Comprehensive Molecular Diagnostics and Advanced Gene Expression Analysis

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Lecture 57 : Quality control (QC) in molecular diagnostics

Namaskar. Welcome back students to our lecture series on Comprehensive Molecular Diagnostics and Advanced Gene Expression Analysis. We are in module 12 and today's topic is Quality Control in Molecular Diagnostics and we will be covering the entire topic under these headings. So, we are referring quality control as the acronym QC. So, whenever you are listening to some QC we are referring to quality control.

So, what is quality control, what is the need of it, what are the various best practices in QC program, what are the rules and regulation and standard guidelines in QC, what are the various molecular testing process that we are going through, where as testing controls what is PT that is proficiency testing, how does it differ from quality control very essential part of it, what are the variables for high quality indices right. And finally, we will be discussing the QC planning draft for generic testing for which our whole module is designed. So, we have a lot to cover I may sound a bit of overwhelming at some point. So, I always encourage you to stop the video at any point.

So, that you can get back you can rewatch before going ead right. So, what is quality control varies it is the process right to ensure that the products or services meet standard criteria and customer expectations. So, if I am to deliver a product and a process I am making it by a process it should be done properly and I have to ensure the process is going properly. So, that ultimately the customer satisfaction is expected this is a general definition of quality control. So, it involves monitoring and evaluating of the production process to identify and correct any deviation or defect any problematic scenario you have to take care of before the final product is released to the customer.

So, QC does not necessarily mean to the lab. So, what will it translate if you are going through the lab definition. So, in diagnostics it refers to the procedures may the concept is very similar procedures measure implement to ensure the accuracy reliability and consistency of the diagnostic test result in healthcare settings, if it any healthcare not only molecular diagnostics right. So, what does it involve when we are referring it to diagnostic procedures. So, it involves various aspects of monitoring various aspects of

the testing process right.

So, including whether the machine that is running the test is performing adequate equipment performance the chemicals that we are using re reagent quality very important the process that we are following the standard operating procedure the guidelines. So, procedural adherence right as well as the person who is doing it personnel competency everything needs to fall in place. So, that the final result will be reliable. So, quality control. So, what if we wanted this whole thing.

So, what will come up. So, if there is any problem it helps us to identify and correct any issues that may affect the accuracy of diagnostic tests thereby ensuring the reliable results for patient care and clinical decision making. So, this is the overall concept of quality controller QC. Now you can extrapolate this concept to any diagnostic test any procedure and to monitor everything that is happening and thus you have already learned about quality control in the very first slide right. So, in the next part of the generally very easy.

So, let us follow along and see what other area we need to focus on. So, again so, right from the first slide you will be able to decode or answer many information hence forth on your own right. So, why why do we need number one to protect the patients very very very important right our main goal is to deliver correct results. So, that the patient gets a proper treatment the patient does not get in unwanted treatment right very important. Again protection of reputation or clinical lab or a hospital reliable report very important the hospital will be gaining reputation again a report a bad report from any center any diagnostic test any genetic test the reputation will be very much hampered and for that quality assurance quality monitoring is very very very important.

Again it ensures appropriate testing procedure equipment and materials. So, basically the definition if you want to answer the why if we understand the what will be a easy level to answer the why ensures personal competence. So, it is why do we need QC quality control ensures us that we have hired the right person the right person is doing the right job in the right way all right. Again it improves daily workflow procedures and constant having to deliver consistent and reliable results within a time frame all right something that is known as turn around time TAT the time from which the test is ordered to which we deliver very important. And if we need to do it consistently the over time the workflow will be very streamlined.

If we are not bothering about how the results are the technicians or the doctors or the certifying personnel or the specialist who is doing it might not be I might be reluctant enough not to deliver the results in a correct way or may follow a procedure which is not the optimal one right. So, proper quality monitoring will ensure and if we are providing

the proper result it reduces the risk of misdiagnosis very important. Suppose a borderline result right due to a wrong procedure may alter the treatment workflow may alter the clinical decision, but if a result is absolutely reliable then the clinical decision will be very easy to take for the concerned team of physicians. So, proper quality check quality monitoring quality control will ensure that aspect. So, a good quality control program a good QC program tests various parameters right.

So, the test accuracy reproducibility are actually dependent on few parameters again already answered I am just repeating myself, but it is for you it is becoming much easier for you if you already know what are the parameters what are the dependent variables on with the QC program is actually relying on reagents, primer, sample media for example, microbiological procedure for infectious disease, cultural media is very important aspect of a good QC program it has to be made maintained and sterilized properly again test methods equipment and lastly personnel. So, all of these programs needs to be followed right. So, a good QC program follows 10 practices to ensure the best results. So, what are those 10 practices here it is right number 1 use of a quality control material with known values now what is this quality control material we will be discussing it, but basically it is a sample whose value is already known. Now we are testing many unknown sample and along with that we are running a sample whose value is already known.

Now if our test results gives the result of that known sample in a range which is already preset by the quality control program in the acceptable range suppose my blood glucose value I am not going to genetic part I am just making you understand with the help of a simple thing I have my blood glucose level 200 right I am diabetic I am just taking into consideration fasting blood glucose level. Now the machine may give it 180, 160, 170, 220, 200, 220 anything because variation can happen. Now if I have got a control sample whose value is 210 right and along with many sample that control sample is run and the machine gives a very accurate result it gives 208, 215 of that sample then you can easily rely that the test results that this machine has given in this run are actually reliable. So, the main in any infectious is you are running an RT-PCR a CT value right. So, if we have got a control a synthetic made material which will amplify and whose CT value is known I mean we can predict.

So, if the machine is giving an acceptable range of a value of a predetermined sample whose value is already known that actually behaves as a control sample right. So, this quality control material with known value has to be used in order to follow the best QC practice include quality control in the procedure manual very important every lab especially genetic lab as well as diagnostic lab should have a quality manual right where everything is written and documented very important. Monitoring of media reagents stains antigens for infectious disease very these are all very important antigens antibodies for serology right any molecular diagnostic test very important monitor the

equipment of course, train and monitor personnel training and monitoring of personnel competency the people who are doing whether they are well acquainted with the job whether they are having continuous upgrades with the new technologies that are coming in right. Participation in inter laboratory comparison program. So, I might be a very good lab right, but I might not be so sure that I am giving the most accurate result until I compare my result with another lab who is also claiming to give accurate result.

Then healthy relationship competitive health relationship can happen where I am sending my sample which has given this result in my lab to that lab and that lab is also sending a sample which has given some result in that lab. So, in a way we can cross check. So, participation in inter laboratory comparison program very healthy to monitor to practice quality control procedures. Again test like verification and validation will be discussing what is verification what is validation those are very important those are needed and again keeping detailed records and finally, evaluating the whole thing so that what went wrong. So, these are actually 10 best QC practices that I would suggest you to adopt in any laboratory specially if you are working in a molecular genetics laboratory very important because our today's topic is quality control in molecular diagnostics.

So, for I mean, but we need a guide right that guide is coming from one very important reliable source that is CLSI quality and laboratory standard institute. This is the website link and if you open the website link this is how it looks like they have got multitude of sub type sub area you can see over here if you click over here you can I mean this is the thing you will be getting. So, there are multiple sub domains based on which it is divided. So, maybe we are choosing molecular diagnostics for our today's area. So, if we choose molecular diagnostics again this whole thing is divided into two section number one educational program and number two standard.

So, multiple educational programs are always going on. So, there are multiple webinars in which can be participated to learn about all these guidelines or discussion experts are there to guide us in every step we can discuss situation what is happening in our lab and they can suggest we may participate in healthy panel discussion. So, that some problem may be there in our lab how other experts are solving right and there are multiple guides and booklets some of them are free some of them needs to be procured from them. So, these are various guidelines, but for specially molecular diagnostics and infectious disease I would like to mention and these are various code numbers for example, mm 01 mm 07 mm 05 right. So, what are these for example, mm 01 handbook stands for molecular testing for heritable disease and specimen identification right c 62 stands for liquid chromatography and mass spectrometry method.

So, you can see whatever we have taught we have learnt in this entire course you can monitor their quality using guidelines from CLSI. Micro area diagnosis and monitoring

infectious diseases all right mm 22 mm 14 a 2 designing of molecular proficiency testing external quality experience program validation and verification of multiplex nucleic acid assays mm 07 fish folation c in situ hybridization mm 28 q c management for molecular testing right this is an approved guidance. So, there are multiple and these actually takes a long time to adopt the whole team needs to study that specially laboratory director should take initiative to implement themselves every category of staff are well equipped in those guidelines. So, definitely I would encourage all of you who are located I mean who are employed or working or are specializing any specific labs because we have covered the entire huge spectrum of possibility in our entire course. So, you might it might not be possible for a single person to monitor and monitor and work on every aspects right.

So, there are molecular genetics there are infectious disease there are proteomics metabolic disorders every guideline is available you can go through each and every one of them and adopt those best practices. So, regarding molecular genetics the whole stages generally involve three major procedures number one is extraction procedure amplification and then detection right. And each and every one of them may require some bit of monitoring at any stage right for example, if we are dealing with DNA and RNA extraction then the control format might be suppose with our extracted DNA control sample might be a whole bacteria virus right known sample because they will mimic the patient sample. Whenever we are using a control sample we are using a sample with known value all right. Regarding the amplification again if you are amplifying using PCR right a synthetic extract of the whole genomic extract with a known value if this sample have will give positive results the positive control right.

So, at every step there are there are controls that needs to be used and what about the detection detection again a positive controls will be verified nucleic acid such as synthetic extract or whole genome extract which will give a positive result the positive graph or positive CT value in detection that will be a positive signal. And if the patient sample gives signal similar to that positive control then we can claim that our result is positive if the patient sample does not give a signal similar to the positive control we can confidently say that the result is negative. So, now we are coming to verification and validation. So, what is verification very important those two are very close, but there are few lines verification involves confirming that a test performs reliably within a specific level of validation. So, it is about only one library I am working here it is out in my laboratory settings right.

So, it is generally conducted when it happens upon installation of a system or a new method right and it needs to be done a certain number of times for example, often labs repeat a test or a method 20 times in order to verify. So, that the value or the test method is actually yielding reliable results. So, we are verifying whether this method is at par

with a previous method standard method gold standard method right this is verification. What is validation? Validation is a general terminology. So, it involve it as in the accuracy and effectiveness of the test in identifying the intended condition or target.

So, whether we are giving a test it is suppose to happen like that way or not. So, I am actually determining the accuracy and effectiveness of a test in identifying various conditions. So, I have this result and I have to give a positive I mean I know a sample or even if I do not know a sample which has got a positive finding should come out positive right. So, this is validation meaning a sample a patient who does not have the disease should give a negative result a person with the disease should give a positive result. So, this is validation the concept of validation.

Verification is something else whenever something new is coming you are verifying with the technique in a single lab validation is a global thing. Anyway again validation is performed if an instrument is moved. So, we are not adopting any new method. So, if any instrument was is moved from one place to another right may be it may so happen in equipments may or behave differently if they are moved from one place to another because there are multiple tubings multiple fluids immiscible fluids inside the machine multiple sensors which may behave differently all right. So, validation of a test is very very important.

So, also performed on semi routine basis to ensure an equipment or process working properly depending on the lab and regulation is followed. So, I mean are you being able to understand or appreciate the difference between verification and validation. Whenever you find the word new or something which is newly installed it is verification whenever we are trying to reconfirm an existing thing that is validation very important MCQ purpose you should be very cautious the new a newly installed verification right and something which has moved validation. Now, there are multiple types of testing that we do in ongoing quality control. So, what is the frequency generally depending again depending on the turnover depending on the sample load depending on what lot of material I mean what lot lot does not mean here an enormous amount lot means batches of reagents if something a lot is changed then again we have to go through this.

So, the this is not a fixed criteria as per lab, but the type of or the frequency of ongoing quality control generally is determined from laboratory to laboratory based on the amount of sample right. However, there are few things regulation to which a lab should adhere to basically at least it has to be done once in a month or when we get a new reagent lot right. Now, even if we get I mean if we are not having a new reagent lot if we are having a immense number of sample the amount or the frequency of quality control checking should be very frequent and believe me in various big labs quality control is done multiple times even a single day and with every run or every two to three runs of

the entire batch of samples all right. So, it actually very varies from laboratory to laboratory. Now, we are discussing type of control in molecular diagnostics controls may vary or majority two types all right number one IPC internal process control what are they they are built into instruments again for multiple choice question MCQ for purpose very important whenever something is built in it is internal process control to ensure that the instruments are running properly.

So, what happens they are extract simultaneously extracted and then amplified or in some cases only amplified in the same tube with the pathogen target very important these controls are already built into the machine and we are adding samples from outside all right. However, the machine is designed as such it is totally built as a part of the system there might be in a cartridge which might need to refill. However, in case of mainly it deals with the microbiological samples right infectious disease it ensures that inhibition and other malfunctions is not due to a negative sample or if the result is negative it is actually truly negative. So, what it needs to be done? So, see intervals control should always be combined with an external positive control we are discussing what is external positive control to prove that the pathogen functionality of the reaction mix of amplification of the pathogen target. So, what do you mean over here? So, wait we will come back to this slide again.

So, what is external control and external control is an independent control. So, I have taken a complete external sample with a known value that provides a true challenge to the system or process being tested to ensure the system is working properly means my machine basically treats that control as an external sample all right, but since we know what the result of that sample will be we can analyze it and can certify that fine my machine is running properly this concept we have already discussed a minute back. Now, what is internal control? An internal process control is built into the machine which is being amplified in the same tube as pathogen target. Now, if we combine this internal control with external control we have two levels of checking. So, that number one whatever the machine is performing whatever step the machine is performing on the sample right the sample treatment everything the same internal control is already being going through that sample again external control also goes to the same sample, but external control is being provided by third party company internal controls are always provided by the manufacturer right.

So, there might be an problem when the manufacture designs the control in such a way that it will always be positive result even if the sample is not giving a reliable result right that is why we should always combine internal control with an external control. So, what happens even if there is any malfunction or even if there is any inhibition right if we see that both external control and internal control has failed to run and the sample is negative then we can confidently say that the result is truly negative. Whereas, suppose

our internal control has given positive result right, but the sample has given negative result it might not be so sure right. Whereas, if external control and internal control somehow give positive result, but the sample has given negative result then also we can say that the result is negative.

So, see there are possibilities. So, we have internal control external control and sample. So, when internal control and external control has amplified properly and we know that they are they are supposed to give this known value. So, whatever the result of our sample is there we can accept. So, it can be positive or it can be negative. If due to some reason one of these controls fails to amplify then our result will become non reliable we cannot provide the result we have to rerun the controls or we need to recalibrate the machine in order to check for the machine reliability and integrity before delivering the test results right.

So, now considering all of this if a if we are dealing with a human genetics lab then what needs to be done right. So, that we can adhere to proper QC practices number one review of available scientific literature and references right. So, in order to draft a proper procedure for any genetic test which is actually an ongoing innovation because there might not be multiple convincing evidences in your local area for inter laboratory comparison. We should always conduct a thorough review of literature to see what methods are being adopted what methods give a positive results. So, what is our area of expertise what is our area of demand to design a proper method to adopt a proper method or to procure a proper equipment.

Again define approval patient population for what is the test should be done we saw in European population cystic fibrosis is very prominent or I mean prevalent and in Indian population thalassemia or hemolytic disease very important right. Again select appropriate test methodology for the disease condition very important for molecular diagnostics establish analytic performance specification determine quality control procedures using appropriate number type and variety of samples this is very important. So, this self explanatory we to determine it is preset all this things should be predefined before starting or developing or while defining any human genetics lab. And lastly we need to ensure that the results can be interpreted for individual or patient and the limitation of the test are well defined and reported. Number one the reporting should be clear enough so that there are not many technical jargon for the patient or the case or the relative to understand the result right.

And there should also be clear cut mentioning about what are the chances what are the positive and negative predictive value etcetera of these test right. So, a positive test will not guarantee the outcome or a negative test does not guarantee immunity for example, all of these are very important when we are dealing with genetics lab. These have

already been discussed when are when we are discussing specialty counselling and patient education right. So, all of this needs to be in place. So, quality control is the thing where we are monitoring whether all of these things we have learnt are being applied or implied properly while developing a lab procedure.

Again how do we select a specimen for test validation number one adequacy of the specimen for prevalence of the disease and mutation of variant. So, whether we are having adequate specimens in order to run the test if not we may not even think or consider developing that procedure for our lab right for any lab we can refer it to any higher centre. Specimen types so what are the specimen types generally that include blood, buccal swab, dried blood, spots we are doing genetic we are in genetics lab it can use a post mortem as well as anti mortem samples it can be anything any body fluid fresh or frozen tissue paraffin embedded tissue, pre-entered specimen anything right anything can be a sample. So, all of these samples or specimens there should be provisions for treating all of these samples in lab and again that has to be monitored. For multiplexing a genetic test all mutation and variants should be detected right.

So, once the disease have got multiple possible multiple mutations. So, in order to provide a negative result we should make sure that all of these mutations main mutations are being tested before giving a negative result how will we get that information again by reviewing of literature. So, very important what we need to implement in order to develop a proper quality manual for a genetics lab. Very important for rare genotypes whether alternative samples are acceptable or not suppose a rare disease only single type of sample is considered and the patient has come with very amount of inadequate sample. So, whether that test can be done with any other type of sample this has to be clearly documented in a policy document in a quality manual right and that should be properly adhered to.

So, procedural adherence mind it is a part of QC training or QC practice and specimen selection for test validation should be always done and the actually these all of these ensures that the proper specimen is actually selected for test validation. Because the final result aim is to validate whether the patient or the specimen that is coming from a disease or suspected disease personnel is validated by giving positive or negative results all these factors need to be considered. Now, regarding documentation of data doc why document documentation should be complete it should be consistent it should accurate and it should be reconstructable. So, you can read this slide you can pause this slide and read this slide this is the basically verbatim I mean representation reproduction of what has been told or by FDA right. Now, completeness it should be very complete there should not be any loop holes anything should not be left out nothing should be left out right.

It should be consistent the way how we are taking the data how we are documenting should be same similar for each and every test each and every category of test right. It should be accurate whatever data we are documenting should actually represent what the situation is there is no scope of writing something which is unwanted right and again it should be reconstructable. So, something if it is coded if you are writing short hand if you are following any pre structured questionnaire someone who has not taken the data for I mean if someone leaves the station or some new personnel comes to do the duty the and if you are pulling the data from the record section for future any cases your legal issue the thing should be reconstructable one should be able to understand the entire case from the documented data. So, very important from for the angle of documentation all these things needs to be considered.

Next we move on to PT or proficiency testing. So, what is PT? This is the evaluation of a laboratory performance against a pre established criteria. So, I have there are some pre established criteria for example, CLSI right quality laboratory standard institute they have this mention some criteria or there might be some criteria some gold standard. So, whether the laboratory is performing as per those pre established criteria or not right. Now, these proficiency testing this PT I am I am see this proficiency testing is also very big topic in itself.

So, we are just over being the whole thing here right. Now, this PT you can read more if you want and we can discuss more in live sessions there is always a room for to discuss more in live sessions right. So, see this proficiency testing can be internal and external right. So, external PT may be used for you guessed it inter laboratory comparison. So, whenever I am testing my results with some other labs right.

So, whatever they have done we know they are good. So, now, we are doing we are also reproducing the same data similarly. So, now, we are proficient enough we are participating external proficiency testing. Internal proficiency testing may be used for intra laboratory comparison. So, I have two equipment one both I have to follow same criteria right. So, I have one equipment that is delivering a result as per a known criteria I have another equipment that should also deliver a result as per the set criteria.

So, since it is in my lab I have two different equipment giving the same result because I have more samples. So, to compare that that is where internal proficiency testing comes. So, much like you see I will tell you what is the difference much like you see a proficiency testing is one of the many quality assurance measures that allows a laboratory to demonstrate its ability to. So, what does it do confirm continued competent performance.

So, a lab should be able. So, if a lab is I mean participating continuous in proficiency

testing program it is excelling right it is meeting the criteria then it will ensure that the lab is competent enough to deliver a consistent reliable results. Again compare performance with other laboratories may always. So, happen that one laboratory give some result and our laboratory in which I or even I are working is giving a different result right. And then there might be legal issues someone might put a court case that your laboratory give me the wrong result. But if we are participating and meeting the in proficiency testing meeting the criteria ensuring that all things are in place then you can confidently say the result of our lab is the best and you can easily rely.

And if we are doing that there will be no chance that our lab will give a different result from the different lab considering all the other random errors and systematic errors that are always possible, but other than that whenever a quality run is fine whenever our result is out we can confidently report that and we can compare it confidently to other laboratories as well. And again proficiency testing ensures that is to be done. Compare performance among analytical staff. So, if we are so one thing leads to other our lab is giving right results.

So, definitely the ones who are doing are doing it correctly right. So, compare performance amongst analytical staff. So, all of the performance analysis are actually evaluated via proficiency testing as well. Again if something is not happening correctly it can also reveal the loopholes for identifying areas for improvement right. So, ultimately it ensure customer confidence in the reliability of laboratory work for just as I told. So, if I am excelling in my p t if I know I am doing my things right whatever my result is there the patient can rely on my result and then the patient will not have a dilemma that oh I need to spend again some money in order to check my sample from a second laboratory.

It is true for any diagnostic parameter not only molecular diagnostics all right. So, in addition the proficiency tests assess the quality of operation definitely is done at the level at laboratory level. So, at laboratory level what does it reveal any ambiguities and in frequencies or any other problems with SOP. So, the procedures that I have jotted down the in the manual whether they are right or wrong if things are going well they are right if not they need to be changed right gaps in training program. So, all these things are now we are now highlighting whatever p t goes wrong right.

So, again if something lab is not performing well in a proficiency test there are gaps in quality training program all right. Problem with equipment equipment. So, what may be the problem equipment may be the equipment is very costly, but it is not being maintained properly it is not being calibrated properly right. There are various performance check programs web based or a engineer can come there are multiple equipments the multiple chemicals reagents many things are there, but all these things

need to be done routinely in a cyclical manner to ensure that the performance of the equipment is up to the mark.

Then only we can rely on the result that the equipment is giving. Again in suppose everything is right, but the reagent that we are using is unstable may be the temperature has not been maintained properly a primer needed to be stored at minus twenty may be the freezer was off. So, it has given negative result may be very much possible right. So, very important. So, instability of examination material is revealed via proficiency test performance when everything is right again there might be problem with the method.

So, that is actually ties with this point. So, anything if it is not right these are the areas which we need to look into right and if things are actually happening properly right then good if not the data that will be measuring will be uncertain right. So, mainly the genetic test since we are concerned about molecular diagnostics if proficiency testing of the lab is not performing well the result the outcome we will not be confident enough to tell you or the patient relative right. There is a very dangerous situation right that should always be avoided. So, even if we are planning all these things should be done first before starting a diagnostic test very important again identifying inter laboratory trends and trends in laboratory system. So, someone is constantly I mean some laboratories constantly training in a this category of test and there might be a problem in that laboratory how it does practice may be the cold chain or the reagent is not properly maintained may be the disinfection is not proper that is why something is getting contaminated and inhibited right.

And this actually helps us since external proficiency testing deals with comparison whether it is equipment to equipment or laboratory to laboratory external PT by looking into the inter laboratory comparison can actually identify loophole in the specific laboratory practice trend and generate inter observer error and data trends very important. So, what laboratory is doing wrong how can it be corrected or one lab is doing it right one lab is doing wrong how one can modify the author how where we are wrong and they are right all these things can be taken care of and I mean pointed out and then can be modified by this proficiency testing. So, a quick comparison or the difference between QC and PT see you already know this right now you can read out quality control involves routine check during testing process. So, we are doing at our level. So, whether all these thing 1 2 3 4 5 this process are right or wrong and I am checking during the test that is QC right.

So, it focuses on monitoring equipment performance reagent quality procedural adherence and personal competency already discussed right. So, they are conducted internally by the laboratory as a part of it daily operations and aims to identify and correct any deviation or defect and maintain quality mind it. There are also external

quality assurance program that is also we call as EQAS external quality assurance program right where we take sample with known value from with a control sample with known value from outside any company third party company, but we are running those samples while running the test. So, basically it is a part of quality control right whereas, PT you already know it evaluates the lab overall performance analyzing the ability to detect and identify specific targets. So, it involves external assessment right whenever someone from outside is trying to monitor what we are doing not the person who is in the laboratory right then it falls in the domain of PT right and distribution of samples with known characteristic by an independent proficiency testing provider.

So, there are labs which are specialized in proficiency testing right they will provide some samples which we need to analyze and let them know and they will judge whether we are up to the mark or not ok. Laboratory analyze this sample using standard testing methods and report this result back to the PT provider for evaluation just as I discussed. So, what PT does it aims to assess competency ensures reliability and comply with regulatory requirements by comparing laboratory performance with its peers and expected value. So, whatever the value of the laboratory is whether the laboratory is doing and whether it is doing at par with other laboratory this is the domain of PT whereas, if I am trying to monitor my results I can just do it. So, what we do is we run inside the lab sticking to various methods that becomes a quality controller QC right.

So, what are the variables that are associated with higher quality indices now that is very easy to discuss. So, SOP standard operating procedure should exist without a written procedure nothing will go someone who is knowing what is doing no not allowed standard operating procedure not only issued by the laboratory director right. A very important as laboratory test result report is issued written or electronic this is a no brainer nowadays because everything is being reported maybe in earlier times something nothing verbal is allowed right I will I am telling you what is the result no it should always be written and documented right and again the laboratory test report mind it not only just giving the result right the value is not important reporting means we are the special is also giving some comments. So, what is there what is the final diagnosis so that will help the physician take a clinical decision. The reporting personnel is giving a report and that should be documented and then again it should be reviewed by the laboratory director.

So, laboratory director is reviewing both the SOP as well as the laboratory test result report right. Again offering the pre medical implementation testing and affiliation with the genetics unit these are very essential for genetics laboratory and to maintain higher quality indices very important. Not only that time to time the laboratory should also participate in licensing accreditation there are multiple accreditation body that accreditation means having a brand or being accredited by a body that will give us a

certificate that this lab is proficient enough and this lab is reliable. So, they will conduct rigorous quality check and then they will pass based on what method. So, suppose I have to test value of RT-PCR for my COVID examination right now I am applying for India we do apply for NABL national board of accreditation for laboratories in western countries also CAP colleges American pathology so very important.

So, either CAP accreditation or NABL accreditation there is also ISO. So, there are multiple accrediting bodies right they have got different levels of requirement. So, some are easy to follow some are hard to follow, but when whether the laboratory is adhering to all of these then these accreditation bodies will visit they will conduct the thorough examination they will have their external assessors and then they will certify accreted accredit whether this lab is suppose example NABL certified lab then it will become very much reliable . So, licensing and accreditation very important indicator that this laboratory is following a high quality indices or the result from this laboratory is very much reliable and the laboratory who is not accredited with any of the licensing bodies mind it there is a high chance that the result will not be reliable might not be reliable. So, participation in external proficiency testing maintaining a data on turnaround time I told you TAT very important we should provide early result as soon as we as early as possible because it will help us to take immediate clinical decision for the patient, but problem is that should always be documented as well. So, maintaining data on turnaround time just by claiming that we give very fast results not possible.

So, in accreditation visit this is very checked very much. Again laboratory director should be someone who is credible with an M D or PhD degree in that specific diagnostic area right. So, he has certified and has a formal training not only the laboratory director all the lab technician should also have a university degree and should have relevant training other than that following high quality indices is not actually possible. So, this is the final draft in QC testing. So, in molecular genetics what we do from our practical experience as well as some literature review entire draft should be formed right based on various templates. Then multiple workshops practices the personnel should undergo training from multiple workshops the external quality assurance schemes that actually can identify help to identify multiple problems that should be considered then finally, a consensus guideline should be drafted that has to be published we just cannot that has to be peer reviewed rigorously.

So, number we can publish those guidelines though we can publish those intended things either on web or for open consultation. And finally, after editing from multiple experts who are experts in this genetic field then only we can come up with a consensus guideline for a testing procedure. So, whether it be SOP what is equipment that is the procedure what who will do the training what should be the turnaround time very important. So, to summarize this is the infographic summary that everything we have

discussed. So, the entire quality assurance services is basically consisting of documentation which relies on continuous quality improvement and quality assurance right there should be adequate resources for reviewing the literature resources for I mean reagents batches lots right we can take help of additional proficiency testing additional external proficiency testing accreditation bodies there are specialist services who can provide all this to help us attain these things again regarding the management every very important laboratory director should have a PHD laboratory director should be qualified enough and he has to review not only laboratory director the staff they should have a formal training the laboratory director reviews all the SOPs standard operating procedures as well as the test report and finally, with all of them now we are confident enough that we can start or initiate a test process.

So, whether the test process upon request is clearly reported to the patient right and the patient is easily able to interpret the whole thing all right. So, it was a very informative class. So, I request you to go back revisit the concept and so that if nothing is clear I mean you can always discuss it in the live session. So, these are my references for today's class and I thank you for your kind attention.