Together, we move forward to achieve better patient care.
# Proficiency Testing Manual

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Interlaboratory Comparison Program Cycle

1. CAP Catalog Delivery
   September: The catalog is sent to your laboratory.

2. Your Laboratory Subscriptions
   September–December: Your laboratory places its order.

3. CAP Order Processing
   September–December: Order quantities are reserved.

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

5. Surveys Mailing Kits Mailed
   Kits are prepared and sent from the manufacturer to your laboratory.

6. Your Laboratory Result Form
   Completed result forms are returned via mail, fax, or online submission to the CAP where data are summarized.

7. Scientific Resource Committee Evaluation Criteria
   The scientific resource committee reviews results and the impact of evaluation criteria.

8. CAP Reports Mailed/Available Online
   Reports are sent to or made available online for your laboratory, regulatory agency, and/or consultants.

9. Certificate Certificate of Participation
   As a CAP Surveys and Anatomic Pathology Educational Programs subscriber, your laboratory is entitled to receive a certificate of participation. The certificate will be issued at the beginning of the program year.
Order Confirmation, Specimen Handling, and Customer Service

Confirmation

After your order is received, an order confirmation report 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 report be sent

Please review your laboratory order confirmation report carefully. If you have changes, return the form within two weeks of receipt to:

Customer Data Management  
College of American Pathologists  
325 Waukegan Road  
Northfield, Illinois 60093-2750  
Fax: 847-832-8168 (Country code: 001)

Binders/Glossaries

Please see your catalog for instructions on how to obtain three-ring binders for filing results and reports. Surveys results are printed on three-hole-punched sheets for storage in the binders.

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, please call the CAP Customer Contact Center.

Alerting the Mailroom

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.

The CAP will automatically forward results for analytes regulated for proficiency testing to the Centers for Medicare & Medicaid Services (CMS) for laboratories that have provided a CLIA identification number.

To request that no results be forwarded or to make changes to your laboratory’s analyte selection report for the information provided to CMS, please contact the Customer Contact Center at 800-323-4040 option 1 or access your report online at 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 Chapter 8 of this manual.
CAP Identification Number

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

Replacement Specimens

The kits contain a result form and specimens for analysis. Check the contents of the kit against the instructions. If the kit is incomplete or contains broken or unlabeled specimens, contact the College within the number of days indicated in the kit instructions following the actual shipping date for a free replacement. Additional replacement specimens may be purchased within the same time frame. Because proficiency testing (PT) materials must be procured in advance of shipment, on occasion, additional inventory is available for a nominal fee. To purchase these materials contact the Customer Contact Center at 800-323-4040 option 1. All literature associated with this product including the summary data would be provided. This option does not replace routine proficiency testing.

These materials may be used for but not limited to:

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

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, you will be allowed the same amount of time for analysis as was allowed with the original shipment. You are ensured an evaluation.

Occasionally, it may not be possible for the manufacturer to replace your specimen(s) kit. In this case, fill the exception code 33 bubble on the result form. Specimen Problem will appear on your evaluation report, and you will not be penalized.

Testing Instructions and Completion Time

Per the 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.

The Surveys program is used for certification of certain laboratories. Since promptness is considered in determining certification, we cannot accept late entries. Results are due by the date noted 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 Participant Summary that can be used for self-evaluation.

Second Instrument Reporting

In 2014, the Centers for Medicare & Medicaid Services (CMS) directed all PT providers that laboratories subject to Clinical Laboratory Improvement Amendments (CLIA) regulations are not allowed to test and report PT specimens from a second/back-up instrument unless that is how they routinely test 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 Clinical Laboratory Improvement Amendments (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 reporting with your PT results. To meet your laboratory needs, the CAP now offers its Quality Cross Check program. See the Surveys catalog for details.

Changing Results and CMS Reporting Instructions

- Changes to submitted data cannot be made after the due date listed on the result form. Review all entries made on the result form for accuracy prior to submission. For results approved online, corrections must also be done online. Faxed or mailed corrections will not be accepted.

- If you have registered your lab on the CAP website, you may view the status of your results on the Result Form Data Entry and Receipt Verification screen.

- For any testing that you do not routinely perform in your laboratory, leave all reporting areas for that test blank, including method information. Please 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.

- If you do not perform specific testing in a Surveys program, please refer to the kit instructions and result form for the appropriate instructions.

For any regulated analytes that your laboratory does not report or may have discontinued, you must notify the CAP in writing. Please fax any changes in writing on your CMS report to 847-832-8168 to avoid receiving a zero score on your next PT evaluation. (Your reporting preferences are outlined on the CMS Analytes Reporting Selections document, which is available online at cap.org on the Accreditation and Laboratory Improvement tab.) If you have any questions, please 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 Cervicovaginal and Nongynecologic Cytopathology (PAP/NGC)
- Fine-Needle Aspiration Glass Slide Program

Individual result forms can be submitted online (preferred method) or faxed to the CAP. CME/CE forms will be self claimed online through the Learning Portal tab.

Evaluation Reports

The evaluation report will be posted online and mailed approximately two to five weeks after the ship date of the kit. This time is needed for processing data, establishing evaluation criteria, and preparing the summary report.

Corrections

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, please contact the Customer Contact Center at 800-323-4040 option 1 for further assistance.

Customer Support

Customer Contact Center Hours

7:00 AM–5:30 PM CT

Extended Customer Contact Center hours ensure coverage for all time zones. Call 800-323-4040 option 1 to speak with a Contact Center representative. For international customers, please call 847-832-7000 option 1 (Country code: 001).
24-hour Messaging Service
The CAP’s 24-hour voice mail system allows you to leave a message after hours. A response will be provided the following business day.

24-hour Service Fax Hotline (800-289-1815)
As with the 24-hour voice mail system, the Service Fax Hotline makes it easy for you to fax requests any time, day or night. Response is guaranteed by the next business day.

Contact the CAP via the Website
You can submit your request or question conveniently online via the CAP Web page. Log on to cap.org and click on the Contact Us icon located at the top of the main page.

CAP Mail
The CAP has implemented an email notification service, CAP Mail, designed to keep you informed of our receipt of your order form(s) and result forms. For each document type, the CAP will notify the appropriate individuals that we have received your information.

- All result form receipt acknowledgment messages include a result form receipt.
- Link to the CAP website page where you can review detailed information for each kit on the number and specific pages received and method of receipt.

To take advantage of this service, ensure the CAP has the appropriate email addresses for your laboratory.

- 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 Customer Contact Center at 800-323-4040 option 1.

Contact the CAP via Email
General inquiries may be routed to the CAP at the following email address: contactcenter@cap.org.

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

Letters
All letters received by the CAP are reviewed and, if appropriate, forwarded to a medical technologist or a scientific resource committee member for response. Your input is encouraged and has always served as a valuable vehicle for changes and improvements to the interlaboratory comparison programs.

The CAP does not require that you submit documentation for all proficiency testing 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.

Limitations of Proficiency Testing
Due to the manufactured nature of the specimens and the logistics of shipping, proficiency testing does not always correlate with the manner in which fresh, clinical specimens are handled. A letter addressing these differences is included on page 8 for general use by your laboratory.

Handle With Caution
Proficiency testing 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 needlesticks, 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

Please try to 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.
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,

Elizabeth A. Wagar, M.D.
Chair, Council on Scientific Affairs
Completing the Result Form

The result form is a prepared form on which you record your methods of analysis and results of laboratory testing. The completed result form must be returned online or by fax to the CAP for evaluation. Prepare your result form carefully according to the instructions. Double-check your answers for accuracy and completeness.

It is important to photocopy or print a copy of the completed forms for your records before mailing or submitting them online to the CAP.

Per directive from the Centers of Medicare & Medicaid Services (CMS), changes to submitted data cannot be made after the due date printed on the result form. Review all information on the method summary page and all entries made on the result form for accuracy prior to submission. Once you have opted in, you can use the “Result Form Data Entry and Receipt Verification” option on the CAP website (under e-LAB Solutions) to verify the submitted data.

Preprinted Method Summary Page

The computer system is designed to enhance result reporting from your laboratory. Once you have initially provided a master list code for a method, instrument, and/or reagent, the computer will maintain these codes, ending your need to report them throughout the year. Please check each master list to ensure the correct codes are listed. Should you need to change a code, enter it in the appropriate boxes on the result form.

Exception Codes

If it is necessary for you to report an analytical problem for an entire test or individual specimens within a test, leave the result area blank and fill the bubble for the appropriate exception code. Select the appropriate two-digit code from those listed and fill the appropriate bubble.

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

* It is the laboratory’s responsibility to document the appropriate use of these exception codes should this be requested during a laboratory inspection. Please refer to the kit instructions for more information.

Teleforms

Teleforms are scannable forms. Because these forms are scanned, please refer to the kit instructions for more detailed instructions on completing the result form.
Identification Master Lists

Master lists of possible identifications are provided for microbiology, blood cell identification, urine sediment, clinical microscopy, and provider-performed microscopy. Select your answers from the appropriate master lists provided. Record the appropriate master list code for your choice 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.

Method/Instrument Master Lists

Method/instrument master lists are provided in the kit instructions. Choose the appropriate instrument and/or method and provide this information on the result form.

It is important that you notify the CAP and the manufacturer if your instrument or method is not listed on a master list. This may be done by listing this information in the “Use of Other” section of the result form. You may also contact the CAP directly while completing the result form to see if a code has already been established for your method and/or instrument but was not available in time for printing of the result form.

Handwriting

The result forms are designed for quick, easy scanning by our computers. If you fax your results, the information on your result form must be clearly readable.

Decimal Points and Box Positions

The computer is programmed to accept only those answers conforming to the boxes and decimal points on the result form.

If a number is not large enough to fill the boxes, insert zero in the remaining spaces. Results should be right-justified. When submitting results online, this will be done automatically.

Example: Correct Incorrect

| Glucose     | 73 mg/dL | 0 7 3 | 7 3 |
| Urea Nitrogen | 12.8 mg N/dL | 0 1 3 | 1 2 8 |

“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 provision is made to report “less than” or “greater than” results, you must fill in the bubble of the appropriate 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 “exception codes” on page 10 or in your kit instructions.
Using Online Features

Powerful Internet-based tools are available to give participating laboratories many exciting choices. Simple instructions for use of these tools are provided. And as always, CAP Customer Contact Center representatives stand ready to offer assistance.

In order to take full advantage of the functionalities available online, users can selectively enable laboratories and personnel by undertaking enrollment procedures as outlined below:

Self Registration

This is the process of creating an account with the CAP for online activities. All users of the advanced features of the CAP website are required to have a personal Web account and be logged in to be able to use the site. This process only needs to be done once per user; it allows the user to select an ID that can be easily recalled and that belongs to the user, regardless of laboratory affiliation. Both members and nonmembers are required to be registered, thereby allowing the entire laboratory community to participate online. This registration is also valid for CME/CE online learning activities.

Logging In

Once users have established an account with the College, they will be prompted by the system to enter their user ID and password. This must be done every time users visit the site, or users can choose to have the system remember their login. Both members and nonmembers utilize the same login functionality.

Opting In

A user (the laboratory administrator, by default) enters a CAP # and CAP-provided PIN, thereby enabling the laboratory to access advanced features online. This process only needs to be done once per lab; once accomplished, the lab will have access to all of the features currently accessible online as well as those that will be offered in the near future.

Security

The nature of the individualized accounts for laboratory users allows for flexibility in determining what levels of access each user should have. Because users are independent entities from the laboratory, the users can be associated with multiple laboratories and their security can be administered in a different manner at each site. This is carried out by the delegated security administrator at the laboratory who is responsible for overseeing the access and site privileges for each user associated with that lab. Because of the changing nature of the employee-employer relationship in the laboratory, this feature allows the most flexibility for the administrator to add, modify, and/or remove users’ access privileges as the administrator sees fit. This has the overall effect of eliminating the need to have to call the Customer Contact Center to carry out some of the more routine maintenance of an account. The delegated security administrator(s) can confer as many or as few permissions as they see fit, and the administrator(s) can configure personnel security so that it closely matches individuals’ roles within the laboratory. This will enable the lab to replicate the same workflow model that it employs for
paper-based submission of results, thereby helping to increase the integrity and confidence in the data entered online.

**Online Data Submission**

Once the lab has opted in and security for employees has been administered, one of the first features a lab can take advantage of is the ability to submit its data results online. A lab will receive its PT material and paper result forms as usual and will test them in its customary manner. Most laboratorians may prefer to record their results on the paper result form for ease of transcription to the online system. The users will log in to the site, navigate to their lab and kit, and they will be presented with an Adobe PDF version of the same paper result form they have in hand. The form is designed to prevent errant data from being saved to the form. Users will be able to select method and qualitative codes from drop down lists rather than having to refer to a separate document for the code. Invalid codes and data will prevent the user from saving the form. Users will enter the data into the virtual form and save the data as they finish. For Surveys in which multiple laboratorians perform the testing and resulting, the flexible nature of the data entry system will allow multiple users to log in to the system at different times and enter their data, so as to minimize any interruption to their normal laboratory work.

Depending on the normal workflow within the lab, the administrator has a choice to designate an additional approver role for another user whose job it is to verify that all data was entered as intended and to submit the data. Once this step is finished, the data is committed to the CAP’s system and is ready for normal processing. The advantages to this system lie in speed, efficiency, and clarity of the resultant data.

In addition to these benefits, labs who continue to fax their result forms in can also take advantage of the online entry since the system will be able to present the data as it has been interpreted by computerized scanning equipment. Users can access their interpreted data and will have the opportunity to correct any scanning errors that may have occurred due to the nature of errors inherent in these media. Giving the participants the opportunity to correct for these scanning errors also increases the accuracy of their data which, if allowed to propagate through the system, could have negative consequences in their performance interpretation.

Automated PT data transmission laboratories have the option to transmit data through an automated proficiency test reporting service called e-LAB Solutions Connect. With e-LAB Solutions Connect, the CAP’s quantitative proficiency test results are automatically transmitted from your laboratory’s instruments or laboratory information system to e-LAB Solutions. The CAP has partnered with Data Innovations Instrument Manager™ middleware solution to help facilitate the connection and transmission. Go to the CAP website or call the Customer Contact Center for more information.

**Interactive Evaluations**

As soon as the due date indicated on the result form has past, the data are processed and graded according to stringent governmental and committee criteria. The lab results and grading interpretations are displayed in an individualized report that will be available to all users via paper or online. The online version is available in a static format that can be printed or downloaded and stored locally, thereby negating the need to create a separate library of evaluations for future reference. In addition, the online evaluation will allow the user to navigate through the evaluation and browse the data analyte by analyte. Also, users will benefit by the inclusion of detailed images that will be hyperlinked from the online evaluation report only. Laboratory managers will find a useful tool in the All Analyte Scorecard, which will allow them to filter and customize the scorecard data for their laboratory as a means of identifying deficiencies or trends in performance.

**Online Reports**

Other ancillary reports that accompany the evaluation report will be available online, as well, for review and to download for future reference. This includes participant summary reports, final critiques, and annual summaries, which contain useful data and education that can be reviewed and accessed by all users with appropriate security. These documents may be downloaded and stored locally for future use.
This will help to increase the dissemination of the information contained in these documents to multiple personnel, especially now that the information contained therein is being used increasingly for educational enhancements for which individuals can obtain continuing medical education/continuing education (CME/CE) credits.
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 published the final rules implementing the Clinical Laboratory Improvement Amendments (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 proficiency testing 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, ± 5 mg/dl), a percentage of the mean (eg, ± 25%), an SD (eg, ± 3 SD), or a variable range (eg, ± 6 mg/dL or 10%, whichever is greater). The Participant Summary included with your evaluation will list 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.

### 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 ± 4 mmol/L. The acceptable range is determined by the formula 139.5 mmol/L ± 4 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 ± 10%. Ten percent of 3.39 mg/dL is 0.34 mg/dL. The acceptable range is determined by the formula 3.39 mg/dL ± 0.34 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 TSH result of 16.4 µU/mL. The peer group statistics are as follows: mean = 15.7 µU/mL, SD = 1.5, and CV = 9.6. The evaluation limit for TSH is ± 3 SD. 3 x 1.5 = 4.5. The acceptable range is determined using the formula 15.7 µU/mL ± 4.5 µU/mL, which is 11.2 to 20.2 µU/mL when using benefit-of-the-doubt rounding. Therefore, your result of 16.4 µU/mL is within the acceptable range of 11.2 to 20.2 µU/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 ± 0.4 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 ± 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 Participant Summary Report included with your evaluation report 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. The upper limit of acceptability is obtained by rounding up to the next reportable result, while the lower limit is determined by truncating.
Calculation of the Standard Deviation Index (SDI)

The computer-printed evaluation report lists your results and the evaluation statistics for your peer group. It also lists 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 on the printout 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 report will display 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:

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

If your result is less than the target mean:

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

Qualitative Procedures

For qualitative responses, consensus agreement of referee or participating laboratories is used for evaluation. Generally, 80% agreement is required.
CME Category 1

The College of American Pathologists (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 catalog for available CME programs.

Continuing Education (CE) for Nonphysician Laboratory Personnel

This activity is acceptable to meet the continuing education requirements for the 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 may now earn individual CE credits by completing the related education reading and online learning assessment questions on the CAP website.

| Surveys CE Programs |
|---------------------|------------------|
| Discipline          | Maximum CE Credits |
| Chemistry           |                  |
| Coagulation         |                  |
| Hematology          |                  |
| Histology (HistoQIP)|                  |
| Immunology          |                  |
| Microbiology        |                  |
| Therapeutic Drug Monitoring/Endocrinology |                  |
| Toxicology          |                  |
| Transfusion Medicine|                  |
| Reproductive Medicine|                |

The number of credits are specific to the program mailing.

Please go to cap.org for up-to-date activity listings.
Learning Cycle Information

Each education activity provides information on common technical and nontechnical issues encountered in all laboratory settings. To receive continuing education credit, you must complete the education reading provided in your Participant Summary and answer the online learning assessment questions. Each education activity will be available for 12 months and must be completed within that time frame. Continuing education 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 Participant Summary.

CE for Cytotechnologists

Cytotechnologists may apply the credits from the gynecologic and nongynecologic (FNA, FNAG, NGC, and TICP) 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 advanced imaging technology to present 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 catalog for available online virtual microscopy education programs.
How to Complete the Result Form

To ensure statistically valid data, it is essential that participants provide all necessary unit of measure, method, reagent, and/or instrument information as required. Please remember, once you have provided accurate information, our computer system will retain this information.

Verify that the correct unit of measure, method, reagent, and/or instrument code is noted on the preprinted method summary page included with your result form or listed on the online result form. If a code is not noted or you’ve changed instruments, you must enter the correct code on the result form.

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. To assist you with blood cell identification, the Hematology, Clinical Microscopy, and Body Fluids Glossary is available online at 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 (PT, APTT, Fibrinogen), an instrument and reagent code are required for proper evaluation. Participants enrolled in whole blood proficiency testing for PT need only indicate an instrument (if requested) and their results. For all prothrombin time modules, reporting of International Normalized Ratio (INR) results is optional. Plasma-based and whole blood INR are evaluated.

Urinalysis

There is a separate urinalysis and specific gravity method master list and instrument master list. 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 ensure an accurate peer group evaluation of your results, it is critical to select an appropriate result that the method allows.

To report urine sediment, clinical microscopy, or provider-performed microscopy, select the best identification code from the Urine Sediment/Clinical Microscopy Master List provided. To assist with identification, the Hematology, Clinical Microscopy, and Body Fluids Glossary is available online at 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 samples 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

Please note that 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 FDA 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.
Evaluation and Participant Summary Reports

Your Evaluation Report

Shortly after you submit your proficiency testing results to the CAP, an evaluation report evaluating your submitted results will be available online or mailed back to you. Your evaluation report can be used as a quality assurance tool to assess how you performed compared to other participants. To benefit from this report, it is important that you review and understand the information presented. Here is a review of the information contained on your evaluation report:

- **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 Participant Summary.

- **CMS Performance Summary Report**: Includes information on current and cumulative performance for regulated analytes to be sent to the CMS.

Reviewing Your Evaluation Report

To truly realize the benefit of proficiency testing, 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 report. If any information is incorrect or has changed, contact the CAP at 800-323-4040 option 1.

2. Compare information on your evaluation report 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. Although the results may not be formally evaluated, you can compare your results with the data provided in the Participant Summary. You can use the “all method mean” or median, low, and high values to compare your results for a self-assessment of your performance.

5. 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 ±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 ±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.

6. When the evaluation report has a nonevaluation code listed, refer to your Participant Summary for valuable information.

7. Verify that all regulated analytes for which you reported results are included on the CMS Performance Summary Report.

8. Make sure the laboratory director reviews and signs all proficiency testing evaluations.

**Participant Summary**

In addition to your evaluation report, each laboratory receives a Participant Summary 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 proficiency testing (PT) results. The report lists the mean, standard deviation (SD), and coefficient of variation (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 Participant Summary 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 proficiency testing as outlined in CLIA, you must have some mechanism to evaluate your proficiency
testing results. Here are a few examples of how the data presented in the Participant Summary can 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 Participant Summary (if provided). For example, you perform hemoglobin analysis using the Coulter S-plus IV. There are an insufficient number of results to form a peer group (<10); therefore, your results are not graded. Note that in the Participant Summary 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 (±7%) to this mean, you can determine how well you performed compared to this reference value.

For example:

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

In this example, your result would be considered within range when compared to the all-instrument mean. Document this self-assessment on your evaluation report. 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 Participant Summary. 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 Participant Summary indicates that the organism was *Pseudomonas aeruginosa*, a gram-negative rod/bacilli.
On February 28, 1992, the Secretary of Health and Human Services (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 non-waived. Laboratories performing provider-performed microscopy or nonwaived testing must meet requirements for proficiency testing (PT), patient test management, quality control, quality assurance, and personnel. These specific requirements do not apply to tests in the waived category.

The uniform proficiency testing 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 proficiency testing 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 proficiency testing samples must not engage in interlaboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in communications or discussions concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing 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.

Please note that 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 Consideration 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)

**Important 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 proficiency testing 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 proficiency testing 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 access.gpo.gov/su-docs/.

If you have any questions regarding the automatic transfer of results to CMS or your performance summaries, please 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 reports, along with a brief explanation of what that code means. Below is a ledger of possible reason codes that can be assigned.

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

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

#### Evaluation Original

**CMS Performance Summary for Analytes Regulated Under the Clinical Laboratory Improvement Amendments of 1988**

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Event</td>
<td>Score</td>
<td>%</td>
<td>Test Event</td>
<td>Score</td>
</tr>
<tr>
<td>Ethanol</td>
<td>Z-C</td>
<td>5/5</td>
<td>100</td>
<td>Z-C</td>
<td>5/5</td>
</tr>
<tr>
<td>Blood Lead</td>
<td>Z-C</td>
<td>5/5</td>
<td>100</td>
<td>Z-A</td>
<td>5/5</td>
</tr>
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<td>Catheterine</td>
<td>Z-C</td>
<td>5/5</td>
<td>100</td>
<td>Z-A</td>
<td>5/5</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>Z-C</td>
<td>5/5</td>
<td>100</td>
<td>Z-A</td>
<td>5/5</td>
</tr>
<tr>
<td>Lithium</td>
<td>Z-C</td>
<td>5/5</td>
<td>100</td>
<td>Z-A</td>
<td>5/5</td>
</tr>
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<td>Phenobarbital</td>
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<td>5/5</td>
<td>100</td>
<td>Z-A</td>
<td>5/5</td>
</tr>
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<td>Phenytoin</td>
<td>Z-C</td>
<td>5/5</td>
<td>100</td>
<td>Z-A</td>
<td>5/5</td>
</tr>
<tr>
<td>Primidone</td>
<td>Z-C</td>
<td>5/5</td>
<td>100</td>
<td>Z-A</td>
<td>5/5</td>
</tr>
<tr>
<td>Quinidine</td>
<td>Z-C</td>
<td>5/5</td>
<td>100</td>
<td>Z-A</td>
<td>5/5</td>
</tr>
<tr>
<td>Theophylline</td>
<td>Z-C</td>
<td>5/5</td>
<td>100</td>
<td>Z-A</td>
<td>5/5</td>
</tr>
<tr>
<td>Tobramycin</td>
<td>Z-C</td>
<td>5/5</td>
<td>100</td>
<td>Z-A</td>
<td>5/5</td>
</tr>
<tr>
<td>Valproic Acid</td>
<td>Z-C</td>
<td>5/5</td>
<td>100</td>
<td>Z-A</td>
<td>5/5</td>
</tr>
</tbody>
</table>

#### Summary of Your Previous Responses

- The total number of specimens you have tested and the number of acceptable responses for previous testing events.

#### Summary of Your Current Responses

- The total number of specimens you have tested and the number of acceptable responses for that testing event.

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1. **Kit ID**: defines the customer’s unique kit number for each mailing.

2. **Kit Mailed**: lists the date the Surveys mailing was shipped.

3. **Original Evaluation**: lists the date the evaluation report was originally generated.

4. **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.

5. **Summary of Your Previous Responses**: lists the total number of specimens you have tested and the number of acceptable responses for previous testing events.

6. **Summary of Your Current Responses**: lists the total number of specimens you have tested and the number of acceptable responses for that testing event.
7. **Current Event Performance Interpretation:**
   indicates either satisfactory (≥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 (≥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.