وزارة التعليم العالي والبحث العلمي
الجامعة التقنية الجنوبية
المعهد التقني العمارة
قسم تقنيات المختبرات الطبية

الحقيبة التدريسية لمادة سيطرة نوعية نظري+عملي

الصف: الأول

تدريسي المادة

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الفصل الدراسي الثاني

جدول مفردات مادة سيطرة نوعية نظري+عملي

Weeks	Syllabus detail (theory and practice)
1	Introduction to quality control.
2	Medical relevant of QA, Standard units of the international system.
3, 4, 5	Balancing error detection and false rejection.
6, 7	Quality control materials.
8	QA techniques for quantitative results.
9	QA techniques for qualitative results.
10	QA techniques for semi-quantitative results.
11	Troubleshoot based on QA results.
12, 13, 14	Review.
15	Final exam.

الهدف من دراسة مادة تقنيات مختبرية (الهدف العام):

تهدف دراسة مادة سيطرة نوعية للصف الأول إلى:

1- أن يفهم الطالب كيف يضبط الاختبارات.

2- أن يفهم الطالب كيف يصف النتائج.

الفئة المستهدفة:

طلبة الصف الأول/قسم تقنيات المختبرات الطبية.

التقنيات التربوية المستخدمة:

1- سبورة وأقلام.

2- السبورة التفاعلية.

3- عارض شاشة Data Show.

4- جهاز حاسوب محمول Laptop.

الأسبوع الأول

الهدف التعليمي: التعرف على السيطرة النوعية.

مدة المحاضرة: 6 ساعات (ساعتان نظري+ 4 ساعات عملي).

الأنشطة المستخدمة: أسئلة عصف ذهني.

أساليب التقويم: التغذية الراجعة النهائية (التقويم الختامي).

عنوان المحاضرة: **Introduction to Quality Control**

Quality Control:

Monitors activities related to the examination (analytic) phase of testing.

History:

In 1981, the World Health Organization (WHO) used the term "internal quality control" (IQC), which it defined as “a set of procedures for continuously assessing laboratory work and the emergent results”. The terms QC and IQC are sometimes used interchangeably; cultural setting and country may influence preferences for these terms.

To avoid confusion, the term "quality control" will be used here to mean use of control materials to monitor the accuracy and precision of all the processes associated with the examination (analytic) phase of testing.

Purpose of QC:

Quality control goals are:

Accuracy.

Precision.

The total error of the chemical method.

Quality Assurance (QA):

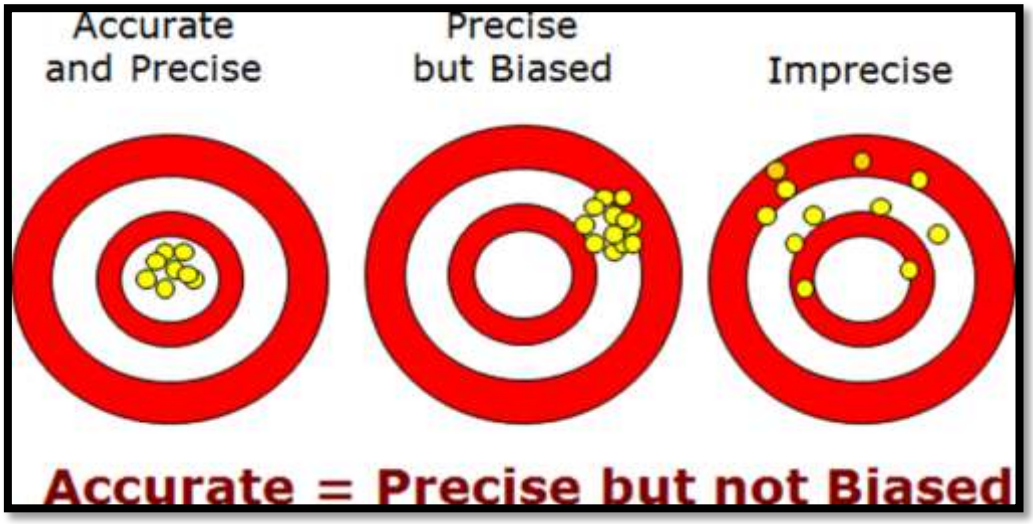
It consists of plans, policies, and procedures that provide an administrative structure for a laboratory’s efforts to achieve quality goals. It has three components:

1- Assessment and monitoring.

2- Development of the program.

3- Quality improvement (quality control).

Quality Control is used to monitor the accuracy and the precision of the assay.



Accuracy: refers to how close a value is from its true value. One example of accuracy is the distance an arrow gets from the bullseye center.

Precision: refers to how repeatable a measurement can be. A good example of precision is the distance between the second and first arrows, regardless of whether they are near the mark.

Quality Control Objectives:

1- QC provides continuous accuracy of the results.

2- QC gives an early warning about the accuracy of the test so that early remedies may be taken

to avoid great mistakes.

3- QC compares the tests at a different time from the same control sera.

Quality control depend on:

1- Specimen storage.

2- Time between the test performed.

3- Calibration of the instruments.

4- Training of the technician.

5- Clerical mistakes.

الأسبوع الثاني

الهدف التعليمي: التعرف على الأهمية الطبية للجودة النوعية والوحدات المعيارية في النظام الدولي.

مدة المحاضرة: 6 ساعات (ساعتان نظري+ 4 ساعات عملي).

الأنشطة المستخدمة: أسئلة عصف ذهني.

أساليب التقويم: التغذية الراجعة النهائية (التقويم الختامي).

عنوان المحاضرة: Medical Relevant of QA, Standard Units of the International System

A quality system is defined as the organizational structure , responsibilities , processes , procedures and resources for implementing quality management . Quality management includes those aspects of the overall management function that determine and implement the Company quality policy and quality objectives. Both quality control and quality assurance are parts of quality management.

QC Measures:

Internal Quality Control (IQC): is a set of measures that the project undertakes among its own samplers and within its own lab to identify and correct analytical errors. Examples include lab analyst training and certification, proper equipment calibration and documentation, laboratory analysis of samples with known concentrations or repeated analysis of the same sample, and collection and analysis of multiple samples from the field.

External Quality Control (EQC): is a set of measures that involves laboratories and people outside of the program. These measures include performance audits by outside personnel, collection of samples by people outside of the program from a few of the same sites at the same time as the volunteers, and splitting some of the samples for analysis at another lab.

There are 4 main components of every quality management system (QMS):

1- Quality control planning: identifying your quality goals and standard, the requirements necessary to meet these criteria are being met.

2- Quality control: the process of physically inspecting and testing what you laid out in the planning stage to make sure it is obtainable.

3- Quality assurance: reviewing the delivery process of goods.

4- Quality improvement: thoroughly review your findings from the last 3 components and come up with a way to improve your methods going forward.

ISO as a Data Quality Management System:

The international organization for standardization (ISO) series programmed provides standards for data documentation and audits as part of a quality management system. The following standards and guidelines published under the ISO series may supplement source category-specific QA/QC procedures for inventory development and provide practical guidance for ensuring data quality and a transparent reporting system.

ISO 9004-1: general quality guidelines to implement a quality system.

ISO 9004-4: guidelines for implementing continuous quality improvement within the organization, using tools and techniques based on data collection and analysis.

ISO 10005: guidance on how to prepare quality plans for the control of specific projects.

ISO 10011-1: guidelines for auditing a quality system.

ISO 10011-2: guidance on the qualification criteria for quality systems auditors.

ISO 10011-3: guidelines for managing quality system audit programmers.

ISO 10012: guidelines on calibration systems and statistical controls to ensure that measurements are made with the intended accuracy.

ISO 10013: guidelines for developing quality manuals to meet specific needs.

Standard Units of the International System:

The International System of Units is the standard modern form of the metric system. The name of this system can be shortened to SI, from the French name Système International d'unités. The International System of Units is a system of measurement based on 7 base units: the meter (length), kilogram (mass), second (time), ampere (electric current), kelvin (temperature), mole (quantity), and candela (brightness). These base units can be used in combination with each other. This creates SI derived units, which can be used to describe other quantities, such as volume, energy, pressure, and speed. The system is used almost globally. Only Myanmar, Liberia, and the United States do not use SI as their official system of measurement. In these countries, though, SI is commonly used in science and medicine.

The Seven Base SI Units

Quantity	Unit	Symbol
Length	meter	m
Mass	kilogram	kg
Temperature	Kelvin	K
Time	second	s
Amount of substance (quantity)	mole	mol
Luminous intensity (brightness)	candela	cd
Electric current	ampere	a

Derived units are used for measurements such as volume, density, and pressure.

Quantity	Unit	Symbol
Volume	cubic meter	m^3
Density	kilogram per cubic meter	kg/m^3
Speed	meter per second	m/s
Newton	$kg.m/s^2$	N
Energy	Joule ($kg.m^2/s^2$)	J
Pressure	Pascal ($kg/m.s^2$)	Pa

Units of Length:

In SI, the basic unit of length, or linear measure, is the meter (m). All measurements of length can be expressed in meters. For very large and very small lengths.

Name	Symbol	Analogy
gigameter	Gm	10^9
megameter	Mm	10^6
kilometer	km	10^3
decimeter	dm	10^{-1}
centimeter	cm	10^{-2}
millimeter	mm	10^{-3}
micrometer	µm	10^{-6}
nanometer	nm	10^{-9}
picometer	pm	10^{-12}

Units of Volume:

The space occupied by any sample of matter is called volume. You calculate the volume of any cubic or rectangular solid by multiplying its length by its width by its height. The unit for volume is thus derived from the units of length.

The SI unit of volume is the amount of space occupied by a cube that is 1 m along each edge. This volume is a cubic meter (m^3). A more convenient unit of volume for everyday use is the liter, a non-SI unit. A liter (L) is the volume of a cube that is 10 centimeters (10 cm) along each edge (10 cm x 10 cm x 10 cm = 1000 cm^3 = 1 L).

Units of Mass:

The mass of an object is measured in comparison to a standard mass of 1 kilogram (kg), which is the basic SI unit of mass. A kilogram was originally defined as the mass of 1 L of liquid water at 4°C. The relationships among units of mass are shown in the table below

Unit	Symbol	Relationship
kilogram (base unit)	kg	$1\ kg = 10^{3}\ g$
gram	g	$1\ g = 10^{-3}\ kg$
milligram	mg	$1\ mg = 10^{-3}\ g$
microgram	µg	$1\ \mu g = 10^{-6}\ g$

Units of Energy:

The capacity to do work or to produce heat is called energy. The SI unit of energy is the Joule (J), named after the English physicist James Prescott Joule (1818-1889). A common non-SI unit of energy is the calorie. One calorie (cal) is the quantity of heat that raises the temperature of 1 g of pure water by 1°C. Conversions between joules and calories can be carried out using the following relationships.

1 cal = 4.184 J ; 1 J = 0.2390 cal , 1 kilojoule = 1000 joules ; 1 kilocalorie = 1000 calories.

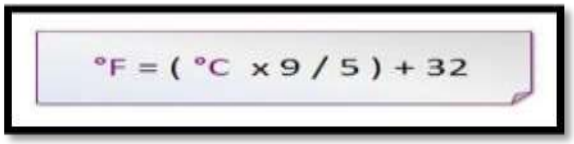
Temperature Scales:

Temperature is a measure of how hot or cold an object is. An object's temperature determines the direction of heat transfer. When two objects at different temperatures are in

contact, heat moves from the object at the higher temperature to the object at the lower temperature.

The Celsius scale sets the freezing point of water at 0°C and the boiling point of water at 100°C. The distance between these two fixed points is divided into 100 equal intervals, or degrees Celsius (°C).

To convert temperatures in degrees Celsius to Fahrenheit, multiply by 9/5 and add 32. To convert temperatures in degrees Fahrenheit to Celsius, subtract 32 and multiply by 5/9.



الأسبوع الثالث والرابع والخامس

الهدف التعليمي: التعرف على الأخطاء التشخيصية.

مدة المحاضرة: 6 ساعات (ساعتان نظري+ 4 ساعات عملي).

الأنشطة المستخدمة: أسئلة عصف ذهني.

أساليب التقويم: التغذية الراجعة النهائية (التقويم الختامي).

عنوان المحاضرة: **Balancing error detection and false rejection**

Errors classification:

Quality assurance considers diagnostic errors under three main headings:

1- Pre-analytical errors: errors before the sample reaches the laboratory.

2- Analytical errors: errors during the analysis of the sample.

3- Post-analytical errors: errors occurring after the analysis.

Pre-analytical errors:

Although they occur before the sample reaches the lab , they directly affect the quality and usefulness of the result.

There are many types of pre-analytical errors:

a- Improper preparation of the patient:

- Patient fasting: a glucose test provides a more useful result after a period of fasting.

- Stress and anxiety: urinary protein levels will be affected.

b- Improper collection of the blood sample:

- Sample haemolysis: will affect tests such as LDH , potassium and inorganic phosphate.

- Insufficient sample volume: the lab may not be able to carry out all tests requested.

- Collection timing: collecting an accurately timed volume of urine is extremely important when looking at analyte levels in a 24 hour urine sample.

c- Incorrect specimen container:

- Serum and plasma: serum is obtained from clotted whole blood and plasma from unclotted blood . Sample collection for plasma must be done into a tube containing anticoagulant such as EDTA or heparin.

- Fluoride tubes for glucose: to inhibit glycolysis. Otherwise , the time taken to reach the lab will have a significant effect on the results.

- EDTA unsuitable anti-coagulant for calcium: EDTA binds calcium.

d- Incorrect specimen storage:

- Sample left overnight at room temperature: falsely elevated potassium , phosphate and red cell enzymes [e.g. aspartate aminotransferase (AST) and lactate dehydrogenase (LDH)] due to leakage of the intracellular fluid into the plasma.

Delay in sample delivery: falsely lowered levels of unstable analyses

such as non -

esterified fatty acids (NEFA) and unstable analyses require fast handling and analysis.

Other factors:

The sex of the patient: male or female.

The age of the patient: new born, juvenile, adult , geriatric.

Dietary effects: low carbohydrate / fat, high protein / fat.

When the sample was taken: early morning urine collection pregnancy testing.

Patient posture: urinary protein in bed-ridden patients.

Effects of exercise: creatine kinase, CRP (C- reactive protein).

Medical history: heart disease, diabetes, existing medication.

Pregnancy: hormonal effects.

Effects of drugs and alcohol: liver enzymes, dehydration.

How do these factors come under the banner of quality assurance?

- The quality of the final result will be seriously affected by these outside factors.

- The lab must minimize these risks:

a- Establishing effective standard operating procedures (SOPs).

b- Providing training for people using the laboratory service.

Analytical errors:

a- The sample:

- Incorrect labelling: barcoding / liquating.

- Incorrect preparation: centrifugation / aspiration.

- Incorrect storage: short-term refrigeration, medium term freezing at - 20 ºC and long term freezing at - 80 ºC.

- Correct test selection: laboratory information management system (LIMS).

b- Glassware / pipettes / balances:

- Used incorrectly. - Contaminated. -Poorly calibrate. - Reuse of pipette tips.

c- Reagents / calibrators / controls:

- Poor quality.

- Inappropriate storage: incorrect temperature, poorly maintained fridges or freezers, use of domestic freezers for storage of frozen control materials.

- Stability: use outside the shelf-life, working stability period.

- Incorrect preparation: e.g. reconstitution of lyophilized materials.

d- The application:

- Incorrect analytical procedures.

- Poorly optimized instrument settings.

The above will lead to errant results with even the best quality reagents.

e- The instrument:

- Operational limitations: temperature control, read times, mixing, carry-over.

- Lack of maintenance: worn tubing, optics, cuvettes, probes.

Other factors:

Calculation errors: incorrect factor, wrong calibration values.

Transcription errors.

Dilutions errors: dilutions may be done when a sample value exceeds the assay linearity, incorrect dilution or dilution factor used.

Lack of training.

The human factor: tiredness, carelessness, stress.

Post-analytical errors:

the prompt and correct delivery of the correct report on the correct patient to the correct doctor.

الأسبوع السادس والسابع

الهدف التعليمي: التعرف على مواد السيطرة النوعية.

مدة المحاضرة: 6 ساعات (ساعتان نظري+ 4 ساعات عملي).

الأنشطة المستخدمة: أسئلة عصف ذهني.

أساليب التقويم: التغذية الراجعة النهائية (التقويم الختامي).

عنوان المحاضرة: **Quality Control Materials**

Quality control materials should have the following characteristics:

1- They should have the same matrix as patient specimens, including viscosity, turbidity, composition , and color. For example , a method that assays serum samples should be controlled with human serum based

2- Quality control material should be simple to use because complicated reconstitution procedures increase the chance of error . Liquid controls are more convenient than lyophilized controls because they do not have to be reconstituted.

3- Quality controls should have minimal vial to vial variability , because variability could be misinterpreted as systematic error in the method or instrument.

4- Quality control materials should be stable for long periods of time. Controls with short shelf lives necessitate frequent reordering and verification against the outgoing material, creating more unnecessary work

5- Quality control material should be available in large enough quantities to last at least one year.

الأسبوع الثامن

الهدف التعليمي: التعرف على الفحوصات والنتائج الكمية.

مدة المحاضرة: 6 ساعات (ساعتان نظري+ 4 ساعات عملي).

الأنشطة المستخدمة: أسئلة عصف ذهني.

أساليب التقويم: التغذية الراجعة النهائية (التقويم الختامي).

عنوان المحاضرة: **QA Techniques for Quantitative Results**

Quantitative examinations: measure the quantity of an analyze present in the sample, and measurements need to be accurate and precise. The measurement produces a numeric value as an end-point , expressed in a particular unit of measurement . For example , the result of a blood glucose test might be reported as 5 mg/dL.

Since quantitative tests have numeric values, statistical tests can be applied to the results of quality control material to differentiate between test runs that are "in control" and "out of control". This is done by calculating acceptable limits for control material, then testing the control with the patient's samples to see if it falls within established limits.

Advantages of quantitative data

1. It's relatively quick and easy to collect .

2. The type of results will be statistical tests are appropriate to use.

3. As a result, understanding data and presenting those findings is

direct and less error.

Disadvantages of quantitative data

1. Quantitative data doesn't always tell you the final result (full story).

2. With choppy information, it can be inconclusive.

3. Can be limited, which can lead to overlooking broader themes and relationships.

4. By focusing solely on numbers, there is a risk of missing larger focus information that can be beneficial.

الأسبوع التاسع

الهدف التعليمي: التعرف على الفحوصات والنتائج النوعية.

مدة المحاضرة: 6 ساعات (ساعتان نظري+ 4 ساعات عملي).

الأنشطة المستخدمة: أسئلة عصف ذهني.

أساليب التقويم: التغذية الراجعة النهائية (التقويم الختامي).

عنوان المحاضرة: **QA Techniques for Qualitative Results**

Qualitative examinations: are those that measure the presence or absence of a substance , or evaluate cellular characteristics such as morphology . The results are not expressed in numerical terms , but in qualitative terms such as “positive” or “negative” ; “reactive” or “nonreactive” ; “normal” or “abnormal” ; and “growth” or “no growth” . Examples of qualitative examinations include microscopic examinations , serologic procedures for presence or absence of antigens and antibodies, and many microbiological procedures. Examples of qualitative examinations include microscopic examinations for cell morphology or presence of parasitic organisms, serologic procedures for presence or absence of antigens and antibodies, some microbiological procedures and some molecular techniques.

A color change is observed if the concentration of the compound is above a specific minimum detection limit. Visualized by colored capture line(s). One of the earliest examples of this assay is the pregnancy test. When a sufficient sample volume is added, the conjugate selectively reacts with HCG in the test samples, with a high degree of sensitivity, forming an antibody-antigen complex. The mixture then moves upward on the membrane arriving at the test zone by capillary action producing a blue band.

Advantages of qualitative data:

1. Visualized coloration

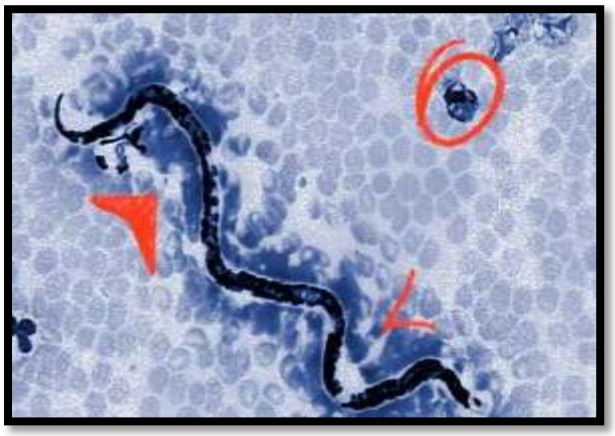
2. Faster time to result

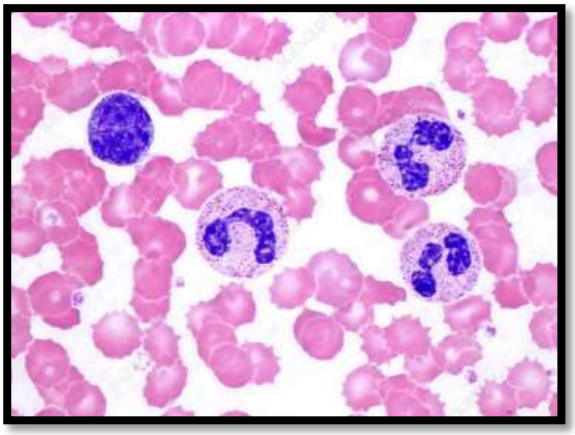
3. Easy to use

Disadvantages of qualitative data:

1. It’s not a statistically representative form of data collection.

2. It can also require multiple data sessions, which can lead to misleading conclusions**.**





الأسبوع العاشر

الهدف التعليمي: التعرف على الفحوصات والنتائج شبه كمية.

مدة المحاضرة: 6 ساعات (ساعتان نظري+ 4 ساعات عملي).

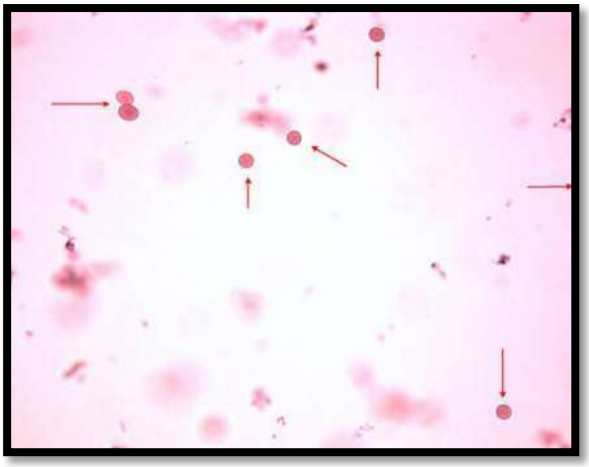
الأنشطة المستخدمة: أسئلة عصف ذهني.

أساليب التقويم: التغذية الراجعة النهائية (التقويم الختامي).

عنوان المحاضرة: **QA Techniques for Semiquantitative Results**

Semiquantitative examinations: are similar to qualitative examinations, in that the results are not expressed in quantitative terms. The difference is that results of these tests are expressed as an estimate of how much of the measured substance is present. Results might be expressed in terms such as “trace amount”, “moderate amount”, or “1+, 2+, or 3+”. Examples are urine dipsticks, tablet tests for ketones and some serologic agglutination procedures. In the case of other serologic testing, the result is often expressed as a titer-again involving a number but providing an estimate, rather than an exact amount of the quantity present.

Some microscopic examinations are considered semi quantitative because results are reported as estimates of the number of cells seen per low-power field or high- power field. For example, a urine microscopic examination might report 0-5 red blood cells seen per high-power field.



الأسبوع الحادي عشر

الهدف التعليمي: التعرف على كيفية تصحيح الخطأ اعتماداً على نتائج الجودة النوعية.

مدة المحاضرة: 6 ساعات (ساعتان نظري+ 4 ساعات عملي).

الأنشطة المستخدمة: أسئلة عصف ذهني.

أساليب التقويم: التغذية الراجعة النهائية (التقويم الختامي).

عنوان المحاضرة: **Troubleshoot based on QA results**

Troubleshooting is determine the source of a systematic error and correct it. It is a necessary part of the profession , it was important to take a step back when I wasn't sure of what to do. The goal of troubleshooting is to determine why something does not work as expected and explain how to resolve the problem. Problem descriptions help to start to find the cause of the problem. Some common steps for troubleshooting problems in the lab are:-

1. Identify the problem.
2. List all possible explanations.
3. Collect the data.
4. Eliminate some possible explanations.
5. Check with experimentation.
6. Identify the cause.

Example : no clones growing on the agar plate.

1. Identify the Problem:

First, check all the transformation plates and see if any colonies are growing on your control plates. If there were colonies on your plates, then the problem is the transformation of your plasmid DNA .

• A plasmid is a small circular DNA molecule found in bacteria and some other microscopic organisms.

2. List all possible explanations:

After you identified that the problem is not the competent cells, the possible explanations for your failed cloning may be your plasmid, the antibiotic, or the temperature during heat shock procedure.

3. Collect the data:

Controls:

If you included your controls in your transformation, your positive control plate should be the cells transformed with an uncut control plasmid. This plate should contain many colonies. If there are only few colonies growing on this plate, the efficiency of the competent cells may be too low.

Procedure:

To find out if your antibiotic is the cause, check if you used the correct antibiotic for selection and the concentration recommended for selection . To see if the incorrect temperature during the heat shock could be the cause, find out if the temperature water bath was at 42˚C.

4. Eliminate explanations:

Now you can start eliminating some of the possible explanations. For example, based on your data collection, there were many colonies growing on your positive control plate . It means that your competent cells were efficient. You also found out that you used the correct antibiotic with the recommended concentration for selection. Then , you can eliminate antibiotic as a possible cause. Moving on to the temperature during the heat shock, you found out that the temperature of the water bath was at 42˚C . Therefore , the procedure was not the problem and this should be eliminated from your list. Now the only possible cause is your plasmid DNA.

5. Check with experimentation:

In order to test if your plasmid is the problem, check if it is intact using gel electrophoresis and the plasmid concentration is not too low . In addition , check your ligation by sequencing your plasmid to make sure the insert DNA is in the plasmid. Make sure you follow the instruction from your transformation protocol regarding the concentration of plasmid you should use.

6. Identify the cause:

For the last step, gather all the information you need after you ran the experiments. For example , you made sure that there was no problem with your ligation based on your sequencing data, but you saw a faint band on the gel electrophoresis and found out that the concentration of your plasmid was too low. Therefore, you identified that the cause of your failed transformation was that your plasmid DNA concentration was too low.

الأسبوع الثاني عشر والثالث عشر والرابع عشر: مراجعة

الأسبوع الخامس عشر: امتحان نهائي