# Focus Session B: Molecular Peak Theatre

Chair: Dr Christopher Dalley, Consultant Haematologist, The Royal Sussex County Hospital, Brighton, UK

# Focus Sessions

- Stuart Scott – Dept. Operations Manager
  - Unsatisfactory Performance/Root Cause Analysis
  - Misc
- Debbie Travis – Clinical Scientist
  - Nomenclature
- Annie Tapley – Medical Technical Officer
  - Sample handling

# Unsatisfactory Performance and the Root Cause Analysis Process

# Unsatisfactory Performance: what now?

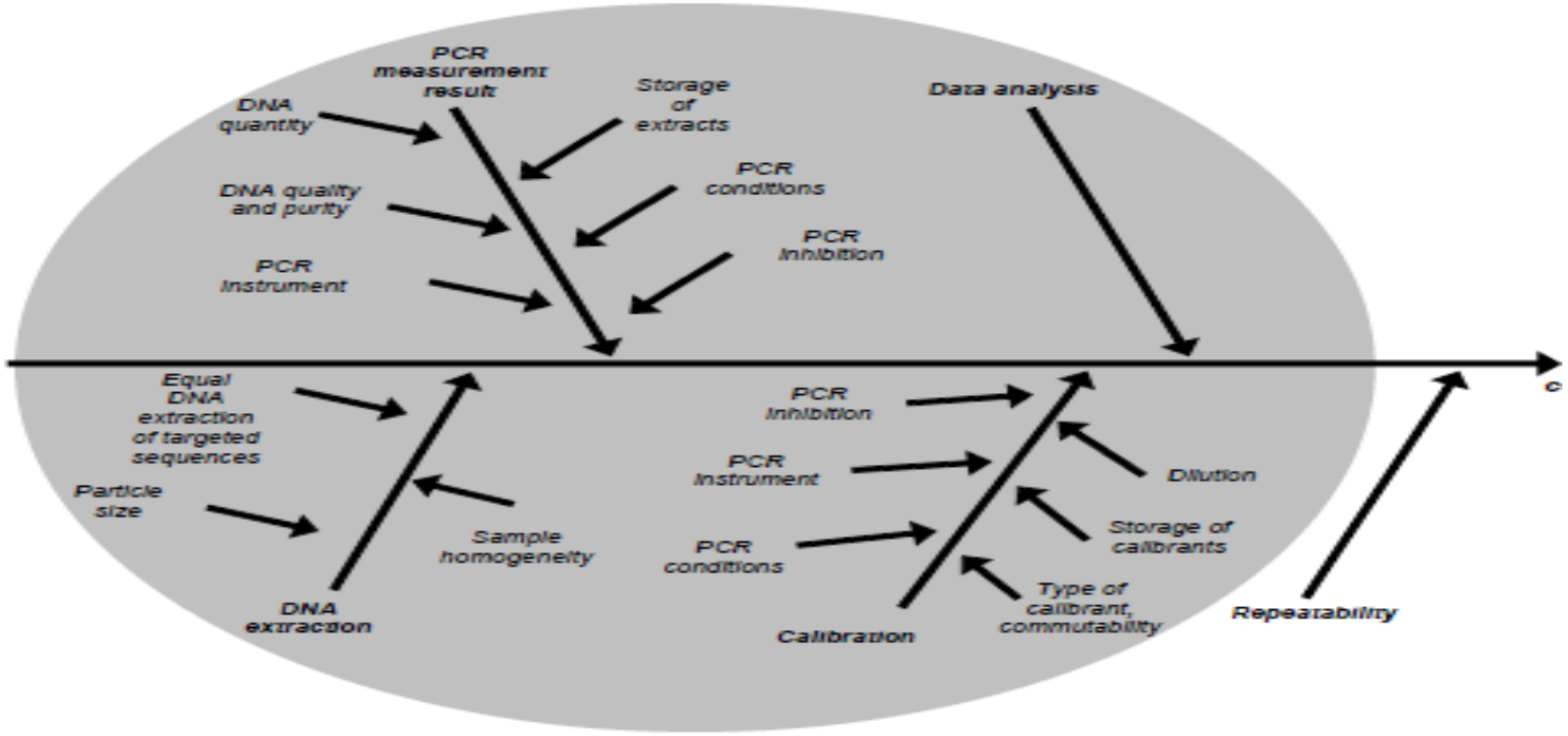
- **ALL** laboratories will occasionally have unsatisfactory performance
- Investigation
  - Recorded
  - Reviewed
- What should a root cause investigation entail?
- Depth of investigation?

Selection Use and Interpretation of Proficiency Testing Schemes. Second Edition, 2011 Eurachem. Available from: http://www.eurachem.org/index.php/publications

# Classification of unsatisfactory EQA performance

- Technical problem
- Clerical error
- Problems related to the EQA scheme

# Sources of technical error



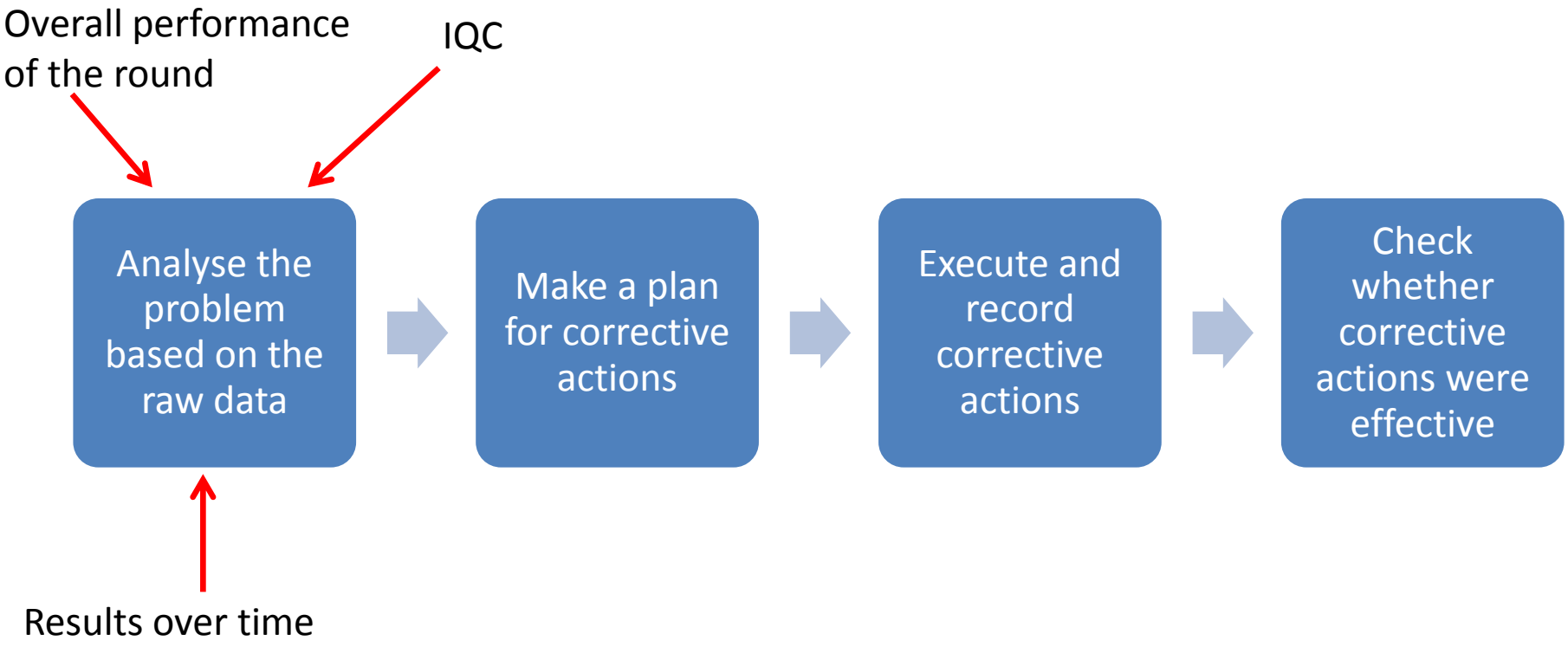
# The 5 Whys

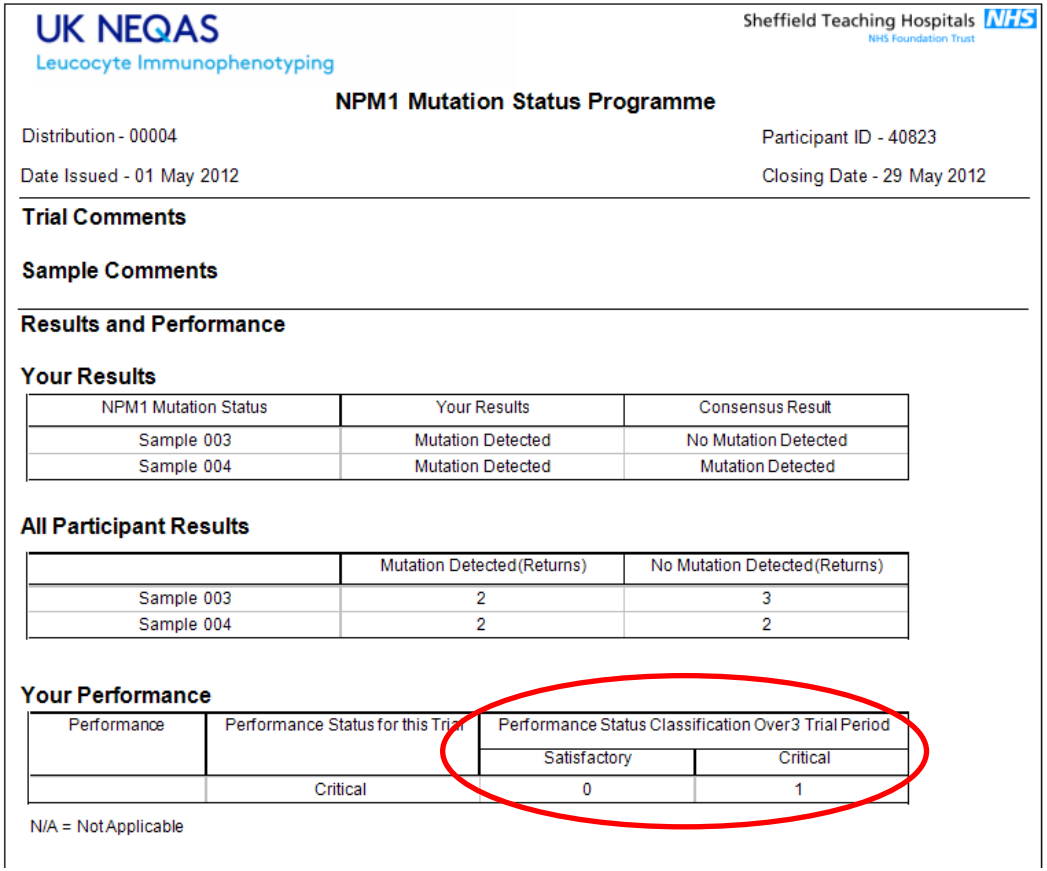
- The vehicle will not start. (the problem)
  - ***Why?*** - The battery is dead. (first why)
  - ***Why?*** - The alternator is not functioning. (second why)
  - ***Why?*** - The alternator belt has broken. (third why)
  - ***Why?*** - The alternator belt was well beyond its useful service life and not replaced. (fourth why)
  - ***Why?*** - The vehicle was not maintained according to the recommended service schedule. (fifth why, a root cause)

# Out-of-consensus EQA result

- Why? Wrong result transcribed
- Why? Result not checked
- Why? Checking process in place but not followed.
- Why? No training/competency process in place
- Why? Department training programme does not include EQA

# Root cause analysis process





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**NPM1 Mutation Status Programme**

Distribution - 00004 Participant ID - 40823

Date Issued - 01 May 2012 Closing Date - 29 May 2012

**Trial Comments**

**Sample Comments**

**Results and Performance**

**Your Results**

| NPM1 Mutation Status | Your Results | Consensus Result |
|---|---|---|
| Sample 003 | Mutation Detected | No Mutation Detected |
| Sample 004 | Mutation Detected | Mutation Detected |

**All Participant Results**

| | Mutation Detected(Returns) | No Mutation Detected(Returns) |
|---|---|---|
| Sample 003 | 2 | 3 |
| Sample 004 | 2 | 2 |

**Your Performance**

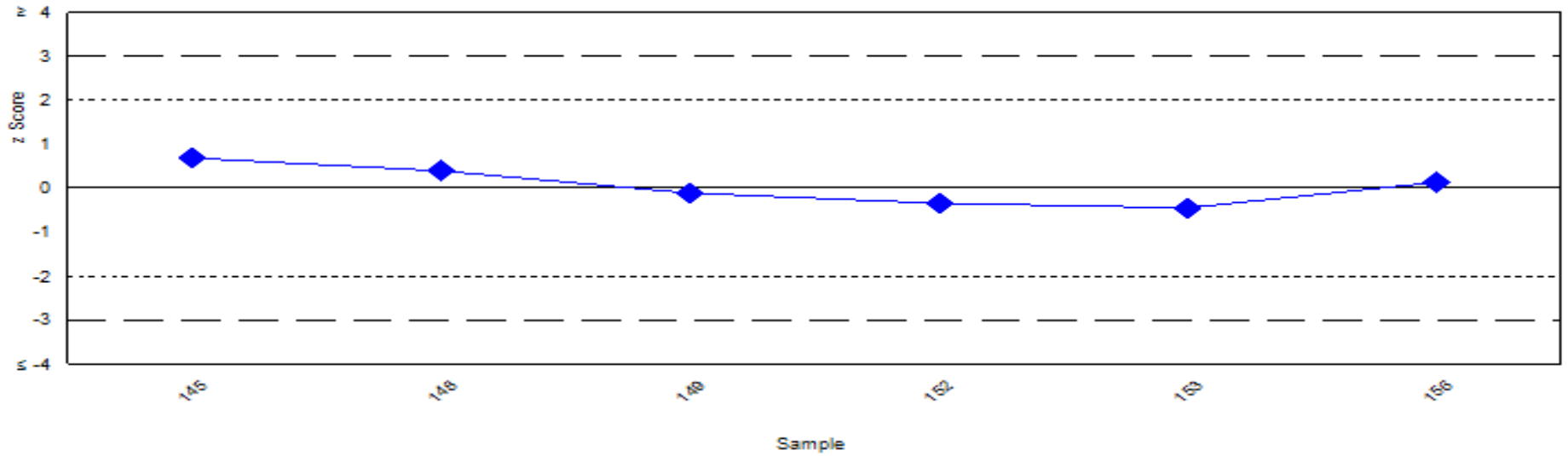
| Performance | Performance Status for this Trial | Performance Status Classification Over3 Trial Period | |
|---|---|---|---|
| | | Satisfactory | Critical |
| | Critical | 0 | 1 |

N/A = Not Applicable

## Shewhart Control Charts

(Please note each data point represents a single sample)

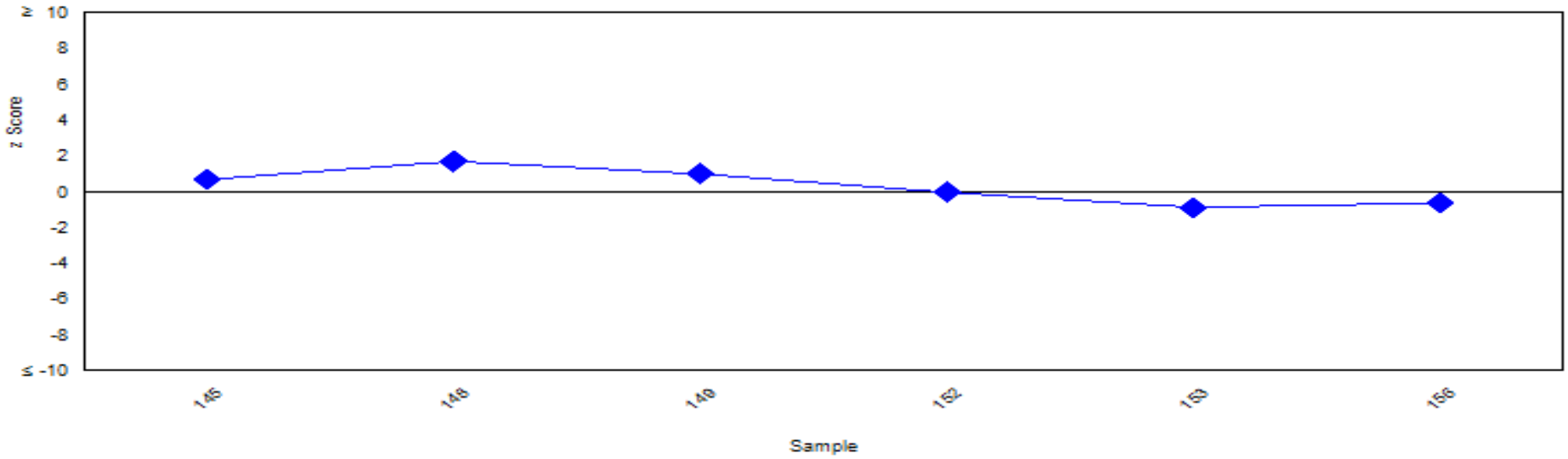
Values (Percentage (%) Donor)




## Cusum Control Charts

(Please note each data point represents the sum of the z scores of the current sample and the two previous samples)

Values (Percentage (%) Donor)



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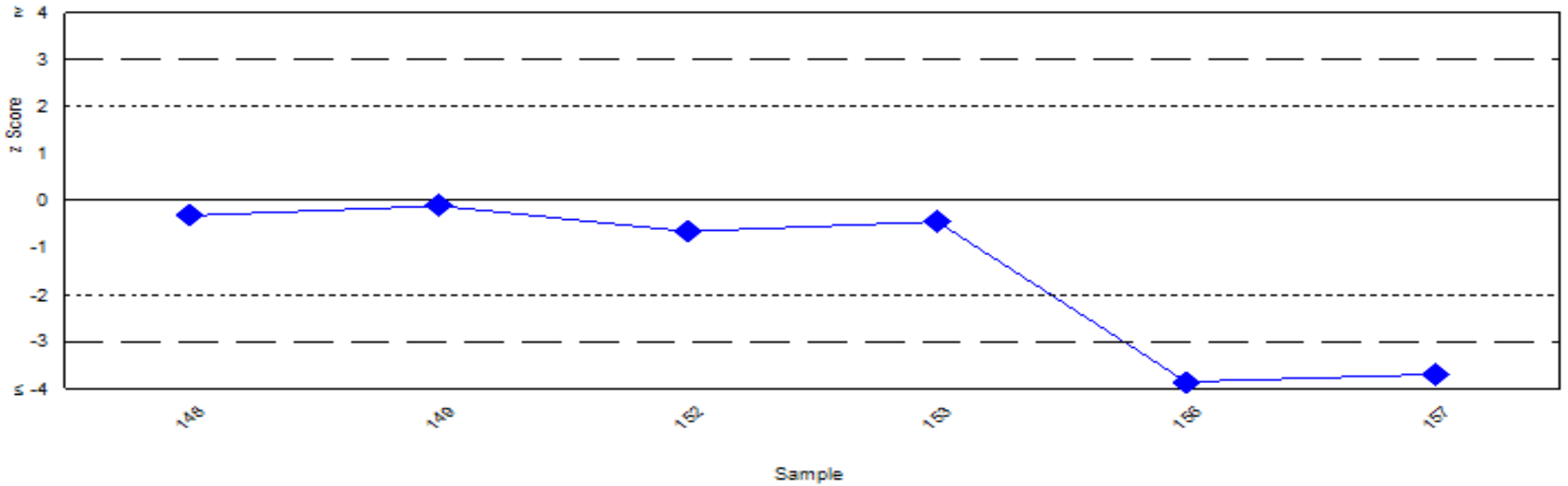


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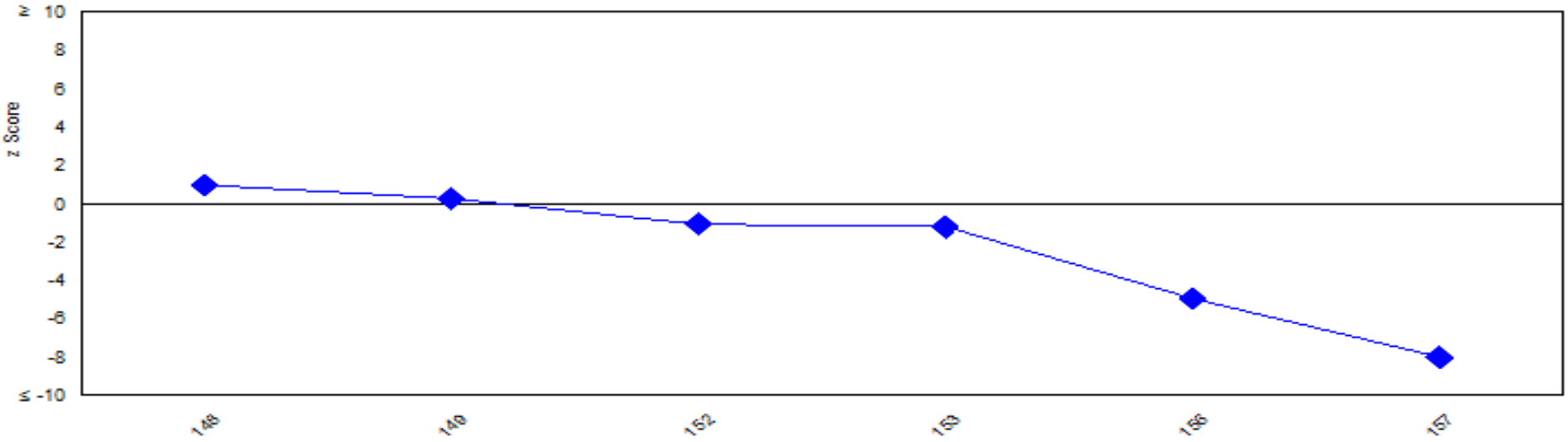

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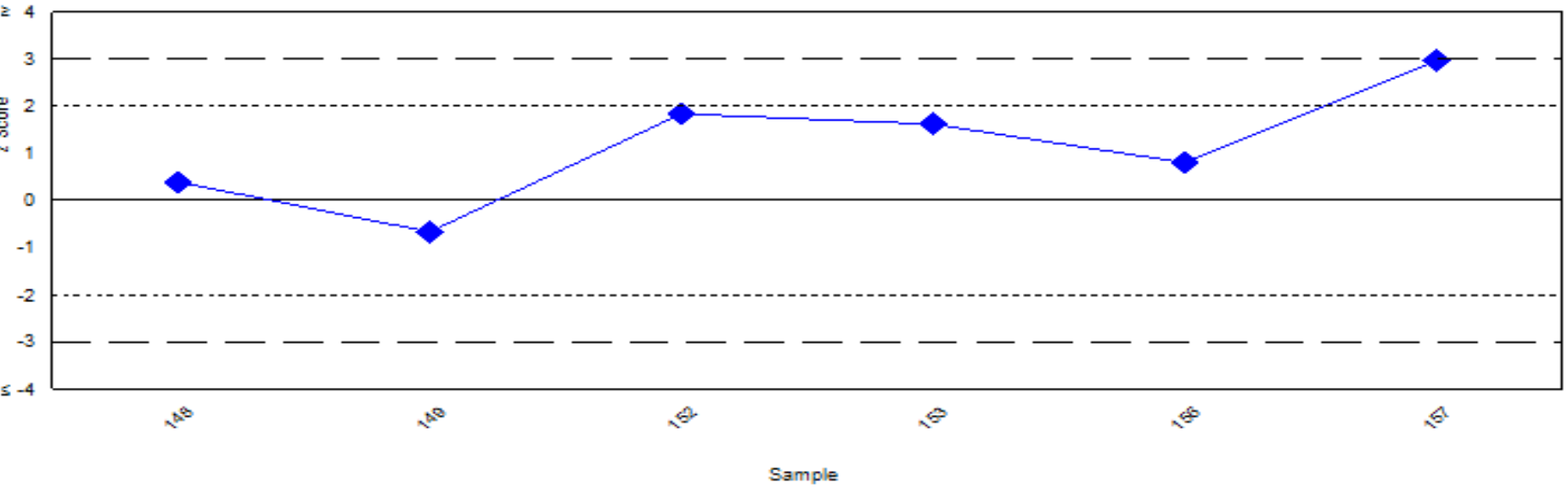


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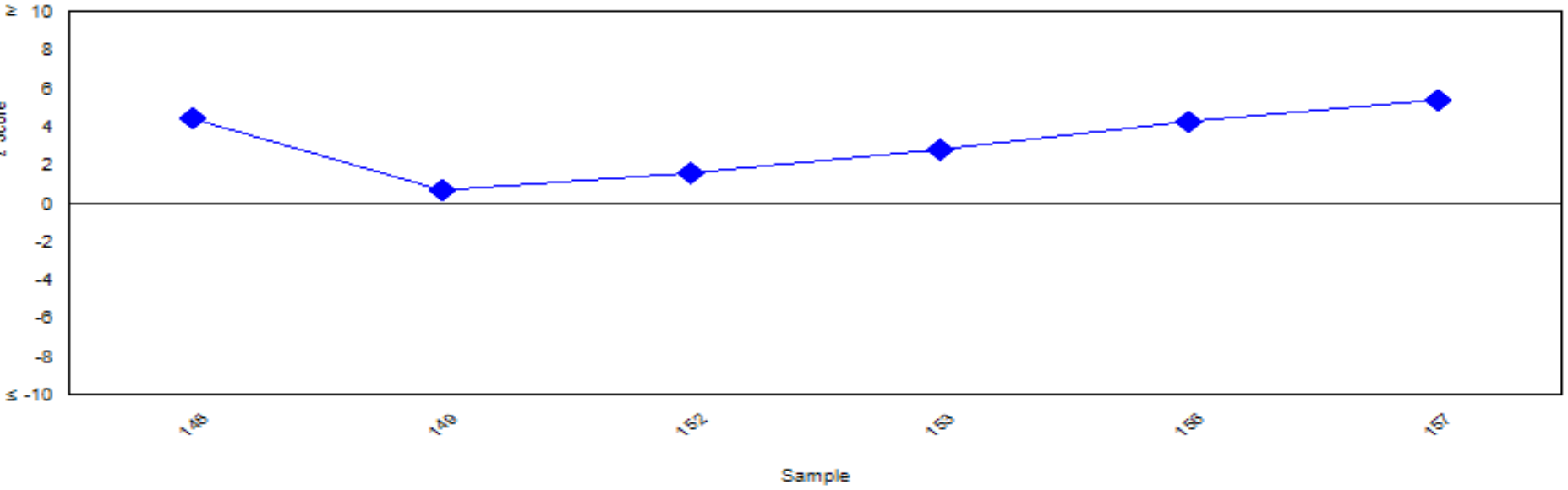

# Assessment of EQA programme

- Parameter range
- Methodological splits

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Mr L Whitby (Scheme Manager): +44 (0) 114 267 3607

# EQA Performance Issues – Incident Form

Following your laboratory's performance issues identified over recent distributions, can you inform us of the actions being taken by your laboratory.
Please complete the form and return to the above address by **XX/X/XX**. We will then keep the completed form on file as evidence of actions taken to ensure quality performance of testing within your laboratory. This form will be available to you on request at any future date if required.

Participant number

Scheme / Distribution

Description of Problem

## ROOT CAUSE

Has your laboratory identified the root cause of the recent performance issue(s)?
(e.g. transposition/ transcription/ sample handling/ reagents/ equipment/ staff training etc.)

Please provide details

## IMMEDIATE ACTION

What immediate action has been taken following your laboratory's performance issue(s)?
(e.g. corrective/ observations/ recalibration/ re-analysis/ review of IQC etc.)

Please provide details



## CONSEQUENCES/ RISKS

What consequences/ risks does this issue pose to patient care?
(i.e. Is it likely to affect patient results, would it affect clinical utility of test or decision making? Is it a critical/ non critical incident?).

Please provide details

## CORRECTIVE/ PREVENTATIVE ACTION

What procedures have been implemented to prevent reoccurrence of the performance issue(s)?
(e.g. issue corrected results for EQA or patient samples/ training of staff/ dissemination of knowledge/ SOP changes etc.).

Please provide details

## FOLLOW UP/ REVIEW

What procedures will be used to review performance to ensure your corrective actions have been successful?

Please provide details

Grade: _____ Date: _____

Completed by: _____

Please return within 14 days from the date of issue of this letter. Please note that if a response has not been received your laboratory will be referred to NQAAP.

## EQA PERFORMANCE FORM

Investigation performed by: Date:

| |
|---|
| Parameter: |
| EQA item: |
| Method: |
| EQA scheme: Round N°: |
| Laboratory's result(s): Acceptable result/ range: |
| Performance evaluation (score): |
| Parameter critical: o YES o NO |
| How relevant is the EQA scheme compared to routine analysis (e.g. matrix, parameters, concentration level, etc)? |

| |
|---|
| Do the results of previous rounds in the EQA scheme indicate a questionable or unsatisfactory trend?<br><br>If yes, analysis of this trend should be provided: |

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## INITIAL INVESTIGATION

| |
|---|
| Was the EQA item received in a satisfactory condition? o NO o YES |
| If no, could this condition explain the poor result? |
| Was the EQA item equivalent to a routine sample? o YES o NO |
| If no, could this explain the poor result? |
| Was the EQA item tested as a routine sample? o YES o NO |
| If no, could this be the cause for the poor result? |
| Is the evaluation based on results grouped according to method?<br>o YES o NO |
| If yes, can this explain the poor result? |
| Based on the comments given above, should the relevancy of the EQA scheme be reviewed?<br>o YES o NO |
| Was the initial EQA item remeasured after receipt of EQA evaluation?<br>o YES o NO |
| If yes, is the result comparable? |
| Was a repeat item requested and remeasured? o YES o NO |
| If yes, is the result comparable? |

## CLERICAL INVESTIGATION

Typical clerical errors can be for example: transcription errors, data entry error, EQA provider not informed of method change, incorrect units used.

| | | |
|---|---|---|
| Was the poor result due to a clerical error? | o YES | o NO |
| Corrective action taken, if any? | | |
| Corrected result: | | |
| Is this result still questionable or unsatisfactory? | o YES | o NO |
| If yes, the investigation should be continued. | | |

## TECHNICAL INVESTIGATION

The following aspects should be taken into consideration:

| |
|---|
| Analytical procedure: |
| Internal quality controls: |
| Storage/preparation of the EQA item: |
| Equipment: |
| Environmental conditions: |
| What impact is there on past and future routine results? |
| Conclusion: |

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## CORRECTIVE/ PREVENTATIVE ACTION

What procedures have been implemented to prevent reoccurrence of the performance issue(s)? (e.g. issue corrected results for EQA or patient samples/ training of staff/ dissemination of knowledge/ SOP changes etc.).

## FOLLOW UP/REVIEW

What procedures will be used to review performance to ensure your corrective actions have been successful?

| | |
|---|---|
| Approved by : | |
| Technical Manager: | Date: |
| Quality Manager: | Date: |

# How can UKNEQAS LI help?

- Repeat samples
- Advice re: sample extraction/processing
- Advice re: root cause analysis process
- Technical advice
- Access to international experts
  - Specialist Advisory Group
  - Other participants

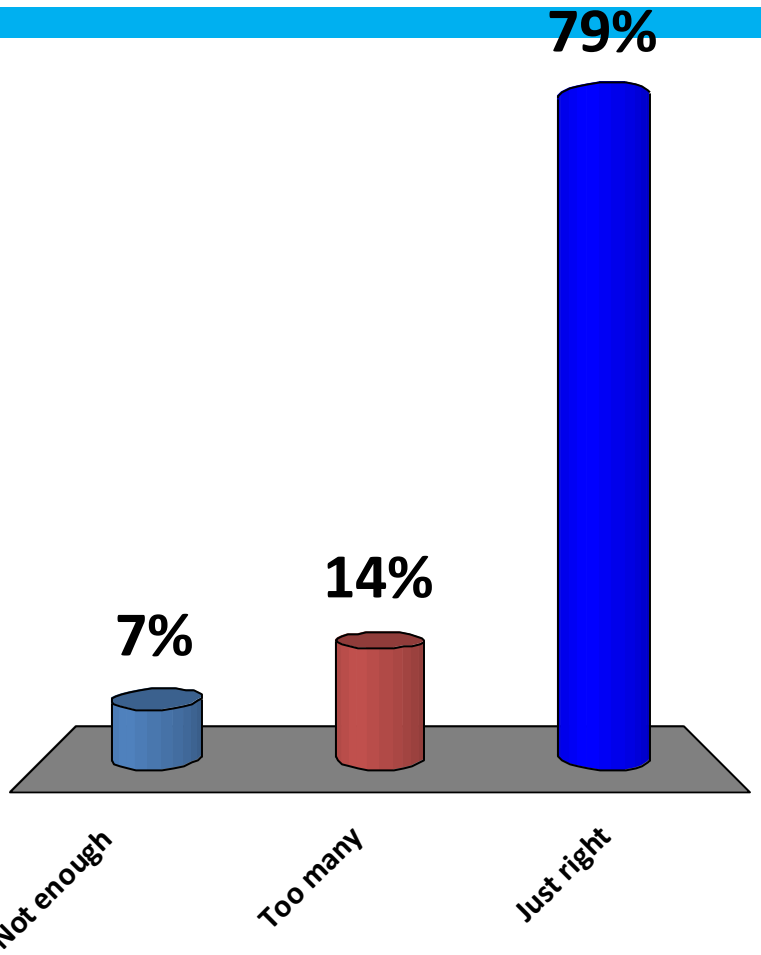
# Live Polling!

# How would you describe UKNEQAS LI trial distribution frequency?

A. Not enough

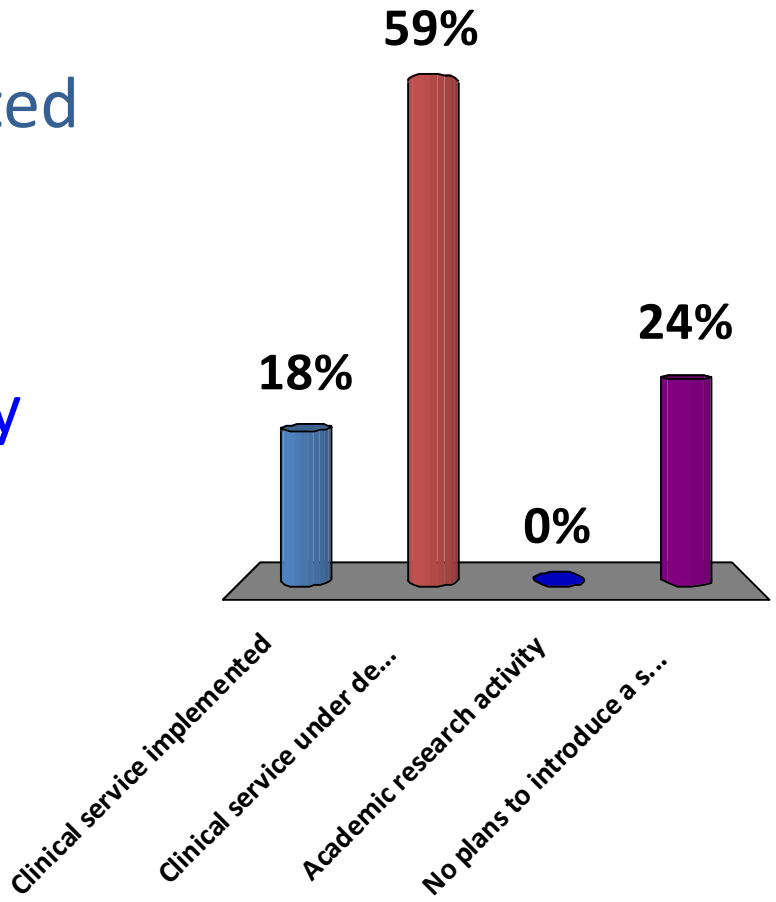
B. Too many

C. Just right!



# What best describes your laboratory's current status with regard to Next Generation Sequencing (NGS) in Haemato-oncology?

A. Clinical service implemented
B. Clinical service under development
C. Academic research activity
D. No plans to introduce a service



# Changes to programmes

- Revamped data entry, analysis and reporting process
- *Accreditation*
  - *KIT p.Asp816Val (D816V) Mutation Status for Mast cell disease*
  - *BRAF p.Val600Glu (V600E) Mutation Status for Hairy Cell Leukaemia*
- Z-scores
  - BCR-ABL1 Quantification
  - Chimerism z-score

# TP53

- ERIC has launched the European TP53 Network.
- The aim of the Network is to improve the performance of TP53 mutational analysis in diagnostic labs.
- Contact: David.Gonzalez-de-Castro@icr.ac.uk

WE NEED ~~YOU~~ SAMPLES!