1. Why did the CAP develop an accreditation program for biorepositories?
   Excellence and quality measures in biorepositories are interrelated concerns that have a direct bearing on research that can help advance health care. The CAP is introducing multiple, scalable tools specifically designed to improve and validate the quality of biospecimens and biorepositories. Our new Accreditation for Biorepositories Program will help ensure consistent, industry-wide verification of biospecimen quality. Thousands of biorepositories exist, varying in size, nature of collections, specimen types, purpose, quality, and age. Recently, there has been a realization that some biorepositories do not fulfill research requirements (most importantly personalized medicine); a high degree of heterogeneity exists in the methods used to collect, process, and store biospecimens.

2. What is a biorepository?
   A biorepository is defined as an entity that receives, stores, processes, and/or disseminates biospecimens, their derivatives, and relevant data, as needed. For purposes of CAP accreditation, a biorepository encompasses the physical location as well as the full range of activities associated with its operation.

3. Are facilities that store biospecimens for transplant purposes eligible for the CAP’s Biorepository Accreditation Program?
   The program is only applicable to those facilities that store biospecimens for research. The program is not applicable to tissues being stored for transplant purposes; however, the CAP Laboratory Accreditation Program does inspect the storage of transplant tissues when they are under the purview of the laboratory director.

4. My laboratory participates in the Laboratory Accreditation Program and stores blood and tissues. Does this mean that we must complete the Biorepository Accreditation Program Checklist?
   The Biorepository Accreditation Program Checklist applies only to those laboratories that participate in the Biorepository Accreditation Program.

5. What is the goal of the Biorepository Accreditation Program?
   Our goal is to improve and standardize quality and consistency in collecting, processing, storing, distributing, and computerizing information for biospecimens while ensuring the quality of human specimens (eg, serum, urine, blood, and tissue) and genetic material (eg, RNA and DNA).

6. When did the CAP introduce the Biorepository Accreditation Program?
   The program was developed and introduced in 2011.

7. Is participation in the Biorepository Accreditation Program mandatory?
   No. The program is not CLIA-based and is voluntary.

8. Will CAP staff inspectors or volunteer inspectors lead the inspections?
   The program is based on a peer-inspection model, similar to the CAP’s Laboratory Accreditation Program. The inspectors may be pathologists, PhDs, or managers of biorepositories (typically with a medical technology, biomedical, or nursing background). Most critical is their current experience in an active biorepository. Inspectors will be qualified through a CAP training program. During early program development, CAP staff inspectors will supplement peer inspectors to ensure each inspection’s timely execution and quality.

9. How many inspectors will come to perform my on-site inspection?
   One to two inspectors will inspect most biorepositories.
10. How will participating biorepositories be assessed?
The peer-based inspector(s) will perform the on-site inspection using CAP Accreditation checklists to provide a comprehensive and up-to-date blueprint of quality practices enabling biorepositories to improve their operations and ensure quality. The desk assessment offers a remote review of a biorepository’s quality management plan, specified procedures (related to key accreditation requirements), and select quality and process statistics. It will assist biorepositories in strengthening their procedures through the identification of areas that need improvement.

11. Does CMS or CLIA oversee the program?
Oversight of biorepository quality is not covered under CLIA, nor does a single set of standards (eg, CLIA) for biorepositories exist.

12. How will accreditation benefit my biorepository?
The CAP believes that inspection and accreditation will drive consistency in achieving compliance with multiple processes within a biorepository. We believe there are many best practices within the industry, but wide variability in their application. Accreditation will ensure a more level playing field.

13. How do I become CAP-accredited?
Complete a Request for Application Form. Once the CAP receives the application, we will assign an inspection team leader and a team will be assembled. The team will conduct an inspection. If deficiencies are cited, the facility must provide documentation in support of the correction or plan of correction for each deficiency cited. The CAP staff and pathologists who actively lead our accreditation programs will review the findings and make a determination of accreditation status.

14. Is the accreditation process a two- or three-year cycle?
The biorepository accreditation program is a three-year program. The first year includes the application process and initial on-site inspection. The second year is a self-inspection and the third year is a self-inspection with customized consultation, or CAP staff-led overview.

15. How do I know if my biorepository is ready for a CAP inspection?
A biorepository interested in the program but not confident in its “readiness” may purchase a set of the requirements and perform a self-inspection.

16. Are the CAP requirements available for purchase?
Yes, they can be purchased by completing the CAP Checklist Order Form.

17. If my facility purchases the checklists and later applies to the program, do I still have to pay for the application fee?
Any laboratory that purchases the checklists and applies for accreditation within 12 months will not be required to pay the accreditation application fee, because the checklists were purchased in preparation for a CAP inspection.

18. How can I become trained to be a CAP Inspector?
Working professionals of biorepositories—peers—conduct inspections. Therefore, each inspector must complete training prior to conducting an inspection. The training will be interactive and covers the inspection process, cycle, and review of the requirements used to assess compliance along with scenarios to assess the learning objectives.

19. Is there a fee associated with this training?
No. The training will be conducted via live seminars in 2012; in subsequent years, the training will be on-line.

20. Who can I contact for additional information about the Biorepository Accreditation Program?
Please contact Danette Godfrey (800-323-4040 ext. 7078) or Nancy Yeransian (800-323-4040 ext. 7388).