



PROFICIENCY TESTING MASTER LIST CHANGE FORM PRODUCT ADDITION

This form is exclusively for use by manufacturers of laboratory instrument, reagents, and kits.

Date of request: _____

Contact information

Mr. Ms. Dr.

First name (given name or forename)

Middle initial

Last name (surname or family name)

Credentials, eg, MT(ASCP), MBA, PhD, etc

Job title

Telephone number

Email

Company name

Street address

City

State or Province

Postal (ZIP) code

Country (if outside US)

Details of request

For product deletions, name changes, or reformulations, see the separate dedicated forms.

Product name (as marketed)

Analytes tested

Instrument Closed system Open system Reagent Kit

Estimated number of users: US: _____ Non-US: _____

New product details

This is a new test or instrument that has never been on the market previously. Launch date: _____

This is a test/instrument that has been on the market, but is not on the CAP PT master list.

This is a market expansion: From US to outside US From outside US to US

For reagent reformulation/recalibration/restandardization complete separate form.

US regulatory information

FDA approval: Received Pending Not applicable; product used outside the US only

CLIA complexity: Waived Moderate High

Specimen type (Check all that apply.)

- Serum Plasma Urine Whole blood Cerebrospinal fluid
 Body fluid Other, specify: _____

Compatibility

Compatibility verification

CAP PT Surveys tested: _____

- We have completed in-house testing using CAP PT specimen material, with acceptable results.
 Our customers are running CAP PT on the instrument/reagent/kit, with no reported problems.

Product equivalence

- Our instrument/reagent/kit has an analytical platform or formulation identical to that of another product already on the CAP PT master lists.

Specify equivalent product: _____

Special handling or testing instructions

Additional comments or information (Provide supplemental documents as needed.)

Attach package insert or instrument specification sheet with test menu and methodologies.

Failure to provide information or required documents may cause your request to be delayed or denied.

The documentation you provide will be used by CAP staff **only**; we will not share it with customers. If you have more than one request, please complete additional forms, or provide a list or spreadsheet that incorporates the information in this form.

Email form(s) and supplemental documentation to masterlists@cap.org.

For Questions Contact:

**masterlists@cap.org
1-800-323-4040, option 1 (domestic)
001-847-832-7000, option 1 (international)**