Laboratory Accreditation

Guide to CAP Accreditation for International Participants
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About the CAP Laboratory Accreditation Program

The CAP Laboratory Accreditation Program is an internationally recognized laboratory inspection program, the only one of its kind utilizing multidisciplinary teams of practicing laboratory professionals as inspectors. Because they deal with laboratory issues on a daily basis, these inspectors are uniquely qualified to provide you with a thorough inspection that is specific for each section of the laboratory.

A laboratory inspection occurs every two years. In the years when an on-site inspection does not occur, the laboratory must perform a self-inspection using materials provided by the CAP. The accreditation program is voluntary and helps laboratories achieve the highest standards of excellence in patient care.

The program is based on accreditation requirements. These requirements are included in documents called checklists, which are used both by the laboratory to prepare for inspections and by the inspection team as a guide to assess the overall quality of the laboratory.
Laboratory Accreditation and the College of American Pathologists

What Is CAP Laboratory Accreditation?

Accreditation is a continuous process by which the CAP reviews and monitors the laboratory’s performance.

All testing performed at a single location under the leadership of one laboratory director must be reported during the application process. The CAP does not accredit portions of laboratories.

CAP Accreditation Process

1. Enroll in CAP PT/EQA
   • Enroll in CAP PT/EQA for all patient reportable tests, when PT is required
   • Perform CAP PT for a minimum of six months prior to application request

2. Application for Accreditation
   • Request CAP application material
   • Complete and submit application
   • Prepare for on-site inspection using CAP materials

3. On-Site Inspection
   • Inspection team leader schedules inspection date
   • Participate in an on-site inspection

4. Inspection Results
   • Inspection team leader will submit report to CAP and provide a copy to the laboratory at the conclusion of the inspection
   • Review your copy of the inspection report

5. Inspection Follow Up
   • Respond to findings (deficiencies) from on-site inspection
   • Submit responses to CAP within 30 calendar days of the inspection

6. Evaluation
   • CAP Commissioner reviews results, provides accreditation expertise, and ensures continuous compliance

7. Certificate of Accreditation
   • CAP awards accreditation and issues a Certificate of Accreditation
   • Maintain compliance to accreditation standards within a two-year program

8. Self-Inspection
   • Receive and review self-inspection materials
   • Perform self-inspection at the time of the one-year anniversary

Outcome of Completing a Successful Inspection

The laboratory is awarded a “CAP Laboratory Accreditation” certificate upon successful completion of the inspection process and becomes part of an exclusive group of more than 7,300 laboratories worldwide that have met the highest standards of excellence.
Things to Know Before Applying for CAP Laboratory Accreditation

Eligibility
To be eligible for CAP Laboratory Accreditation, the laboratory must have a qualified laboratory director, participate in proficiency testing/external quality assurance, and perform patient testing.

Director Qualifications
The CAP requires specific qualifications for the laboratory director, the person responsible for operation of the laboratory. Qualifications may differ based on the type of testing performed; more complex testing may require a more experienced individual. A laboratory director must have an MD, DO, PhD, or must have commensurate education and experience necessary to meet personnel requirements as determined by the CAP.

A director of a laboratory subject to US regulations (CLIA), educated outside of the United States must provide documentation of a third-party education equivalency assessment from a NACES (National Association of Credential Evaluation Services) accredited organization or the AICE (Association of International Credential Evaluators). If the laboratory director is boarded by an HHS-approved (Health and Human Services) board, the third-party equivalency assessment is not required.

Laboratory Personnel Qualifications
CAP requires that all testing personnel have earned an associate degree in a laboratory science or medical technology from an accredited institution, or equivalent laboratory training OR have earned a high school diploma or equivalent and documented training.

The laboratory must provide documentation that all testing personnel have satisfactorily completed initial training on all instruments/methods applicable to their designated job.

External Quality Assurance
External quality assurance (EQA) also known as proficiency testing (PT) is an interlaboratory peer program that compares a laboratory’s test results using unknown specimens to results from other laboratories using the same or similar methods.

The laboratory must enroll in CAP PT/EQA and must do so a minimum of six months prior to the CAP application process.
External Quality Assurance (continued)

Requiring enrollment and participation for six months helps the laboratory build the discipline necessary to monitor laboratory testing quality and to better ensure that processes and procedures exist for corrective action. This time frame also enables the laboratory to become familiar with the requirements to obtain permits and any other documents necessary to receive PT/EQA shipments. It also ensures the inspection team has sufficient data to verify testing quality when conducting the first on-site laboratory inspection.

Key Components

In order to meet CAP Laboratory Accreditation requirements, the laboratory must have the following key documents/processes:

- Quality Management Program
- Chemical Hygiene Plan
- Document Control Process
- Competency Assessment Program
- Test Method Validation Documentation
- Laboratory Director Oversight Documentation
- Laboratory Information System (LIS) – if applicable

Additional Resources

- The following products and documents are available for purchase from the CAP to assist laboratories contemplating accreditation or in the process of preparing for accreditation:
  - CAP Accreditation Readiness Assessment (CARA)
  - Audioconferences/Webinars
  - Online Inspector Training
  - CAP Accreditation Checklists *
  - Laboratory Accreditation Manual *
  - Online Competency Assessment Program
  - Standards for Laboratory Accreditation*

* These items are included as part of the accreditation application.
Cost of Accreditation

Accreditation fees are paid annually and are based on the institution’s laboratory sections, list of performed testing (activity menu), organization structure and complexity.

To receive an estimate of annual accreditation fees, complete and return the International Fee Estimate Worksheet.

International laboratories are required to pay for roundtrip, business-class airfare for intercontinental travel by inspector(s). The number of inspectors sent will be based on the volume and/or testing type in the laboratory. The CAP will pay for all hotel accommodations, meals, ground transportation and in-country air travel. Inspections typically occur once every two years.

Please note that accreditation fees do not include the cost of proficiency testing (external quality assurance).
Request for Application

Overview
Review the “Things to Know Before Applying for CAP Accreditation” section of this document. Laboratories ready to become accredited must request an application.

How to Request an Application
Download the CAP Accreditation Request for Application form at cap.org.
- Complete the form
- Print
- Submit via email, mail or fax (information provided on form)
- Include the nonrefundable fee
  - Credit card
  - Wire transfer
  - Check

For additional information on payment refer to the “Placing an International PT/EQA Order” section for specific payment requirements.

What Next?
After the Request for Application is processed by the CAP, the laboratory will receive a paper copy of the application and an email notification, including instructions for accessing the application online through the CAP’s online resource (e-LAB Solutions).

Application
The application may be completed online through e-LAB Solutions™. Information about e-LAB Solutions may be found at:
- cap.org/accreditation – select the e-LAB Solutions tab.
- For online assistance, contact Customer Contact Center at 001-847-832-7000 or email accreditationonline@cap.org.

OR
A paper application may be completed and returned to the CAP via email, fax, or mail.

Applications must be submitted within six months of receipt by the laboratory.
What Is the Director’s Responsibility?

The director of a CAP-accredited laboratory is responsible for ensuring ongoing compliance with the Standards for Laboratory Accreditation and implementing the requirements of the accreditation checklists. The director must have the qualifications and authority to fulfill these responsibilities effectively.

Key Components

An effective director ensures:

- The following components are defined, implemented, and monitored:
  - An effective quality management program.
  - Adequate number of appropriately trained and qualified personnel.
  - A safe laboratory environment.
- Availability of consultations for ordering appropriate tests and the interpretation of laboratory findings’ medical significance.
- Anatomic pathology services are provided by a qualified anatomic pathologist.
- The ability to function effectively with applicable accrediting and regulatory agencies, the medical community, patients, and administrative officials.
- Educational programs, strategic planning and research, and development appropriate for the laboratory and institution. If delegating activities to others, documentation specifying which individuals are authorized to act on his/her behalf.
- If not present full-time, a written agreement defining the frequency of, and responsibilities for, on-site visits. Activities performed during visits must be documented.
Director Responsibilities

Who Is Responsible?

The director of a CAP-accredited laboratory is responsible for ensuring ongoing compliance with the Standards for Laboratory Accreditation and implementing the requirements of the accreditation checklists.

Outcome of an Effective Director

Laboratory benefits include:

- A culture committed to continuous improvement.
- A testing environment always prepared for an inspection.
- Having an involved director who serves as a mentor and promotes a culture of quality.
- A safe environment.
- Ongoing compliance with CAP requirements.
Document Control System

What Is Document Control?

Document control is the management of all paper or electronic documents, including policies, procedures, and forms. A written document control system outlines how all documents are initiated or revised, approved, utilized, reviewed, retained, and discontinued.

Every document within the laboratory must be:

- Current – have up-to-date review and reflect current practices.
- Accurate – only authorized revisions are made to documents, substantial revisions are reviewed and approved before implementation, and revisions are reflected on all copies of documents.
- Available – readily accessible to all staff utilizing them.

Key Components

A laboratory’s document control system must ensure:

- All copies of policies, procedures, and forms are current.
- Personnel have read the policies and procedures relevant to their job activities.
- Personnel are knowledgeable about the contents of procedure manuals (including changes) and demonstrate proficiency relevant to the scope of their testing activities.
- All policies and procedures have been authorized by the laboratory director before implementation.
- Policies and procedures are reviewed at least annually by the laboratory directors or designee.
- Discontinued policies and procedures are quarantined in a separate file for a minimum of two years from the date of discontinuation (five years for transfusion medicine).

Who is Responsible?

- The laboratory director who meets CAP director qualifications is responsible for implementing and maintaining an effective document control program.
Outcome of an Effective System

The laboratory will benefit by:

- Ensuring on any given day that practice matches policies and procedures.
- Promoting the use of only approved policies, procedures, and forms.
- Organizing procedures for ease of accessibility by testing personnel.
- Tracking the status of approvals and reviews to ensure they occur in a timely manner in accordance with CAP requirements.
- Maintaining ongoing compliance with CAP requirements.
What Is a Chemical Hygiene Plan?

A Chemical Hygiene Plan (CHP) includes procedures to protect employees from the health hazards of chemicals and keep exposures below specified limits. All personnel involved in the laboratory must receive training on the CHP and understand how it applies to their role.

Key Components

An effective CHP includes:

- Laboratory director responsibilities and the assignment of a chemical hygiene officer.
- Material safety data sheets (MSDS) for all hazardous chemicals used in the facility. The MSDS must be accessible for review by all laboratory employees during every work shift.
- A training program on interpreting chemical labels and MSDS, and the use of proper protection for chemical handling and disposal.
- Proper labeling on all chemical containers.
- Informing all laboratory employees of the right to know the hazards associated with their job.
- Evaluation of every chemical used in the laboratory for carcinogenic potential, reproductive toxicity, and acute toxicity.
- Review of all incidents and occurrences of the past year.

Who Is Responsible?

- The laboratory director is responsible for the CHP and must assign a chemical hygiene officer.

Outcome of an Effective System

- Laboratory benefits include:
  - Increased employee safety and awareness.
  - Reduction in laboratory accidents and improved spill responses.
  - Ongoing compliance with CAP requirements.
  - Safe and efficient organization for chemical storage.
Laboratory Information Systems

What Are Laboratory Information Systems?

Laboratory information systems (LIS) provide a database serving the information needs of the laboratory by linking patient test results to the ordering clinician/client, in addition to the patient’s medical record.

Overview

Multiple LIS are available, including:

- Systems with a local host database (computer hardware and software on site) where the laboratory is the only user.
- Systems with a host physically removed from the laboratory, where multiple user laboratories may share the same database.

The Laboratory Accreditation Program does not consider the following types of devices a LIS:

- Small programmable technical computers or dedicated microprocessors that are an integral part of an analytic instrument.
- Purchased software services used for quality assurance and data analysis.
- Microcomputers used for non-patient test result word processing, spreadsheets, or other single-user functions.

Key Components

- The laboratory must ensure the LIS is able to accurately and reliably send test results and other patient-specific information from the point of data entry (whether interfaced or entered manually) to the final report destination in a timely manner.

The laboratory must provide the following:

- Computer facility and equipment with appropriate environmental controls and safety elements.
- Written LIS policies and procedures with instructions for daily operations appropriate to the level of use.
- Software validation for new installation and software updates, including staff training.
- System security policies and practices for confidentiality of patient data and protection against unauthorized alterations.
- Error detection and timely communication of patient data to the ordering clinician/client.
Laboratory Information Systems

Key Components (continued)

• Auto-verification, if used, with system logic and rules to prevent release of test results not meeting defined criteria.
• Data retrieval and preservation for the required regulatory retention period available, within a time frame consistent with patient care needs.
• Accurate transmission of data across instrument interfaces and interfaces with other computer systems (e.g., middleware, hospital information systems, and other output devices).

Who Is Responsible?

The laboratory director who meets CAP director qualifications is responsible for ensuring communication of laboratory data.

The director may delegate some LIS-related functions to others and is responsible for determining the qualifications of these individuals. It is the director’s overall responsibility to ensure these functions are properly carried out.

Outcome of an Effective System

Laboratory benefits include:
• Accurate and timely transmission of patient data.
• Effective presentation of patient data.
• Retention and retrieval of patient data consistent with regulatory requirements.
• Improved efficiency and productivity in the laboratory.
• Ongoing compliance with CAP requirements.
Test Method Validation

What Is Test Method Validation?

Test method validation verifies or establishes test method performance specifications; these include analytic accuracy, precision, sensitivity, interferences (specificity), reportable range, and reference intervals (normal values), as applicable.

Overview

The test method validation process must include:

- Written procedures describing the validation process for new instruments and methods.
- Documentation of data collected in the testing environment where the method will be implemented.
- Data obtained from studies performed by the manufacturer and from published literature, as applicable.
- Summary statement documenting approval of the validation studies by the laboratory director or qualified designee prior to initiation of patient testing.

Key Components

- The type of method validation required depends on the type of testing as defined by the CAP.
- Unmodified Commercial Assays – verify manufacturer claims for each aspect listed below, as applicable:
  - Analytic accuracy – closeness of agreement between a test result and an accepted reference value.
  - Analytic precision – reproducibility of a test result.
  - Analytic sensitivity – smallest quantity reliably detected of a given analyte.
  - Analytic interferences (specificity) – ability of an analytic method to detect only the analyte it was designed to measure.
  - Reportable range – interval of test results over which the laboratory can establish or verify accuracy.
  - Reference intervals – range of test values expected for a designated population.
  - All other characteristics required for test performance.
- Laboratory-developed tests and modified commercial assays – requires the laboratory to establish all aspects listed above, as applicable.
Test Method Validation

Who Is Responsible?

The laboratory director who meets CAP director qualifications is responsible for ensuring each method performed is of sufficient scope and scientifically valid. The director documents final approval of the validation prior to the initiation of patient testing.

Outcome of an Effective System

The laboratory benefits include:

• Organized and clear evidence of method validation.
• Accurate patient test results when the new method is implemented.
• Ongoing compliance with CAP requirements.
Competency Assessment Program

What Is Competency Assessment?
A competency assessment program appraises an individual’s knowledge and mastery of skills needed to properly perform a specific job.

Key Components
A laboratory must have:
- A defined set of skills and knowledge specific to job descriptions.
- Tools to document and organize assessments.
- Criteria for acceptable levels of competency.
- A process for reevaluation, if personnel fail to meet competency criteria.

Six Elements of Competency Assessment
- Direct observations of test performance.
- Monitoring of test result reporting.
- Review of quality control records, proficiency testing results, and preventive maintenance records.
- Direct observation of instrument maintenance and function checks.
- Assessment of test performance by external proficiency testing or internal blind testing samples.
- Evaluation of problem-solving skills.

System Components
- A laboratory must have a system ensuring:
  - Employees’ competency assessments are completed semiannually for the first year of patient testing, and annually thereafter.
  - Competencies are appropriately customized.
  - All six methods of competency assessment for each test system are addressed.
  - Employees are documented as competent to perform the list of tests, procedures, or duties for which they are responsible.

Who Is Responsible?
- The laboratory director who meets CAP director qualifications is responsible for implementing and maintaining an effective competency assessment program.
Outcome of an Effective System

The laboratory will benefit by:

- Organizing and scheduling staff competencies in a manner that assures annual completion. For employees’ in their first year of patient testing, competency must be assessed semiannually.
- Incorporating the six required elements into routine supervisory surveillance conducted throughout the year, efficiently avoiding duplication of effort.
- Determining employees perform and document laboratory tests and functions according to established laboratory procedures.
- Retraining and reassessing should employee performance problems be identified.
- Assessing all testing personnel.
- Maintaining ongoing compliance with CAP requirements.
What Is Quality Management?

A dynamic quality management program (QMP) enhances any and all activities that impact patient care, promoting quality and patient safety through risk reductions and continuous improvement.

Overview

A laboratory must have a written and implemented QMP plan specific to the laboratory that includes:

- All disciplines of the laboratory.
- All inherent processes, including quality control, assurance, and improvement, operating on a continuous basis to provide quality patient care.

Key Components

- A QMP system requires:
- A set of processes for preanalytic, analytic, and postanalytic phases of laboratory work.
- A system for monitoring these processes which must include:
  - A set of metrics or monitored key indicators for preanalytic, analytic, postanalytic phases of testing and patient safety. For each key indicator, the laboratory must specify:
    - Criteria of acceptance
    - Data collection, analysis, and evaluation
    - Frequency of review
  - Annual evaluation of effectiveness
  - Measurement of patient and/or physician satisfaction.
- A documented quality control system and evidence quality control has been reviewed.
- Internal and external communication of quality management outcomes.
- A process improvement system, which must include:
  - Review of errors, complaints, and incidents.
  - Identification and implementation of corrective action.
- An infrastructure for the quality management system, including aspects such as a document control system.
Quality Management Program

Who Is Responsible?

The laboratory director is responsible for the implementation of the QMP plan with assistance and involvement from the:

• Manager
• Supervisor
• Laboratory staff
• Non-laboratory staff (e.g., hospital quality assurance coordinator or safety and regulatory personnel)

Outcome of an Effective System

• Laboratory benefits include:
  • Continually ensuring that practice matches policies and procedures.
  • Providing opportunities for quality improvement.
  • Improving patient and/or clinician satisfaction.
  • Maintaining ongoing compliance with CAP requirements.
Overview

External quality assurance (EQA), also known as proficiency testing (PT), is a key indicator of laboratory quality monitored on an ongoing basis.

What Is PT/EQA?

Each CAP-Accredited laboratory must be enrolled in CAP PT/EQA under its own assigned CAP number.

- PT/EQA is an external quality assurance program that uses unknown samples and allows laboratories to compare their own testing results with other laboratories using the same or similar instruments or methods.
- The PT/EQA program regularly sends specimens for testing.
- The laboratory sends the results back to the PT/EQA program for evaluation, and then receives a performance report and summary.
- To determine which testing requires enrollment in PT/EQA, the laboratory can refer to the Quote Request Form. Additional information is available in the CAP Surveys or Excel catalogs.

When Must the Laboratory Enroll?

The laboratory must be enrolled (using CAP PT/EQA) and performing PT/EQA for all required analytes for a minimum of six months.

This time frame helps the laboratory build the discipline necessary to monitor laboratory testing quality and to better ensure that processes and procedures exist for corrective action. Prior enrollment also ensures that the laboratory is familiar with the requirements to secure permits and any other documents necessary to receive PT/EQA shipments and also provides sufficient data for review during on-site inspections.

Country Requirements

The laboratory should be familiar with its country’s requirements (including customs/importation) and documents required to import PT/EQA shipments.

- Import permits are obtained by the laboratory and forwarded to the CAP to be included with the PT/EQA shipment. The laboratory may also need to provide these documents to brokers or the local shipping office.
Country Requirements (continued)

- Laboratories should work with local authorities to determine if any permits are required.
- Use of order descriptions in the CAP PT/EQA catalogs will prevent discrepancies in permit preparation and customs clearance documents.
- Orders will not ship without required documentation.
- The laboratory is responsible for monitoring permit expiration dates and submitting new permits.
- Permits should be submitted at the time of ordering or at least six weeks prior to the stated order ship date to ensure on-time delivery.

Who Is Responsible?

The laboratory director is responsible for ensuring PT/EQA requirements are met for the laboratory's current testing menu. For assistance or questions in enrolling, contact the Customer Contact Center at contactcenter@cap.org or 001-847-832-7000.

Outcome of an Effective System

Laboratory benefits include:

- Ensuring quality of laboratory testing.
- Maintaining ongoing compliance with CAP requirements.
International PT/EQA Process Overview

**Prepare information prior to CAP PT/EQA purchase**
1. Define laboratory test menu.
2. Identify the needed CAP PT/EQA programs.
3. Select CAP programs to order through the Quote Request Form or contact the CAP for selection assistance.

**Place a CAP PT/EQA order**
1. Begin applying for any permits needed to import your PT/EQA.
2. Complete order form.
3. Email the order to the CAP including a form of payment.
4. Request a pro forma invoice/quote, if needed.

**When the CAP receives an order**
1. CAP enters order and creates an invoice.
2. CAP sends order confirmation to the laboratory.

**Once kit arrives**
1. Unpack the kit.
2. Read the kit instructions and complete testing.
3. Review result form.
4. Submit results.

Contact the CAP with questions: contactcenter@cap.org or 001-847-832-7000
Preparing an International PT/EQA Order

Identify PT/EQA Needed

Make a list of all tests performed in the laboratory, including the following information for each:

- Test name
- Instrument model or kit, and manufacturer
- Specimen type (e.g., whole blood, urine)

Complete the Quote Form

- The PT/EQA Quote Request Form is available online at cap.org/accreditation and will guide you through the required information.

Include the following:

- Name, email address, and phone number of the laboratory director
- Name, email address, and phone number of the person organizing the order (order contact)
- Mailing address for letters
- Shipping address for packages (post office box addresses will not be accepted)

- Select one of the following categories:
  - Private laboratory
  - Private hospital
  - Public/Government laboratory
  - Public/Government hospital
  - Contract Research Organization (CRO)

- State whether the order is for one or more locations
- Requirements for making payment to a US company
- Indicate if the laboratory is CLIA-certified (or planning to become so)
- Include whether the laboratory is CAP-accredited (or planning to become so)

Identify the CAP Programs

- To receive an itemized list of the needed CAP programs, send the Quote Request Form to contactcenter@cap.org.
Placing an International PT/EQA Order with the CAP

Complete a CAP Order Form

- Download the order form at cap.org/catalogs.
- Complete the form.
- Attach all needed permits for receiving international goods.

Payment

- Orders must contain payment or payment information to be accepted. Include a form of payment with your order:
  - All payments should include:
    - Customer name
    - CAP number (if available)
    - CAP account number (if available)
    - Invoice and/or order number
  - Acceptable payment forms include:
    - Check: Make payable to the College of American Pathologists in US dollars.
    - Credit Card: Include number, expiration, cardholder’s name, and authorized signature.
    - Purchase Order: A purchase order indicates a future commitment to pay using a purchase order number.
    - Letter of Authorization: Include a signed letter of authorization on your institution’s letterhead if your institution does not use a purchase order system. Also include payment method (draft, bank transfer, etc) information in your letter of authorization and enter “Letter of Auth” in the purchase order field of the payment information section on the order form.
    - Wire transfer: Include all bank fees with your payment. The CAP is not responsible for bank fees incurred while remitting payment. Once the transfer is complete notify the CAP at arcap@cap.org.
    - Remit wire transfer payment to:
      BMO Harris Bank, 311 West Monroe Street, Chicago, IL 60606 USA
      Phone: 312-461-2121
      Account Number: 223-733-7
      ABA Number: 071000288
      SWIFT #: HATRUS44
  - Quote Request: If your organization requires a quote (pro forma invoice) prior to payment, please notify contactcenter@cap.org (quoted values will be reduced if orders are received after scheduled ship dates).

Order

Email completed order form and payment to contactcenter@cap.org.
Tip #1
List CAP number if available.

Tip #2
CLIA Number is not required for international customers. However, if the laboratory has a CLIA number please provide it here.

Tip #3
Provide laboratory director and order contact information.

Tip #4
Provide laboratory shipping information for package delivery. Post Office boxes are not acceptable for sample deliveries.
Tip #1
Provide payment information in US dollars if not using wire transfer.

Tip #2
List Purchase Order Number if it must appear on shipment.

Tip #3
Provide billing contact information for the organization.
Tip #1
List names of programs being ordered. Specify by quantity needed and catalog price.

2012 Laboratory Improvement Programs Order Form

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<th>Description</th>
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Thank You!

Page Total $  
Subtotal from Prior Pages(s) $  
Estimated Sales Tax $  
Shipping & Handling $  
Order Total $  

*Actual sales tax will be calculated based upon your ship-to address and the taxability of the items purchased.
After an order is placed:

- Order and payment information is entered, and an invoice is created.
- If a valid shipping email address is provided on the PT/EQA order form, an email is sent to confirm the order. To ensure receipt of the order confirmation, please ensure that an accurate and functional email address is provided to the CAP.
- Orders placed by December 1 of the year prior to the upcoming year ship according to the CAP shipping calendar.
- A unique CAP laboratory identification number is assigned.

To ensure appropriate quantities of materials, the CAP recommends that all orders for PT/EQA program materials are placed annually on or before December 1. Orders received by December 1 will be shipped according to the CAP shipping schedule located at cap.org/accreditation (the shipping calendar published in the CAP PT catalog.)

- Orders received after December 1 will be shipped within six weeks of the order date if material is available. If material becomes unavailable due to late ordering, the CAP will adjust the invoice to reflect removal of those shipments.
- The CAP ships PT/EQA via Federal Express delivery service and packs materials to ensure material stability upon arrival. Post Office boxes are not acceptable for these shipments; a street address is required.

There is the possibility of materials being out of stock. Out-of-stock materials will be reflected on the order confirmation. If the CAP is able to obtain additional materials, the invoice and the order will ship. The CAP will issue a credit for orders that do not ship.

Materials requiring permits will not appear on the order confirmation if the permits are not submitted with the order. A notification will be sent if the CAP has not received a permit with the order. The CAP is unable to ship the order until receipt of required permits.

Assign a person to monitor the shipping schedule and to contact the CAP with any questions. Each laboratory’s customized shipping schedule can be found at cap.org under e-Lab Solutions.
Successful Shipping of International PT/EQA Orders

Requirements

International shipping requires laboratory involvement to ensure the PT/EQA kits are delivered quickly and in good condition.

Key Components

Effective involvement includes the following:

• Meeting with local shipping representatives and laboratory staff responsible for receiving packages
  - Discuss the importance of quickly delivering PT/EQA kits to the laboratory.
  - Ask for advice on importing PT/EQA materials.
• Contact the necessary government agencies for advice on importing and required permits.
  - Contact the CAP for additional information to complete permit applications.
  - The CAP ships orders from 14 different packaging sites. Contact the CAP for specific shipper information.
  - Permits must be submitted to the CAP six weeks prior to the ship date.
• Notify the CAP of any special shipping requirements six weeks prior to the first shipment.

Direct questions to contactcenter@cap.org.

Additional CAP PT/EQA Shipping Information

• The CAP must have a valid email address and phone number on file for shipping purposes.
• PT/EQA kits are typically shipped via FedEx.
• FedEx brokerage is included in the CAP international shipping fee.
• The CAP is not responsible for international duties and taxes.
  - Participating laboratories should establish a FedEx account to direct invoice duties and taxes.
• The CAP packages and ships according to US 49CFR, IATA, and ICAO.
Successful Shipping of International PT/EQA Orders

Additional CAP PT/EQA Shipping Information (continued)

- Some CAP materials ship on dry ice as “UN 1845 dangerous goods” shipments.
  - Not all locations accept dry-ice shipments.
  - Some locations require dry-ice shipments be picked up at the airport.
  - Cool packs are sometimes used as an alternative to dry ice.
- Every shipment has a commercial invoice attached.
  - Commercial invoices are for customs purposes only and do not require payment.
- A limited number of CAP materials cannot be delivered via FedEx.
  - The CAP will identify a freight forwarder or a premium freight forwarder to deliver kits.
  - Brokerage fees are not included with freight forwarding shipments.
  - A notification will be sent if there is an impact on the laboratory.
  - There are additional shipping charges for freight forwarder shipping.
- Please respond to all contacts from FedEx or other package carriers regarding PT/EQA kits.
- The laboratory “ship to” contact will receive a CAPTRAKer™ email when the kit is shipped via FedEx to assist in tracking the shipment.
- Contact the CAP if there are delivery problems.
- Contact the CAP for additional shipping information.

Direct questions to contactcenter@cap.org.
Inspect Your International PT/EQA Shipment

What to Do?

Upon receipt:
- Unpack the kit, removing all packaging materials and cool packs.
- Check for the following:
  - Kit instructions, which include specific kit contents and storage directions
  - Result form(s)
  - PT/EQA samples
- Read the kit instructions.
  - Store the kit according to the instructions until testing the samples.
- Review the result form.

Questions?

For questions regarding the kit or if the materials are damaged, please contact the CAP by email at contactcenter@cap.org. Include your laboratory specific CAP number, the program code, and specific specimen numbers in all communications.
### Sample Kit Instructions

**Tip #1**
Product Fulfillment Group (PFG) and CAP program year displayed

**Tip #2**
CAP number displayed here

**Tip #3**
Laboratory's address displayed here

**Tip #4**
Results due date displayed here

**Tip #5**
Survey reporting information displayed here

**Tip #6**
Analyte displayed here

**Tip #7**
Results recorded here
(Either report results online or fax this form to the CAP)

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### General Chemistry Survey Result Form

**Reporting Code Selection**

- If your method summary page states, “Please Provide a Valid Code,”
- If your code is listed incorrectly, or
- If you have changed your methodology,
  Review the master list for an appropriate code and enter it on the result form. If there is no master list, select the code directly on the result form.

- If you cannot find an appropriate code:
  Select Other from the kit instructions or result form and describe your method in the Use of Other section of the result form.

If you need assistance, please call the Customer Contact Center at 800-323-4040 option 1 (domestic), or 847-832-7000 option 1 (international).

View the e-LAB Solutions™ user guide via www.cap.org

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#### First Instrument Results

<table>
<thead>
<tr>
<th>ALT (SGPT) IU/L</th>
<th>Method Code not required</th>
<th>Instrument Code</th>
<th>Reagent Code</th>
<th>Exception Code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>CMA.06</td>
<td>CMB.07</td>
<td>CMB.08</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Albumin**

- Alert! Abnormal values: Fill the bubble for the reagent being used. See kit instructions for details.

<table>
<thead>
<tr>
<th>Method Code</th>
<th>Instrument Code</th>
<th>Reagent Code not required</th>
<th>Unit of Measure</th>
<th>Exception Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMA.06</td>
<td>CMB.07</td>
<td>CMB.08</td>
<td>g/dL</td>
<td></td>
</tr>
</tbody>
</table>

Customer Contact Center 800-323-4040 option 1 (domestic), or 847-832-7000 option 1 (international).
Tip #1
Survey programs included in the Product Fulfillment Group (PFG) displayed here.

Tip #2
Survey PFG and program year displayed here.

Tip #3
Specimens included in the PT kit displayed here.

Tip #4
Storage and stability information displayed here.

General Chemistry and Therapeutic Drug Survey

Table of Contents

Kit Contents

C1  CHM-06 — CHM-10
C3  CHM-06 — CHM-10
C3X  CHM-06 — CHM-10 (2 vials each)
C7  C7-02
CZ  CHM-06 — CHM-10
CZX  CHM-06 — CHM-10 (2 vials each)
CZ2  CHM-06 — CHM-10 (2 vials each), double instrument reporting
CZ2X  CHM-06 — CHM-10 (3 vials each), double instrument reporting

Important: Before You Begin

Please answer supplemental questions at the end of the result form.

Storage and Stability Instructions

1. Shipping details: Specimens are shipped frozen on a cold pack but may arrive partially frozen or completely thawed. Store at 2 - 8°C upon receipt.
2. Unopened/Open: Analytes are stable at 2 - 8°C for 7 days.

Exceptions:

- Lactate, ammonia: Analyze within 24 hours of receipt.
- Alkaline Phosphatase, Acid Phosphatase, bilirubin, and Ionized Calcium*: Analyze within 3 days of receipt.
- Pseudocholinesterase: Stable for 2 days after reconstitution.

*Do not correct ionized calcium for pH or preheat specimens with CO₂.

3. Special Handling: Keep vials tightly sealed and protected from light.
4. Instrument systems and methods that are sensitive to ammonium ions (i.e., i-STAT, NOVA Nucleus, etc.): The ammonia concentrations of the Survey specimens may increase with time, even when refrigerated at 2 - 8°C. Therefore, all analyses should be completed within 24 hours of receipt.

Critical Reporting Information

1. For all regulated analytes:
   - If your laboratory is discontinuing or beginning any testing, you must check your Analyte Reporting Selection (ARS) document to ensure no changes are needed. If changes are needed, indicate the modifications and note that they are effective immediately on the document and submit to the CAP.

Important: See the Biohazard Warning at the end of these instructions.
The CAP will send renewal information every September to renew your PT/EQA order for the next program year. Review the catalog for:

- New programs
- Discontinued programs
- Program changes

Make any necessary changes and submit your order, including payment information, by December 1 of the current year. Orders received after December 1 will be shipped within six weeks of the order date if material is available. If material becomes unavailable due to late ordering, the invoice will be adjusted to reflect removal of those shipments.

Review individual permit needs for the upcoming program year, and start governmental reapplication process as soon as possible.
**Questions and Answers**

### Tracking Shipments

**Q:** What if the kit has not arrived on schedule?

**A:** Call the CAP at 001-847-832-7000, or email at contactcenter@cap.org.

**Q:** What if the kit is delayed in customs?

**A:** Call CAP at 001-847-832-7000, or email at contactcenter@cap.org.

### Kit Contents

**Q:** What should I do if I think a specimen is missing?

**A:** Check the content list on the kit instructions against the samples received. Be sure to check under and inside all packaging materials in the kit. Some specimens are placed under cool packs or can be found inside other packing material.

If you still believe your kit is incomplete, contact the CAP at 001-847-832-7000 for a replacement. Be sure to include contact information, your CAP number, PT/EQA program code, and specimen number.

**Q:** What if the paperwork for the kit is missing?

**A:** Email contactcenter@cap.org or you can access the information in e-Lab solutions.

**Q:** What if the kit is damaged?

**A:** Email contactcenter@cap.org. Store the undamaged material according to the kit instructions while waiting for a reply.

**Q:** If the samples have been held in customs, are they suitable for testing?

**A:** Email contactcenter@cap.org. Provide any known details about the condition of how the kit was held (stored) by Customs.

**Q:** If samples have been at room temperature for awhile, are they still suitable for testing?

**A:** Some kits ship at ambient temperatures without cool packs. Follow storage instructions upon receipt. If the storage instructions indicate storage at cold temperatures please email contactcenter@cap.org.

**Q:** Are safety data sheets (SDS) available?

**A:** You can find SDS for materials purchased from the CAP on cap.org (requires e-LAB log in).
Questions and Answers

Problems in the Laboratory

Q: What if our instrument is not working?
A: Enter code 11 on result form and submit. Document the reason why testing was not performed and maintain the record.

Q: What if the kits or reagents will not arrive in time to perform the test?
A: Email the CAP at contactcenter@cap.org for an extension.

Q: What if our laboratory cannot enter the results by the due date?
A: Email the CAP at contactcenter@cap.org for an extension.

Q: What if our laboratory has questions about the evaluation report?
A: Email your questions to CAP at contactcenter@cap.org for assistance.

Q: What if a specimen is damaged while testing?
A: Follow your standard laboratory procedures and contact the CAP at contactcenter@cap.org.

Q: What if there is an accident with the material and it involves a person?
A: Contact the Laboratory Accident Hotline at 001-847-470-2812. Provide specific details including the program, specimen number and your contact information.

e-LAB Solutions

Q: How do I get into e-LAB Solutions?
A: You can access e-LAB Solutions only by creating an account. Use the “Getting Started with e-LAB Solutions” guide on cap.org. You will need the PIN sent to your laboratory. The CAP sends a communication to the laboratory director with the PIN and instructions upon confirmed payment of the laboratory’s Proficiency Testing order.

Documents Submitted to the CAP

Q: Can we submit documentation in our native language?
A: Not at this time. All submitted documentation must be in English.
Accreditation PT

Q: How much PT is required?
A: Each laboratory must cover its current testing menu to ensure PT requirements are met for their entire testing menu. The amount of PT required is dependent on the testing performed by the laboratory.

To receive an itemized list of the needed CAP programs, complete and submit a Quote Request Form.

Cost of CAP Accreditation

Q: What does it cost to become CAP accredited?
A: Please submit the Request for Application Form, including the non-refundable fee as listed on the form.

Accreditation fees are paid annually. The cost is determined by the complexity and size of the laboratory. To receive an estimate of annual accreditation fees, complete and fax the International Fee Estimate Worksheet to the number on the form.

International laboratories are required to pay for roundtrip, business class airfare for intercontinental travel by inspector(s). The number of inspectors sent will be based on the volume and/or testing type in the laboratory. The CAP will pay for all hotel accommodations, meals, ground transportation and in-country air travel.

Please note that accreditation fees do not include the cost of proficiency testing (external quality assurance).

Am I Ready to Become Accredited?

Q: How can I tell if the laboratory is ready to become accredited?
A: Using this guide and ensuring all requirements are met is the first step. Once the laboratory has started the application process, you can also evaluate your laboratory using the CAP Accreditation Checklists.

For additional information on the accreditation process, please visit cap.org/accreditation.