



COLLEGE of AMERICAN  
PATHOLOGISTS  
Laboratory Quality Solutions

# PROFICIENCY TESTING MANUAL

# Table of Contents

## Proficiency Testing (PT) Manual

---

<b>1 General Customer Information</b> .....	3–10	<b>4 How to Interpret Your Evaluation</b> .....	17–20
• Order Confirmation .....	3	• General Guidelines for Evaluation .....	17
• Regulatory Reporting .....	3	• Selection of a Target Value .....	17
• Binders/Glossaries .....	4	• Calculation of Summary Statistics .....	18
• Kit Delivery and Storage .....	4	• Comparative Statistics.....	20
• CAP Identification Number .....	4	<b>5 Continuing Education (CE)</b> .....	21–22
• Replacement Specimens .....	4	• Continuing Medical Education (CME) Category 1.....	21
• Testing Instructions and Completion Time .....	5	• CE for Nonphysician Laboratory Personnel .....	21
• Second Instrument Reporting.....	5	• CE for Cytotechnologists.....	22
• Corrections to Results and CMS Reporting Instructions .....	6	<b>6 Discipline-Specific Reporting Information</b> .....	23–25
• Fax-Back Response Programs.....	7	• How to Complete the Result Form.....	23
• Evaluations.....	7	<b>7 Evaluations and Participant Summaries (PS)</b> .....	26–29
• Corrections to Results .....	7	• Overview.....	26
• Customer Support .....	7	• Reviewing Your Evaluation .....	26
• Program Certificates .....	8	• PS .....	28
• Limitations of PT .....	9	• How to Perform a Self-Evaluation .....	29
• Laboratory Accidents .....	9	<b>8 Laboratory Legislation and Centers for Medicare &amp; Medicaid Services (CMS) Reporting</b> .....	30–37
• Limitations of PT Letter .....	10	• Provision of Results to CMS and State Agencies .....	33
<b>2 Result Form Data Entry</b> .....	11–13	• Use of Reason Codes for Nonevaluated Specimens ..	35
• Overview.....	11	• CMS Performance Summary .....	36
• Preprinted Method Summary Page .....	11	• CMS Performance Summary Data .....	36
• Exception Codes.....	12		
• Master Lists .....	12		
• Reporting Boxes and Decimal Precision .....	13		
• “Less Than” or “Greater Than” Values .....	13		
<b>3 e-LAB Solutions Suite (ELSS)</b> .....	14–16		
• Getting Started .....	14		
• Online Data Submission .....	15		
• Online Reports .....	16		
• Performance Analytics Dashboard .....	16		

# Interlaboratory Comparison Program Cycle

---

## 1 Catalog Delivered

September: The catalog is sent to your laboratory.

## 2 Orders Completed

September–December: Your laboratory places its order.

## 3 Orders Processed

September–December: Order quantities are reserved.

## 4 Order Confirmations Sent

September–December: Confirmation reports are sent to your laboratory after your order is processed.

## 5 Kits Mailed

Kits are prepared and sent from the manufacturer to your laboratory.

## 6 Results Submitted

Completed result forms are returned to the CAP where data are summarized.

## 7 Evaluation Criteria Reviewed

The scientific resource committee reviews results and the impact of evaluation criteria.

## 8 Reports Available

Reports are sent to and made available online for your laboratory, regulatory agency, and/or consultants.

## 9 Certificate of Participation Provided

At the beginning of the program year, your laboratory receives a certificate of participation.

# 1

## General Customer Information

### Order Confirmation

---

After your laboratory's order is received, an order confirmation is sent that contains the following information:

- Shipping address
- Billing address
- Telephone and fax number
- List of programs ordered
- List of agencies and/or consultants to whom you have requested copies of your evaluation be sent

Review the confirmation document carefully. If you have changes, return the document within two weeks of receipt to:

Mail: Customer Data Management  
College of American Pathologists  
325 Waukegan Road  
Northfield, Illinois 60093-2750

Fax: 847-832-8168 (country code: 001)

### Regulatory Reporting

---

The CAP will automatically forward results for analytes regulated for PT to the CMS for laboratories that have provided a Clinical Laboratory Improvement Amendments (CLIA) identification number.

To make changes to your laboratory's analyte reporting selections (ARS), contact the CAP at 800-323-4040 option 1 or access your report online at [cap.org](http://cap.org).

Documentation will be requested and may be faxed to 847-832-8168. An explanation of regulatory reporting and current laboratory legislation is included in section 8.

### Binders/Glossaries

---

To provide you with an easy way by which to store your Surveys program materials, for every nine eligible programs, one three-ring binder with tabs and custom labels will be sent to you at no charge. There is no need to order the binders as they will be shipped automatically upon placement of your order. Additional binders are available for purchase through the online store.

If you are enrolled in hematology and/or clinical microscopy Surveys containing photographs for morphologic identification, you will be able to access an online glossary of terms for your general use. If you need a hardbound copy, call the CAP.

## Kit Delivery and Storage

---

Refer to the shipping schedule and advise your receiving department accordingly. A shipping schedule is provided to your laboratory with the order forms, or you can obtain a customized shipping calendar by logging in to e-LAB Solutions Suite (ELSS) at cap.org and clicking on **My PT Shipping Calendar**.

The receiving department of your hospital or laboratory should be advised how to handle the CAP kits. Insist on prompt transfer to the laboratory. Kits received by the hospital but not delivered to the laboratory are not eligible for free replacement. Unless otherwise specified, store the specimens in the refrigerator.

## CAP Identification Number

---

Each Survey participant receives a CAP identification number that is printed on all result forms. This number will also appear on each evaluation received by your laboratory. It is helpful to have this number available when contacting the CAP.

## Replacement Specimens

---

Kits may contain specimens for analysis. Check the contents against the kit instructions upon receipt. If the kit is incomplete or contains broken or unlabeled specimens, contact the CAP as soon as possible for a free replacement.

In the event that a replacement specimen is required, retain your original result form while awaiting the arrival of the replacement specimens. The replacement specimens will be sent in the same manner as your original specimens. When you receive the replacement specimens, it is imperative that you complete testing as soon as possible to comply with the original due date. Due to regulatory restrictions, a due date extension may not always be possible. Occasionally, it may not be possible for the manufacturer to replace your specimen(s) or kit. In this case, fill the exception code 33 bubble on the result form. A note will appear on your evaluation report and you will not be penalized.

Because PT materials must be procured in advance of shipment, on occasion, additional inventory is available for a nominal fee. Additional material may be purchased after the close of the formal PT event.

To purchase these materials contact the CAP at 800-323-4040 option 1. All literature associated with this product including the summary data will be provided. **This option does not replace routine PT.**

These materials may be used for but not limited to:

- Competency assessment
- Instrument troubleshooting
- Training
- Education
- Research

## PT Referral Information

---

Per CLIA, as published by the United States *Federal Register*, PT specimens must be tested with the laboratory's regular workload, using routine methods and testing the PT specimens the same number of times it routinely tests patient specimens.

When handling PT specimens, laboratories must not communicate results nor share or refer specimens for tests not on the laboratory's menu. If referral for testing is routinely performed for patient specimens, the practice cannot be followed for PT specimens. Referral is considered to be movement of the specimen from a laboratory with a CLIA identification number to another laboratory that has a different CLIA identification number. Laboratories must ensure that personnel do not share results or refer PT specimens for any reflex or testing outside their CLIA identification number.

## Results Due Date

---

The Surveys program is used for certification of certain laboratories. Since promptness is considered in determining certification, we cannot accept late entries. **Results must be received at the CAP no later than midnight, Central Time by the due date on the result form.** Result forms received beyond the date noted will not be evaluated. Participants will receive an evaluation indicating that the results were received past the evaluation cut-off date along with a PS that can be used for self-evaluation.

## Second Instrument Reporting

---

In 2014, the CMS directed all PT providers that laboratories subject to CLIA regulations are not permitted to test PT specimens on multiple instruments unless that is how the laboratory routinely tests patient specimens.

Recently, the CMS communicated to approved PT providers that **this directive applies to all analytes**, including those not listed in Subpart I of the CLIA regulations, as well as analytes/methods categorized as waived tests (such as whole blood glucose meters).

Because the sanctions are severe if the regulations are not followed, the CAP PT program no longer includes the option for second instrument. To meet your laboratory's needs, the CAP now offers its Quality Cross Check program. See the current Surveys and Anatomic Pathology Education Programs catalog or the Regulatory Information page via [cap.org](http://cap.org) for further details.

## Corrections to Results

---

- Corrections to results can be made any time **prior** to the due date listed on the result form; review your laboratory data carefully prior to submission. For results approved online, corrections must also be made online. Faxed or mailed corrections will not be accepted.
- To view the status of your results, go to [cap.org](http://cap.org) and click on Submit/Enter PT Results.

- For any testing that you do not routinely perform in your laboratory, leave all reporting areas for that test blank, including method information. Exceptions are noted in the Critical Reporting Information section of the kit instructions or on the result form.  
*Note:* A penalty will not be applied for blank responses in the case of educational challenges, challenges not formally graded, or the proper use of exception codes.

## CMS Reporting Instructions

---

For any regulated analytes that your laboratory does not report or may have discontinued, you must update your reporting settings via the online CMS Analyte Reporting Selections tool via ELSS. Additional regulatory information can be found via [cap.org](http://cap.org) on the Proficiency Testing page under Laboratory Improvement. If you have any questions, call the customer contact center at 800-323-4040 option 1.

## Fax-Back Response Programs

---

The CAP offers immediate (fax-back) responses for the submission of the laboratory forms for the following educational anatomic pathology programs:

- Interlaboratory Programs in Gynecologic and Nongynecologic Cytopathology (PAP/NGC)
- Fine-Needle Aspiration Glass Slide Program (FNAG)

Individual result forms can be submitted online (preferred method) or faxed to the CAP. CME/CE certificates may be self-claimed via [cap.org](http://cap.org) by clicking on the Learning tab.

## Evaluations

---

Evaluations are posted online and mailed approximately 2–5 weeks after the ship date of the kit. This time is needed for processing data, establishing evaluation criteria, and preparing the participant summary (PS).

## Customer Support

---

Regular Hours: Monday-Friday, 7:00 AM – 5:30 PM CT

Extended Hours: Monday-Friday 9:00 PM – 5:00 AM CT (email only)

<p><b>Contact us to:</b></p> <ul style="list-style-type: none"> <li>• Update contact information (telephone number, email address, fax number, or address)</li> <li>• Receive additional supporting information or documents for ordering or importing purposes</li> <li>• Ask a CAP expert questions about a specific CAP program</li> </ul>	<p><b>Phone:</b> 001-847-832-7000 option 1</p> <p><b>Email:</b> Go to <a href="http://cap.org">cap.org</a> and select <b>CONTACT &amp; SUPPORT</b> at the bottom of the home page.</p> <p><b>OR</b></p> <p>Send an email to <a href="mailto:contactcenter@cap.org">contactcenter@cap.org</a></p>
---	--

<p><b>Laboratory Accident Hotline:</b></p> <p>Accidental exposures while processing specimens from the CAP, including cuts and contamination of mucous membranes or non-intact skin, should be reported to the CAP hotline for evaluation and questions regarding prophylaxis. Please provide the identification number of the relevant specimen.</p>	<p><b>Phone:</b></p> <p>001-847-832-7000 option 1 During Contact Center hours</p> <p>001-847-470-2812 All other hours</p>
<p>In countries where the CAP has a designated distributor, directly contact your CAP distributor if you have questions related to pricing or any other inquiry not listed above.</p>	

Your laboratory will be notified of kit shipment via CAPTRAKer<sup>SM</sup> and email. If you do not receive your kit within 7–10 calendar days following the ship date, or if you receive an incomplete or damaged shipment, call the customer contact center. Requests for replacements after the 10th calendar day cannot be accepted.

For document acknowledgment, include the appropriate email address on the first page of your order form in the section titled “PT Shipping Contact.”

To choose not to participate in this program, participants can contact the CAP at 800-323-4040 option 1.

## Program Certificates

After the completion of the program year, participating laboratories will receive a certificate recognizing each institution’s participation in the CAP PT program and its commitment to patient care. Certificates are signed by the CAP president and are suitable for framing.

## Deficiency Response

The CAP does not require that you submit documentation for all PT deficiencies. However, it is recommended that such documentation be retained in your laboratory. The CAP Laboratory Accreditation Program issues a separate report, the “Proficiency Testing Exception Summary,” that addresses deficiencies for CAP-accredited laboratories. Instructions for response will be included with the report.

## Handle With Caution

PT specimens must be handled with caution. Each shipment includes a biohazard warning statement explaining proper handling.

## Laboratory Accidents

Incidents of personnel exposure to infectious specimens, through needle sticks, contamination of the mucous membranes through splashes or aerosolization, or cuts from containers, should be reported immediately to the CAP.



24-hour hotline: 800-443-3244

Have the following information available:

- CAP number
- Phone number
- Name of institution/city/state
- Name of person affected, if other than caller
- Date and time of incident
- Where and how affected
- Survey and specimen number
- Name and telephone number of laboratory director

This information will be relayed to a pathologist member of the appropriate resource committee who will contact the participant's laboratory director or hospital employee health services physician with instructions concerning prophylaxis.

## Limitations of PT

---

Due to the manufactured nature of the specimens and the logistics of shipping, PT does not always correlate with the manner in which fresh, clinical specimens are handled. A letter addressing these differences is included for general use by your laboratory.

## Limitations of PT Letter

---



COLLEGE of AMERICAN  
PATHOLOGISTS

The College of American Pathologists (CAP) Surveys program is the largest external quality assessment program in the world. As such, it provides an unparalleled selection of challenges and offers the largest database in existence for interlaboratory comparison. The CAP has accumulated significant experience in managing this type of program and is knowledgeable in its uses and limitations.

Performance on CAP Surveys is not to be taken as the sole indicator of a laboratory's abilities. A proficiency testing Survey is but one of a number of programs that laboratories should employ to assess, manage, and improve quality. In addition to Surveys, proper method validation, quality control testing, periodic calibration and instrument maintenance, employee competency testing, and laboratory inspection and accreditation provide important tools for measuring laboratory performance and ensuring quality.

The Surveys program, although outstanding, is not a perfect measuring device. A number of factors limit this tool's ability to measure laboratory accuracy. Specific limitations include requisite use of matrix materials that may impact test systems differently than patient specimens; the appropriateness of grouping responses according to methodology, instrumentation, and test platforms; varying size of comparison groups with attendant variability of statistical parameters; regulated limitations in sampling of laboratories' testing systems; difficulties in quantitation at the extremes of analyte concentration; and unsuitability of certain federally-mandated evaluation limits.

Thus, a certain number of responses that are graded as unacceptable in Surveys will in fact be acceptable, and a certain number of responses graded as acceptable will in fact be unacceptable. Although unsuccessful or unsatisfactory Surveys performance may reflect problems within a laboratory, it does not constitute proof of inadequate performance or an inability to meet patient needs.

Sincerely,

Raouf E. Nakhleh, MD, FCAP

Chair, Council on Scientific Affairs

# 2

## Result Form Data Entry

### Overview

---

The result form is a document on which you record your methods of analysis and PT data. The completed result form must be returned online (preferred) via ELSS or by fax to the CAP by the due date listed on the form.

Retain a copy of the completed result form for your records before submitting it to the CAP.

Per the Centers for Medicare & Medicaid Services (CMS), changes to submitted data cannot be made after the due date on the result form. Review all information on the preprinted method summary page and all entries made on the result form for accuracy prior to submission. Once you have enrolled/registered, log in to ELSS via cap.org, and click on Submit/Enter PT Results to view the status of your submitted data.

### Preprinted Method Summary Page

---

Once your laboratory initially provides a master list code for a method, instrument, and/or reagent, the CAP will retain this information, no longer requiring you to report them repetitively throughout the year. Carefully check each master list selection to ensure the correct codes are listed. To change a code, enter it in the appropriate boxes on the result form.

### Exception Codes

---

If your laboratory needs to report an analytical problem for an entire test or individual specimens within a test, leave the result area blank and fill the appropriate two-digit exception code bubble on the result form.

Exception Code	Reason
11	Unable to analyze (documentation to be provided by laboratory).
22	Result is outside method/instrument reportable range.
33	Specimen determined to be unsatisfactory after contacting the CAP.

It is the laboratory's responsibility to document the appropriate use of exception codes if requested during a laboratory inspection. Refer to the kit instructions for more information.

## Master Lists

---

Choose the appropriate method or instrument provided on the kit instructions or result form.

Notify the CAP and the manufacturer if your method or instrument is not listed. If the manufacturer of your method or instrument is not listed on the kit instructions or result form, enter it in the “Use of Other” section at the end of the result form.

Identification master lists are provided for microbiology, blood cell identification, urine sediment, clinical microscopy, and provider-performed microscopy. Select a code from the appropriate master list and enter it on the result form.

For blood cell identification, urine sediment, clinical microscopy, and provider-performed microscopy, all possible identifications are included on the master lists. **Do not** use the code 010, “Other, Specify.” The use of this code will be evaluated as an unacceptable response.

## HTML Section

---

The CAP has implemented a more customer-friendly online interface for entering results via ELSS. The enhancement provides online result forms in an HTML format, replacing the PDF technology, but retains the design. The form helps:

1. Reduce common clerical errors
2. Increase data accuracy
3. Approve online data efficiently
4. Search and navigate with ease

### What is different about the form?

It provides validation for required information. For example, if a value/result is populated for any specimen for a single test, then a value/result must be populated for manufacturer, method, instrument, or reagent. It also prevents incomplete data from being submitted to the CAP. For example, if you:

- Do not enter a unit of measure in the online result form, a pop-up message will appear and ask you to provide the required information.
- Enter a value/result in an incorrect format (eg, ###.# instead of ###.) on the online result form, a pop-up message will appear and ask you to revise the information.

In addition, the form:

- Allows navigation by test (for laboratories that do not report every test in a PT event)
- Provides an approval button on the top of each result form page
- Aims to lessen browser compatibility issues.

## **‘Less Than’ or ‘Greater Than’ Values**

---

Do not attempt to add “less than” or “greater than” to the value you submit unless this option is provided on the result form. Where the option to report “greater than” or “less than” is given, you must select the bubble underneath the appropriate reporting box to indicate your response is a “less than” or “greater than” value. All other results will be considered “equal to” values.

Where no option to report “greater than” or “less than” is given, refer to the Exception Codes section or the General Reporting Information section of the kit instructions.

# 3

## e-LAB Solutions Suite (ELSS)

### Getting Started

---

ELSS is the CAP's online portal to manage your laboratory improvement programs. In order to take full advantage of the functionalities available online, users can selectively enable laboratories and personnel by:

#### Creating an Online Account

In order to access ELSS, you must create a personal Web account by going to [cap.org](http://cap.org) and clicking on Login. Under New Users, click on CREATE AN ACCOUNT; this only needs to be done once per user.

#### Logging In

Once you have established an online account, you will be prompted to enter your user ID and password. This must be done every time you visit [cap.org](http://cap.org). Both members and nonmembers utilize the same login functionality.

#### Enroll/Register

When your laboratory first places an order, the laboratory director will receive an enroll/register email with a CAP Number and PIN #. The laboratory director must designate who will be the laboratory's site administrator. Your laboratory only has to enroll/register once. The enrollment/registration process establishes the laboratory's online access to CAP programs through ELSS and defines the site administrator's responsibilities.

#### Requesting Access

Individualized accounts for laboratory users allow flexibility in determining access levels. Because users are independent entities from the laboratory, users can be affiliated with multiple laboratories and their security can be administered in a different manner at each site.

To request access to a laboratory, go to [cap.org](http://cap.org), click on Access e-LAB Solutions Suite, and log in. Click on Request Permission from Your Site Admin, and enter your laboratory's CAP#.

Individual privileges can be accessed by clicking on View/Update My Lab Permissions.

## Online Data Submission

---

Online result forms make data entry faster and more accurate. Your laboratory will minimize PT failures on data entry through the use of an enhanced HTML-based result form. You can also verify receipt of data and view faxed or mailed data.

Automated PT data reporting is available through e-LAB Solutions Connect. The CAP has partnered with Data Innovations Instrument Manager™ middleware solution to help facilitate the connection and transmission. With e-LAB Solutions Connect, the CAP's quantitative PT results are automatically transmitted from your laboratory's instruments or laboratory information system to ELSS.

If necessary, faxed results must be sent to 866-FAX-2CAP (866-329-2227).

## Online Reports

---

When the result form due date has past, data are processed and graded according to stringent governmental and committee criteria. Laboratory results and grading interpretations are displayed in an individualized report accessible by clicking on Evaluation Reports under Proficiency Testing/Quality Management. Using the filter options, select the program and report.

The online evaluation allows the user to easily navigate the data analyte by analyte. Also, users benefit by the inclusion of detailed images hyperlinked on the report. Laboratory managers can access the All Analyte Scorecard, allowing them to customize the scorecard data for their laboratory as a means of identifying deficiencies or trends in performance.

Other ancillary reports that accompany the evaluation are available online, as well, for review and to download for future reference, including the PS, final critiques, and annual summaries, which contain useful data and education that can be reviewed and accessed by all users with appropriate security.

## Performance Analytics Dashboard

---

Our Performance Analytics Dashboard gives the comprehensive data view you need to proactively focus energy on areas that need immediate attention while filtering out distractions. Updated daily, this Web-based reporting solution for your CAP PT and accreditation performance reduces the stress of managing today's single laboratory or an expansive network's performance with only a few clicks.

# 4

## How to Interpret Your Evaluation

This chapter includes general information regarding evaluations. A section explaining how to interpret your individual evaluation will be included with each mailing.

### General Guidelines for Evaluation

---

On February 28, 1992, the Secretary of Health and Human Services (HHS) published the final rules implementing the CLIA of 1988. These regulations established evaluation criteria limits for many of the analytes included in the CAP Surveys programs. The target values are determined by the scientific resource committees of the CAP. For those analytes not included in the PT portion of CLIA, the target values and evaluation criteria are determined solely by the scientific resource committees.

### Selection of a Target Value

---

To minimize the effect of method differences and to allow comparison of all methods, participants' results are combined into comparable method/instrument groups called peer groups. It is important for participants to provide complete information regarding the method or instrument used in order to be combined in the appropriate peer group.

For most analytes, the peer group mean is designated as the target value for evaluation. The peer group mean is the preferred target if no single target value exists that can provide an accuracy-based target that is traceable to the "true value" as determined by a definitive or reference method analysis. The peer group must consist of greater than nine results after outlier exclusion, and the variability of the peer group data must not be too great.

If peer group data are not available or are too variable, method group statistics may be used. The method group must also consist of greater than nine results and demonstrate acceptable variability before it is used as the target group.

If peer and method group statistics are not available, a comparative method group may be designated as the target mean. The comparative method is not the method recommended by the CAP; however, it is established as a historically reliable method and is used for evaluating results from methods that have an insufficient number of participants to generate a separate peer group and/or method group statistics. If no comparative method exists for the analyte, results will not be evaluated.

For some analytes, a single target value is used in which consistent results are



demonstrated across all peer groups.

## Calculation of Summary Statistics

---

### Peer Group Results

Results are grouped according to the method used for analysis and screened for outliers. Various statistics are calculated from the remaining data that summarize the peer group's responses. These summary statistics may include the following:

- the mean (the average of the reported results)
- the standard deviation (a measure of the variability of the participant results, often abbreviated as SD)
- the coefficient of variation (CV)
- the median (the middle value in an ordered list of the non-outlier results)
- the low value (the lowest value reported)
- the high value (the highest value reported)
- the final count of reported results that were not excluded as outliers.

### Outlier Detection Technique

Outlier exclusion is necessary because a large series of results frequently will include some aberrant values. These may arise from instrument malfunction, technical errors, specimen mix-ups, misplaced decimals, incorrect units of measure, or data entry errors. If any results are excluded, the outlier process is repeated using the remaining values. The summary statistics that appear on your reports do not reflect results that were considered to be outliers during either outlier pass.

### Quantitative Procedures/Rounding

All quantitative responses are evaluated based on a range of acceptability. This range is determined using a target value and a limit. The limit will be either a fixed interval (eg,  $\pm 5$  mg/dL), a percentage of the mean (eg,  $\pm 25\%$ ), an SD (eg,  $\pm 3$  SD), or a variable range (eg,  $\pm 6$  mg/dL or 10%, whichever is greater). The PS included with your evaluations the criteria used to evaluate your performance. The following sections provides specific examples of how to calculate the range of acceptability depending upon the criteria used.

Benefit-of-the-doubt rounding is used to determine the range of acceptable results. The upper limit of acceptability is obtained by rounding up to the next reportable result, while the lower limit is determined by truncating.

### Fixed Range Example

Your laboratory reports a sodium result of 138 mmol/L. The peer group mean is 139.5 mmol/L.

The evaluation limit for sodium is  $\pm 4$  mmol/L. The acceptable range is determined by the formula  $139.5 \text{ mmol/L} \pm 4 \text{ mmol/L}$ , which is 135 to 144 mmol/L; therefore, your reported result of 138 mmol/L is within the calculated acceptable range of 135 to 144 mmol/L when using benefit-of-the-doubt rounding.

### Percentage of the Mean Example

Your laboratory reports an albumin result of 3.1 mg/dL. The peer group mean is 3.39 mg/dL. The evaluation limit for albumin is  $\pm 10\%$ . Ten percent of 3.39 mg/dL is 0.34 mg/dL. The acceptable range is determined by the formula  $3.39 \text{ mg/dL} \pm 0.34 \text{ mg/dL}$ , which is 3.0 to 3.8 mg/dL when using benefit-of-the-doubt rounding; therefore, your reported result of 3.1 mg/dL is within the calculated acceptable range of 3.0 to 3.8 mg/dL.

### Standard Deviation Example

Your laboratory reports a thyroid stimulating hormone (TSH) result of 16.4  $\mu\text{U/mL}$ . The peer group statistics are as follows: mean = 15.7  $\mu\text{U/mL}$ , SD = 1.5, and CV = 9.6. The evaluation limit for TSH is  $\pm 3 \text{ SD}$ .  $3 \times 1.5 = 4.5$ . The acceptable range is determined using the formula  $15.7 \mu\text{U/mL} \pm 4.5 \mu\text{U/mL}$ , which is 11.2 to 20.2  $\mu\text{U/mL}$  when using benefit-of-the-doubt rounding; therefore, your result of 16.4  $\mu\text{U/mL}$  is within the acceptable range of 11.2 to 20.2  $\mu\text{U/mL}$ .

### Variable Range Example

Your laboratory reports a total bilirubin result of 4.5 mg/dL. The peer group mean is 4.68 mg/dL. The evaluation limit for total bilirubin is  $\pm 0.4 \text{ mg/dL}$  or 20%, whichever is greater. Twenty percent of 4.68 is 0.936. Since the percentage limit of 0.94 is greater than the interval limit of 0.4, the percentage limit is applied to the target value. The acceptable range is determined using the formula:  $4.68 \pm 0.936$ , which is 3.7 to 5.7 mg/dL when using benefit-of-the-doubt rounding; therefore, your result of 4.5 mg/dL is within the acceptable range of 3.7 to 5.7 mg/dL.

The PS included with your evaluation will list the criteria used to evaluate your performance. To determine the acceptable range, a benefit-of-the-doubt rounding procedure is utilized when grading.

### Calculation of the Standard Deviation Index (SDI)

The evaluation lists your results, the statistics for your peer group, and your normalized results as an SDI. This value is obtained by subtracting the group mean from your result and then dividing by the SD.

The SDI is expressed in terms of the number of SDs from the mean, with an arithmetic sign indicating the direction of the difference. The calculation of the SDI normalizes your result and, therefore, allows for a comparison of results from specimens of different concentrations of an analyte.

When a comparative method has been designated for Surveys analysis, a second set of statistics is listed comparing your results with those obtained using the comparative method. The figures shown are the mean and SD for the comparative method and your result as an SDI using these statistics. It is possible for your result to be defined as “good” performance in your method group and yet produce a comparative SDI greater than two. This will occur if your method has a large analytic bias or a large SD. It is possible to receive a comparative SDI lower than the method group SDI, although this rarely occurs. In practice, most participants receive similar method group and comparative SDIs.

## Comparative Statistics

---

### Quantitative Procedures

Your evaluation contains plots of the relative distance of your reported results as a percentage of allowable deviation from the target value. The numeric digit indicates the number of results at a plot location. The allowed deviation may be calculated as follows:

If your result is greater than the target mean:

$$\text{Percentage of Acceptable Deviation} = 100 \times \frac{\text{your result-target}}{\text{upper limit-target mean}}$$

If your result is less than the target mean:

$$\text{Percentage of Acceptable Deviation} = 100 \times \frac{\text{your result-target}}{\text{target mean-lower limit}}$$

### Qualitative Procedures

For qualitative responses, consensus agreement of referee or participating laboratories is used for evaluation. Generally, 80% agreement is required.

# 5

## Continuing Education (CE)

### Continuing Medical Education (CME) Category 1

The CAP is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The CAP designates these educational activities for a maximum of the stated number of AMA PRA Category 1 Credits™. Physicians should only claim credits commensurate with the extent of their participation in the activity.

The American Medical Association has determined that physicians not licensed in the US who participate in these CME activities are eligible for AMA PRA Category 1 Credit™.

See the current Surveys and Anatomic Pathology Education Programs catalog for available CME programs.

### CE for Nonphysician Laboratory Personnel

This activity is acceptable to meet the CE requirements for the American Society for Clinical Pathology (ASCP) Board of Registry Certification Maintenance Program. This activity is approved for continuing education credit in the states of California and Florida.

All nonphysician laboratory professionals in your laboratory can earn individual CE credits by completing the related education reading and online learning assessment questions via cap.org.

Surveys CE Programs	
Discipline	Maximum CE Credits
Chemistry Coagulation Hematology Histology (HistoQIP) Immunology Microbiology Therapeutic Drug Monitoring/Endocrinology Toxicology Transfusion Medicine Reproductive Medicine	<p><b><i>The number of credits are specific to the program mailing.</i></b></p> <p><b><i>Go to cap.org for up-to-date activity listings.</i></b></p>

## Learning Cycle Information

Each education activity provides information on common technical and nontechnical issues encountered in all laboratory settings. To receive CE credit, you must complete the education reading provided in your PS and answer the online learning assessment questions. Most education activities are available for 12 months and must be completed within that time frame. CE credit will be applied toward the year in which the activity is completed. Detailed information on how to access the online components will be included in each PS. The CAP is an approved provider of accredited CME. In order to remain a CME provider the CAP must abide by all ACCME and AMA rules for accredited CME. This means that the CAP cannot open a course to allow completion of the course after the expiration date.

## CE for Cytotechnologists

---

Cytotechnologists may apply the credits from the gynecologic and nongynecologic (FNA, FNAG, NGC, and TICIP) programs toward the required educational activities for the American Society for Cytopathology (ASC) Continuing Education Credit Program.

### Online Virtual Microscopy Education Programs

The CAP offers online education programs that use DigitalScope technology to present whole slide images from actual glass slides for a variety of sites and specimen types. This technology simulates a microscope, allowing you to scan the image and use multiple magnifications to view the material. From the images and clinical information provided, you select a diagnosis, answer learning assessment questions, and receive immediate feedback online.

See the current Surveys and Anatomic Pathology Education Programs catalog for available online virtual microscopy education programs.

# 6

## Discipline-Specific Reporting Information

### Hematology

---

To report your blood cell identification, select the best identification code from the Hematology Blood Cell Identification Master List provided in the kit instructions. For further description of the Hematology Blood Cell Identification Master List choices, refer to the Blood Cell Identification section of the current *CAP Hematology and Clinical Microscopy Glossary*, which can be accessed at [cap.org](http://cap.org).

If results are reported for both blood cell identification and auto differentials, the blood cell identification will be reported to CMS.

The Hematology Blood Cell Identification Master List choice, “Immature cell or abnormal cell, would refer for identification,” must be reserved for cells you rarely encounter and are unable to specifically identify. Grading of this response will follow the guidelines set forth in the July 26, 1993, *Federal Register* Notice.

### Coagulation

---

For plasma-based coagulation testing [prothrombin time (PT), activated partial thromboplastin (APTT), fibrinogen], an instrument and reagent code are required for proper evaluation. Participants enrolled in whole blood testing for PT need only indicate an instrument (if requested) and their results. For all PT modules, reporting of international normalized ratio (INR) results is optional. Plasma-based and whole blood INR are evaluated.

### Urinalysis

---

There are separate urinalysis and specific gravity method and instrument master lists in the kit instructions. To ensure an accurate peer group evaluation of your results, it is critical to provide accurate method and instrument information.

A specific list of reporting options is provided for each urinalysis procedure. It is not feasible to provide a list of reporting choices specific for every possible dipstick being marketed to laboratories. Subsequently, the result ranges listed may not exactly correlate with the ranges used with your instrument/dipstick. In these few cases, choose the range that most closely matches your intended result.

To report urine sediment, clinical microscopy, or provider-performed microscopy, select the best identification code from the Urine Sediment Master List provided. For further description of the Hematology Blood Cell Identification Master List choices, refer to the Blood Cell Identification section of the current *CAP Hematology and Clinical Microscopy Glossary*, which can be accessed at [cap.org](http://cap.org).

## Urinalysis Dipstick Tests

---

For qualitative procedures in urinalysis, evaluation is based on participant consensus by method and instrument. For each analyte, a minimum of two, but not more than four, responses will be given a passing score. Analyte results graded “good” performance must have 80% participant consensus. Eighty percent participant consensus can be determined by grouping the mode with the next one or two most frequent responses. This group will be given “good” performance. “Acceptable” performance will be given to additional responses until a minimum of 90% of participant results are given a passing score. In the case of a negative specimen, negative responses must constitute 90% participant consensus. Specimens with results for one or more methods distributed over both negative and positive response (nonconsensus) will not be evaluated. Specimens for which there is greater than 90% of participant responses distributed over more than four responses will be graded as nonconsensus.

## Microbiology

---

Where appropriate, a clinical diagnosis, age, and source are listed to simulate a true clinical situation and to allow laboratory personnel to select appropriate media or methods for processing these specimens. However, as the pathogenic bacteria present in any of these specimens may be isolated from multiple sources of the body, all participants should attempt identification of the organisms present in all these specimens.

Per the *Federal Register*, a Survey must grade a laboratory’s ability to distinguish between a pathogen and a contaminant. Culture challenges will be designated in the instructions to be handled as “identify principal pathogen” or “identify all organisms” challenges. Participants must report in this manner even when this differs from their laboratory’s routine practice. For example, a urine specimen contains *Klebsiella pneumoniae* and *Staphylococcus epidermidis*. If the instructions indicate to “Identify all organisms,” both organisms should be reported. If the instructions indicate to “identify principal pathogen,” only the *Klebsiella pneumoniae* should be reported. If the *Staphylococcus epidermidis* is reported, it would be penalized.

Specimen results will be evaluated if 80% or more of the participant laboratories agree on the identification of the test organism(s) to genus or to genus and species. In the absence of participant consensus, referee laboratories will be used.

The CLIA regulations state that a laboratory must perform a minimum of five specimens in each testing event for the subspecialty of bacteriology. The five challenges can include a combination of the following specimens:

- Bacterial antigen detection
- Bacterial identification (culture)
- Gram stain
- Antimicrobial susceptibility

Procedures assayed with waived methodologies will not count toward the five-challenge minimum. The laboratory is responsible for maintaining the five specimens per testing event for its remaining nonwaived tests in the subspecialty when a test is waived by the Food and Drug Administration midyear.

## Antimicrobial Susceptibility Testing

---

Participants will be asked to perform susceptibility tests using the antimicrobial agents and techniques in routine use in their individual laboratories. The laboratories should report only antibiotics appropriate for therapy of infections at the site indicated in the patient history. See current Clinical and Laboratory Standards Institute (CLSI) documents M2, M7, M100, or other appropriate documents for guidance.

Interpretation results (susceptible, intermediate, and resistant) will be penalized for:

- Agents that are not clinically appropriate for the site of infection (meningitis, pneumonia, urinary tract, etc)
- Use of methods CLSI advises against
- Use of methods that the manufacturer recommends against using, due to poor performance

Selective reporting for the presumed site of infection helps improve clinical relevance, encourages appropriate therapy, and helps to minimize selection of resistance.



# 7

## Evaluations and Participant Summaries (PS)

### Overview

---

Shortly after you submit your PT results to the CAP, an evaluation of your submitted results will be available online or mailed back to you. Your evaluation can be used as a quality assurance tool to assess how you performed compared to other participants. It is important that you review and understand the information presented in your evaluation:

- **Demographic information:** Provides information about your laboratory, including the name of your institution, your CAP identification number, and any agencies or consultants you have designated to receive copies of your evaluation.
- **Result area:** Contains all results reported for a particular mailing and statistical data used for evaluation purposes. A detailed description of evaluation data specific for each discipline is presented in each PS.
- **CMS performance summary report:** Includes information on current and cumulative performance for regulated analytes to be sent to the CMS.

### Reviewing Your Evaluation

---

To truly realize the benefit of PT, it is important that you take the time to carefully review your evaluation. You can gain valuable insight into your laboratory's overall processes by following these easy steps in reviewing this report.

1. Review the demographic information on the evaluation. If any information is incorrect or has changed, contact the CAP at 800-323-4040 option 1.
2. Compare information on your evaluation with results on your photocopy or printed copy of the result form. If any of your data was entered by the CAP incorrectly, contact us immediately. Corrections due to data entry errors made by the CAP must be requested within four weeks after the first evaluation was mailed.
3. Look for any unacceptable results. Common, easily corrected reasons for unacceptable results include:
  - Incorrect or incomplete method/instrument data
  - Clerical error
  - Decimal point placement
  - Specimen handling error

Remember, whatever the cause, CLIA states that all PT deficiencies must be documented and corrective action taken to resolve the deficiency.

4. Occasionally, incorrect entry of submitted data occurs. If this is due to your transcription error or failure to complete the result form appropriately, your entry cannot be reevaluated. If the error is made by the CAP, contact the CAP at 800-323-4040 option 1 for further assistance.
5. Although the results may not be formally evaluated, you can compare your results with the data provided in the PS report. You can use the “all method mean” or median, low, and high values to compare your results for a self-assessment of your performance.
6. For quantitative data, just knowing that you are “within limits” does not tell you if you are experiencing a slowly developing bias that may result in future failures. The key to optimal use of your evaluation data is to look at the column where standard deviation indexes (SDI) are reported. If you note any of the following tendencies, it may be advantageous to examine your laboratory processes further:
  - The average SDI is more than  $\pm 1.5$ : this may indicate a significant systematic error. Review calibration data and technique. Review expiration dates of calibrators and reagents.
  - One of your SDIs is greater than  $\pm 3$  or total SDI is greater than 4 (one SDI is -2 and one is +2.5 for a total of 4.5): this may indicate a significant random error. Review your procedure to determine where any unwanted imprecision may be occurring.
7. When the evaluation has a nonevaluation code listed, refer to your PS for valuable information.
8. Verify that all regulated analytes for which you reported results are included on the CMS Performance Summary Report.
9. Make sure the laboratory director reviews and signs all PT evaluations.

## PS

---

In addition to your evaluation, each laboratory receives a PS for that mailing that lists results from all participants for each analyte grouped by the methodology. This report provides valuable information to the participant in the form of comparative data and education activities.

### Program Update

This section of the participant summary contains information about evaluation criteria in use for that mailing. It also highlights important method, manufacturer, and specimen information that pertains to that mailing.

### Quantitative Data

The participant summary provides the statistical data needed to review your PT results. The report lists the mean, SD, and CV for peer groups consisting of 10 or more laboratories.

### Qualitative Data

Qualitative data evaluation is based on consensus of participant and/or referee responses. The PS lists the participant responses along with the percentage reporting that response. Where available, referee data is also included. This practice provides higher-quality, evaluated challenges to our participants.

## How to Perform a Self-Evaluation

---

As mentioned previously, occasionally a PT challenge cannot be evaluated for a variety of reasons:

- Lack of participant consensus
- Insufficient data (<10 responses for a given method)
- Perceived compatibility issues

In order to comply with the quality assurance aspect of PT as outlined in CLIA, you must have some mechanism to evaluate your PT results. Here are a few examples of how the data presented in the PScan assist with this task.

### Quantitative Results

If you perform a test and there are fewer than nine other laboratories reporting results for that test, your result will not be evaluated. You can determine how well you performed compared to all participants who reported results by using the “all instrument method” data presented in the PS (if provided). For example, you perform hemoglobin analysis using the Coulter LH500. There are an insufficient number of results to form a peer group (<10); therefore, your results are not graded. Note that in the PS there is an all-instrument mean, standard deviation, and coefficient of variation, which can be used as a reference value. By applying the published CMS evaluation limits ( $\pm 7\%$ ) to this mean, you can determine how well you performed compared to this reference value. For example:

<b>Your result:</b>	<b>13.8 g/dL</b>
<b>All Instrument Mean:</b>	<b>13.77 g/dL</b>
<b>Range of Acceptability:</b>	<b>12.8–14.8 g/dL</b>

In this example, your result would be considered within range when compared to the all-instrument mean. Document this self-assessment on your evaluation. When you perform this self-assessment, any unacceptable result should be documented and investigated and corrective action should be taken as would be done for formally evaluated results. This same technique can be used when only a median, low, and high value are reported for an analyte.

### Qualitative Results

If a qualitative result is not evaluated due to lack of referee or participant consensus, you can still evaluate how well your laboratory’s result agreed with the correct response by using the data in the PS. For example, one of the Gram stain challenges could not be graded due to lack of participant consensus (77% reported gram-negative, 23% reported gram-positive). The PS indicates that the organism was *Pseudomonas aeruginosa*, a gram-negative rod/bacilli. Compare your result with the correct result. Investigate and document any corrective action taken. Review the educational critique accompanying the result for helpful suggestions on laboratory technique.

# 8

## Laboratory Legislation and CMS Reporting

In February 28, 1992, the Secretary of HHS published the final rules implementing CLIA. The CLIA regulations replaced the Medicare, Medicaid, and CLIA '67 standards with a single set of requirements that apply to almost all laboratories testing human specimens. Standards for laboratory personnel, quality control, and quality assurance are based on test complexity and risk factors. The regulations also establish application procedures and fees for CLIA certification, as well as enforcement procedures and sanctions applicable when laboratories fail to meet standards.

CLIA applies to all laboratories, physician offices, or other entities performing testing on human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of disease or impairment of human beings. Laboratories that conduct testing for the purpose of assessing the health of individuals (eg, testing for insurance purposes) are also subject to CLIA. The following lists certain laboratories that are not subject to CLIA:

- Laboratories conducting only forensic testing
- Research laboratories that do not report patient results
- Components or functions of laboratories certified by the Substance Abuse and Mental Health Services Administration
- Laboratories located in a state in which the licensure program is approved by the CMS as meeting CLIA standards
- International laboratories not performing tests on United States citizens

Under CLIA, all clinical laboratories, regardless of location, size, or type, must meet standards based on the complexity of the tests they perform. Three levels of testing complexity are defined in the regulations: waived, provider-performed microscopy, and nonwaived. Laboratories performing provider-performed microscopy or nonwaived testing must meet requirements for PT, patient test management, quality control, quality assurance, and personnel. These specific requirements do not apply to tests in the waived category.

The uniform PT program regulations mandate that your laboratory must enroll in a PT program approved by the Department of Health and Human Services, the CMS parent regulatory agency, for each of the specialties and subspecialties for which it seeks certification. All analytes that are regulated for PT appear in bold type in the Surveys and Anatomic Pathology Education Programs catalog.

Your laboratory must notify CMS of the approved program(s) in which you participate and authorize the PT program to release all data to the CMS. Your laboratory must participate in an approved PT program for one year before designating a different program. CMS must be notified before your laboratory changes PT programs. For tests that are not subject to PT in these regulations, your laboratory must still establish the accuracy and reliability of its test procedures at least twice a year.

PT specimens must be tested with the regular patient workload by personnel who routinely perform testing. Your laboratory's routine testing methods must be used. The individual testing the specimens and the laboratory director must attest to the routine integration of specimens using a form provided by the PT program. Laboratories that perform tests on PT specimens must not engage in interlaboratory communications pertaining to the results of PT specimen(s) until after the date by which the laboratory must report PT results to the program for the testing event in which the specimens were sent. Laboratories with multiple testing sites or separate locations must not participate in communications or discussions concerning PT specimen results until after the date by which the laboratory must report PT results to the program. Your laboratory must also maintain a copy of all records, including the form used to record the PT results (including the attestation signatures), for a minimum of two years.

Your laboratory must successfully participate in a PT program approved by CMS. "Unsuccessful proficiency testing performance" is a "condition level" deficiency and may result in laboratory sanctions such as suspension of the CLIA certificate and Medicare payments for the specialty, subspecialty, and analyte involved. Failure to achieve a satisfactory overall testing event performance for two consecutive testing events or two out of three consecutive testing events is considered unsuccessful performance.

Procedures assayed with waived methodologies will not count toward the five-challenge minimum.

Failure to attain an overall testing event score of at least 80% is unsatisfactory performance for analytes in all specialties and subspecialties except ABO group, D(Rh) typing, and compatibility testing for which 100% is required.

Failure to return PT results for a testing event is unsatisfactory performance and will result in a score of "0." For any unsatisfactory testing event for reasons other than failure to participate, your laboratory must undertake appropriate training and employ the technical assistance necessary to correct the problem. All remedial action must be documented and such documentation kept for two years at your laboratory for possible reference by inspection and accreditation teams. As part of these regulations, criteria have been established by which a PT provider's program may be evaluated for approval by HHS. The CAP has made every effort to ensure that the Surveys program has met the requirements set forth by the February 28, 1992, Final Rule.

### **Special Considerations for the Regulatory Requirements for the Specialty of Immunohematology**

The specialty of Immunohematology comprises four subspecialties as follows:

- ABO/Rh
- Unexpected antibody detection
- Compatibility testing
- Antibody identification

A 100% score is required to achieve satisfactory performance for ABO/Rh and compatibility testing.

For unexpected antibody detection and antibody identification, an 80% score is required. The consensus percentage required to establish a graded challenge is set at 95% participant or 100% referee consensus for ABO/Rh and compatibility testing and 95% referee or participant consensus for unexpected antibody or antibody identification challenges.

## Special Considerations for the Regulatory Requirements for the Specialty of Microbiology

The CLIA regulations state that a laboratory must test a minimum of five specimens in each testing event for the subspecialties of bacteriology, mycobacteriology, mycology, parasitology, and virology. Within each of these subspecialties, various types of testing are required.

For bacteriology, the five challenges may include a combination of the following specimens:

- Bacterial antigen detection
- Bacterial identification
- Gram stain
- Antimicrobial susceptibility

*Chlamydia trachomatis* results are aggregated under the subspecialty of bacteriology.

For mycobacteriology, the five challenges may include a combination of the following specimens:

- Acid-fast stain
- Mycobacterial identification
- Antimycobacterial susceptibility

For mycology, five identifications are required.

For parasitology, five identifications are required and may consist of testing by fecal suspension, Giemsa-stained blood smear, antigen detection, and/or PVA slide.

For virology, the five challenges may include a combination of the following specimens:

- Viral antigen detection
- Viral identification (culture)

**Note: In order to meet the regulatory requirements for microbiology subspecialties, carefully follow the kit instructions included with each Surveys mailing.**

## Regulatory Requirements for the Specialty of Cytology: Gynecologic Examinations

For cytology, the examination consists of ten slides from four diagnostic categories, including Unsatisfactory, Negative or Benign, LSIL and HSIL or carcinoma. To be successful in cytology, a score of 90% must be achieved. Detailed instructions will be provided with the test materials.

## Provision of Results to CMS and State Agencies

---

To assist in complying with the requirement that your laboratory results be released to HHS, the CAP will transfer data to the CMS if you have provided a CLIA identification number. We will forward paper or electronic copies of your results to your state department of health, acting on behalf of the CMS, if you authorize us to do so. To authorize release of results to state agencies, indicate your request on the order confirmation report sent after your Surveys order is processed, or send a letter to the CAP. Your Surveys evaluation will then reflect the name of the agency to which the information was provided. Any questions regarding requirements for forwarding your PT results may be answered via your state department of health or one of the CMS regional offices.

Consult with your state department of health for additional laws or regulations concerning inspection, accreditation, and PT requirements that may affect the licensing of your laboratory and its personnel.

Copies of the February 28, 1992, CLIA regulations can be obtained by contacting the Government Printing Office by telephone at 202-512-1800 or by fax at 202-512-2250 and requesting CFR Title 42 Parts 400-429 and 430-End. You may also access documents online at <https://www.gpo.gov/fdsys/pkg/FR-1992-02-28/pdf/FR-1992-02-28.pdf>

If you have any questions regarding the automatic transfer of results to CMS or your performance summaries, contact the CAP at 800-323-4040 option 1.

## Use of Reason Codes for Nonevaluated Specimens


Some individual results are not evaluated for certain laboratories for a variety of reasons. A reason code explaining the specific circumstance will appear on individual evaluation, along with a brief explanation of what that code means. Below is a ledger of possible reason codes that can be assigned.

Reason Code	Description or Explanation
11	Unable to analyze (documentation to be provided by laboratory).
20	No appropriate target/response could be graded.
21	Specimen problem.
22	Result is outside the method/instrument reportable range.
24	Incorrect response due to failure to provide a valid response code.
25	Inappropriate use of antimicrobial.
26	Educational challenge.
27, 31	Lack of participant or referee consensus.
28	Response qualified with a "greater than" or "less than" sign; or unable to quantitate.
29	Inappropriate response.
30	Scientific committee decision.
33	Specimen determined to be unsatisfactory after contacting the CAP.
35	Testing not performed on this specimen type.
40	Results for this kit were not received.
41	Results for this kit were received past the due date.
42	No credit assigned due to absence of response.
43	The order for this kit was canceled; results not evaluated.
44	This drug is not included in our test menu. Use of this code counts as a correct response.
46	Quantitation not appropriate.
55	Exemption granted due to a natural disaster.
77	Improper use of exception code for this mailing.
88	Lab does not perform tests from this source or does not perform this test on patients.
91	There were an insufficient number of contributing challenges to establish a composite grade.
92	Composite grade could not be established due to the use of multiple non-graded reason codes for the individual challenges.

**It is the laboratory's responsibility to document the appropriate use of these exception codes should this be requested during a laboratory inspection.**



# CMS Performance Summary

 <b>COLLEGE of AMERICAN PATHOLOGISTS</b> <small>325 Washington Road, Northfield, Illinois 60093-3780 800-323-6040 • cap.org</small>	<b>CAP Number:</b> 1234567-01 <b>4</b> <b>Kit#</b> 1 <b>Institution:</b> Community Hospital <b>Attention:</b> Lab Director <b>City / State:</b> Anytown, USA 12345		<b>Kit ID:</b> 87654321 <b>1a</b> <b>Kit Mailed:</b> 2/1/2017 <b>1b</b> <b>Original Evaluation:</b> 3/15/2017 <b>1c</b>								
	<b>EVALUATION ORIGINAL</b>		<b>C-A 2017 General Chemistry/Therapeutic Drugs</b>								
<b>CMS Performance Summary for Analytes Regulated Under the Clinical Laboratory Improvement Amendments of 1988</b>											
<b>CLIA ID #:</b> 39D0101012 <b>Subspecialty:</b> Toxicology											
<b>2</b> Regulated Analyte	<b>5</b> Proficiency Event 2016 <b>3</b> 2			Proficiency Event 2016 3			Proficiency Event 2017 <b>6</b> 1			<b>7</b> Current Event Performance Interpretation	<b>8</b> Cumulative CLIA '88 Performance Interpretation
	Test Event	Score	%	Test Event	Score	%	Test Event	Score	%		
Ethanol	AL2 B	5/5	100	AL2 C	5/5	100				Pending	Successful <4>
Blood Lead	BL-B	5/5	100	BL-C	5/5	100				Pending	Successful <4>
Carbamazepine	C-B	5/5	100	C-C	5/5	100	C-A	5/5*	100	Satisfactory	Successful
Digoxin	C-B	5/5	100	C-C	5/5	100	C-A	5/5*	100	Satisfactory	Successful
Gentamicin	C-B	4/5	80	C-C	5/5	100	C-A	5/5*	100	Satisfactory	Successful
Lithium	C-B	5/5	100	C-C	5/5	100	C-A	5/5*	100	Satisfactory	Successful
Phenobarbital	C-B	5/5	100	C-C	5/5	100	C-A	5/5*	100	Satisfactory	Successful
Phenytoin	C-B	5/5	100	C-C	5/5	100	C-A	5/5*	100	Satisfactory	Successful
Primidone	C-B	5/5	100	C-C	5/5	100	C-A	5/5	100	Satisfactory	Successful
Procarinamide/Metabolites (NAPA)	C-B	10/10	100	C-C	10/10	100	C-A	10/10	100	Satisfactory	Successful
Theophylline	C-B	5/5	100	C-C	5/5	100	C-A	5/5	100	Satisfactory	Successful
Valproic Acid	C-B	5/5	100	C-C	5/5	100	C-A	5/5*	100	Satisfactory	Successful
Toxicology		<b>64/65</b>	<b>98</b>		<b>65/65</b>	<b>100</b>		<b>55/55</b>	<b>100</b>	<b>Satisfactory</b>	<b>Successful</b>

<4> Scorecard performance pending future evaluation or may not be applicable due to discontinued testing or use of a waived method.  
 <^> This score is taken from another kit.

## CMS Performance Summary Data

- Kit ID:** defines the customer's unique kit number for each mailing.
  - Kit Mailed:** lists the date the Surveys mailing was shipped.
  - Original Evaluation:** lists the date the evaluation was originally generated.
- Regulated Analyte: lists all regulated tests included in the specialty/subspecialty as defined by the CLIA regulations for the modules in which you are enrolled.
- Summary of Your Previous Responses: lists the total number of specimens you have tested and the number of acceptable responses for previous testing events.
- CAP Number and Kit: defines the CAP number and kit sequence.
- Test Event: identifies the product fulfillment group and shipment.
- Summary of Your Current Responses: lists the total number of specimens you have tested and the number of acceptable responses for that testing event.
- Current Event Performance Interpretation:** indicates either satisfactory ( $\geq 80\%$ ) or unsatisfactory ( $< 80\%$ ) performance for each analyte and the overall performance for the specialty/subspecialty. For ABO group, D (Rho) type, and compatibility testing, a score of 100% is required. When results have not been received from your laboratory for a shipment, this area will be blank.
  - A score may not appear (field is blank) due to the following reasons:
  - Lab has indicated to the CAP that the regulated analyte should not be reported to agencies

- Challenges were not graded, using reason codes that are not reported on the scorecard
  - The method reported for the analyte is waived by the CMS
  - No results were reported
8. **Cumulative Performance Interpretation:** indicates successful ( $\geq 80\%$ ) or unsuccessful ( $< 80\%$ ) performance for each analyte and for the specialty/subspecialty. For ABO group, D (Rho) type, and compatibility testing, a score of 100% is required. A <1> symbol denotes that your performance is successful; however, because you had less than 80% on the previous mailing, you are still at risk to be unsuccessful for the next mailing. A <2> denotes you are currently successful but at risk for the next two mailings as you were unsatisfactory for this mailing. These codes are applicable to both the analyte and the overall specialty/subspecialty scores. A <3> denotes currently unsuccessful performance. A <4> denotes that scorecard performance is pending a future evaluation or may not be applicable due to discontinued testing or the use of a waived method.