Laboratory & Blood Bank Student Training Program According To International Quality Standards JCIA,ISO

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خبير الجودة ومكافحة العدوى

مدير مركز بنك الدم وأبحاثه

مستشفى ٤٨ النموذجي

كلية الطب المخبري

جامعة ٢١ سبتمبر

Training program content

- Introduction
- Objective
- TRAINING LEARNING METHODS
- METHOD OF ASSESSMENT
- General orientation program for student .
- Laboratory Student Training Program
- - student orientation and laboratory rules .
- Laboratory policies
- Laboratory procedures
- Total quality management system in laboratory

Introduction

- This straining program has been developed to enable the recognition of structured, standardized training and assessment of students in laboratory medicine. Successful completion of the program will lead to the award competent laboratory specialized and has knowledge in Quality.
- This training program is comprised of core sections and used a advanced & effective training method .
- . Based on the requirements of international quality laboratory standards(ISO 9001 -2015 –JCIA – CAP) & should have a training content including:
- Phlebotomy and Reception policies and produces and Quality control .
- Clinical Chemistry policies and produces and Quality control
- hematology, policies and produces and Quality control
- microbiology, & policies and produces and Quality control
- molecular biology and genetics .
- Parasitology and protozology .
- Viruses & immunology
- Blood bank
- Histopathology .
- Total quality management system in laboratory medicine

Objective

- Trainees should demonstrate:
- knowledge of laboratory policies .
- The trainee should be competent to perform the task/procedure and demonstrate a level of clinical and professional judgement commensurate with independent practitioner, And act according to the laboratory Standards operating procedures in all Lab section .
- The trainee should demonstrate an in-depth knowledge and understanding of the principles and practice in all sections of laboratory medicine and its clinical application and interpretation of results.
- The trainee should be Sufficient understanding laboratory safety & infection control program .
- The trainee should be Sufficient understanding laboratory (TQMS)

TRAINING LEARNING METHODS

- Trainees will achieve the competencies described in the syllabus through a variety of learning methods.
- There will be a balance of different modes of learning from formal teaching programmes to experiential learning ‘on the job’.
- Trainees will learn analytical skills appropriate to their level of training through work-based placement within the appropriate department.
- To achieve full exposure to a variety of practical &clinical experiences, as laboratory medicine specialists it may be necessary to receive training in more than one hospital laboratory and . Educational supervisors may play a role in organizing a rotational training plan that fulfils the training requirements.
- The training program aims to provide the trainee with both practical theoretical knowledge as well as scientific, clinical and managerial skills via range of activities such as:
- Firstly starting by observation and performing task with assistants .
- Participating in performing Laboratory testing in all section according to SOPs.
- Participating in performing Laboratory policies
- Participating in performing Laboratory quality control .
- Participating in performing Laboratory testing result interpretation .
- Case presentations in hospital, seminars and conferences
- Attending relevant clinical and scientific meetings and appropriate management training courses.

METHOD OF ASSESSMENT

- Internal/external formal examination – components may include essays, short answer and/or multiple choice questions, laboratory-based practical, oral examination, critical scenario appraisals, written dissertations.
- Direct observation – capturing the supervisor's and others' perception in internal and external environments of the trainee's understanding of the specialty, his/her skills acquisition, his/her personal and professional presentation and development
- Multi-source feedback – capturing others' perception of the trainee's knowledge, skills, competence, attitude, behaviour, learning need and potential.
- Case-based discussion – through capturing the trainee's perspective on a range of topics – clinical, scientific, professional – a picture builds of strengths, weaknesses, personal qualities, his/her understanding of roles and contributions.
- Use of log books/personal portfolios that record expectations of the education programme against achievements and progression milestones, and which may invite supervisor input
- Evaluation of written output – examples include (peer reviewed) publications, audits, policy and procedure documents
- Internal and external appraisal

METHOD OF ASSESSMENT

Items	Maximum Degree	Trainee intern degree	Notes
A. Experience & skill requirement			
1-Performed of the technical activates by laboratorian – train according to section of Policies and SOPs.	50		
2- Performed of the technical activates according to international quality standards.	10		
3-Recording reporting of laboratory result	5		
B-. Behavior and attitudes:			
1- Attitude toward patient and units.	5		
2- Interpersonal relationship	5		
3-Sense of responsibility	5		
4-Ability to accept more teaching & responsibilities	5		
5-Punctuality & commitment	10		
6- General appearance	5		
Total degree	100		

General orientation program for student

- trainee policies .
- General infection control and safety policies .
- Quality concept and international safety goals and patient right .

Laboratory students orientation program

- Laboratory policies .
- Specimen collection manual
- Laboratory SOPs .
- Blood Bank policies and procedures.
- Blood safety .
- Laboratory safety and infection control program .
- TQMS in Laboratory & Blood Bank .

Laboratory medicine policies

- **تحتوي السياسة على العناصر التالية:**
- **الترويسه:**

١. عنوان السياسة: مختصر ، لا تذكر كلمة سياسة أو بروتوكول.
٢. رقم السياسة: يستخدم نمط موحد في الترميز بكتيب التطبيقات.
٣. التاريخ: تاريخ الوضع ، تاريخ الموافقة والاعتماد ، تاريخ المراجعة.
٤. اسم القسم أو الوحدة التي تخصه السياسة.

- **السياسة**

١. الهدف الأساسي.
٢. التعريف عند الحاجة.
٣. المهام والمسئوليات.
٤. الإجراءات.
٥. التوثيق : طريقة التوثيق ، نماذج التوثيق.
٦. المصادر والمراجع.

السياسات والإجراءات	عنوان الوثيقة: إنشاء ومعالجة السياسات والإجراءات
الجهة المنشأة: لجنة إدارة المعلومات والسجلات الطبية	
تاريخ الإصدار: 1/1/2010م	رقم الوثيقة: POL-MCI-0018
الموافقة من: رئيس لجنة إدارة المعلومات والسجلات الطبية تاريخ الموافقة: 1 / 1 / 2010م	المراجعة النهائية: 8 / 2 / 2010م رقم النسخة: 00
الموافقة من: رئيس لجنة قيادة الاعتماد تاريخ الموافقة: 8 / 2 / 2010م	تاريخ المراجعة القادم : 8 / 2 / 2012م صفحة 1 من 3

الإجـــراءات

- يجب صياغة السياسة بحيث تحدد الحد الادنى المطلوب من حيث السياسة عند تطبيقها من قبل المريض أو الكادر في الظروف العادية .
- تحديد الهدف الأساسي من السياسة وجعلها أداة تعليمية مقنعه.
- استخدام المسميات العلمية فقط.
- عدم استخدام أسماء الموظفين وأرقام هواتفهم.
- تعرض السياسات والإجراءات من قبل منسق الجودة على المعنيين في وقت انعقاد الاجتماع الدوري.
- يجب توفر النقاط الأساسية في نموذج السياسة.

سياسة معالجة او تعديل السياسات.

١. **الهدف:**

- تحديد الأشخاص المخولين بكتابة السياسات وتحديد أوقات مراجعتها ونظام الترميز المعتمد للحفاظ على ديمومتها وتوحيدها.

٢. **السياسة:**

- تكتب السياسة على النموذج الخاص المعتمد بالمستشفى.
- يتم الموافقة على السياسة من قبل لجنة الجودة ومدير المستشفى بعد إعدادها من قبل المسئولين.
- تعمم السياسة على المعنيين من خلال لوحات الأوامر والمحاضرات.
- تحفظ السياسات في الأقسام المتخصصة وتحفظ النسخة الأولية بمكتب الجودة.
- تراجع السياسة من قبل المسئولين كل سنتين أو عند اللزوم.

٣. **المسئوليات :**

- رؤساء الأقسام ورؤساء اللجان.
- الممرضين والمهنيين.

no	Name of policy	demonstration	application		Level of student On application			
			yes	no	bad	good	v.good	excellent
1	Request for Laboratory Tests							
2	Patient Identification Policy							
3	Specimen Identification Policy							
4	Specimen Labeling Policy							
5	Specimen container Policy							
6	Sample storage Policy							
7	Sample Discarding Policy							
8	sample handling Policy							
9	Emergency (Stat) Requests Policy							
10	Specimen Transport Policy							
11	Result Reporting Policy							
12	New Staff training Policy							
13	Critical Value Handling Policy							
14	Inventory policy							

no	Name of policy	demonstration	application		Level of student On application			
			yes	no	bad	good	v.good	excellent
15	**Inter Lab Comparison policy.**							
16	**Laboratory Safety policy.**							
17	**Instrument and equipment lab Calibration policy**							
18	**Laboratory Quality Program**							
19	**Nonconforming Even Management**							
20	**Policy Validate Results In The lab**							
21	**Bio-safety manual for laboratory staff**							
8	Blood banking policies							
9								
10								
11								

no	Name of policy Blood bank & transfusion services policies	demonstration	application		Level of student On application			
			yes	no	bad	good	v.good	excellent
1	Blood Donor Registration Policy.							
2	Donor selection Policy.							
3	Whole Blood Collection Policy.							
4	Aphaeresis policy							
5	Manual Blood Component Separation Policy.							
6	Labeling of Blood Bags and Blood Components Policy.							
7	Preservation of Blood and Blood Components Policy.							
8	Inventory of Blood Bags and Blood Components Policy.							
9	Supply of Safe Blood for transfusion Policy.							
10	Blood Donor Registration Policy.							
11	Pre- transfusion Policy.							
12	Blood Transfusion Reaction Policy.							
13	Blood transfusion request policy							

no	Name of policy	demonstration	application		Level of student On application			
			yes	no	bad	good	v.good	excellent
1	Patient Identification Policy.							
2	Specimen Identification Policy.							
3	Specimen Transportation Policy.							
4	Emergency (Stat) Requests Policy. .							
5	Turn Around Time Policy.							
6	Blood rejected Policy.							
7	Bio-Safety.							
8	blood bank Specimens storage Policy.							
9	Blood bank Critical Value Handling Policy.							
10	Specimen Rejection Policy.							
11	Emergency Sample Handling Policy							
12	Waste Management Policy.							
13	New Staff Training Policy.							
14	Quality Performance Indicators.							

RESULT REPORTING POLICY

- DEFINITION OF TERM:
  - **Result Reporting:** That means all the way that the tests should be reported as .
- OBJECTIVES:
  - To control the way that test should be reported as .
  - To check the quality of Lab.specimens.

RESULT REPORTING POLICY

- APPLICABILITY:
  - *Applies to: All Lab Staff.*
- PROCRDURE
  - When verified and released, all patient laboratory results are available electronically on HIS.
  - Requests for hard copies of the outpatient reports could be made up on request.
  - Result for critical and stat specimen will be given over the phone as soon as it is ready.

NEW STAFF TRAINING POLICY

- DEFINITION OF TERM:
  - **New Staff:** Any person who joins the laboratory and contribute towards the services offered by the laboratory.
- OBJECTIVES:
  - To maintain the proficiency of the new staff
  - To maintain the standards of quality of 48MH lab.

CRITICAL VALUE HANDLING POLICY

- DEFINITION OF TERM:
  - **Critical value:** That means any report which requires immediate attention of health care workers towards the patient, failing which a fatal outcome ensues.
- OBJECTIVES:
  - To know about critical values of tests in various sections of lab.
  - To ensure the quality for critical values reported.
  - To record, and convey the critical values to the clinician.
  - To follow Write, Recall and Document the critical values

CRITICAL VALUE HANDLING POLICY

- APPLICABILITY:
- *Applies to: All Lab Staff.*
- PRINCIPLE
- To assure that patient results deemed to be "critical" are phoned to the patient's physician or nurse and documented by the technologist.
- All critical values are reported and documented in the laboratory system.

CRITICAL VALUE HANDLING POLICY

- PROCEDURE
- Critical/Panic values are defined as values that are outside the normal range to a degree that may constitute an immediate health risk to the individual or require immediate action on the part of the ordering physician. It is the policy of the clinical laboratory to call the critical values listed as soon as completed and verified.

CRITICAL VALUE HANDLING POLICY

- The ordering physician's office will be called and the results communicated to an RN or MD.
- Documentation will be made of the call listing the first initial, last name, title of the person receiving the call and the time the call was made.
- For verification the person receiving the call will be asked to repeat the critical value results back.
- If there is no answer, the physician's answering service or physician that is covering for the ordering physician will be called or paged.
- If unable to contact a responsible party within 30 minutes, the supervisor will be notified. Documentation will be made of all attempts (times and phone numbers called) into the computer and a Panic Notification Form will be completed. The supervisor will contact the on call clinical pathology resident or the laboratory director.

INTER LAB COMPARISON POLICY.

- DEFINITION OF TERM:
  - **Inter Lab:** That means two laboratories are compared for their test results of common samples processed.
- OBJECTIVES:
  - To match the standards of referral lab.
  - To check the quality of referral lab.
  - To check the quality of 48MH lab.
- APPLICABILITY:
  - *Applies to: All Lab Staff.*

INTER LAB COMPARISON POLICY.

- Tests sent of interlab comparison:
  - Few tests are selected from different sections of the lab to outside lab to check the accuracy of the test.
  - Different tests sent for comparison.
    - **Hematology Tests**
      - CBC
    - **Clinical Chemistry**
      - Routine Chemistry tests

Laboratory SOPs

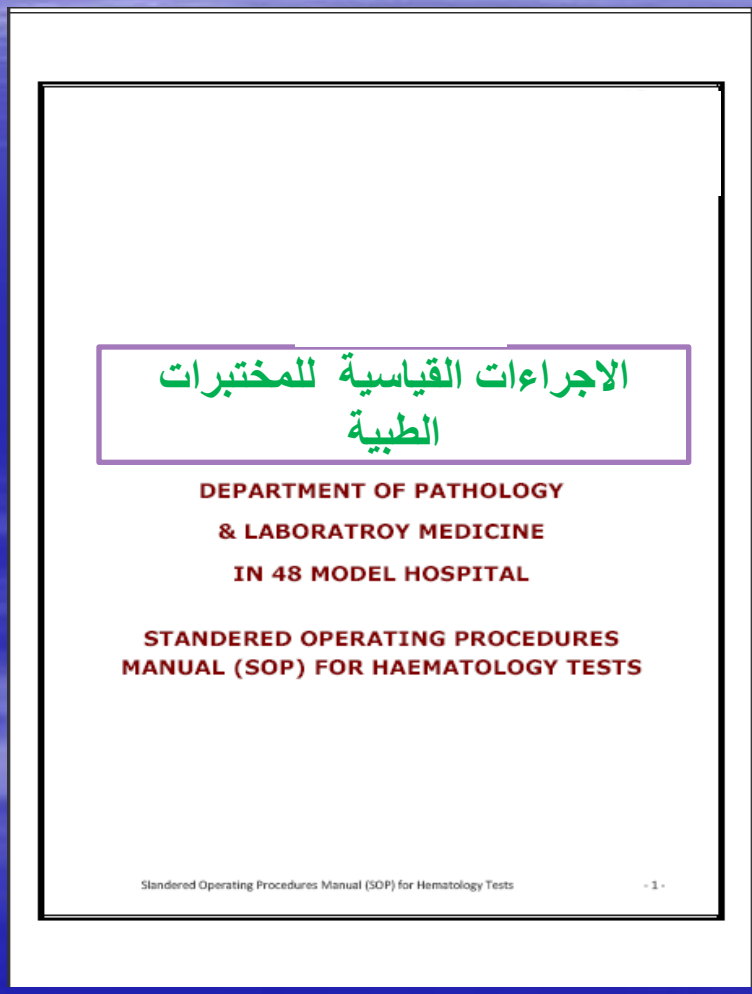
اجراءات العمل القياسية في المختبر


الاجراءات القياسية لبنوك الدم

DEPARTMENT OF PATHOLOGY & LABORATROY MEDICINE IN 48 MODEL HOSPITAL

STANDERED OPERATING PROCEDURES MANUAL (SOP's) FOR CLINICAL PATHOLOGY TESTS :

Standered Operating Procedures Manual (SOP) for Clinical Pathology Test


الاجراءات القياسية للمختبرات الطبية

DEPARTMENT OF PATHOLOGY

& LABORATROY MEDICINE

IN 48 MODEL HOSPITAL

STANDERED OPERATING PROCEDURES MANUAL (SOP) FOR HAEMATOLOGY TESTS

Standered Operating Procedures Manual (SOP) for Hematology Tests - 1 -

Laboratory SOPs

اجراءات العمل القياسية في المختبر

- STANDERED OPERATING PROCEDURES MANUAL (SOP) FOR HAEMATOLOGY TESTS.
- STANDERED OPERATING PROCEDURES MANUAL (SOP's) FOR BIOCHEMISTRY TESTS :
- STANDERED OPERATING PROCEDURES MANUAL (SOP's) FOR MICROBIOLOGY TESTS .
- STANDERED OPERATING PROCEDURES MANUAL (SOP's) FOR PARASITOLOGY TESTS :
- STANDERED OPERATING PROCEDURES MANUAL (SOP's) FOR IMMUNOLOGY AND VIRUSES TESTS
- STANDERED OPERATING PROCEDURES MANUAL (SOP's) FOR molecular biology TESTS :

Laboratory SOPs

اجراءات العمل القياسية في المختبر

Pus Swab Culture & Sensitivity

- **INTENDED OF USE:**
- it use for Isolation and Identification of Bacteria Causing pus production infection . It also indicate the type of organisms in the Specimen, and the antibiotics to which the organisms are susceptible or sensitivity to (treatment).
- **INSTRUMENT USED:**
- incubator
- sterile wire loop
- blood agar, chocolate agar, MacConkey agar, and cooked meat medium.
- Gloves, mask, gown (optional)

Laboratory SOPs

اجراءات العمل القياسية في المختبر

- **TEST PRINCIPLE:**
- Wound cultures are tests that are done to check for the presence of bacteria or fungi in a wound. The wound culture procedure is generally not conducted for mundane and small wounds but is rather conducted for extremely large and visibly infected wounds or even if the area of the wound could pose a cosmetic problem. A sample that is used in the wound culture technique is generally acquired from the exudates that are coming out of the wound that include mucus, serous fluid, and pus. The wound culture and sensitivity of the test can be subjective since a large part of the accuracy of the test lies in finding the exact source and core of infection. For example, a wound that is probably deep in the skin tissue may not be found accurately if just a surface swab is taken.
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- **REAGENT:** Catalase, Coagulase, Oxidase reagents, Biochemical test reagent, Gram stain, Ziehl-Neelsen stain.
-)
-

Laboratory SOPs

اجراءات العمل القياسية في المختبر

- **PRECAUTIONS OF SPECIMEN HANDLING:**
- If there is any volume of pus present it should be collected with a syringe into a sterile universal container rather than on to a swab. The site of origin of the material must be stated. Anaerobes and fastidious organisms die if subjected to delay or dehydration. Transport medium must always be used for swabs. Pus is always preferable to a wound swab, and essential if M. tuberculosis is to be identified. There is a better yield from wound swabs if the swab is premoistened with transport medium before it is taken. Specimens from patients with suspected plague or anthrax are highly infectious. Label such pecimens HIGH RISK and handle them with care.
- **STORAGE AND STABILITY:** 2 – 8 ° C.
- **SPECIMEN COLLECTION:**
- The area around the wound is cleansed to remove flora indigenous to the skin. A Culture swab is placed in the most excessive exudate in a superficial wound without touching the wound edges. The swab soaked with the exudate is placed in the tube, and the tube is squeezed to allow for dispersion of the medium.
- A deep wound specimen is obtained by aspiration with a sterile syringe and needle inserted directly into the wound. After the aspiration, the air is expelled from the syringe and the needle covered with a rubber stopper or the material injected into a tube containing an anaerobic culture medium.

Laboratory SOPs

اجراءات العمل القياسية في المختبر

- **TEST PROCEDURE:**
- When a swab has been used to collect the pus, inoculate the culture media first before using the swab to make smears.
- Culture the specimen on Blood agar, MacConkey agar, cooked meat medium (or thioglycollate broth)
- – Inoculate the specimen:
- – On blood agar to isolate S. aureus and streptococci. Add a bacitracin disc if streptococci are seen in the Gram smear.
- – On MacConkey agar to isolate Gram negative rods.
- – Into cooked meat medium or thioglycollate broth
- Incubate the inoculated blood agar plate at 35–37 ° C in a carbon dioxide atmosphere (candle jar) and the MacConkey agar plate aerobically. Incubate the inoculated cooked meat medium at 35–37 ° C for up to 72 hours. Subculture after 24 h, and if indicated at 48 h and 72 h.
-

Laboratory SOPs

اجراءات العمل القياسية في المختبر

- **Most Comment Organism Isolated :**
- S. aureus, S. pyogenes, P. aeruginosa, Proteus species, E. coli, Enterococcus species, Klebsiella species, Anaerobes: C. perfringens, Bacteroides fragilis group, Peptostreptococcus species
-
- **Sensitivity test**
-
- Using disc diffusion techniques: A disc of blotting paper is impregnated with a known volume and appropriate concentration of an antimicrobial, and this is placed on a plate of sensitivity testing agar(Muller Hinton) inoculated with the test organism, after overnight incubation, bacterial strains sensitive to the antimicrobial are inhibited at a distance from the disc whereas resistant strains grow up to the edge of the disc.
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-
-
-
-

Laboratory SOPs
اجراءات العمل القياسية في المختبر

- **If gram negative:**
- Ciprofloxacin(CIP),, Ampilox(AMX), Augmentin(AMC), Ampecillin(AMP),Cefeprim(CPM), Cefadroxil(CFR), Erythromycin(E), Amikacin(AK), Azithromycine(AZM).
- **If gram Positives:** Ciprofloxacin(CIP),, Amoxicillin(AMy), Augmentin(AMC), Ampecillin(AMP), co-trimoxazole(SXT), Gentamycine(GM), Lincomycine(L), Chloramphenicol(C), Ampilox(AMX), Cefuroxime(CXM), Kanamycine(K), Cefotaxime(CTX).
- In the case of staph, aurous we add Methicillin (MET) and Vancomycin(VA).
-
- **QUALITY CONTROL:**
- Internal quality control: Each day of operation use control for catalase, coagulase, beta-lactamase and oxidase reagents should be checked.
- Each day of operation , test appropriate control organisms to check the procedure.
-
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Laboratory SOPs

اجراءات العمل القياسية في المختبر

- **TURN AROUND TIME:** Turnaround time is routinely 3days after receipt the specimen in microbiology department
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- **CALCULATION:** Not applicable
-
- **CALIBRATION:** Not applicable
-
- **PRECISION:** Not applicable
-
- **REFRENCE:**
- MEDICAL LABORATORY MANUAL FOR TROPICAL COUNTRIES, Volume 2: microbiology.
- Manual of basic Techniques for Health laboratories 2nd edition, word health organization, Geneva, 2018

Quality section :-
Total quality management system in laboratory

Quality Control program of the BTS

برنامج ضبط الجودة في بنوك الدم

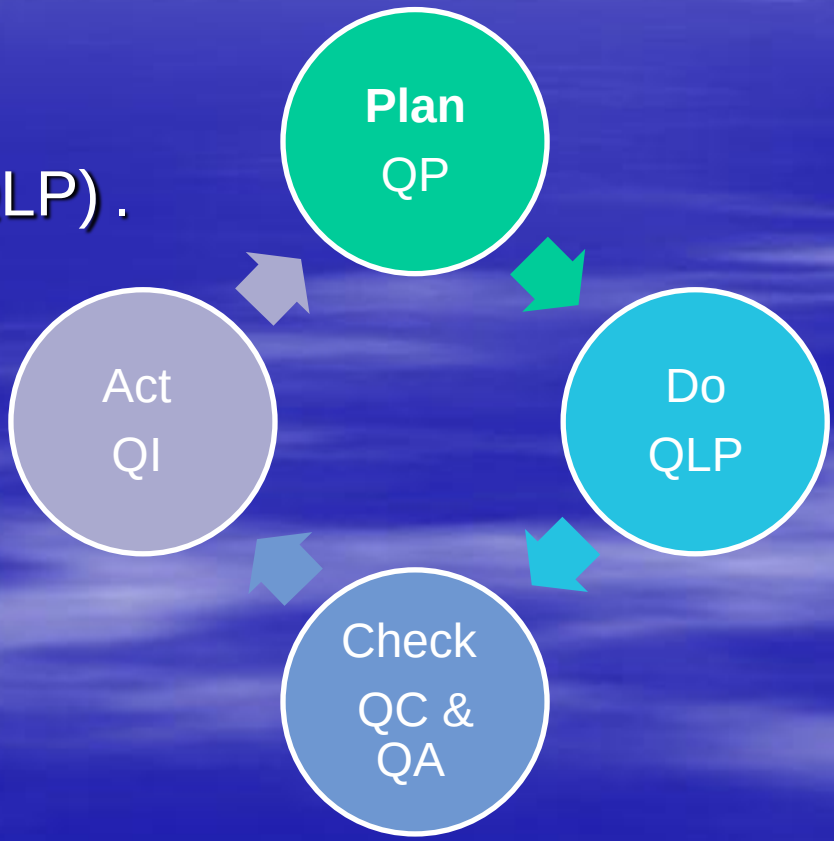
Quality Control program of the Lab .

برنامج ضبط الجودة في المختبرات الطبية

How can we Implement TQM for any Lab ?

Five Q frame work of (TQM) !!!

1. Quality Planning (QP)
2. التخطيط لعمل نظام جودة
3. Quality Laboratory Processes (QLP) .
   التركيز على الاليات او عناصر الجودة
4. Quality Control (QC).
   التحكم بالجودة
1. Quality Assessment (QA).
   التدقيق وفحص الجودة
1. Quality Improvement (QI).
   تحسين وتطوير الجودة



The Quality Management System

INTERNSHIP TRAINING PLAN

	Clinical area unit	Period		
1-	Phlebotomy and Reception	One weak		
2-	**Hematology**	One Month		
3-	Clinical Chemistry	One Month		
4-	Microbiology and molecular biology	One Month		
5-	Parasitology and protozology	One weak		
6-	Viruses & immunology	Tow weak		
7-	Blood bank	One Month		
8-	Histopathology .	One Month		
9-	Total quality management system in laboratory medicine	One Month		

Questions

- Thank You .