Preparation Educational Materials For The Certified Clinical Laboratory Quality Professional (CCLQP) Examination

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Introduction:

The Accreditation and Quality Doctor (TAAQD) in collaboration with the CPD Standards Office (**Our Accreditation Body)** are offering two professional certificate programs:

1. Certified Clinical Laboratory Quality Professional (CCLQP), and
2. Certified Clinical Laboratory Safety Professional (CCLSP), which are the first of their kind worldwide. They enable laboratory professionals, to differentiate themselves by becoming certified as CCLQP and or CCLSP.

The certificate programs are personally developed by The Accreditation and Quality Doctor (TAAQD), a pioneer provider of clinical laboratories quality and safety educational training materials for more than 10 years. The certifications cover everything about accreditation, quality, and safety in clinical laboratories from "A" to "Z". The attendees will gain skills they can immediately apply in their laboratories and earn a designation certificate at the same time.

Certificate / Certification Programs:

1. Certified Clinical Laboratory Quality Professional (CCLQP):

CCLQP certification course is developed to have hands on knowledge that will have a clear, direct, and positive impact on the laboratory professionals ability to improve and sustain quality and safety in their laboratories. Whether you are looking to enhance your skills within your current position as a quality manager or looking to make a change by getting a quality manager position, or simply for your personal development by improving your knowledge of laboratory quality, the CCLQP is the right course for you.

The course goes along with an examination (if you choose to take it) that gives you the opportunity to earn a certificate in the clinical laboratory quality field and demonstrate your mastery of the subject matter.

The CCLQP certification course gives an understanding of clinical laboratories quality and its implementations. **List of topics included / covered in this course**:

1. Quality Assurance In Clinical Laboratories
2. Specimens' Stages: Preanalytical, Analytical, Postanalytical
3. Quality Control (QC) In Clinical Laboratory
4. Writing Policies/Procedures (SOPs / IPPs)
5. Quality Management Program for Clinical Laboratories
6. Implementing a Document Control Program In Your Laboratory
7. Training Checklists Vs. Competency
8. Introduction to CAP Accreditation
9. External Quality Program-Proficiency Testing (PT)

10. Maintenance In Clinical Laboratories
11. Panic (Critical Values) / LIS (Lab Information System) / Quality of Water / Specimens And Records Retention
12. Verification / Validation for Qualitative Instruments / Methods / Tests
13. Verification / Validation for Quantitative Instruments / Methods / Tests
14. POCT (Point of Care Testing) Program
15. Quality Indicators (Key Performance Indicators)
16. CAP Calibration Verification & Linearity (CVLs) Surveys
17. Equipment / Instruments Performance Qualification / Validation / Verification
18. CAP Inspection Stages (Before, During, & At The End Of The Inspection)
19. How To Be CAP Ready Every Day In Your Laboratory
20. How To Become An Excellent CAP Inspector
21. The Most Common CAP Inspections Deficiencies (Citations) & How To Avoid Them
22. Individualized Quality Control Plan (IQCP)
23. Introduction To Safety In Clinical Laboratories
24. Effective Leadership Skills
25. Effective Communication Skills
26. How to Provide Exceptional Customer Service?

Why Earn CCLQP Certification?

- Differentiate yourselves: Our accredited certifications are the first of their kind worldwide; be the first ones to earn them.
- They are an investment in your personal growth and your professional future.
- Demonstrates your commitment to your chosen profession. The certification validates your proficiency and commitment to your profession and can play an integral role in your career advancement.
- Improving your earning potential.
- Stand out from the crowd: Giving you a competitive advantage during your job search; which open more doors for opportunities for career advancement even in the face of a tough job market.
- Granting you the recognition you deserve, be different, be an elite.
- Connects you with a strong influential network of peers that shares your certification designation.
- Continuing to expand your skills and expertise through continuing education.
- Help you pass you accreditation inspections (i.e., CAP) with ease.

Examinations And Certifications:

A certified professional in our accredited CCLQP certification program attest that the clinical laboratory professional meet the competency requirements in the areas of clinical laboratory quality and can demonstrate his / her ability to apply the knowledge gained from the program and implement it to quality initiatives in their jobs.

In order to be certified and be awarded the designation CCLQP you must take and pass a written exam which attests and demonstrate your level of knowledge and skills of essential competencies for the subject matter.

The exam will be done online using a remote proctor via Testofy Testing Services who will be actively watching the candidates during the time of the exam administration in order to safeguard the exam reliability and authenticity. See, **Step # 4: Register, Pay, and Schedule for the Exam below for more information.**

The Exam for the CCLQP has 100 multiple choices questions. The passing score for the exam is 80%.

If you pass the exam, you will be awarded the designation Certified Clinical Laboratory Quality Professional (CCLQP), which you can use behind your name.

No one is allowed to use the certification designation unless they receive their final score and designation certificate.

If you fail an exam, you are allowed to retake the exam again, but you must pay the fees again every time you take the exam. See, Step # 4: Register. Pay, And Schedule For The Exam below for more information.

Steps To Prepare For And Obtain The CCLQP Accredited Certification:

Step # 1. Review the Course Content Outline:

While The Accreditation and Quality Doctor (TAAQD) **recommends** the use of its own preparatory materials to study, prepare, and take the exams, it does not mandate that you do so. You may study on your own from any source you like and take the exam. See below for more information.

Furthermore, while the use of the TAAQD materials and or resources by the candidates to prepare for the exams covers all areas of the exam and will make it easy on candidates to pass the exam, it does not guarantee that they will pass the certification exam(s). Candidates with clinical laboratory background should plan to spend about 1-2 months in preparation.

Each question on the exam could be linked directly to one or more of the tasks listed in the content / topics outline, see below for detailed content outline for the CCLQP exam. In addition, each question is designed to test if the candidate possesses the knowledge necessary to perform the task and/or has the ability to apply it to a job situation.

Certified Clinical Laboratory Quality Professional (CCLQP):

Detailed Content Outline For The CCLQP Examination:

Chapter One: Quality Assurance In Clinical Laboratories:

1. **What is Quality?**

6. **Who Must Be Assessed? By Whom?**
7. **How Do You Assess The Performance Of Supervisors / Consultants?**
8. **How Must We Assess Competency?**
9. **Chapter Summary**

Chapter Eight: Introduction to CAP (College of American Pathologists) Accreditation:

1. **What Is CAP?**
2. **Why CAP Accreditation?**
3. **How Can You Become CAP Accredited?**
4. **Other Things Needed In Order To Become CAP Accredited**

Chapter Nine: External Quality Program-Proficiency Testing (PT):

1. **What Is PT (Proficiency Testing)?**
2. **What Are The CAP (College of American Pathologists) Requirements For PT? How Does It Work?**
3. **What Do You Do When You Receive You PT Shipments?**
4. **How To Enter Your PT Results In CAP E-Lab Solution?**
5. **How To Check For and Print Your CAP PT Evaluation Reports?**
6. **How To Evaluate and Investigate Your CAP PT Evaluation Reports?**
7. **Graded Results:**
   - **7.1. Acceptable With <u>No Bias Or Exceptional Codes (Ungraded)</u>**
   - **7.2. Acceptable, But <u>Shows Trends (Bias Results)</u>**
   - **7.3. Unacceptable (Counted Against You)**
   - **7.4. Ungraded Results (Exceptional Codes)**
8. **PT Referral: What Does It Mean? How Can You Comply With It?**
9. **Alternative Assessment (AA)**
10. **Chapter Summary**

Chapter 10: Instruments / Equipment Maintenance:

1. **What Kind Of Equipment / Instruments Are We Talking About?**
2. **How Do You Know If An Equipment / Instrument Need Maintenance?**
3. **How Do You Know What Type Of Maintenance Needs To Be Done On Your Equipment / Instruments?**
4. **How Do You Prove That Your Maintenance Is Done On Your Equipment / Instruments?**
5. **What Would You Do If The Maintenance Is Not Done On Your Equipment / Instruments**
6. **What Would You Do About Maintenance If Your Equipment / Instrument Is Down?**
7. **Who Should Be Reviewing Your Maintenance In Your Laboratory?**
8. **How Often Should Your Maintenance Be Reviewed?**
9. **How Long Do You Keep Your Maintenance Records?**
10. **Chapter Summary**

Chapter 11: Panic (Critical Values) / LIS (Lab Information System) / Quality of Water / Specimens / Records Retention:

1. **Panic (Critical Values):**
   - **1.1. What Is It?**
   - **1.2. What is Required?**
2. **LIS (Lab Information System)**
3. **Quality of Water**
4. **Specimen / Records Retention**

Chapter 12: Verification / Validation for Qualitative Instruments / Methods / Tests:

1. **What Is The Definition Of Analytical Validation And Verification?**
2. **Who Is Responsible For Performing Analytical Validation & Verification?**
3. **What Are CAP Requirements for The Analytical Validation for Modified FDA-Cleared/Approved & LDTs Tests?**
4. **What Are CAP Requirements For Analytical Validation And Verification For Laboratories Subject To USA Regulations?**
5. **What Are CAP Requirements For Analytical Validation And Verification For Laboratories NOT Subject To USA Regulations (Non-USA Labs)?**
6. **How Do You Meet These requirements For Qualitative Methods/Tests? How Do You Perform Them?**
7. **Waived Test Implementation (Validation / Verification) And Approval**
8. **Chapter Summary**

Chapter 13: Verification / Validation for Quantitative Instruments / Methods / Tests:

1. **Introduction**
2. **How Do You Meet These requirements For Quantitative Methods/Tests? How Do You Perform them?**
   - **2.1. Analytical accuracy**
   - **2.2. Analytical precision**
   - **2.3. Reportable range**
   - **2.4. Reference Interval (Normal Ranges)**
   - **2.5. Any Other Performance Characteristic Required To Ensure Analytical Test Performance:**
     - **2.5.1. Specificity (Lower Detection Limit) And**
     - **2.5.2. Analytic Specificity (Interferences) If It Is Required By The Laboratory Policy, And Or The Test Manufacturer**
     - **2.5.3. Or Establish (Validate) Them If The Test Manufacturer Has Not Documented These Test Characteristics.**
3. **Waived Test Implementation (Validation / Verification) And Approval**
4. **Calibration Verification:**
   - **4.1. What Is Calibration Verification?**
   - **4.2. When Is It Required?**

8. **Where Do You Begin?**

Chapter 23: Introduction to Safety in Clinical Laboratories:

1. **What Is Safety?**
2. **Why Safety?**
3. **What Are The General Hazards In A Laboratory?**
4. **Safety Policies And Procedures (IPPs/SOPs)**
5. **Safety Training**
6. **Safe Work Practices Review By Risk Assessment? Why? How Often? By Whom? How?**
7. **Safety And Lab Accidents:**
   - **7.1. Why Accidents happen?**
   - **7.2. How to Manage and Minimize accidents / Risk?**
8. **General Safety Rules In The Laboratory**
9. **Disaster Preparedness**
   - **9.1. Internal**
   - **9.2. External**
10. **Evacuation Plan**
11. **Bloodborne Pathogens**
12. **TB Exposure Plan**
13. **Infectious Disease Reporting**
14. **PPE Provision, Instructions, And Usage:**
    - **14.1. Introduction**
    - **14.2. Selection**
      - **14.2.1. Latex Allergy**
    - **14.3. Training**
    - **14.4. When To Wear Gloves & Dirty Lab Coats**
    - **14.5. When NOT to Wear Gloves**
    - **14.6. When NOT to Wear Dirty Lab Coats**

Chapter 24: Effective Leadership Skills:

1. **What Is The Definition Of Leadership?**
2. **What Is The Difference Between A Leader & A Manager?**
3. **What Are The Qualities And Skills Of Leaders?**
4. **What Are The Different Types / Styles Of Leaders?**
5. **How Can I Become A Great & Effective Leader? A Leader That People Follow!**

Chapter 25: Effective Communication Skills:

1. **What Is The Definition Of Communication?**
2. **Why Is Communication Important?**
3. **What Are The Different Types Of Communication?**
4. **What Is The Communication Process?**

5. **How Do Improve Your Communication Process / Skills?**
6. **What Are The Barriers To Effective Communication & How Can You Overcome Them?**

Chapter 26: How to Provide Exceptional Customer Service?

1. **What Is The Definition Of Exceptional Customer Service?**
2. **Who Are Our Customers?**
3. **What Do Customers Want?**
4. **How Do You Provide Exceptional Customer Service?**
5. **How Do You Deal With Difficult / Complaining / Customers / Patients?**
6. **How Do You Reduce Complaints?**

Note: The exam questions might have one or more item that will require recall, application of knowledge, and analysis on the part of the candidate The exam is a multiple-choice examination consisting of 100 questions. Candidates will have 2.5 hours to complete the examination. The examination will terminate if testing exceeds the time allowed. To pass the exam, a candidate must earn 80% on the exam.

Step # 2: Choose Your Study Materials:

To help candidates who are planning to sit for any of our accredited certification examinations, the TAAQD offers preparation materials to support a variety of learning styles including:

1. **Live Courses / Seminars: Available upon request. To sponsor or request one, please contact us**.

2. **Online Lessons: Available 24/7 on our website. Buy and watch at your convenience, to view, click here (Purchase | Product categories | The Accreditation and Quality Doctor (TAAQD.org).**

3. **Virtual Courses (Webinars): Done 3 times per year**, **to register for one, click here**, **Or see Step # 3 Prepare For The Exams below for more information.**

4. **Self-Study Materials: Will help you prepare and pass the certification exams, which you are viewing here. To buy, click here**.

Note: Exams questions are written from the courses / content outlines (see above, **Step # 1. Review the Courses Content Outlines)** which are prepared from a variety of publications and resources in the field of Medical Technology.

Step # 3: Prepare For The Exams:

To Prepare For The Exams:

- **1. You may buy a copy of our Self-Study Preparation / Educational materials, which you are viewing here. The materials will help you prepare and pass the certification exams:**
    - **The cost for the preparation / educational materials for the Certified Clinical Laboratory Quality Professional (CCLQP) exam is $270.00. Click here to buy.**

- **3. Online Lessons: Available 24/7 on our website. Buy and watch at your convenience, to view, click here (Purchase | Product categories | The Accreditation and Quality Doctor (TAAQD.org).**

- **3. OR, attend one of our Virtual (Webinars) Preparation Courses with a live instructor: They are offered 3 times per year and can help prepare you for the exams:**
    - **1) Course Dates-March 21-25 (Registration ends on March 18)**
    - **2) Course Dates-July 4-8 (Registration ends on July 1)**
    - **3) Course Dates-November 7-11 (Registration ends on November 4)**
    - **The Fee: $500.00. To register for one, click here.**
- **Note:**
    - **If you take / attend a course with the instructor, you will receive a certificate with CE hours, too; see Certification Programs, above.**
    - Exams questions are written from the courses / content outlines (see above, **Step # 1. Review the Courses Content Outlines)** which are prepared from a variety of publications and resources in the field of Medical Technology.

- **4. OR, you may study on your own, using your own resources. Some suggested external options / resources that you can use to study for the exam(s) might include but should not limited to the list below:**
    - College of American Pathologists (CAP) Checklists
    - CLSI (Clinical & Laboratory Standards Institute: CLSI Guidelines) Publications
    - American Medical technologists (AMT)- https://www.americanmedtech.org
    - American Society of Clinical Pathologists (ASCP)- https://www.ascp.org
    - National Library of Medicine (NLM) articles (National Library of Medicine - National Institutes of Health (nih.gov)
    - Center for Disease Control and Prevention- https://www.cdc.gov
    - The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations- https://www.cdc.gov/clia
    - Joint Commission International- https://www.jointcommission.org/accreditation-and-certification/health
    - Point-of-Care Testing Guidelines. Washington State Clinical Laboratory Advisory Council- https://www.doh.wa.gov/Portals/1/Documents/Pubs/681021-POCT.pdf
    - The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) National Hospital Standards- https://portal.cbahi.gov.sa/english/cbahi-standards
    - Occupational Safety and Health Administration- https://www.osha.gov
    - National Science Teaching Association-https://www.nsta.org
    - Bureau of Environmental Health-https://www.mass.gov/orgs/bureau-of-environmental-health
    - Lab Manager Magazine-https://www.labmanager.com

- Health and Safety Magazine-https://www.healthandsafetymagazine.com
- WHO (World health Organization)-https://www.who.int
- American Society of Clinical Microbiology-https://asm.org
- American Society of Clinical Chemistry-https://www.aacc.org
- The No Complaining Rule, a book by Gordon
- Developing The Leaders Around You, a book by John C. Maxwell
- Becoming a person of Influence, a book by John C. Maxwell
- Leadership 101, a book by John C. Maxwell
- Is Everyone on the Bus, a book by Johnson Meller
- Breaking Through Speaking, a book by Mark Sanborn
- Encore Effect, a book by Mark Sanborn
- You Do Not Need a Tittle to be a Leader, a book by Mark Sanborn
- Up, Down, or Sideways, a book by Mark Sanborn
- The Fred Factor, a book by Mark Sanborn

Step # 4: Register, Pay, and Schedule For The Exam:

- **To register and pay for CCLQP certification exam, you must fill** the **Registration Form, and pay the fees before you can set for the exam, please see below:**

- **Exams Fees:**
    - **Cost For Certified Clinical Laboratory Quality Professional (CCLQP) exam is $390.00. Click here to register and pay.**

- **The exams are offered 3 times a year in April, August, and December:**
    - **April 14–16 (application due date ends on March 28)**
    - **August 12-14 (application due date ends on July 30)**
- **December 13–15 (application due date ends on November 30)**

- **The above dates are tentative.**

- **The exam(s) will be conducted using a remote proctor via Testofy Examination Center.** https://www.testofy.com**.**

- PayPal is the primary payment method, and we encourage you to use it. If you do not have one, **click here to create a PayPal account**.

- Though, we do not encourage that, but If you want to pay using other method such as wire transfer, please contact us at **AAQDoctor@gmail.com.**

- **Notes:**
    - **All exams fees are non-refundable.**

- **Candidates need to have access to a computer with web camera that is compatible with the exam center.**

To Schedule Your CCLQP Exam:

1. **Existing Users: Log in with your username and password information by clicking on this link: https://www.taaqd.org/customer-login**
2. **New Users: You need to create an account by registering on our website by following this link: https://www.taaqd.org/customer-register. Use your email as the username and pick a password of your choice.**
3. **To register for the CCLQP exam, click on the link: http://taaqd.org/cclqp-register.**
4. **Fill out the required information on the form. If something is not applicable, write "NA".**
5. **From the dropdown menu, pick up a date and time for your exam that is suitable for you.**
6. **Pay the registration fee of $390.00 via your PayPal account. If you do not have one, you can easily create one.**
7. **After your payment is successful you will receive an invitation email from us with your login credentials for appearing on the online examination you have chosen.**
8. **Please do not use your credentials or log in into your examination before the scheduled date and time. You can login into your online exam for certification program only once, so please USE YOUR ASSESSMENT CREDENTIALS ON THAT PARTICULAR DATE AND TIME ONLY.**
9. **On the date and time of your scheduled exam, follow the link and information sent to your email to take the exam.**
10. **Follow the exam and the proctor instructions to take the exam.**
11. **You will have 2.5 (two and half) hours to take and finish the exam. The exam will terminate at the end of the 2.5 hours.**

Questions? If you have an issue or a question, please contact us **by email** (**AAQDoctor@gmail.com**)

Preparation Educational Materials For The Certified Clinical Laboratory Quality Professional (CCLQP) Examination

Chapter One:

Quality Assurance In Clinical Laboratories

1. **What is Quality? Quality is:**
   - **1.1. C**onsistency, which means Accuracy and Precision.

   - **1.2.** Right result: First time; Every time.

2. **What is Quality Assurance (QA)?**

   - **2.1. QA =** Internal Quality Control (IQC) or "QC" PLUS External Quality Assessment (EQA).
   - **2.2. QA:** The right result, at the Right time, on the Right specimen, from the Right patient, with result interpretation based on Correct reference data, and at the Right price.
   - **2.3.** In clinical laboratories, Quality Assurance: is the sum of all the activities in which the laboratory is engaged in (from the choice of methods to personnel training, to the handling of specimens, and reporting results) to ensure that the final results reported by the laboratory are correct.
   - **2.4. In other words, the real purpose of QA activities is to determine h**ow correct or incorrect the results originating from the lab are, and to allow those managing the lab to determine whether or not the lab is fulfilling its functions satisfactorily.

   - **2.5. There Are Three Major Activities of QA:**
     - **2.5.1.** Preventive: those activities that are done prior to the examination of the specimen or sample; which intended to establish systems contributing to accuracy testing; i.e., maintenance, calibration, and staff training.
     - **2.5.2.** Assessment: those activities that are done during testing to determine whether the test systems are performing correctly; i.e., QC.
     - **2.5.3.** Corrective: those activities that are done, when errors are detected, to correct the

system; troubleshooting, recalibration, rerunning QC…etc.

2.6. A Good QA System Does Four Things:

2.6.1. Establishes SOPs / IPPs for each step of the laboratory testing process, ranging from specimen handling to instrument performance;

2.6.2. defines administrative requirements, such as mandatory recordkeeping, data evaluation, and internal audits to monitor adherence to SOPs / IPPs;

2.6.3. specifies corrective actions, documentation, and the persons responsible for carrying out corrective actions when problems are identified; and

2.6.4. sustains high-quality employee performance.

3. What is the Difference Between Total Quality Management (TQM), Quality System (QS), Quality Assurance (QA), and Quality Control (QC)? And How Does It Work?

3.1. TQM: is closely interlinked with good laboratory practices and goes far beyond the widely practiced conventional Quality Control (QC) procedures.

3.1.1. TQM includes:

3.1.1.1. accuracy and precision,

3.1.1.2. equipment and supplies,

3.1.1.3. staff training and skills,

3.1.1.4. financial management (cost effectiveness), lab safety, communication…etc.

3.1.2. TQM aims at <u>continuous improving</u> of the laboratory as a whole (<u>holistic</u>) leading to improved quality.

3.2. Quality System (QS): Organizational structure, resources, <u>policies, processes, procedures, and forms</u> needed to implement quality management and manage the quality of their services or products. (ISO, CLSI). **In other words, all activities which contribute to quality of testing, directly or indirectly.**

3.3. Quality assurance = Internal Quality Control (IQC) or "QC" <u>PLUS</u> External Quality Assessment (EQA).

3.3.1. External Quality Assessment (EQA) / proficiency testing (PT): Determination of <u>laboratory testing performance</u> of <u>personnel and results generated by the laboratory</u> by means of <u>interlaboratory comparisons</u>, in which a <u>PT program periodically sends multiple specimens</u> to <u>members of a group of laboratories for analysis</u> and/or identification; the <u>program then compares each laboratory's results with those of other laboratories in the group</u> and/or with an assigned value.

3.3.2. Internal Quality Control (IQC) / Quality Control (QC): Operational techniques and activities used to fulfill requirements for quality (ISO, CLSI). **OR**

3.3.3. It refers to the set of procedures undertaken by the laboratory staff for the <u>Continuous</u> and <u>immediate</u> monitoring of laboratory work in order to decide whether the results are reliable enough to be released.

3.4. **How**