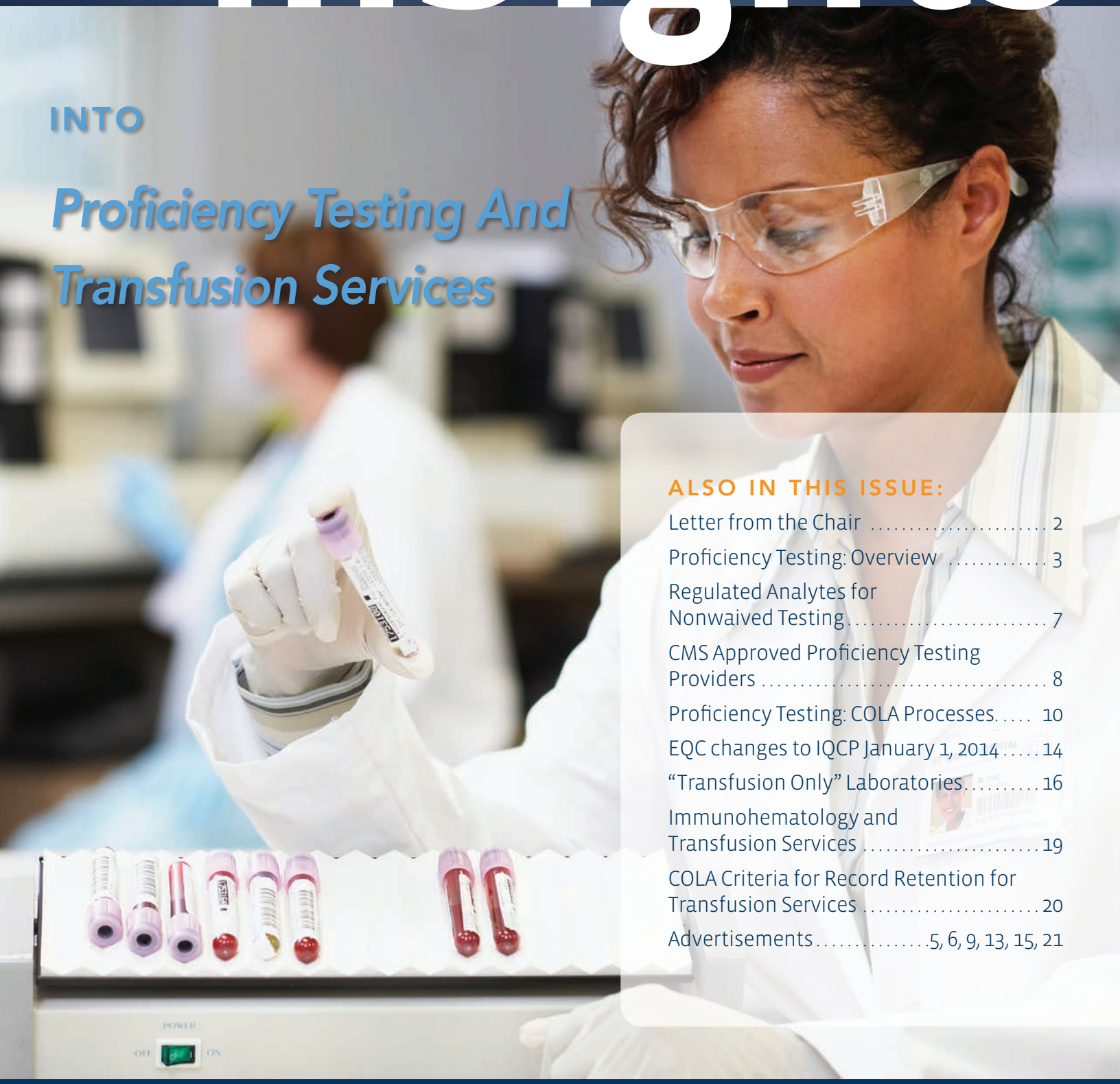
NOVEMBER/DECEMBER — 2013

COLA'S

inSights

INTO

Proficiency Testing And Transfusion Services



ALSO IN THIS ISSUE:

FROM THE CHAIR

As healthcare professionals, we constantly strive to deliver quality patient care. For laboratory medicine, delivery of quality patient care is directly related to the Quality Control (QC) performed in the laboratory. In this issue of Insights we will focus on two areas of laboratory medicine that rely heavily on QC, Proficiency Testing (PT) and Transfusion Services. Many recent regulatory changes have impacted laboratories perfuming both PT and Transfusion Services, and at COLA and CRI® it is our mission to keep you informed of the regulatory and scientific advances.

PT is a means of helping to ensure that your laboratory continually produces the highest quality, most accurate diagnostic results possible. We aim to impart to you the PT process from the Laboratory and COLA perspective. This issue includes a list of CMS-approved PT providers, CMS regulated analytes, and provides an overview of COLA criteria changes that may impact your laboratory's regulatory compliance.

Transfusion medicine is one of the most widely used methods of treating many cancers and immunologic diseases. The information contained in this issue of Insights is focused on reviewing the transfusion process as it relates to the laboratory. Learn about the evolving accreditation criteria and the various personnel involved in this critical area of patient care.

The information outlined in this issue of Insights will provide excellent awareness and education of these topics as you strive to deliver quality patient care.

Richard A. Wherry, M.D.

Chair, COLA Board of Directors

COLA

COLA INSIGHTS

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COLA INSIGHTS
is published periodically by
CRI®, 9881 Broken Land Parkway,
Suite 215, Columbia, MD 21046-1195.

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Proficiency Testing: Overview

A Snapshot of PT in the Laboratory

Proficiency Testing, more commonly known as PT, is an external check used to monitor the quality of test results produced by the laboratory. It is a measure of the lab's ability to analyze specimens of unknown values to obtain accurate results.

For regulated analytes (those analytes specifically listed in the CLIA regulations), the laboratory must be continuously enrolled in a PT program from the time patient testing is first performed. Failure to successfully participate in a PT program can lead to serious sanctions, such as an order to cease testing, loss of CLIA certification, and/or loss of Medicare & Medicaid reimbursements. (See p. 7 for a current list of regulated analytes.)

The Proficiency Testing process begins by choosing a PT provider from the list of CMS-approved providers. (See p. 8 for a current list of approved providers.) Depending on the analyte type, the PT provider will deliver 2 – 5 specimens, known as "Challenges", 2 or 3 times per year. Providers will send five challenges for the regulated analytes at approximately equal intervals three times per year. Non-regulated analytes (those not listed in the CLIA regulations) are required to be challenged twice per year, either by PT or some other scientifically defensible means of comparison, such as split-sample analysis.

LABORATORY RESPONSIBILITIES

The most important aspect of PT is that the PT Challenge specimens must be processed in the same manner as patient specimens. The primary purpose of PT is defeated if the PT Challenges receive special treatment.

- The PT specimens should be incorporated into the routine patient workload. The goal is to not alert the testing personnel to their presence as to not incur bias in testing.
- All testing personnel should perform PT at some point during the year. For larger laboratories or laboratories with a large number of testing personnel it might take more than a year to rotate PT samples. **Do not delegate PT to only select personnel.**
- PT challenges should not be repeated to report an average result. If patient specimens are not repeated, PT specimens should not be repeated.
- For each testing event, the Laboratory Director and the testing personnel (whoever physically performed testing for the PT event) must sign a statement attesting that the PT challenges were handled in the same manner as patient specimens.

OVERVIEW

- Enroll in a PT program from a CMS-approved provider
- Process PT Challenge specimens in the same manner as patient specimens
- Report results to PT provider within the timeframe specified
- PT provider verifies results, prepares and sends graded report packets to labs and COLA

It is important that after testing is completed, the laboratory submit results to the PT provider within the required time frame. The laboratory will receive a grade of zero percent (0%) for the entire testing event if results are not submitted, or if they are submitted after the cut-off date. If results are sent by electronic means, the laboratory should confirm with the PT provider that the results were received to avoid receiving a score of zero percent (0%).

Other important PT rules[1] include:

- Do **NOT** discuss PT or PT results with any other laboratory (including satellite, affiliate, and reference laboratories) prior to the result submission date.
- Do **NOT** send PT specimens to another lab for testing. This also includes satellite, affiliate, and reference laboratories. If specimens would normally be referred for further testing, indicate this on the PT result form, but do **NOT** send the specimen.
- Do **NOT** perform testing on PT specimens received from another lab, but immediately notify CMS that they were received.
- **Document everything involved in performing Proficiency Testing and keep this documentation for at least two years.**

It is good laboratory practice to maintain the PT specimens under proper storage conditions until the graded report packet is received from the PT provider. This means that the specimens will be available for repeat testing if the PT performance review deems it necessary.

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PROFICIENCY TESTING: OVERVIEW

REVIEW PT PERFORMANCE

Laboratories should promptly review and evaluate the data in the graded report packet when it is received.

First, review the report for clerical, transcription, and/or omission errors.

- Ensure that the CLIA ID number is correct.
- Confirm that there is a score for all tests for which results were submitted.
- Verify that the PT provider used the actual submitted results when grading the event.
- Check to see that the correct test method codes were used, to ensure that results were compared to the correct peer group.

Next, review and evaluate the individual challenges.

- Use the Standard Deviation (SD) and Standard Deviation Index (SDI) to help determine if the test system is showing instability or imprecision.
- Pay attention to challenges where consensus is not obtained (automatic scores of 100%). "Self-grade" by comparing submitted results to the provider's expected results as well as results obtained by other laboratories.
- Compare current results to past results to detect trends and/or method bias.

If all results are acceptable, document the review, and maintain all documentation for the required time period which, in most cases, is a minimum of two years. The retention period is determined by Federal, State, local, and institutional requirements. Ensure that you meet the longest retention times.

If any results are unacceptable, determine the cause; implement and evaluate corrective actions; and document everything and maintain documentation for the required time period.

EVALUATE PT PERFORMANCE

Looking at the scope of the problem can help determine its root cause. A problem with the PT specimen itself is indicated if more than one analyte from the same specimen is involved. Improper handling (such as improper reconstitution, or pipetting or dilution errors) and evaporation of the aliquot used for testing are examples of possible causes.

Instrument or test system problems are indicated if more than one analyte or specimen on the same instrument or test system is involved, or if only analytes in a certain range are affected (which indicates a linearity or calibration issue). If the test system or instrument is the cause, patient results should also be evaluated.

If more than one instrument or test system is affected, look for factors that are common to all systems involved. The most obvious commonality is testing personnel. Confirm that all personnel are competent to perform testing, and provide retraining and/or continuing education when necessary. Don't overlook other common factors, such as unforeseen effects of new policies (SOP's); modified kit, reagent, or specimen storage facilities; and/or unusual environmental factors (power outage, extreme temperature changes, electronic interference, etc.) Patient results should also be evaluated in this circumstance.

Finally, look at the overall grade for the PT Event. Each testing Event has three possible outcomes: Satisfactory Performance, Unsatisfactory Performance, or Unsuccessful Performance.

- *Satisfactory performance (PASS)* is attaining the minimum score for an analyte, test, subspecialty, or specialty for a single testing event. For most specialties, the minimum score is 80%; however, exceptions do exist. For example, in Immunohematology, a score of 100% is required when performing ABO & Rh typing and/or compatibility testing.
- *Unsatisfactory performance (FAIL)* is defined as failure to attain the minimum score for an analyte, test, subspecialty, or specialty for a single testing event.
- Repeated *Unsatisfactory Performance* becomes *Unsuccessful Performance (FAIL),* which is failure to attain a satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two-out-of-three consecutive testing events. Unsuccessful Performance can lead to CMS sanctions including an order to cease testing or limitation, suspension, and/or revocation of CLIA certification.

To resolve Unsuccessful Performance, laboratories must:

- Investigate the root cause of the unsuccessful performance.
- Implement and evaluate corrective actions.
- Notify accrediting agencies or CMS of actions taken.

Laboratories that have been required to cease testing due to poor PT performance will have to remain at cease testing for a minimum of six (6) months[2], and also have to successfully complete two consecutive PT events, which can be either scheduled or off-cycle events, before patient testing can be reinstated.

All actions taken during the Proficiency Testing process have to be documented. This includes **ALL records** – from initial receipt in the laboratory; through PT specimen processing and handling, actual test performance, and result submission; to reviewing and evaluating graded reports, investigating problem root causes, and implementing and evaluating corrective actions. All correspondence with PT providers, including details of any phone

calls, should also be maintained. All documentation must be readily available for at least two years. (As stated above, the retention period may be longer in some areas.)

Quality patient care is a goal of all clinical laboratories. Producing accurate, reliable laboratory test results helps ensure quality patient care. PT is a means to monitor the quality of laboratory test results. Therefore, consistent, successful performance of Proficiency Testing is a goal every laboratory should strive to attain.

RESOURCES:

[1] *This is not an all-inclusive list. For more information, refer to subpart H of the CLIA regulations. http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol5/pdf/CFR-2010-title42-vol5-part493.pdf.*

[2] Code of Federal Regulations Title 42 Part 493 Laboratory Requirements, 493.807.(b)

Regulated Analytes for Nonwaived Testing

MICROBIOLOGY

Bacteriology

Aerobic/Anaerobic Culture & Identification

Antibiotic Susceptibility Testing

Direct Bacterial Antigen Detection

Gram Stain

Mycobacteriology

Acid Fast Stain

Mycobacteriology Identification

Mycobacteriology Susceptibility Testing

Mycology

Culture and Identification

Parasitology

Presence or Absence of Parasites

Identification of Parasites

Virology

Direct Viral Antigen Detection

Viral Isolation and Identification

DIAGNOSTIC IMMUNOLOGY

Syphilis Serology

General Immunology

Alpha-1 Antitrypsin

Alpha Fetoprotein (tumor marker)

Antinuclear Antibody

Antistreptolysin O

Anti-Human Immunodeficiency Virus (Anti-HIV)

Complement C3

Complement C4

Hepatitis B Surface Antigen (HBsAg)

Hepatitis B Core Antibody (Anti-HBc)

Hepatitis Be Antigen (HBeAg)

Immunoglobulins, total:
- IgA
- IgG
- IgM
- IgE

Infectious Mononucleosis

Rheumatoid Factor

Rubella

CHEMISTRY

Routine Chemistry

Alanine Aminotransferase (ALT or SGPT)

Albumin

Alkaline Phosphatase

Amylase Aspartate Aminotransferase (AST or SGOT)

Bilirubin, total

Blood Gases:
- pH
- pCO_2
- pO_2

Calcium, total

Chloride

Cholesterol, total

Cholesterol, HDL

Creatine Kinase, total

Creatine Kinase, Isoenzyme (CK-MB)

Creatinine

Glucose

Iron, total

Lactate Dehydrogenase (LDH), total

LDH Isoenzymes (LDH_1/LDH_2)

Magnesium

Potassium

Sodium

Total Protein

Triglycerides

Urea Nitrogen

Uric Acid

Endocrinology

Cortisol

Free Thyroxine

Human Chorionic Gonadotropin

T_3 Uptake

Triiodothyronine

Thyroid Stimulating Hormone

Thyroxine, total

Toxicology

Blood Alcohol

Blood Lead

Carbamazepine

Digoxin

Ethosuximide

Gentamicin

Lithium

Phenobarbital

Phenytoin

Primidone

Procainamide and Metabolite

Quinidine

Theophylline

Tobramycin

Valproic acid

HEMATOLOGY

Cell Identification

WBC Differential

Erythrocyte Count

Hematocrit

Hemoglobin

Leukocyte Count

Platelet Count

Fibrinogen

Partial Thromboplastin Time

Prothrombin Time

IMMUNOHEMATOLOGY

ABO Group

D (Rho) Typing

Unexpected Antibody Detection

Compatibility Testing

Antibody Identification

CMS Approved Proficiency Testing Providers

ACCUTEST, INC.
P.O. Box 999
Westford, Massachusetts 01886
(800) 665-2575

AAFP-PT
11400 Tomahawk Creek Parkway
Leawood, Kansas 66211-2672
(800) 274-7911

AMERICAN ASSOCIATION OF BIOANALYSTS (AAB)
205 West Levee Street
Brownsville, Texas 78520-5596
(800) 234-5315

AMERICAN PROFICIENCY INSTITUTE (API)
1159 Business Park Drive
Traverse City, Michigan 49686
(800) 333-0958

AMERICAN SOCIETY FOR CLINICAL PATHOLOGY
8900 Keystone Crossing Suite 620
Indianapolis, IN 46240
(800)267-2727, (317) 876-4169

CALIFORNIA THORACIC SOCIETY (CTS)
575 Market Street, Suite 2125
San Francisco, California 94105
(415) 536-0287

THE COLLEGE OF AMERICAN PATHOLOGISTS (CAP) -SURVEYS
College of American Pathologists
325 Waukegan Road
Northfield, Illinois 60093-2750
(847) 832-7000

EXTERNAL COMPARATIVE EVALUATION FOR LABORATORIES -EXCEL
College of American Pathologists
325 Waukegan Road
Northfield, Illinois 60093-2750
(800) 323-4040

MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Office of Health Care Quality – Laboratory Care
Spring Grove Hospital Center
Bland Bryant Building • 55 Wade Avenue
Catonsville, Maryland 21228
(410) 402- 8029

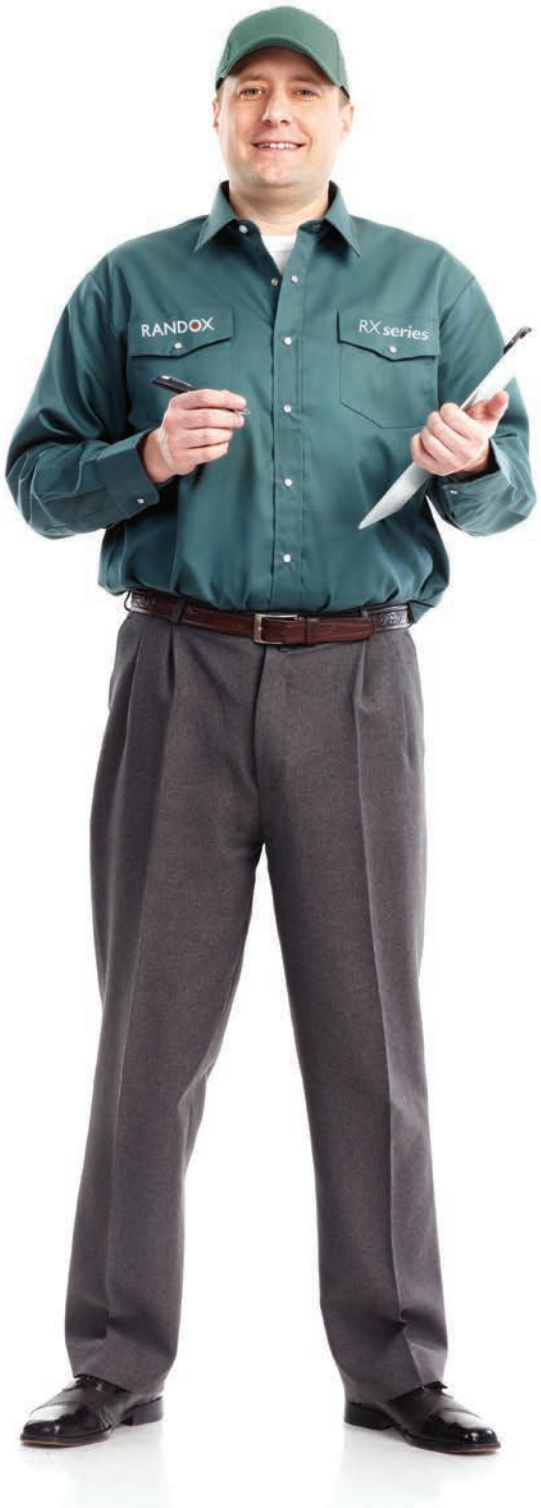
MEDICAL LABORATORY EVALUATION (MLE) PROGRAM
25 Massachusetts Avenue, NW, Suite 700
Washington, DC 20001-7401
(800) 338-2746 or (202) 261-4500

NEW YORK STATE DEPARTMENT OF HEALTH
State of New York Department of Health
The Governor Nelson A. Rockefeller State Plaza
P.O. Box 509
Albany, New York 12201-0509
(518) 474-8739

COMMONWEALTH OF PENNSYLVANIA
Department of Health, Bureau of Laboratories
P.O. Box 500
Exton, Pennsylvania 19341-0500
(610) 280-3464

PUERTO RICO PROFICIENCY TESTING SERVICE
Public Health Laboratories of Puerto Rico
PO Box 70184
San Juan, Puerto Rico 00936-8184
(787) 274-6827

WSLH PROFICIENCY TESTING PROGRAM
465 Henry Mall
Madison, Wisconsin 53706-1578
(800) 462-5261

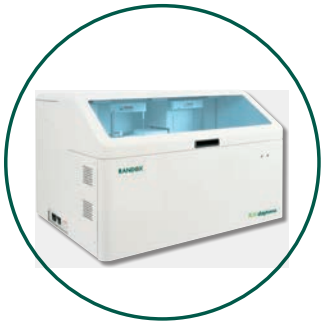


Say hello to John...

John's responsibility is to ensure your analyzer is fully operational at all times.

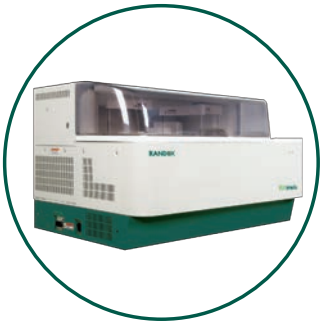
Due to the exceptionally low downtime of our RX analyzers, we thought we should introduce you to John as you will be seeing very little of him in your laboratory this year.

At least you know he's here *if* you need him!



RX daytona

180 photometric tests per hour
450 tests per hour including ISE



RX imola

400 photometric tests per hour
560 tests per hour including ISE

Minimize downtime, maximize your time

Robust hardware combined with intuitive software and low maintenance provides unrivalled performance with superior reliability.

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Proficiency Testing: COLA Processes

COLA is dedicated to provide ample resources to reinforce Proficiency in your Laboratory's Testing

Proficiency testing measures the laboratory's ability to analyze specimens of unknown value and obtain accurate results within an established range. If the laboratory has adequate instrument maintenance, personnel training, and quality control procedures, proficiency testing should be successful. Unsuccessful proficiency testing is an indication of possible problems in these areas, and a warning that patient testing may not be accurate.

CLIA and COLA require laboratories to participate in proficiency testing (PT) for regulated analytes only. COLA also strongly recommends participation in PT for unregulated analytes and waived tests. Proficiency testing or split specimen testing with another laboratory for unregulated analytes is an acceptable check. For split specimen testing, five specimens should be split twice a year. See new COLA criteria WAV 10 (COLA Accreditation Manual June 2013), which requires PT for waived testing. At this time, this criterion is considered educational only, and will not constitute a deficiency citation if cited during your survey. Despite the regulatory emphasis given to proficiency testing for regulated and non-waived analytes by CMS, COLA believes that proficiency testing is an integral part of quality laboratory practice that has value for all testing.

As required by the Centers for Medicare and Medicaid Services (CMS), COLA monitors laboratory Proficiency Testing (PT) performance of regulated analytes and are subject to PT and inspection requirements for all COLA Accredited Laboratories.[1] CMS may take an adverse action against a laboratory that fails to participate successfully in an approved PT program, refers PT samples to another laboratory, or communicates PT results prior to the PT program end date for submission of results.[2] COLA is not a Proficiency Testing (PT) provider, but does monitor your facility's PT performance and offers guidance to help you achieve successful results. COLA will recognize any CMS-approved PT program, and we have an agreement to exchange data with all these providers.

The monitoring process begins a year in advance when COLA contacts each Proficiency Testing (PT) provider[3] to obtain a list of their offerings and PT sample shipping calendar for the upcoming year. COLA uses this information to develop a schedule for results reporting of the three (3) required PT Events for the year, which is made available from each provider for all COLA Accredited Labs. Each lab completes the PT Event and submits their results to the provider for analysis. Each lab's PT Event results performance report are not only sent from the provider to the laboratory who performed the PT Event, but also to COLA's Accreditation Department to ensure compliance and documentation with CLIA and COLA guidelines. For practices with multiple locations, each of which has its own CLIA number, each laboratory location must enroll separately in proficiency testing and independently perform its own proficiency testing.

When the PT Event data is obtained, it is reviewed to determine each laboratory's PT Event performance. This surveillance results in two possible scenarios:

- **PASS – Satisfactory Performance** *No PT Event performance problems are identified.* The laboratory has obtained passing scores for each analyte, test, subspecialty, or specialty. No further action is required until the next PT Event when the process is repeated.
- **FAIL – Unsatisfactory Performance** *PT Event performance problems are identified.* The laboratory has received at least one failing score. Previous PT Event scores are reviewed to determine a pattern of performance, which determines the next action to be taken.

So that the laboratory complies with CLIA, COLA uses the same proficiency testing enrollment requirements and grading criteria as the federal government. Laboratories are required to achieve 80% correct results for most analytes, specialties, and subspecialties, in order to receive a passing score for that event.

The only exceptions are ABO/Rh and compatibility, in which the lab must achieve a score of 100% for each PT event. COLA monitors your laboratory's performance for each analyte and specialty through our PT Tracking System. Laboratories that do not attain the minimum satisfactory score for an analyte, subspecialty, or specialty for a single testing event, or multiple testing events, are subject to additional requirements. All Proficiency Testing (PT) records including instrument tapes, test report forms, attestation statements, graded results, and corrective actions taken for all unsatisfactory scores and evidence of self-evaluation of any ungraded results must be retained for two (2) years at the laboratory site.

A report of FAIL will put the laboratory in one of two categories - Unsatisfactory

Performance or Unsuccessful Performance. *The most important thing to remember is, when a laboratory has had a PT failure it may indicate errors in the laboratory's testing processes and or procedures which can have a negative impact in the quality of patient test results.* COLA employs a three stage Quality Improvement Plan (QIP) process regarding PT failures.

QUALITY IMPROVEMENT PLAN Stages of Unsatisfactory/Unsuccessful Performance		
Failure Level	**Description**	**Required Actions for Labs**
QIP STAGE 1	Unsatisfactory Performance of PT	Laboratories must perform and retain copies of Corrective Action.
QIP STAGE 2	Unsuccessful Performance of PT	Laboratories must submit proof of Corrective Action (Corrective Actions Checklist) to COLA within 21 days.
QIP STAGE 3	Repeated Unsuccessful Performance of PT	Laboratories are mandated to Cease Testing for six (6) months and pass two (2) consecutive PT events, either scheduled, unscheduled or a combination of both.

QUALITY IMPROVEMENT PLAN - STAGE 1:

Unsatisfactory Performance is failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event. (At a minimum, the last three previous PT events are reviewed by COLA to ensure that there is only the single failure and that no other failure pattern exists.) Like the federal CLIA requirements, COLA standards require that a laboratory failing a single testing event (Unsatisfactory Performance) take appropriate action to identify the problem, correct it, and document the corrective action in the laboratory's records. Properly addressing the root cause of the problem traditionally will prevent recurrence of the problem. This process is crucial in preventing Unsatisfactory Performance from becoming Unsuccessful Performance. A COLA laboratory can voluntarily withdraw from patient testing until it corrects its PT performance. The laboratory is not given a time penalty, nor is its accreditation jeopardized by the failure of a single specialty.

QUALITY IMPROVEMENT PLAN - STAGE 2:

Unsuccessful Performance is failure to attain a satisfactory score for an analyte, test, subspecialty, or specialty for **two consecutive or two-out-of-three consecutive testing events.** Laboratories with repeated PT failures (Unsuccessful Performance) must also take appropriate action to identify the problem, correct it, and document the corrective action in the laboratory's records. The original documentation must be retained in the laboratory for the appropriate retention period. In addition, laboratories with unsuccessful PT performance must provide COLA with written documentation of the corrective action taken. Labs may submit this documentation in the form of the laboratory's own or PT Provider Corrective Actions form, or the "COLA Corrective Actions Checklist", a copy of which the lab will receive from COLA once the second PT Event failure results have been received and reviewed from the PT provider. Completed corrective actions documentation must be mailed, faxed, emailed to COLA, or uploaded to the document repository www.COLAcentral.com, within 21 days of receipt of PT failure notification by COLA.

The following patterns indicate Unsuccessful Performance where "F" is a failing score and "P" is a passing score:

- FF (last two events)[4]
- FPF (last three events)
- PFF (last three events)

QUALITY IMPROVEMENT PLAN - STAGE 3:

Under COLA, laboratories with ***continuing or repeated* Unsuccessful Performance will be asked to cease testing** the regulated analyte, specialty, or subspecialty exhibiting the problem. To rectify the cease testing mandate, the COLA laboratory must meet COLA's reinstatement requirements, which, like CLIA, includes a **mandatory six-month cease testing**.

The laboratory must **cease testing** the analyte/test, subspecialty, or specialty when a pattern of repeated **Unsuccessful Performance occurs:**

- FFF (last three events)
- FFPF (last four events)
- FPFF (last four events)
- FPFPF (last five events)

Once a laboratory has been placed at cease testing for an analyte/test, subspecialty, or specialty they must remain at cease testing for a period of **not less than six (6) months from the date of cancellation, limitation or suspension of the CLIA certificate.** This is mandated by Centers for Medicare &

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PROFICIENCY TESTING: COLA PROCESSES

Medicaid Services, HHS regulation §493.803 Subpart H.[5] The date of Cease Testing specifically refers to the date of the letter from COLA, as the Accrediting body. This letter is sent to labs via postal mail, as well as uploaded on COLACentral, where the Laboratory Director and identified staff would receive an email alert regarding account activity. CMS is also sent a copy of the letter within thirty (30) days. The Laboratory Director must sign and return the "Acceptance of Cease and Desist" letter to COLA within 10 days of receipt.

At any step of the PT process, the laboratory has two options to consider in regards to a failed analyte/test, subspecialty, or specialty. The lab can either remove the test from their test menu or apply for reinstatement. If this occurs at QIP Stage 3, the laboratory must remain at cease testing for a minimum of six months, for the failed analyte/test, subspecialty, or specialty, regardless of which action they take. Continuing to test an analyte, specialty, or subspecialty after being directed by COLA to cease testing because of failure to meet proficiency test performance criteria for that analyte, specialty, or subspecialty is cause for termination of a laboratory's Accreditation by COLA.

WHERE DO WE GO FROM HERE?

COLA strives to simplify the reinstatement process, especially to resolve any failing PT Event. To reinstate testing, the laboratory must pass two consecutive PT Events. These events can be two routine events, two off-schedule events, or one routine and one off-schedule event. The PT provider will send results to COLA automatically, but this may not happen until several weeks after the laboratory receives a copy of the graded results. To allow the laboratory to reinstate and resume testing once the six month period is completed, COLA encourages the laboratory to send us a copy of their results, immediately after they have been received by the lab.

COLA understands that laboratory personnel may need help when investigating the root cause of PT failures, developing corrective actions to address them, and/or developing plans to prevent them from recurring, so we offer several different resources of assistance. COLA Resources Inc. (CRI®) offers in-person or online help to reinforce Proficiency in your Laboratory's Testing. These resources include the COLA Accreditation Manual (revised June 2013), online courses such as the Continuous Quality Program & Webinars, downloadable LabGuides, and our latest resource, the new CRI® IQCP educational platform launching in October 2013.

The goal of Proficiency Testing is help ensure accurate laboratory testing which, in turn, leads to quality patient care. COLA and CRI® help your lab achieve this goal by monitoring PT performance and providing the tools and education for you to be able to complete PT events with confidence!

RESOURCES:

[1] *Proficiency Testing (and/or other means used to verify test accuracy) for unregulated analytes is monitored through the PT review process during each laboratory's biennial COLA survey.*

[2] COLA Accreditation Manual - June 2013

[3] http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html

[4] Unless the laboratory's first PT event is a failing score, the patterns listed in this article always follow two consecutive passing events.

[5] Code of Federal Regulations Title 42 Part 493 Laboratory Requirements (Revised 10/01/2011) http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol5/pdf/CFR-2011-title42-vol5-part493.pdf

CRI® IQCP Workshop Attendee Follow Up

Greetings IQCP Workshop Participant,

On behalf of CRI® I would like to again thank you for participating in our first CRI® IQCP Workshop in St. Louis! Our expectation is that the IQCP Workshop provided much needed information, insight and confidence for you to create and implement an IQCP for your laboratory.

As a Thank You, CRI® is extending an EXCLUSVE offer to the IQCP Workshop participants. Please visit our website www.criedu.org Enter Coupon Code: CRIIQCP50 at checkout and receive an instant $50 discount on the CRI® IQCP E-Optimizer and IQCP Implementation Guide. This exclusive coupon code will only be active from November 1 – December 2, 2013!

Remember to visit our websites www.criedu.org or www.labuniversity.org to access our complete portfolio of IQCP products:

- CRI® Educational Video: Implementing an IQCP (Individualized Quality Control Plan)
- Webinar CEexpress 21: COLA Update – Individualized Quality Control Plans*
- Webinar CEexpress 16: CMS CLIA Update – Current and Future Events*
- Risk Management in the Clinical Laboratory*
- LabGuide 53: Individualized Quality Control Plans

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In addition, CRI® is excited to announce our upcoming series of IQCP Webinars and Workshops, presented by leading experts in the field of IQCP, including Judy Yost, CMS' Director of the Division of Laboratory Services. Program schedule and details will be available on our website: www.criedu.org and www.labuniversity.org

Our mission at CRI® is to ***"Provide educational and consultative services aimed at improving laboratory medicine and patient care."*** We would like to thank you for your support of our mission and look forward to our continued partnership as we work to meet this mission.

Respectfully,

Rose Mary Casados
CRI® President

EQC changes to IQCP January 1, 2014

What changes and what remains the same.

Starting January 1, 2014 CMS is implementing a new alternative Quality Control (QC) option. CLIA laboratories can voluntarily begin to transition away from Equivalent Quality Control (EQC) and begin using the default CLIA Quality Control (QC) requirement or Individualized Quality Control Plan (IQCP). The cornerstone of IQCP is identifying, evaluating, and controlling potential sources of error relevant to the individual laboratory. Performing a Risk Assessment will result in the development of an IQCP, achieved by implementing targeted quality control measures. According to CMS "There will be an IQCP Education and Transition Period to allow laboratories an opportunity to learn about IQCP and implement their chosen QC policies and procedures. The IQCP Education and Transition Period will begin on 01/01/2014, and conclude on 01/01/2016." [1]

Laboratories will have three acceptable QC options during the IQCP Education and Transition Period:

1. Follow the CLIA QC regulatory requirements as written
2. Continue to follow the Equivalent Quality Control (EQC) procedures as described in the current Interpretive Guidelines [2]
3. Implement IQCP

At the end of the Education and Transition Period (1/1/2016), EQC will no longer be an acceptable option to meet CLIA QC requirements and will be removed from the regulatory guidelines. Therefore, it is important that laboratories understand that on January 1, 2016, only two options will remain to meet CLIA QC compliance.

1. Follow the CLIA QC regulatory requirements as written (Two levels of QC for each day of testing), or
2. Implement IQCP, as applicable

The Centers for Medicare and Medicaid Services (CMS) define IQCP as the "Right QC" for the test as it is performed in your laboratory given your lab's unique circumstances.

IQCP is Quality Control based on Risk Management.[3] Risk is a measure of the severity of the impact of a potential error, multiplied by the probability of how likely it is that the error will occur, and your ability to detect the error if it should occur. Identifying, evaluating, and controlling these potential errors through quality control measures is the cornerstone of IQCP.

IQCP is inclusive. While only specific tests qualified for EQC (Equivalent Quality Control – the alternative QC program replaced by IQCP), all specialties (except Pathology, and its associated subspecialties of Histopathology, Oral Pathology, and Cytology) are eligible for IQCP.

Keep these important points in mind:

- IQCP includes, for each test, a risk assessment performed within your laboratory based on your unique circumstances.
- IQCP recognizes that all phases of testing impact quality; therefore, the scope of risk assessments must encompass the entire testing process: pre-analytic, analytic, and post-analytic phases.
- IQCP focuses on the "right" QC for each test, which is not necessarily less frequent QC.
- IQCP is formalized as a documented Quality Control Plan. It may be electronic or hard copy; it may be documented as part of the testing procedure or as a separate manual.

IQCP is voluntary. Like the other CLIA QC requirements, IQCP is intended for non-waived testing; however, you may perform a risk assessment and develop an individualized plan for ANY test, including waived testing. You may use IQCP for all, some, or none of the test systems in your laboratory. Laboratories can continue to run the CLIA "default" QC – two levels of external control each day of patient testing – instead of implementing Individualized QC Plans.

The manufacturer's QC recommendation will remain the minimum acceptable QC protocol, but it may be necessary to develop an IQCP if you chose to follow this protocol. If the manufacturer's QC recommendations for the test are less than the default CLIA requirement of two levels per day (for instance, the manufacturer's instructions say to run controls with each lot number change), your lab may:

- Perform the default requirement of two levels per day AND run controls with each lot number change (to satisfy the manufacturer's requirement); OR
- Develop an IQCP for the test to show that all relevant errors will be detected if the manufacturer's protocol is followed.

In other words, you may not simply follow the manufacturer's less stringent QC requirements without first performing a risk assessment to determine if this amount of QC is the "right" QC.

An IQCP is not necessary if the manufacturer's stated number, type, and frequency of control procedures meet or exceed the CLIA requirement of two levels of external controls each day. If the manufacturer's instructions specify more than two levels per day, you may ***not*** use an IQCP to reduce the number of daily controls to less than the manufacturer's recommendation. In other words, since the manufacturer's QC recommendations will remain the minimum acceptable QC requirement, if the manufacturer recommends two or more levels per day, your lab may not develop an IQCP with less than the number specified by the manufacturer.

COLA Resources Inc. (CRI®) anticipated the need and has created a comprehensive program to address the critical changes in laboratory QC. The CRI® IQCP Program is designed to assist you in developing and implementing IQCP, customized to the diversity and unique testing conditions in your laboratory. Our goal is to provide education and technical guidance through the entire process, relieving the burden of Lab Directors who often have limited time and capacity to create QC programs from scratch.

Although the debate surrounding QC may continue, healthcare providers at all levels of patient care (physicians, nurses, laboratory personnel, etc.) will agree that IQCP will enable laboratories to meet their unique quality control requirements while achieving regulatory compliance, thus paving the way to continuous quality patient care.

RESOURCES:

[1] *IQCP announcement letter for CLIA CoC and PPM laboratories* [PDF, 100KB] http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-announcement-letter-for-CLIA-CoC-and-PPM-labs.pdf

[2] *Interpretive Guidelines for Laboratories - Appendix C. Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services.* www.cms.gov/Regulations-and-guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html

[3] COLA Resources Inc. *IQCP Implementation Guide*. 2013.

"Transfusion Only" Laboratories

Is blood transfused in your facility? If so, your laboratory must meet certain criteria – even if you do not perform any transfusion related testing.

Consider this scenario:

> You work in a small Hematology/ Oncology office lab. You do NOT perform blood typing, compatibility testing, or any other transfusion related testing. Blood is not stored in the laboratory. To the best of your knowledge, patients do not receive blood transfusions at your facility.
>
> *However, patients ARE receiving blood transfusions at your facility.* Blood and blood products are tested and cross-matched by an outside contracted blood service, which delivers the products directly to nursing staff. The nursing staff prepares the patients, and takes the necessary steps to properly transfuse blood and blood components.
>
> Since your laboratory was not aware of these activities, and did not process the blood transfusion for compatibility, the assumption may be that you *"do not have to be concerned about these transfusions."*

This assumption is incorrect...

This scenario describes a "Transfusion Only" laboratory. The blood is being transfused to patients under your laboratory's CLIA number therefore your laboratory and your Laboratory Director are responsible for the transfusions. Your laboratory and transfusing facility must comply with certain criteria, specifically those criteria related to blood procurement and administration, including monitoring patients for possible transfusion reactions. In addition, related criteria affects devices and supplements that could be utilized during the transfusions, such as blood warmers and IV solutions.

Your lab and Laboratory Director must be involved in the development, approval, and monitoring of policies and procedures concerning these processes. This will have to be coordinated with nursing staff; however, ultimately, it is the Laboratory Director's responsibility to ensure compliance.

Even in full-service blood bank facilities, the laboratory's responsibility does not end when the blood / blood components leave the lab. The FDA requires tracking the products from the time of blood collection from the donor; through the product manufacturing process, including storage and transportation; until final disposition, whether "transfusion" or "discard". The patient must be properly identified prior to transfusion and monitored for reactions during and after transfusion. All actions must be documented and documentation must be properly maintained. Some records must be retained indefinitely.

"Transfusion Only" laboratories are bound by the same COLA criteria as other laboratories. However, due to the limited services provided by transfusion only labs, some of the criteria do not apply. There is not a single evaluation grouping that lists all of the applicable criteria; rather these criteria are listed among the core criteria and in the "Immunohematology & Transfusion Services" evaluation grouping in the COLA Accreditation Manual. Please contact COLA if you have questions regarding specific criteria that must be met.

TECHNICAL CONSIDERATIONS FOR YOUR LABORATORY

Laboratories should be aware that the following tests, on both donor and recipient testing, are considered high complexity when performed for the purpose of compatibility and transfusion of blood products.

- ABO and Rh Type
- Antibody Screen
- Compatibility

TRANSFUSION SERVICES:

*A facility that is not involved in the collection or processing of blood products, but **is** involved in the administration of blood products to patients.*

Transfusion Services is further divided into two categories.

FULL TRANSFUSION SERVICE:

A facility that performs immunohematology testing and administration of blood products.

BLOOD STORAGE AND ADMINISTRATION:

A facility that does not perform immunohematology testing on site, but receives and administers blood products.

For these facilities, not all criteria will be applicable, considering the limited level of service.

- Direct Antiglobulin Test (DAT)
- Unexpected Antibody Identification
- Antigen typing

As such, the laboratory must ensure that a qualified General and Technical Supervisor is identified to oversee the transfusion service. The functions of a Transfusion Service are unique in comparison to other specialties within the laboratory. Frequently the individual(s) that fulfill the duties of General and Technical Supervisor for other specialties of the laboratory do not have the education, training and experience to perform these functions for transfusion service. For this reason, many laboratories will need to designate different individuals to fill the role of General and Technical Supervisor for the Transfusion Service. These individuals must meet requirements for education and experience as defined in the Personnel Requirements chart in Section III of the COLA Accreditation Manual. This section also details the responsibilities of the individual holding each position.

As part of the laboratory's personnel competency assessment program, the education, training, and performance of duties and responsibilities of the General and Technical Supervisor should be assessed to assure quality of laboratory service and promotion of patient safety.[1]

ENSURING COMPLIANCE

- First you must **determine if transfusions are being performed in your facility**. If the name includes the terms "Specialty Hospital," "Surgical Center," "Hematology / Oncology," "ABG laboratory," or something similar, patients are probably receiving blood transfusions.
- **Engage Nursing/Allied Health staff to ascertain and understand current transfusion procedures in your facility.** Develop a working relationship with Nursing/Allied Health staff and management to ensure all involved parties understand and follow applicable regulations.
- **Review policies and procedures to ensure all required elements are addressed.** The blood supplier should have written procedures pertaining to patient specimens, blood products, and requirements for suspected transfusion reaction work-ups, which can be incorporated into your facility's procedures. Special attention should be noted for adverse reaction events and/or deaths, as these situations must be reported to the COLA Accredited Lab Director for documentation purposes as well as the FDA (usually via the blood supplier) within the same defined timeframes.
- **Periodically, observe transfusions to confirm procedures are being performed properly.** When your laboratory is being surveyed by COLA, the surveyor may request to see the policies and procedures manual used by the nursing staff for transfusion activities. This is done to ensure harmonization in compliance and effective communication between departments.
- **Ensure records are maintained appropriately.** Retain all records beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical reactions. Retention period shall be:
  - Ten years from the date that processing was complete, or
  - Six months after the latest expiration date for individual products, whichever is later;
  - Otherwise, records should be retained indefinitely.

Possible questions to ask in assessing activities include, but are not limited to:

Blood & Blood Products

- Who supplies the blood / blood products for transfusion?
- Is there a written agreement with the blood supplier indicating specific services they will provide?
- Are products manufactured, stored, and transported according to FDA current Good Manufacturing Practices (cGMP)?
- Are all transfusion related tests performed in a CLIA-certified laboratory?

Nursing/Allied Health staff

- Is Nursing/Allied Health staff trained to follow readily accessible written transfusion-related procedures?
- Is their adherence to these procedures monitored?
- Is their competency to perform these procedures assessed according to appropriate timelines?

Pre-transfusion practices

- Does all involved staff know how to properly order blood / blood components to be transfused, including those for emergency transfusion?
- Are patients properly identified prior to drawing specimens to be sent for blood typing and compatibility testing?
- Are specimens properly labeled at the patient's bedside according to blood supplier specifications?
- Are specimens stored and transported appropriately?

Transfusion procedures

- Are patients properly identified prior to transfusion?
- Are blood / blood components transfused immediately upon arrival?

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"TRANSFUSION ONLY" LABORATORIES

- If not, are they stored properly, with appropriate temperature monitoring, until transfusion?
- Are other solutions transfused at the same time as blood / blood components?
- If so, are they limited to only appropriate solutions (e.g., normal saline)?
- Are patients monitored for possible adverse transfusion reactions during and after the procedure?

Post-transfusion practices

- Are suspected adverse transfusion reactions promptly and thoroughly investigated by appropriate personnel according to readily accessible written procedures?
- Is the investigation properly documented?
- Are blood / blood components and other transfusion materials properly disposed?
- Are all transfusion records available for review and maintained for the appropriate retention time?

Documentation and tracking

- Is there a method in place to monitor the number of blood and blood components ordered and transfused?
- Are all ordered products tracked until final disposition (transfused, discarded, returned to blood supplier, etc.)?
- Are problems investigated, resolved, and monitored for recurrence?

COLA Accreditation Transfusion Service Criteria[2]		
Nursing/Allied Health Staff Responsibility	**Lab Responsibility**	**Blood Center Responsibility**
TS2, TS3, TS4, TS17, TS21, TS23, TS31, TS32, TS 33 TS34, TS35, TS36, TS37, TS60, TS 61, TS62, TS63, TS64, TS65, TS72, TS74, TS75, TS76 TS83, TS84	TS2, TS3, TS4, TS5, TS6, TS7, TS8, TS9, TS10, TS11, TS12, TS13, TS14, TS15, TS16, TS17, TS18, TS19, TS20, TS21, TS22, TS23, TS31, TS32, TS 33, TS34, TS35, TS36, TS37, TS48, TS49, TS50, TS51, TS52, TS53, TS54, TS60, TS61, TS62, TS63, TS64, TS65, TS66, TS68, TS69, TS70, TS72, TS73, TS74, TS75, TS76, TS83, TS84, TS85, TS86, TS94, TS95, TS96, TS97, TS98, TS99, TS100, TS101, TS102, TS103	TS38, TS39, TS40, TS41, TS42, TS43, TS44, TS45, TS46, TS47, TS55, TS56, TS57, TS58, TS59, TS60, TS61, TS62, TS63, TS64, TS65, TS66, TS67, TS68, TS69, TS70, TS71, TS72, TS73, TS74, TS75, TS76, TS77, TS78, TS79, TS80, TS81, TS82, TS84, TS85, TS86, TS87, TS87-TS103

The more you know about transfusion practices in your facility, the more you can ensure they are compliant with all applicable regulations. However, as stated earlier, you are not expected to do it alone. Your role is mainly one of monitoring to ensure compliance, but should also include staff education. Personnel who write, follow, monitor, and enforce the policies and procedures in your facility are those who are involved in the collection, storage, and transport of patient specimens and in the storage, transport, and transfusion of blood / blood components. By taking the steps necessary to ensure that all parts of your "Transfusion Only" lab are running smoothly, you can help ensure patient safety and excellence in this critical component of patient care.

RESOURCES:

[1,2] COLA Accreditation Manual - Revised June 2013

Immunohematology and Transfusion Services

Insights from COLA's Accreditation Manual, revised June 2013

The 2013 COLA Accreditation Manual is a wealth of information regarding your laboratory's operation and oversight. In addition to the general Criteria and Self-Assessment questions, the Immunohematology Specialty section contains a separate set of Criteria and Self- Assessment questions that only applies if your laboratory performs compatibility testing, antibody identification, OR if your facility transfuses blood products to patients.

The general Immunohematology criteria address requirements for blood typing and antibody screens, and the appropriate control procedures for these tests. If your laboratory is involved in the transfusion of blood products in your facility, there are additional "TS" criteria in a separate Immunohematology and Transfusion Services section (following the Quality Assessment criteria) that apply to you.

This set of criteria is divided with section headings that indicate the aspect of laboratory operation being addressed. For example, the Immunohematology and Transfusion Services questions have sections for:

- Management
- Storage, Transportation, and Dating
- Quality Control
- Recipient Testing for Transfusion
- Computerized Systems
- Recipients with Special Needs
- Dispensing Requirements
- Units for Reissue
- Transfusion Reactions
- Record Keeping and Documentation

INTRODUCTION

The following standards and criteria are applicable to any facility involved in the provision of transfusion services. This includes facilities that do not perform testing within the specialty of Immunohematology, but administer blood products to patients.

Facilities requiring FDA Registration:

- Those that engage in the manufacture of blood products, to include the collection, component preparation, product testing, labeling, storage, and distribution of blood products.
- Those that manipulate blood products including irradiation, freezing, deglycerolizing, and washing cells.

Facilities that are approved for Medicare reimbursement may be exempt from FDA Registration if their services are limited to the following items (CFR 607.65 f):

- Engage in compatibility testing and transfusion of blood products, but neither routinely collect nor process blood and blood components.
- Those that may collect and process blood and blood components only in an emergency situation as determined by a responsible person and documented in writing.
- Those that perform therapeutic collection of blood or plasma that is not intended for transfusion.
- Those that solely prepare Red Blood Cells or Recovered Plasma, pool Platelets or Cyroprecipitated AHF for ease of transfusion, or issue bedside leukocyte reduction filters.

NOTE: The blood products described above must be intended for use within the facility. If the facility were to send the product to another facility, FDA registration is required.

For additional information contact the Center for Biologics Evaluation and Research at the FDA (by phone 301-827-3546 or email bloodregis@cber.fda.gov).

There are several types of facilities involved in the provision of transfusion services.

Blood Banks: A facility that collects and/or processes blood products in preparation for transfusion. Such facilities may also distribute blood products to outside facilities, perform immunohematology testing and administer blood products to patients.

Transfusion Services: A facility that is not involved in the collection or processing of blood products, but is involved in the administration of blood products to patients.

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IMMUNOHEMATOLOGY AND TRANSFUSION SERVICES

COLA further divides Transfusion Services into two categories.

1. **Full Transfusion Service:** A facility performs immunohematology testing and administration of blood products.
2. **Blood Storage & Administration:** A facility that does not perform immunohematology testing on site, but receives and administers blood products. For these facilities, not all criteria contained in this document will be applicable considering the limited level of service.

COLA Accreditation includes an evaluation of laboratory policies, processes, and records associated with the following:

- Laboratory testing performed on potential blood donors (such as hemoglobin and hematocrit)
- Laboratory testing performed on blood components (such as ABO& Rh, HIV, hepatitis, etc.)
- Laboratory testing of blood products for compatibility with an intended recipient (such as ABO & Rh, Antibody screening, compatibility, etc.)
- Storage of blood products
- Dispensing blood products for intended transfusion
- Basic requirements associated with administration of the product to the intended recipient
- Investigation of suspected transfusion reactions and associated laboratory testing (such as ABO & Rh, DAT, haptoglobin, etc.)

COLA Accreditation does not include evaluation of policies, processes, and procedures associated with donor suitability, collection of the blood product, manufacturing (processing) the blood product, and recall of blood products or donors.

COLA Criteria for Record Retention for Transfusion Services

CLIA regulations state that laboratories providing services in the specialty of Immunohematology must comply with applicable FDA regulations.[1] COLA criteria, documented in the COLA Accreditation Manual under Section III: COLA Criteria for Quality Laboratory Performance – Transfusion Services Criteria TS 103 requires records be maintained for a period of 10 years. If applicable to your laboratory, please adjust your record retention procedures accordingly. In addition, it is a regulatory requirement that all laboratories ceasing operation make provisions to ensure that all records are maintained and preserved, and available for the specified time frames. The detailed requirements for documentation and record retention can be also found in the COLA Criteria for Quality Laboratory Performance (Section III).

Record Retention

TS 103 R

Does the laboratory retain all transfusion-related documentation for the length of time specified by the FDA at 21 CFR 606, Subpart I?

Retain all records beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical reactions. Retention period shall be:

- *Ten years from the date that processing was complete, or*
- *Six months after the latest expiration date for individual products, whichever is later*
- *Otherwise, records should be retained indefinitely*

Types of Records to Retain[2]

Records must be maintained concurrently with the performance of each significant step in the collection, processing, compatibility testing, storage, and distribution of each unit of blood and blood components so that all steps can be clearly traced. All records must be legible and indelible. They must include the following:

- Identification of the person performing the work
- Dates for all entries
- Test results as well as interpretation of results
- Expiration dates assigned to specific products

RESOURCES:

[1] Clinical Laboratory Improvement Amendments, Subpart K – *Quality Systems for Nonwaived Testing,* Sec. 493.1271(b), "Standard: Immunohematology – Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b)." http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_c_lab.pdf; last accessed October 2013

[2] COLA Accreditation Manual- Revised June 2013 p. 132, "PST 27 R LABORATORY DOCUMENT & RECORD RETENTION REQUIRMENTS"

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