



## CAP Innovates Accreditation for Biorepositories

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## Why We Are Here

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College of American Pathologists (CAP) Accreditation focuses on quality, accuracy, and procedural consistency upon which patient outcomes directly depend.



## Challenges Facing Biorepositories

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Lack of standard and uniform operating procedures for:

- Collection
- Processing
- Annotation
- Storage and transport



This results in a **shortage of quality biospecimens.**

## Goal of CAP Laboratory Accreditation

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- To improve the quality of clinical laboratory services, and ensure the accuracy and reliability of test results through an **educational and peer-review inspection** process that utilizes:
  - Practicing laboratory professionals (true peers) in all disciplines.
  - A cadre of staff inspectors who perform inspections and assist peer inspectors to aid in uniformity and quality assessment.



## We Asked You Why A Biorepository Accreditation Program Would Be Valuable\*

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- *"[The program] would offer an independent measure to objectively evaluate our strengths and weaknesses."*
- *"[A biorepository accreditation program] would give our collaborators assurance that our samples have been handled in a rigorous compliant manner."*
- *"[Accreditation] would provide standardization to enable consolidation of all biorepository activity into a central facility."*
- *"[Biorepository accreditation] would assist in creating awareness among senior management of the need for personnel training and infrastructure investment."*
- *"[It] would allow us pursue business with pharmaceutical industry and participate in clinical trials."*
- *"As with all laboratory accreditation, [this program] would allow the biospecimen division to be recognized as having an established level of competency."*

\*CAP Survey conducted in 2010 and sent to biorepository leaders in the US

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## The CAP's Qualifications

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- 50+ year history of leadership in accreditation
- Accredits 7,000+ laboratories, including many that handle biospecimens
- Regarded by the industry as the Gold Standard in accreditation
- Proven peer-inspection model



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## Value of CAP Peer-Based Inspections

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- Equal standing (pathologist, technologist, etc.)
- Laboratory professional
- First-hand knowledge
- Offers constructive feedback
- Inspectors with Specialty Expertise
- Scientific Resources
- New Technology
- Ongoing Monitoring
- Education and Improvement
- Promotes the laboratory profession to the public
- Gains insight through interacting with peer professionals



## The CAP Inspector/Peer Model

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- 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.
- One to two inspectors will inspect most biorepositories.



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## How are Inspectors Trained?

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- Working professionals of biorepositories, i.e., 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.
- The training will be conducted via live seminars in 2012; in subsequent years, the training will be on-line.
- Retraining will be required once every three years.



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## How will Biorepositories be Assessed?

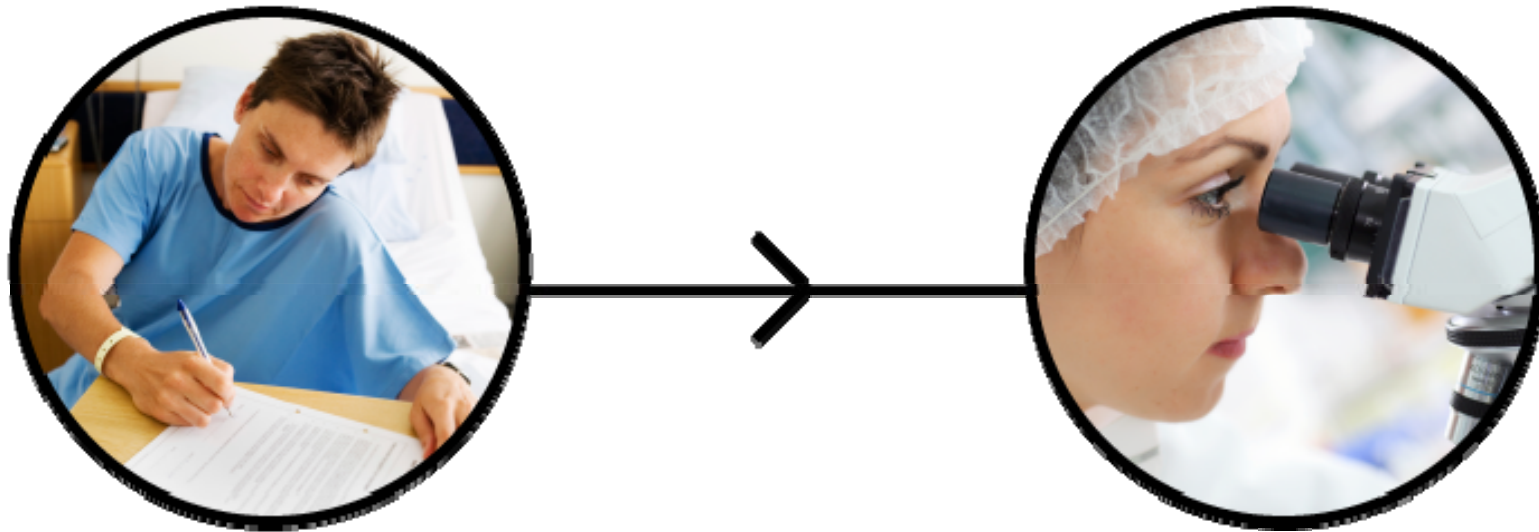
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- The peer-based inspector(s) will perform the on-site inspection using CAP Accreditation checklists to provide a comprehensive and up-to-date blueprint of quality practices enabling biorepositories to improve their operations and ensure quality.
- 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.

## Biospecimen Management Sequence

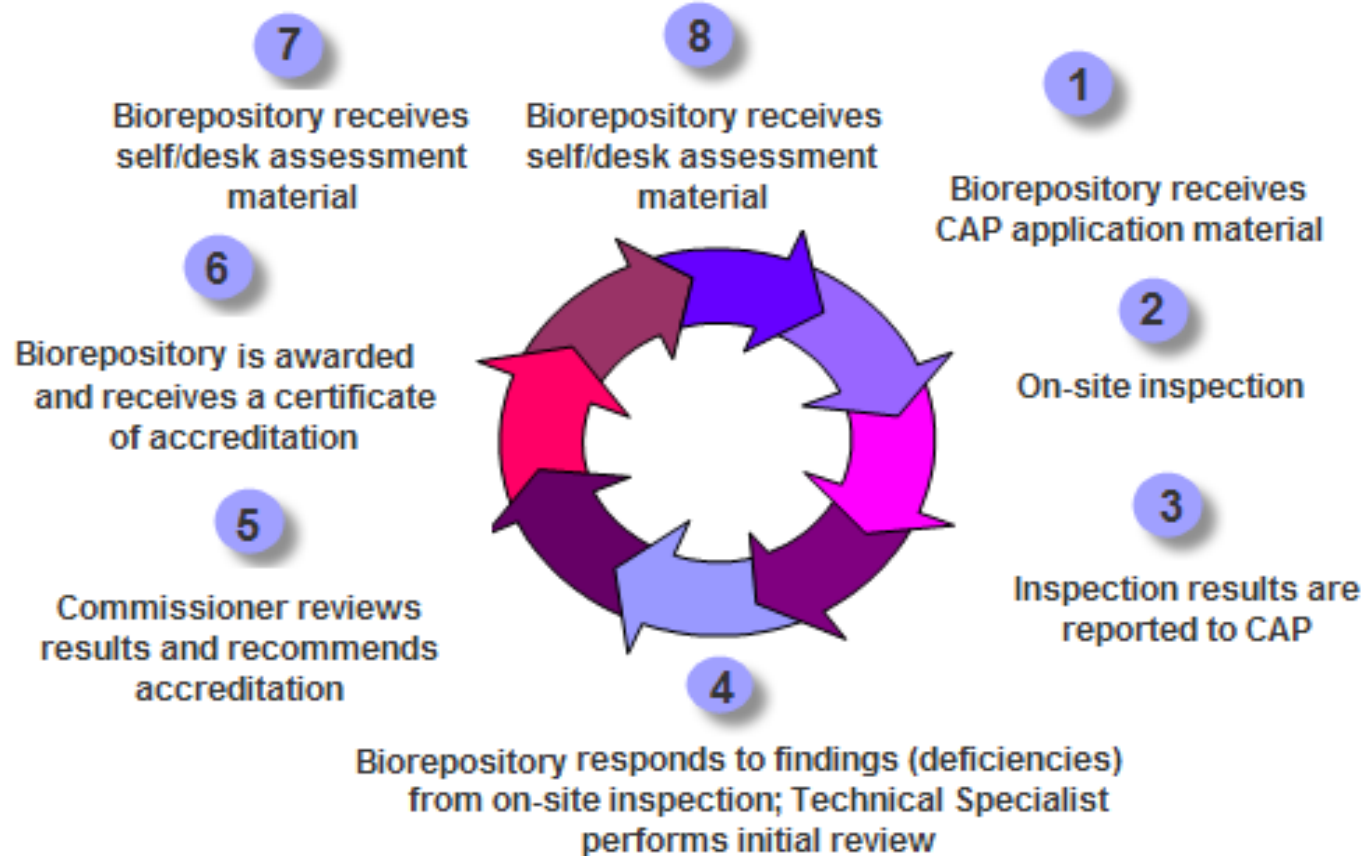
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CAP Accreditation addresses this sequence from patient to analysis.



# Biorepository Accreditation

## Three-Year Cycle



## Application/Acceptance

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### Pre-accreditation support

- Address all biorepository accreditation requirements
- Assist you in achieving compliance with standards



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## Inspection/Accreditation

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### Comprehensive inspection

- On-site inspection by a trained peer-based team
- Guidelines for up-to-date quality practices



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## Maintenance/CQM

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### Desk reviews

- Repository quality management plan
- Procedures impacting re-accreditation
- Selected quality processes and statistics



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# Biorepository Accreditation Program Checklist: Sample Questions



## DNA/RNA EXTRACTION/AMPLIFICATION

### BAP.XXXX Nucleic Acid Quantity Phase II

The quantity of nucleic acid is measured.

*NOTE: The quantity of nucleic acid must be measured prior to use by a standard procedure that allows for the accurate determination of the concentration/quantity of the nucleic acid.*

- ✓ *Evidence of Compliance: Records detailing the concentration and yield of nucleic acid per specimen, per extraction*

### BAP.XXXX Specimen Identification Phase II

There is a system to positively identify all participant specimens, specimen types, and aliquots through all phases of the analysis, including specimen receipt, nucleic acid extraction, nucleic acid quantification, hybridization, detection, documentation, and storage.

### BAP.XXXX Isolation/Preparation Procedures Phase II

The adequacy of nucleic acid isolation/preparation procedures is evaluated.

*NOTE: Adequacy of nucleic acid isolation/preparation procedures (manual or automated) must be evaluated through the use of periodic positive controls. To the extent possible, controls must be processed through all steps of the assay, including the extraction phase.*

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# Biorepository Accreditation Program Checklist: Sample Questions

## TEMPERATURE MONITORING AND ALARMS

### BAP.XXXX NIST Thermometer Phase II

An appropriate thermometric standard device of known accuracy (e.g. guaranteed by manufacturer to meet NIST Standards) is available.

*NOTE: Thermometers should be present on all temperature-controlled instruments and environments and checked daily. Thermometric standard devices should be recalibrated or recertified prior to the date of expiration of the guarantee of calibration; documentation of recalibration/certification should be maintained for review.*

### BAP.XXXX Non-Certified Thermometers Phase II

All non-certified thermometers in use are checked against an appropriate thermometric standard device before initial use.

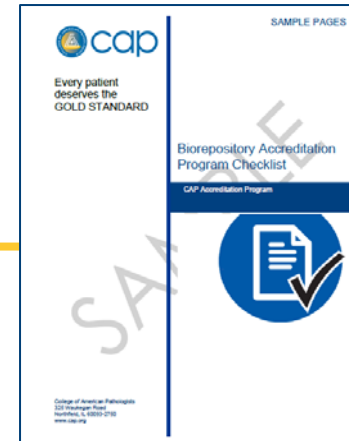
### BAP.XXXX Alarm System Monitoring Phase II

There is a mechanism for monitoring the alarm system.

### BAP.XXXX Alarm System Contingency Plan Phase II

There is a contingency plan in place for monitoring if the alarm system fails.

*Note: downtime procedures should exist and staff should be trained on these procedures. This contingency procedure should be periodically tested.*



# Biorepository Accreditation Program Checklist: Sample Pages at cap.org

- A. Accreditation and Laboratory Improvement
- B. Biorepository Accreditation Program
- C. View a Sample Accreditation Checklist

The screenshot shows the CAP Accreditation and Laboratory Improvement website. Callout A points to the 'Accreditation and Laboratory Improvement' navigation menu. Callout B points to the 'Biorepository Accreditation Program' link in the 'CAP Accreditation Programs' list. Callout C points to the 'View a Sample Accreditation Checklist' link in the 'Related Links' section.

**A.** Accreditation and Laboratory Improvement

**B.** CAP Accreditation and Inspection Information

- CAP Accreditation Programs
  - Laboratory Accreditation Program
  - **Biorepository Accreditation Program**
  - Reproductive Accreditation Program
  - Forensic Drug Testing Accreditation Program
- International Laboratory Accreditation Applicants
- About Accreditation Checklists
- CAP Accreditation Readiness-Assessment (CARA) **NEW**
- Preparing to Inspect/Training
- Applying for the Accreditation Program
- Accredited Laboratory Directory

**C.** View a Sample Accreditation Checklist

## Ongoing Status as a CAP-Accredited Biorepository

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- High-quality standards are verified, and marketable
- Recognition and confidence in your quality practices are increased
- Quality biorepository standards establish a foundation for institutional support



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# Questions

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