws and regulations, including the relevant portions of the current AABB Blood Bank and Transfusion Standards. Making pedi-packs and aliquots may depend upon the method used to create these products, whether additive solutions were placed, and other factors. Please call our office for discussion.