# QUALITY MEASURES OF TTI

A quality oriented approach is essential for TTI screening in Blood Centre in order to provide safe and effective product at all times.

TTI screening of donated blood are critical processes that should be followed to ensure safe blood transfusion. Blood should either be released for clinical use or be discarded on the basis of screening tests.

- **Common pathogens which can be transmitted through transfusion of blood or blood components:-**

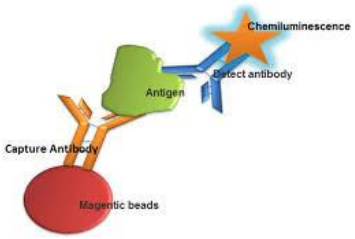
| **Pathogens** | |
|---|---|
| **Viruses** | Human Immune-deficiency Virus I & II |
| | Hepatitis A virus, Hepatitis B virus, Hepatitis C virus, Hepatitis D virus, Hepatitis E virus, Hepatitis G virus. |
| | Human T-cell lymphocyte viruses types I/II ( HTLV-I/II), Torque teno virus, Dengue virus, Chikungunya virus, Ebola virus, Parvo virus, Influenza, West Nile Virus, Lymphatic choriomeningitis virus(LCMV), Epstein Barr virus, Human Herpes virus(EBV), Human Herpes Viruses 6,7 and 8(HHV), etc. |
| **Parasites** | Plasmodium, Babesia microti, Trypanosoma cruzi, Leishmania, Toxoplasma gondii. |
| **Bacteria** | Treponema pallidum, Staphylococcus epidermidis, Staphylococcus aureus, Bacillus cereus, Streptococcus, Propionibacterium acnes, Enterococcus faecalis, Escherichia coli, Serratia, Enterobacter, Klebsiella, Yersinia, enterocolitica, Morganella morganii, Acinetobacter, Proteus, Pseudomonas. |

- **Mandatory tests for screening in BLOOD CENTRE as per the Drugs and Cosmetics Act of India include:-**

1. **HIV-I & HIV-II**
2. **HBsAg**
3. **HCV**
4. **Syphilis**
5. **Malaria**

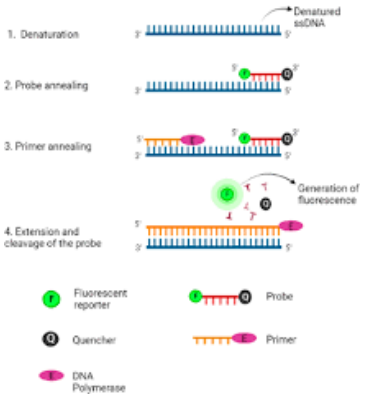
- **TTI screening test methods:-**

**1. <u>Serological test</u>**


**a) Rapid Tests** **b) ELISA Tests** **c) Chemiluminescence Tests**

**2. <u>Nucleic acid testing (NAT)</u>**



# Quality Control in TTI Laboratory

QC is a process not just testing of a sample . QC monitors test system variation over time . The implementation of a quality control program for infectious disease testing requires access to well selected QC samples, a process for collecting and monitoring test results and acceptance limit to detect any abnormal variation. Here we discuss about the quality measures of TTI.

1. Demonstration of preparation & validation of QC sample
2. Documentation and record about TTI testing
3. Equipment management.
4. External quality control
5. Root cause Analysis

## Demonstration of preparation & validation of QC sample -

1. Preparation of weak QC sample for ELISA testing.
2. Plotting of Levey-Jennings chart
3. Application of westgard QC rules

## Preparation of weak QC sample for ELISA testing—

In house control are Positive and negative control provided with the Kit. They do not detect minor error of kits. There is a requirement of external control. External control are set that included from outside. It monitor assay the performance. Here borderline positive sample and negative sample used to detect minor error in the performance.

Strong Reactive sample selected for HIV, HBsAG, HCV, QC Sample, and it confirm by a referral lab for confirmation.

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AB negative plasma which is Non reactive used to serial dilution

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Serial dilution performed and calculated Cut- off value

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A dilution that is double that of the cut off value or slightly more than double should be selected.

Lot validation done with QC sample. After Batch/Lot validation done store the sample in aliquot vial with proper labeling at deep freezer.

## Plotting of Levey-Jennings chart-

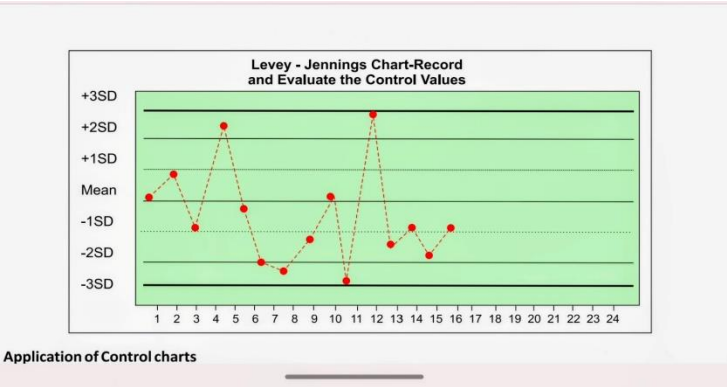
Levey –Jennings chart is a vital quality assurance tool in TTI Tests . It ensures test reliability, detects errors early, supports Westgard rule application, and ultimate guarantees of safe blood transfusion.

## Principle:

**The LJ chart is based on Calculation of Mean, Calculation of Standard Deviation, Plotting control value daily, and monitor the accuracy and precision of Samples over time.**

### Importance in TTI Quality Assurance:

- **Ensures accuracy of test results and prevent false-negative or false-positive donor reports.**
- **Checks ELISA reader stability, reagent deterioration , pipetting or incubation errors.**
- **Provide documented proof of internal QC.**



## Westgard Rules -

**The Levey-Jennings charts can be interpreted using the Westgard rules. These are multi-rules quality control procedures that are designed to minimize false rejections and maximize error detection.**

## Documentation for Quality Control of TTI testing –

In a TTI Laboratory of Blood Centre , proper documentation is mandatory for quality assurance , traceability, legal safety, and accreditation.

- Sample collection and Test date
- The assay procedure
- Maintaning Protocol sheet
- The manufacturer, product number, lot or batch number and expiry date of the assay kits used.
- Proper documentation of Reports.
- Internal quality control record
- Lot-to-Lot validation record
- Reagent stock register
- Equipment calibration maintenance record
- Reactive Donor Unit records

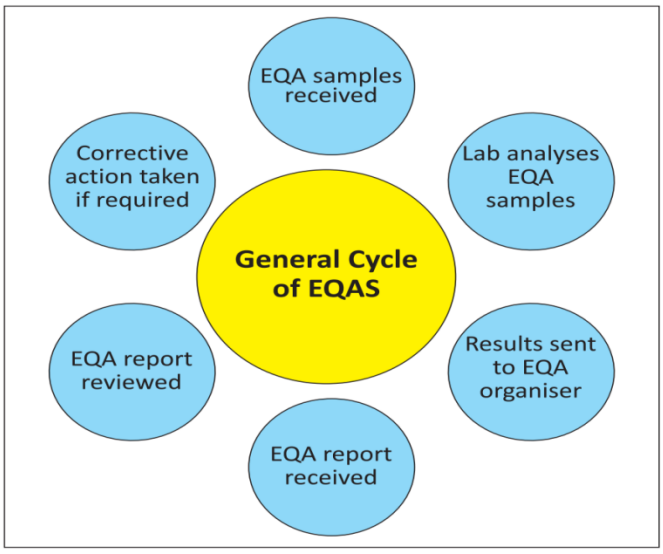
## External quality control-

External Quality Assessment Programs are invaluable tools for Blood Centre to periodically assess their analytical performance and achieve added confidence in reporting their test results or measurements.

**Objective:**

- **Ensures accuracy of Test Result.**
- **Target to achieve excellence in each suevey.**
- **Maintain Standardization.**
- **Detects Systematic Errors.**
- **Mandatory for WHO & NABL guidelines.**

**Steps of analysis :**




**Acceptable Range:**

- The acceptable range is the analytical range around the central value and it is a tool for review for EQA results in both numerical and graphical report formats.
- A result outside the acceptable range should alert the Blood Centre that their assay may produce results that are at risk of determinately affecting report formats.

## Root cause Analysis:

- Root -cause analysis is systemic, extensive and in-depth analysis of a problem with the view to elicit most basic reason that give rise to the problem.
- Failure mode and effective analysis is early detection of defects, determination of the defects and the proactive elimination of the cause of the defects resulting in improved process and product.