Identification of Risks in Medical Laboratories

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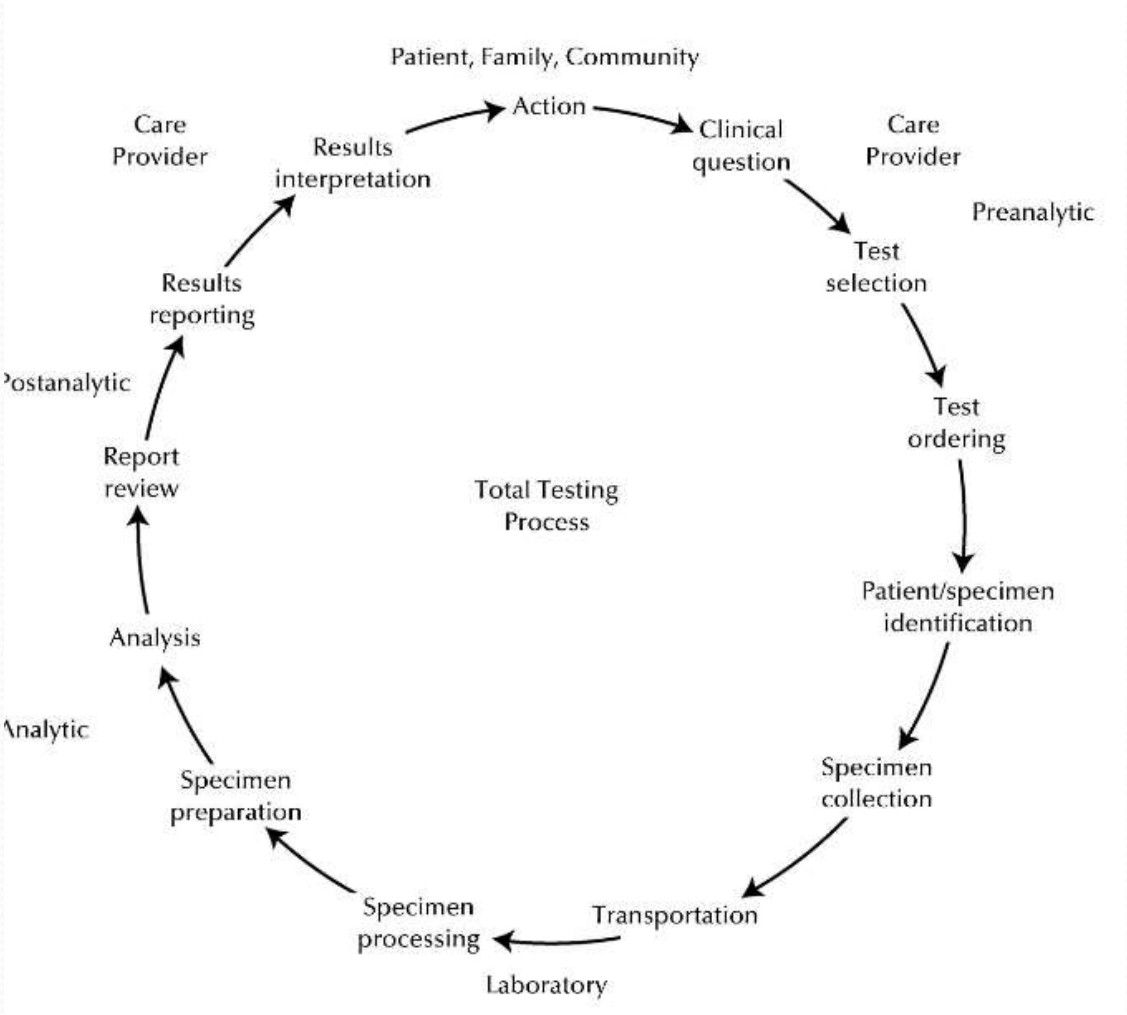
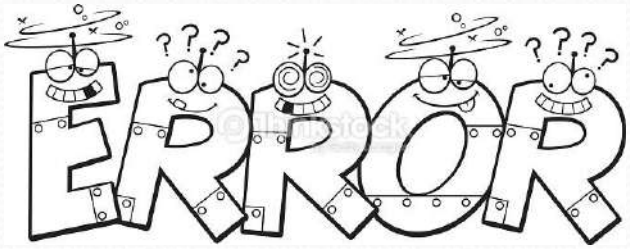
Total Laboratory Process



Sources of Laboratory



Errors within the total testing process

- Incorrect analysis ordered
- Orderer of the test not marked
- Incorrect test request
- Test request lost
- Patient identification error
- Patient preparation error
- Mislabelling of the test tube
- Sample collection error
- Incorrect handling of samples
- Transport error

- Sample lost
- Sample mix up
- Equipment failure
- Analytical error

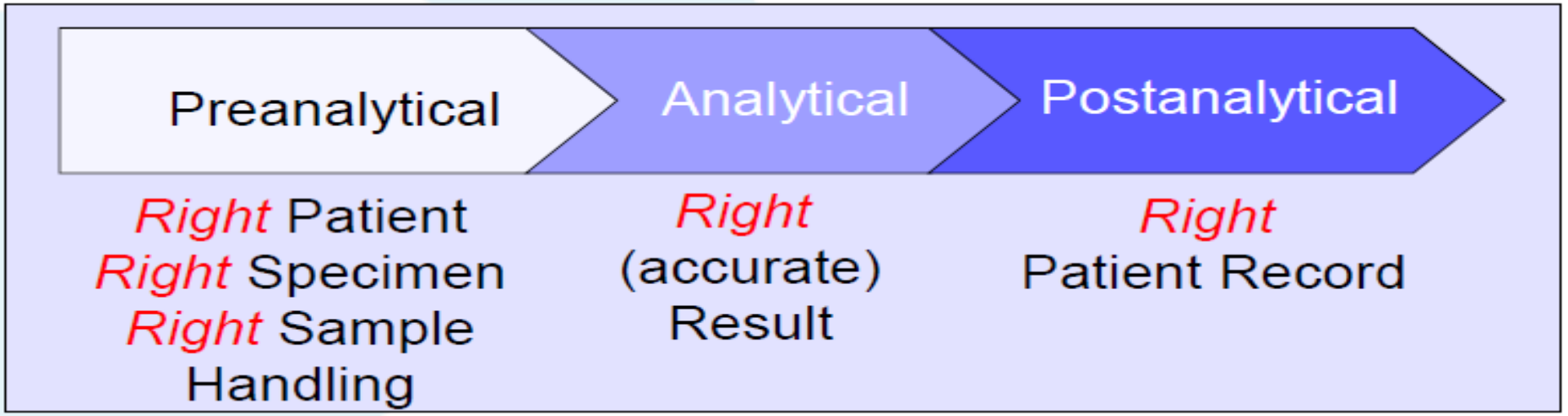
- Test result lost
- Turnaround time
- Transcription error
- Incorrect interpretation

The Medical Laboratory has a wide Risk footprint

Risk Definition

- Risk, essentially, is the potential for an error to occur that could lead to patient/staff harm.
- Risk can be estimated through a combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51, ISO 14971)

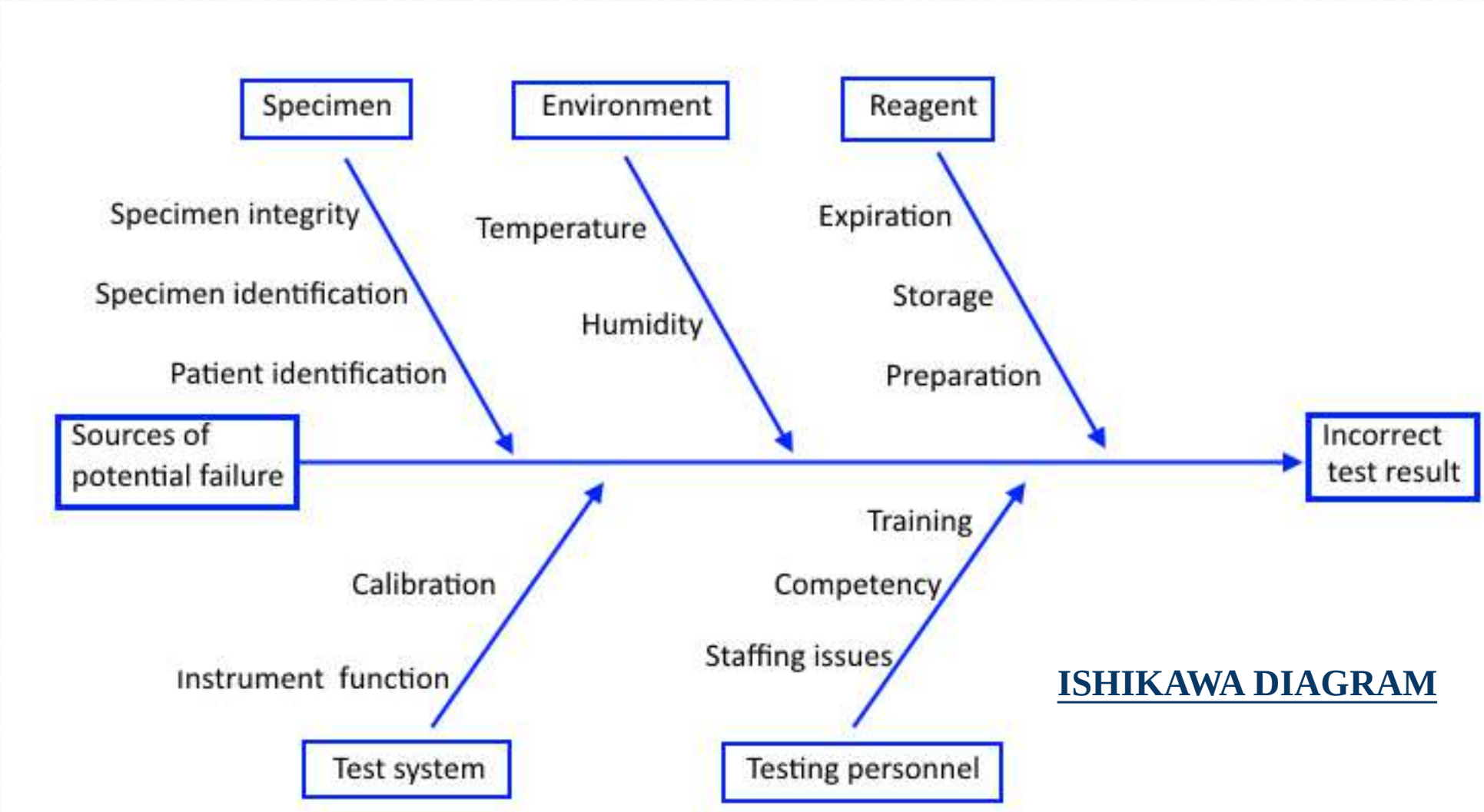
IQCP Development Process



Identify Risks

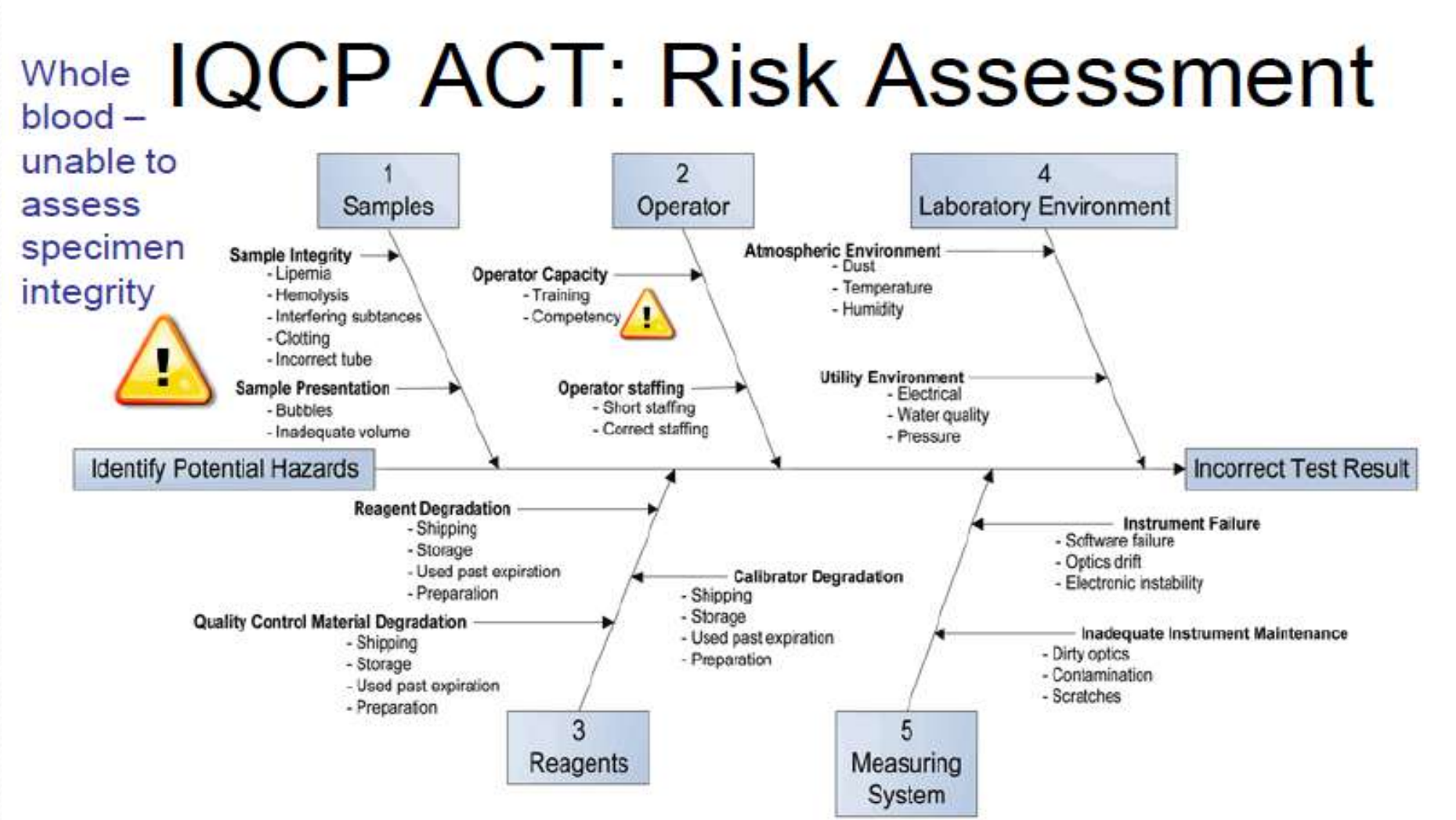
Fish Bone diagram - tribute to its creator

-helps RCA- identity, analyze, improve Quality issues



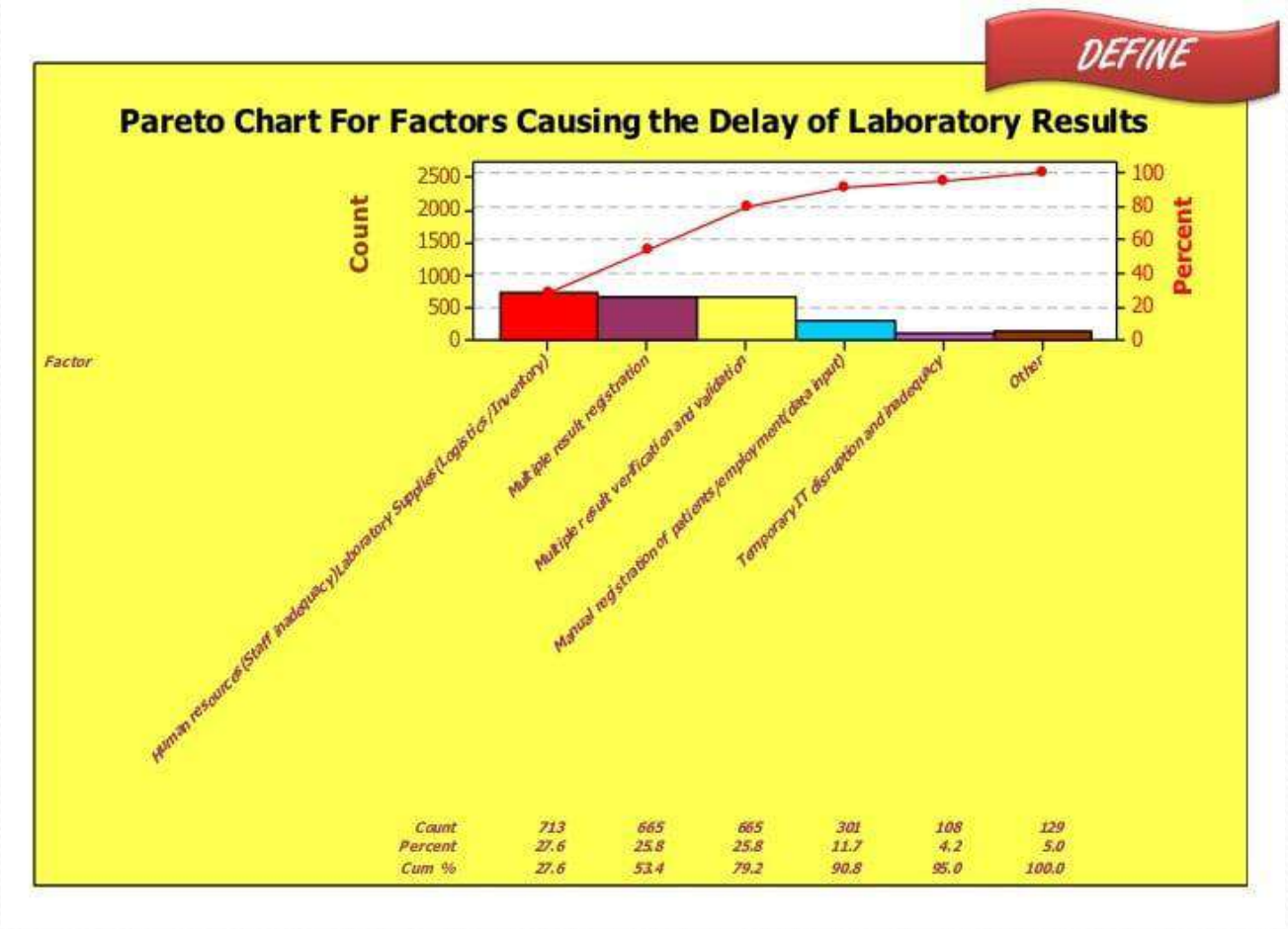
ISHIKAWA DIAGRAM

Fish Bone Analysis

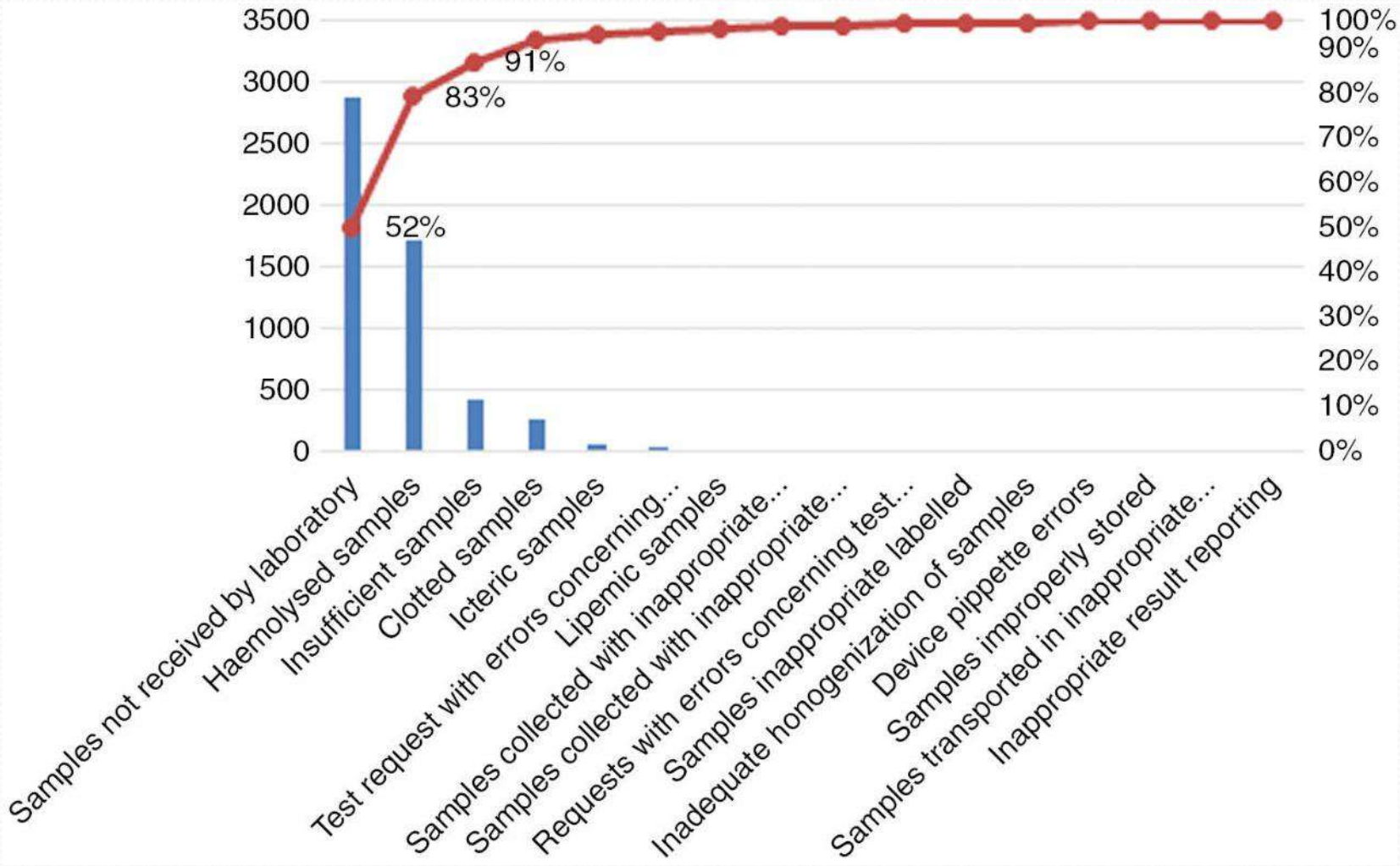


Pareto Analysis – Quality Tool (TQM)

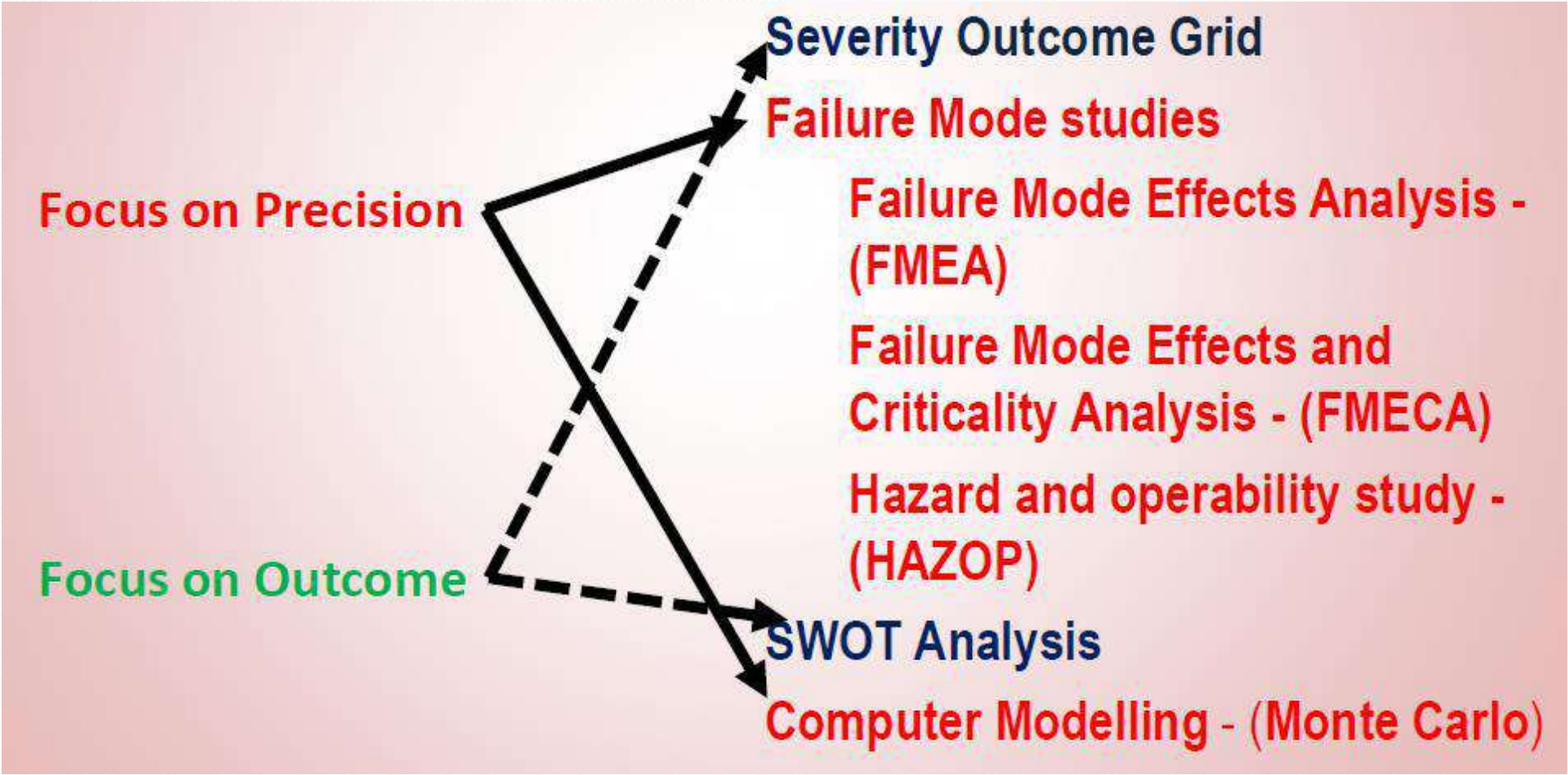
- **Pareto Charts**
- **Trend Analysis:**
- Pareto principle (80/20 rule) is that 80% of problems are produced by 20% of the possible causes
- Bar graph used to rank categories from most to least significant
- Helpful in displaying data presented for management review and action plans



Impact of preventive action on rejection rates in pre analytical phase



Risk Identification/Reduction Tools



- **Failure Modes and Effects Analysis (FMEA)** – systematic review that examines how failures can affect the instrument system or process; a **"bottom-up" analysis**.
- **FMECA**: "Failure Mode, Effects, and Criticality Analysis" estimates risk of failures & harm as part of analysis
- **FRACAS: Failure Reporting & Corrective Action System-** process by which failures are identified and analyzed so that corrective actions can be implemented.
- **FTA: Fault tree analysis** -systematic review of an instrument or system to identify potential sources of failure that starts by assuming a main system failure and determines what could cause it; a "**top-down" analysis**
- FTA and FMEA – analyze comprehensive top-down and bottom-up risk analysis.
- **FMEA/FTA** is ***conducted in clinical laboratory before an assay or an instrument system is implemented/purchased.***
- It is important to include preanalytical (preexamination) and postanalytical (postexamination) process steps in an FMEA/FTA.

FRACAS and CAPA

- FRACAS is sometimes confused with Corrective and Preventive Action (CAPA).
- The difference for a manufacturer of FRACAS and CAPA – is the *FOCUS!!!*
- FRACAS, usually conducted by the **Research and Development (R&D) department,** focuses on design control measures. In a FRACAS conducted before release by a manufacturer, customer complaints do not exist, only *events*. These events could be harmful or could lead to customer complaints.
- **CAPA,** conducted by **Operations Department** and required by **regulatory bodies,** focuses on preventing the recurrence of nonconformities, which in some cases, can result in design control measures.


The 1% failure - catastrophe!!!
PT-TED
TRANSBRASIL

Risk Identification

Pre analytical

Analytical

Post analytical

IQCP ACT: Risk Assessment

Severity of harm

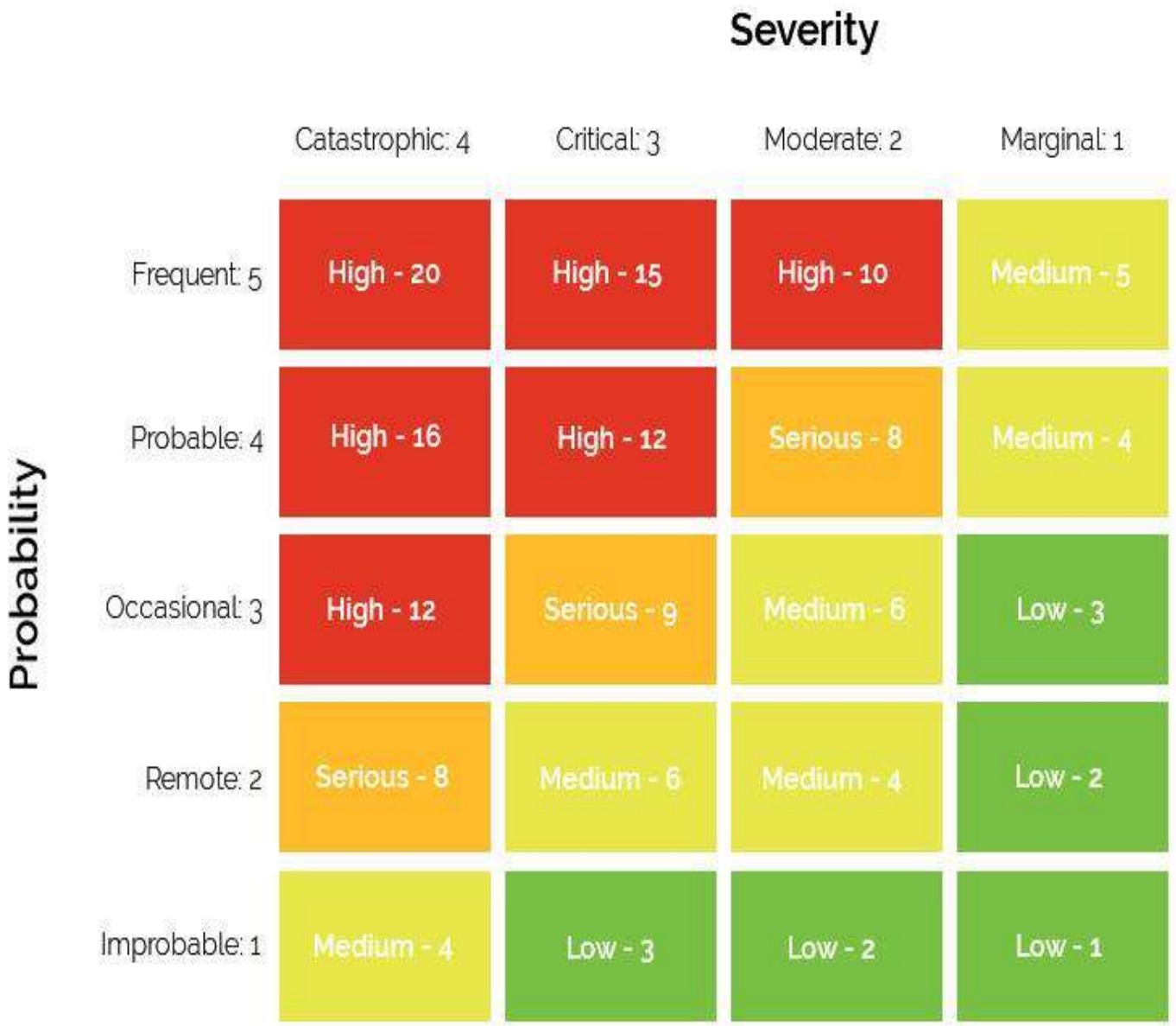
Probability	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	***not ok***	***not ok***	***not ok***	***not ok***	***not ok***
Probable	ok	***not ok***	***not ok***	***not ok***	***not ok***
Occasional	ok	ok	ok	***not ok***	***not ok***
Remote	ok	ok	ok	ok	***not ok***
Inconceivable	ok	ok	ok	ok	ok

ISO 14971

Frequent = once/week
Probable = once/month
Occasional = once/year
Remote = once every few years
Inconceivable = once in the life of the measuring system

Negligible = inconvenience or temporary discomfort
Minor = temporary injury or impairment not requiring professional medical intervention
Serious = injury or impairment requiring professional medical intervention
Critical = permanent impairment or life-threatening injury
Catastrophic = results in patient death

Risk Evaluation- Acceptability Chart (ISO 14971)



The Risk need to be evaluated against criteria approved by the lab director !!!

EXAMPLE OF FRACAS

PRE ANALYTICAL ERRORS (PRE-EXAMINATION)

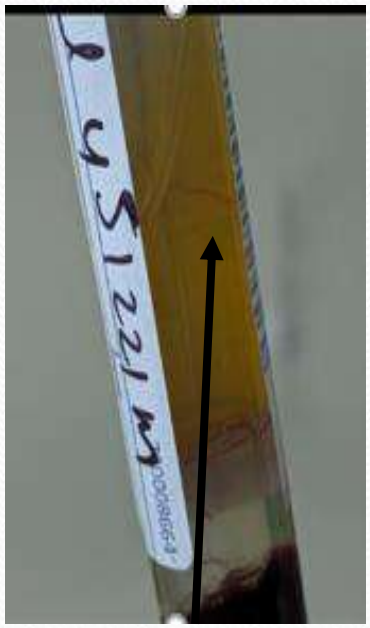
Steps/Type of error in which failure occurs	Failure/ Incident	Cause/RCA	Effect	Risk			CAPA
	Sample Quality Compromised			*Probability*	*Severity*	*Criticality*	
Pre analytical Errors (pre-examination)	Hemolyzed Sample (145/8285) 1.75%	Sample collection protocol not followed strictly	Repricks Patient harm TAT	5	2	10	• Sister on duty informed. • Repeat Sample requested and received. • Staff training • Roving Phlebos • Closed Collections – ECD
	Clotted Sample (92/8285) 1.11%	Sample collection protocol not followed strictly	Repricks Patient harm TAT	5	2	10	• Sister on duty informed. • Repeat Sample requested and received. Staff training
	QNS Quantity not sufficient (4/8285) 0.04%	Sample collection protocol not followed strictly	Repricks Patient harm TAT	4	2	8	• Sister on duty informed. • Repeat Sample requested and received

EXAMPLE OF FRACAS

PRE ANALYTICAL ERROR (PRE-EXAMINATION)							
Steps/Type of error in which failure occurs	**Failure/Incident**	**Cause/RCA**	**Effect**	**Risk**			**CAPA**
Pre analytical Errors (pre-examination)	**Sample Quality Compromised**			***Probability***	***Severity***	***Criticality***	
	Lipemic (7/8285) **0.08%**	**Sample collection protocol not followed strictly**	**Comromised sample**	**4**	**2**	**8**	• **Sister on duty informed.** • **Repeat Sample** • **Report on request**
	Wrong collection (5/8285) **0.06%**	**Sample collected from IV site or diluted Sample**	**Erroneous Results/ Repricks/ Patient harm**	**4**	**3**	**12**	• **Sister on duty informed.** • **Repeat Sample requested and received.** • **Staff retraining.**

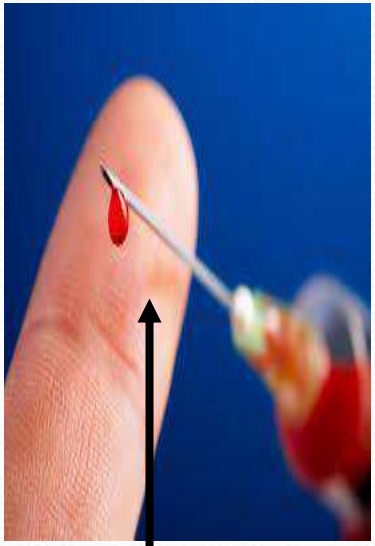
Risk Identification & CAPA

Hemolysis



Fibrin Mass

EDTA Under fill



Needle Stick Injury

Fibrin threads& poor barrier formation

CAPA: Shifting to <u>closed collection system in IPDs & ICUs</u> can reduce the burden of **pre-analytical errors**

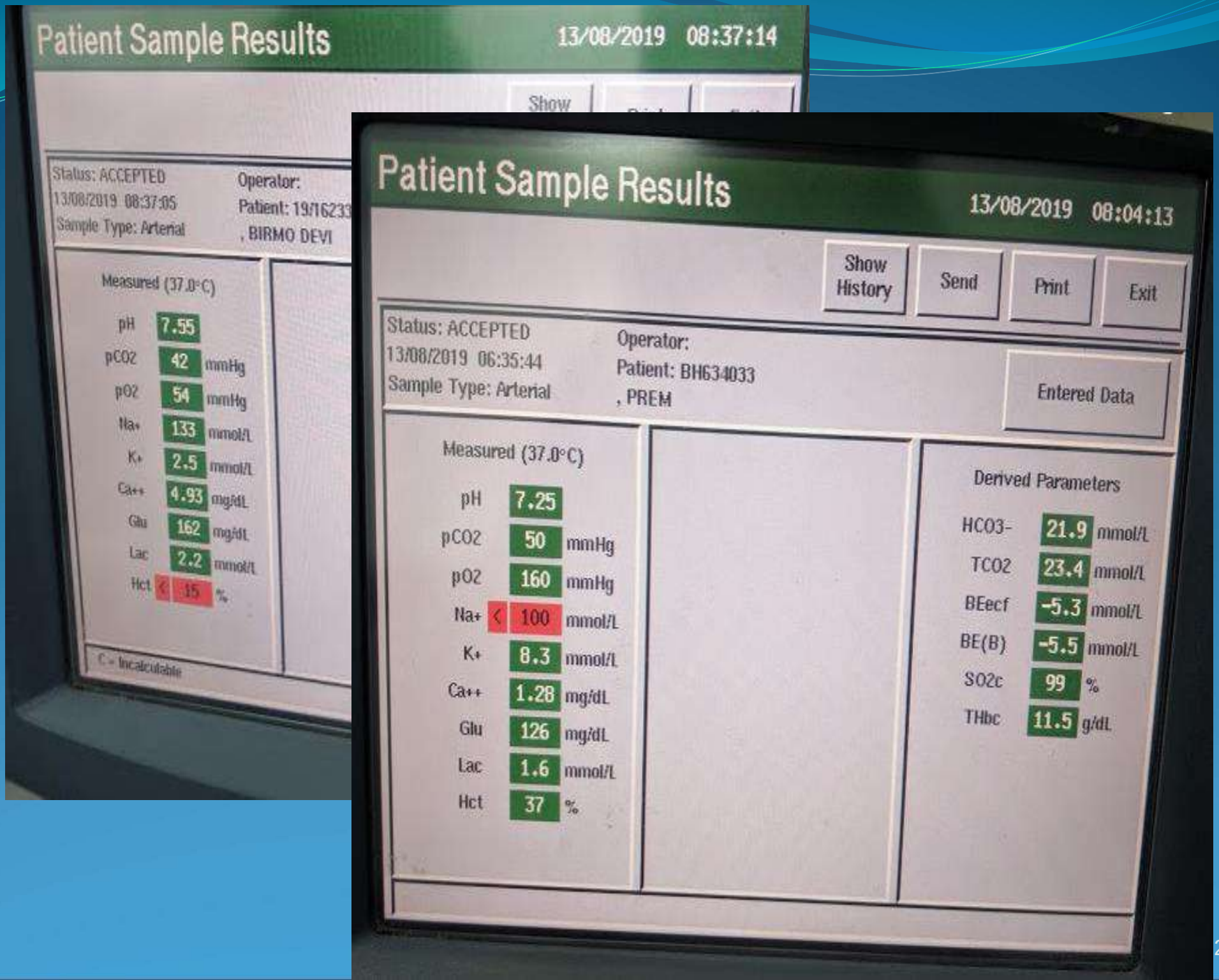
REDUCE – DOUBLE PRICKS, SAMPLE CLOTS, INAPPROPRIATE SAMPLE VOLUMES, NSIs, SPILLAGE, etc.

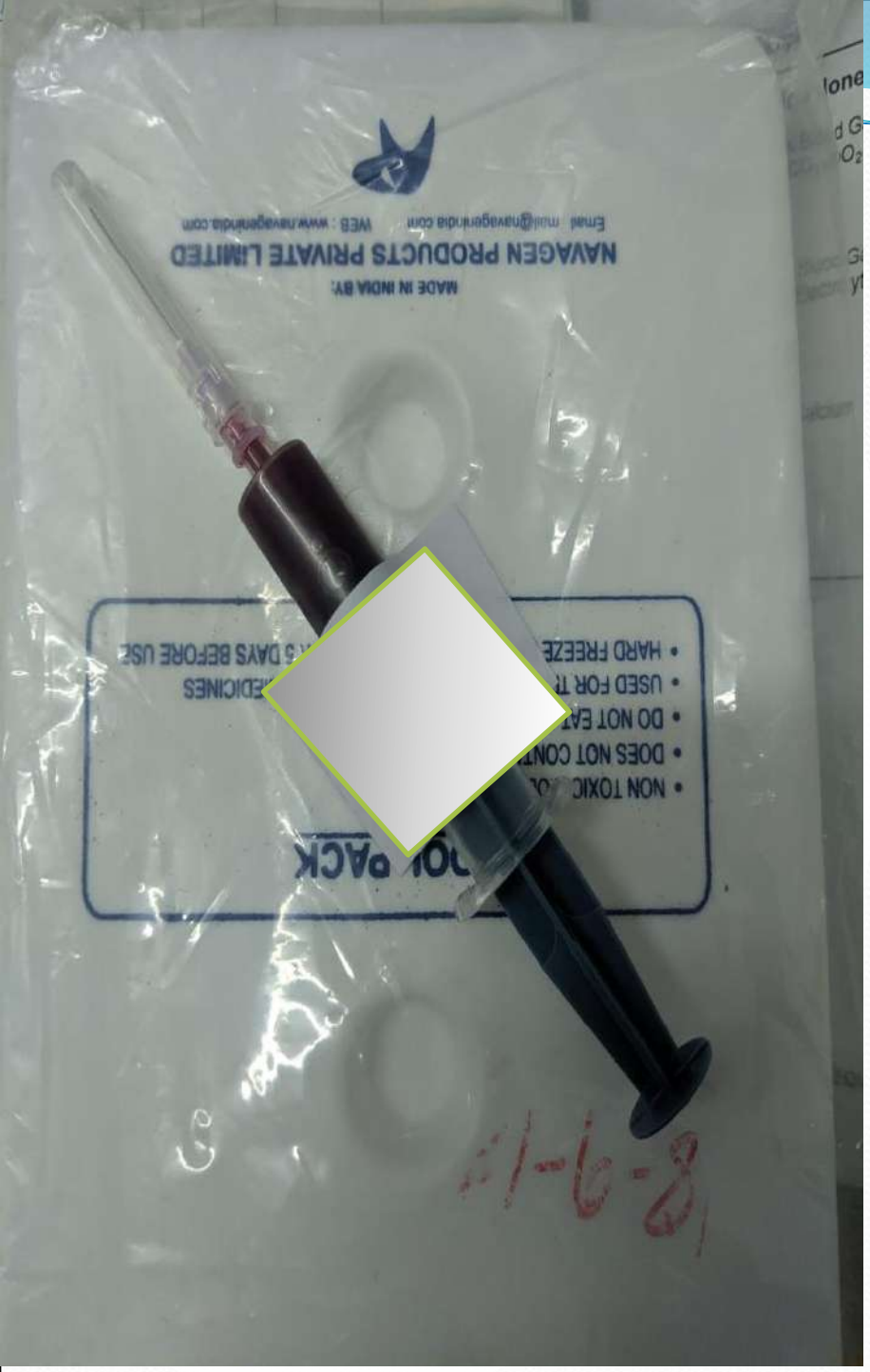
Gaps in Arterial blood collection

Sample flushed with liquid Na Heparin

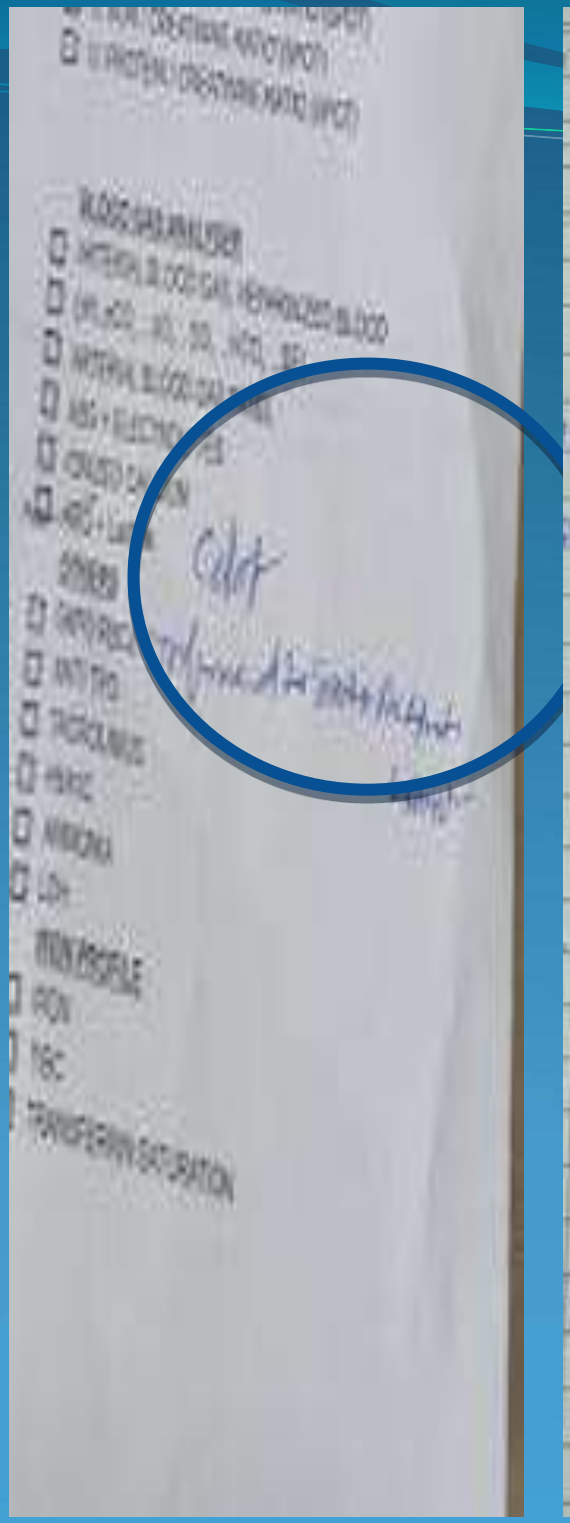
Dilutional effect of liquid heparin

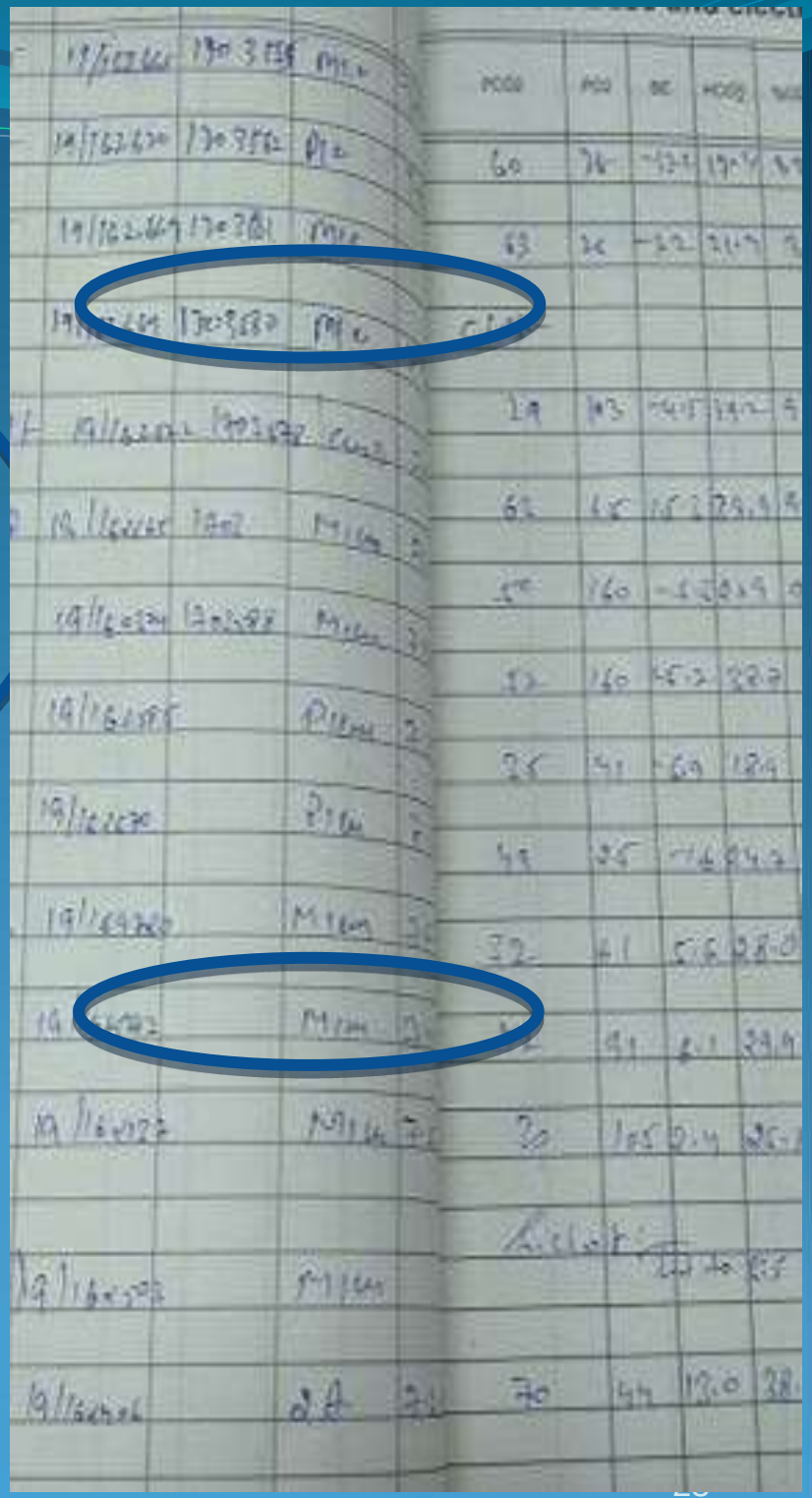
Clotted sample


Patient Sample Results
13/08/2019 08:37:14
Show
Status: ACCEPTED
13/08/2019 08:37:05
Sample Type: Arterial
Operator:
Patient: 19/16233
, BIRMO DEVI
Measured (37.0°C)
pH 7.55
pCO2 42 mmHg
pO2 54 mmHg
Na+ 133 mmol/L
K+ 2.5 mmol/L
Ca++ 4.93 mg/dL
Glu 162 mg/dL
Lac 2.2 mmol/L
Hct < 15 %
C = Incalculable
Patient Sample Results
13/08/2019 08:04:13
Show History
Send
Print
Exit
Status: ACCEPTED
13/08/2019 06:35:44
Sample Type: Arterial
Operator:
Patient: BH634033
, PREM
Entered Data
Measured (37.0°C)
pH 7.25
pCO2 50 mmHg
pO2 160 mmHg
Na+ < 100 mmol/L
K+ 8.3 mmol/L
Ca++ 1.28 mg/dL
Glu 126 mg/dL
Lac 1.6 mmol/L
Hct 37 %
Derived Parameters
HCO3- 21.9 mmol/L
TCO2 23.4 mmol/L
BEecf -5.3 mmol/L
BE(B) -5.5 mmol/L
SO2c 99 %
THbc 11.5 g/dL



ABG sample taken in 5 mL syringe





EXAMPLE OF FRACAS

PRE ANALYTICAL ERROR (PRE-EXAMINATION)

Steps/Type of error in which failure occurs	Failure/Incident	Cause/RCA	Effect	Risk			CAPA
	Sample Quality Compromised			*Probability*	*Severity*	*Criticality*	
Pre analytical Errors (pre-examination)	• Na is 118 in ABG • Discussed with clinician • Not acceptable	• Dilutional • hyponatremia due to liquid Heparin in tuberculin (non-BD ABG syringe) • NON VALIDATED • (Wrong collection)	• Patient discomfort • delay management	5	3	15	• Repeat ABG sample received in BD syringe • RV Na: 132
	• O2 saturation 37 in ABG • Discussed with clinician • Not acceptable	• Suspected VBG collection • (Wrong collection)	• Patient discomfort • delay management	5	3	15	• Repeat ABG sample received • RV O2: 97

BD Critical Care blood collection syringes

BD blood gas syringes

5.2.1 Sample Device

In most instances, the ideal collection device for arterial blood sampling is a 1- to 3-mL self-filling, plastic, disposable syringe, containing a small amount of an appropriate anticoagulant, such as lyophilized heparin. The choice of the type of heparin depends on the specific analytes to be determined and the method of analysis. Because ordinary heparin can bind to ionized calcium and other electrolytes that are often analyzed with blood gases and pH, special preparations of heparin are available, which virtually eliminate the interference from heparin binding of these electrolytes.

Blood Gas and pH Analysis and Related Measurements; Approved Guideline—Second Edition (C46-A2, Vol. 21, No. 11)

All BD A865 syringes contain dry, lyophilized calcium balanced lithium heparin (improved electrolyte accuracy, particularly ionized calcium)

ABG CAPA - Validation Studies

- **ABG BD pre-heparinized syringes Vs 1ml tuberculin liquid heparinizised syringes**

- **Data analysis :** Inter syringe comparison
- **Huge variations in electrolytes**
- **False hyponatremia** - (Na+) > 10% diff - due to dilutional effect of liquid heparin
- **False low Calcium** - since Heparin binds Calcium of blood unlike Lyophilized Heparin saturated with Calcium to avoid any Ca chelation from blood.
- **Erratic results - O**ther analytes ie. lactate, Hct, HCO_3^-, TCO_2, Glucose, etc. ? dilutional effects
- **Effect on pCO_2 and pO_2-** spuriously low in tuberculin syringes, due to the diffusion of gases from thin plastic wall of syringes, while with BD ABG syringe, due to the thick walled ABG syringe and rubber stopper to maintain the anaerobic state, the effect was not there

- ***MEASURE, MONITOR, REDUCE OCCURRENCE***
- ***Management Review : – Circulars – MD***
- ***Trainings – BD – retrainings -Induction plan – Regular plan of all ICUs, wards, ER.***
- ***ABG 10 clots/day to 0-1 Nil today***

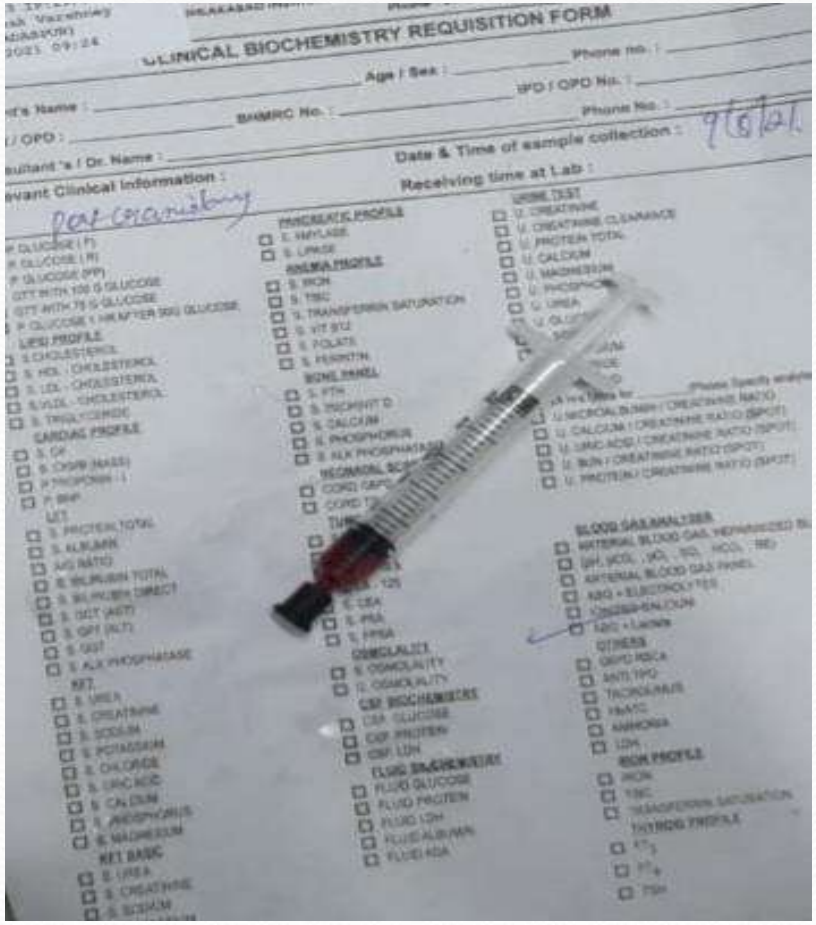
The Covid-19 challenges!!!

Case 1 : The Covid Stories…

ABG sample: Discrepancy found in patient name on ABG sample & TRF

Pre-analytical (*Risk!!*)

- **Wrong labelling/Wrong Identification**
- **Huge Patient Influx**
- **Over-burdened staff**
- **Staff - mistake in carelessness//hurry**
- **PPE issues**
- **Effect- Patient safety/harm**
- **CAPA- Fresh ABG sample, redo work, report ok**
- **Incident Report Raised**
- **DNS Informed/Staff counselling/retraining**

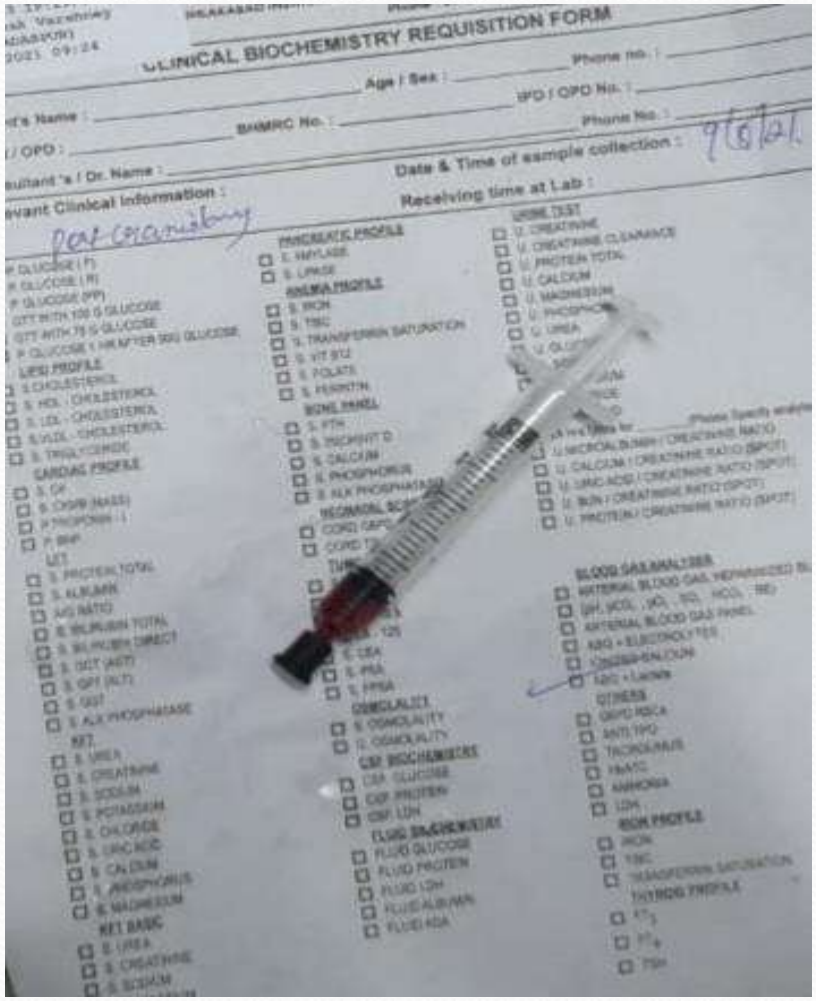


Case 2: The Covid Stories…(2nd wave…)

ABG sample - Without label

Pre-analytical (*Risk!!)*

- **Sample quantity compromised?**
- **Without label ABG sample received in lab**
- **RCA- labelling Error/ Patient Identification**
- **Effect - Patient risk/safety**
- **CAPA- Sample run after discussion with ER Head**
- **RPAs– Internal/Third party**
- **Training Modules/Retraining**



EXAMPLE OF FRACAS

PRE ANALYTICAL ERROR (PRE-EXAMINATION) Case 3 : The Covid Stories…							
Steps/Type of error in which failure occurs	**Failure/Incident**	**Cause/RCA**	**Effect**	**Risk**			**CAPA**
Pre analytical Errors (pre-examination)	**Sample Quality Compromised**			***Probability***	***Severity***	***Criticality***	
	• Wrong report of patient detected by Delta checks • CRP • Day 1:180 • Day 2 :24	• Labeling error due to overburden of staff in pandemic situation • (Wrong identification)	• The Covid Story • Staff shortage • PPE • Misleading information to clinician • Provisional report uploaded	4	3	12	• Fresh sample collected & analyzed • CRP Day 2 RV:380 • Correlating clinically with patient's condition • Final corrected report released

EXAMPLE OF FRACAS

PRE ANALYTICAL ERROR (PRE-EXAMINATION)

Steps/Type of error in which failure occurs	Failure/Incident	Cause/RCA	Effect	Risk			CAPA
	Sample Quality Compromised			*Probability*	*Severity*	*Criticality*	
Pre analytical Errors (pre-examination)	• K value 7.6, Phos- 8.2, • Ca- 8.0; • Not acceptable to clinician	• Tight tourniquet application suspected • Incorrect report	• Patient risk • Psuedo-hyperkalemia • Result uploading provisional report • Lab - clinical validation by lab staff	4	3	12	• Fresh sample collected properly repeated from other arm after stopping dextrose drip for 2 mts. • Fresh sample taken and analyzed • K- 4 .7, • Phosphorus-3.4, • Ca - 8.5 • Training of nursing staff -IP

EXAMPLE OF FRACAS

PRE ANALYTICAL ERROR (PRE-EXAMINATION)

Steps/Type of error in which failure occurs	Failure/Incident	Cause/RCA	Effect	Risk			CAPA
				Probability	*Severity*	*Criticality*	
Pre analytical Errors (pre-examination)	Sample Quality Compromised						
	• K value >10, • Ca <2.0 • Not acceptable	Suspected KCL mix up (Wrong collection)	RESULT HALTED BY LAB (NIL) RISK MITIGATED	4	2	8	• Fresh sample collected after stopping drip and analyzed • RV K 4.6 Ca 9.0 • clinically correlating • Report released
	• Na >200 (NaF) • ALP <5 (Low due to EDTA in NAF vial – chelating effect) • Not acceptable	Serum analyte picked from Glucose vial, Wrong barcode generation (IT error-right click error)	RESULT HALTED BY LAB (NIL) RISK MITIGATED	3	2	6	• Repeat barcode generated for serum sample • Sample reanalyzed • Values ok • Report released

EXAMPLE OF FRACAS

PRE ANALYTICAL ERROR (PRE-EXAMINATION)

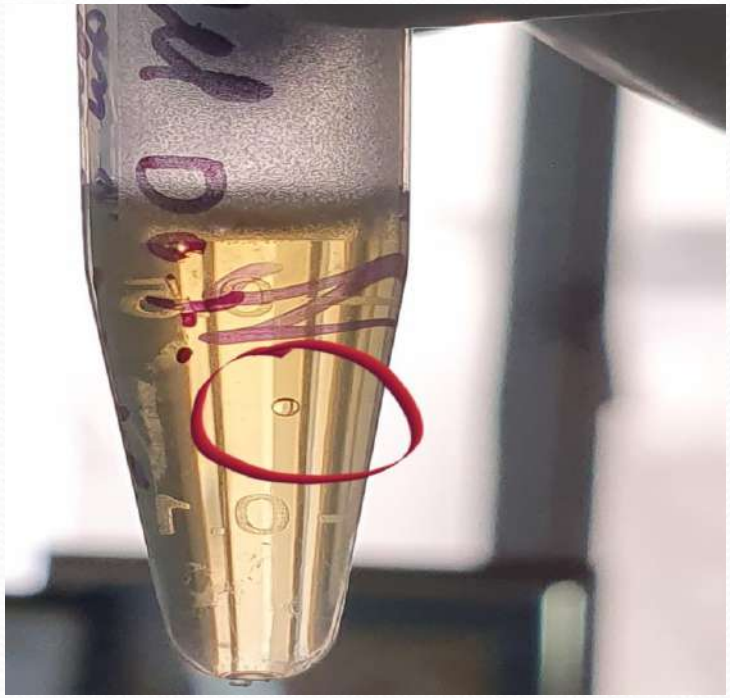
Steps/Type of error in which failure occurs	Failure/Incident	Cause/RCA	Effect	Risk			CAPA
Pre analytical Errors (pre-examination)	Sample Quality Compromised			*Probability*	*Severity*	*Criticality*	
	• Na Value >200 • Not acceptable	• Suspected Saline mix up • (Wrong collection)	Reprick	4	2	8	• Fresh sample collected & analyzed • RV 145 • Acceptable

EXAMPLE OF FRACAS

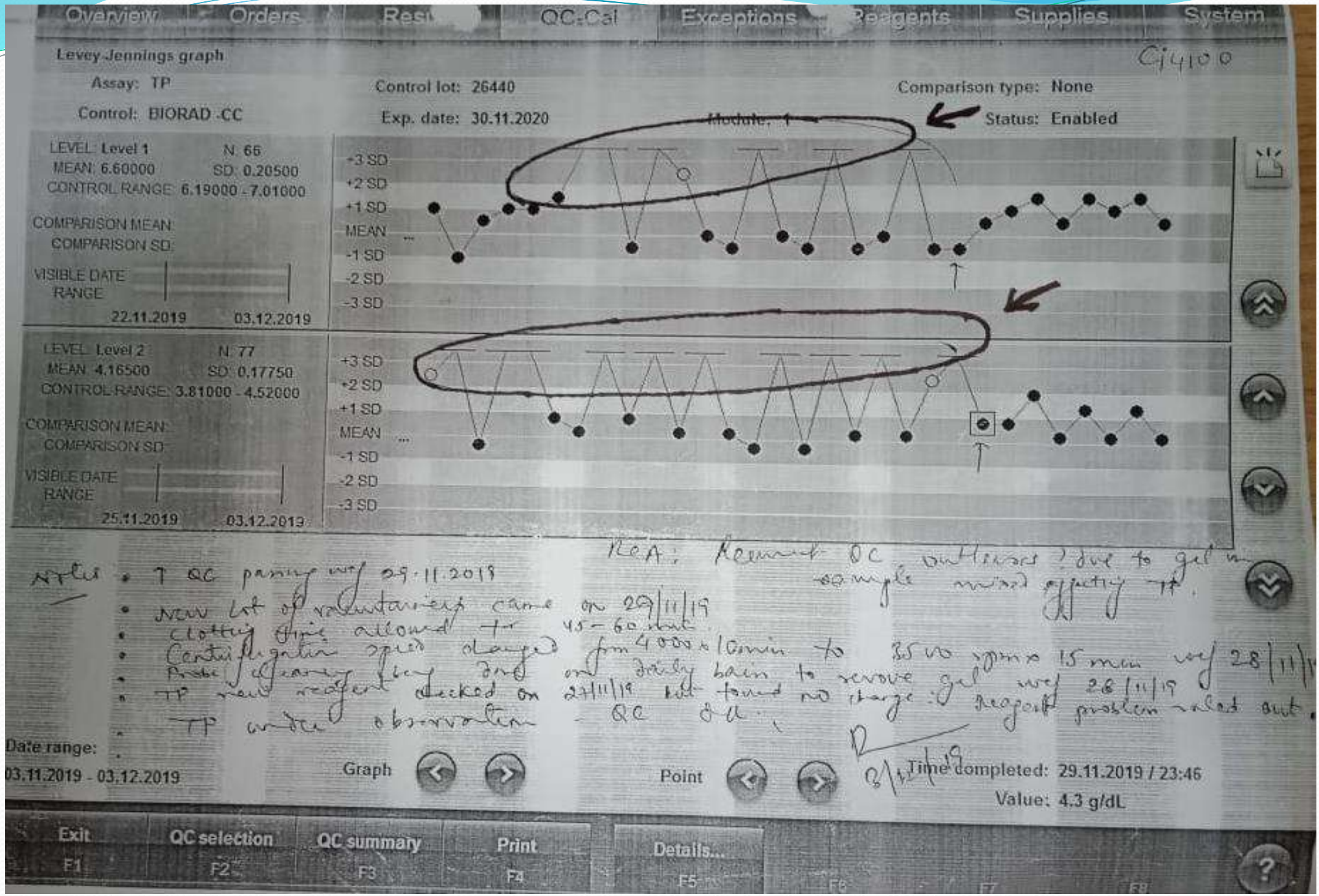
ANALYTICAL ERROR (EXAMINATION)

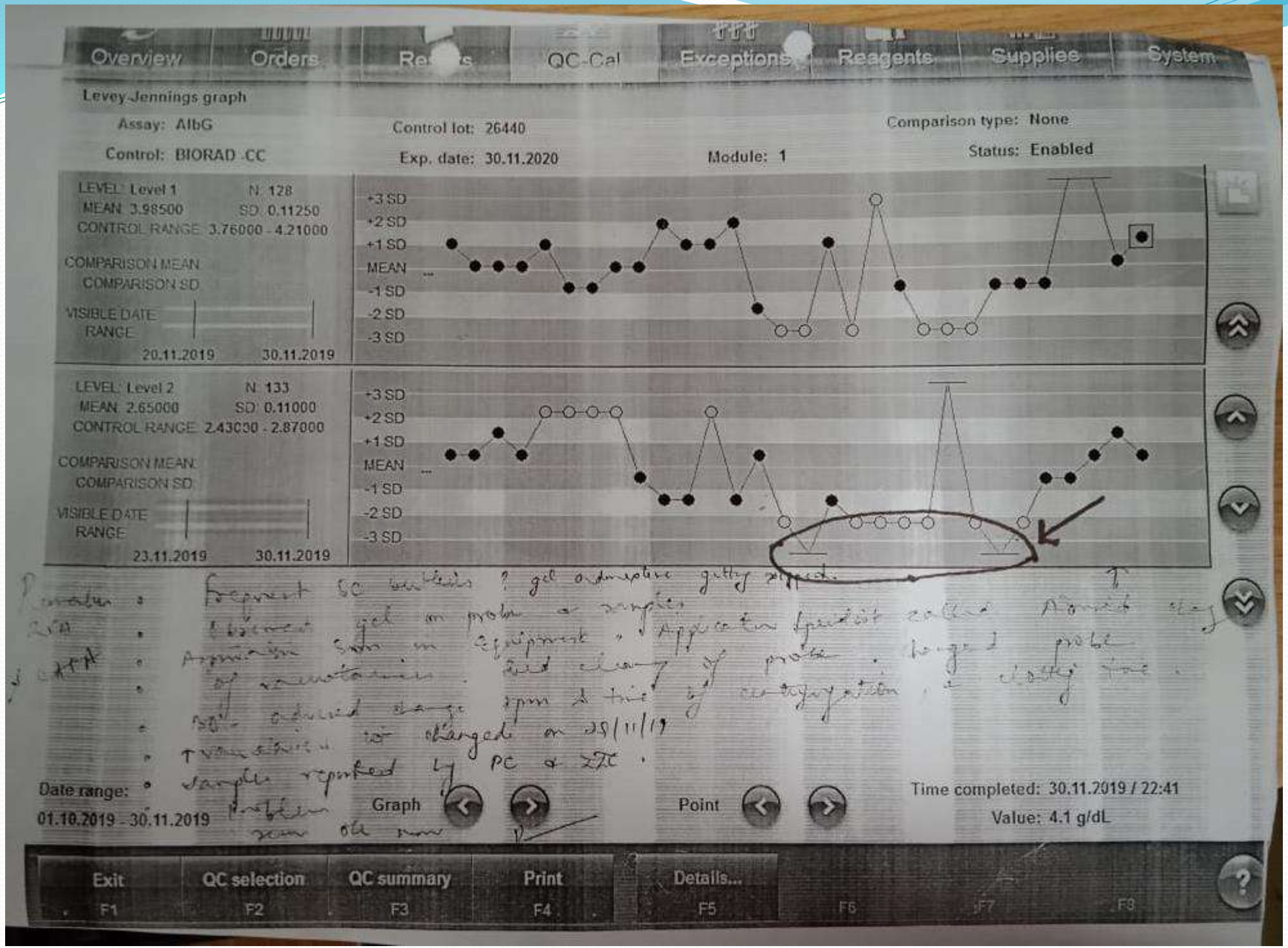
Steps/Type of error in which failure occurs	Failure/Incident	Cause/RCA	Effect	Risk			CAPA
	Sample Quality Compromised			*Probability*	*Severity*	*Criticality*	
Analytical Errors (Examination)	• Frequent and Multiple random errors:1-3s QC failures • Observed in TP, Alb, Calcium etc. • Equipment Flag 3375.	• Aspiration errors. • Gel admixture getting sipped • Gel found on sample probe • Observed gel on some random BD SST tubes, samples • RCA: BD gel melted during centrifugation.	• Chaos • Redo work • Over cautious working • Staff under stress/ • *TAT challenges!!!*	1 *(Improbable)*	3	3	• Complaint raised with company • BD vacutainer lot changed. • Changed probe. • Changed centrifugation speed from 4000rpm for 10mts to3500rpm for 15mts.

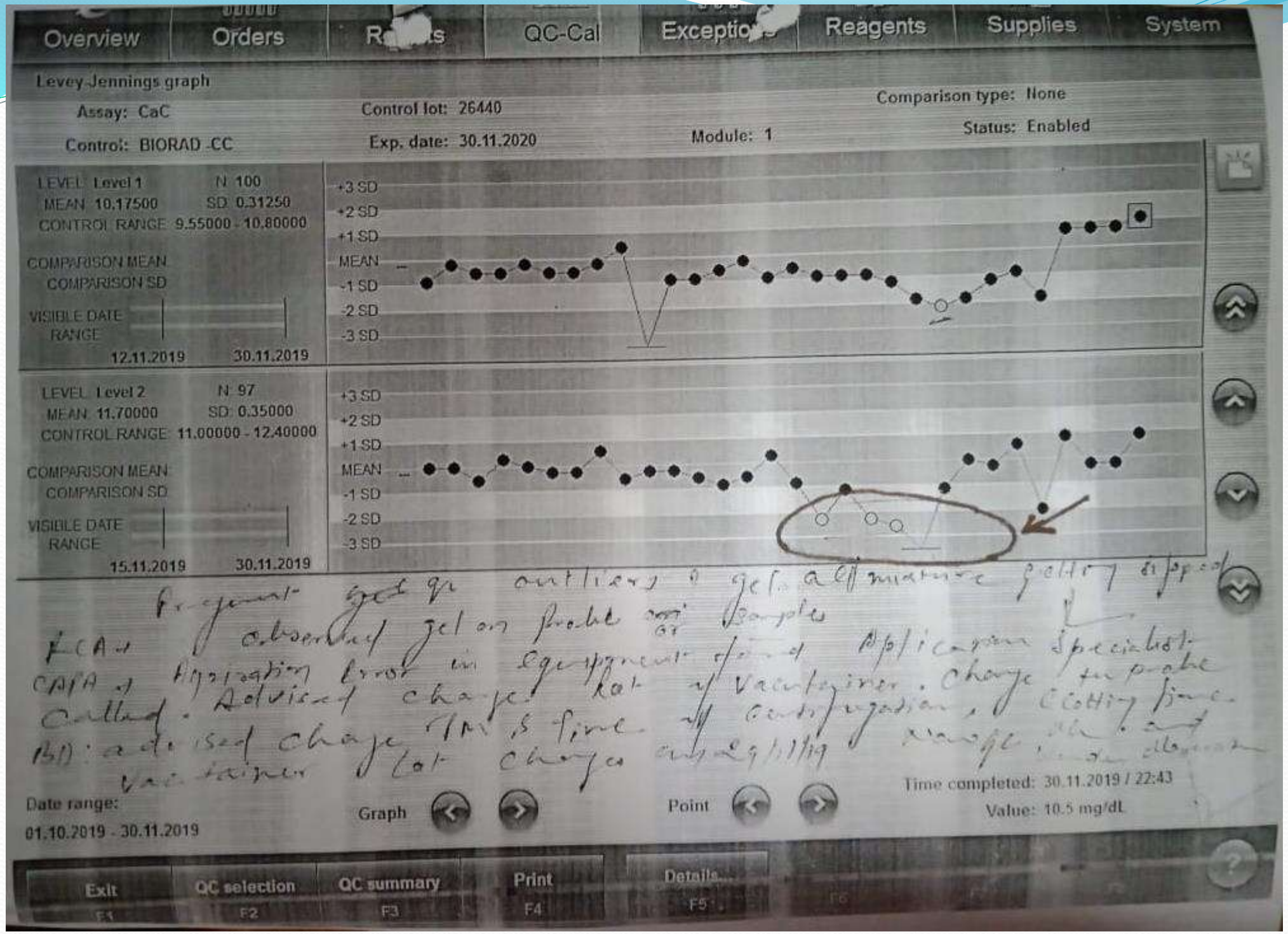
Gel in Serum Sample



EXAMPLE OF FRACAS




Overview
Orders
QC-Cal
Exceptions
Reagents
Supplies
System
Levey-Jennings graph
Assay: AlbG
Control lot: 26440
Comparison type: None
Control: BIORAD CC
Exp. date: 30.11.2020
Module: 1
Status: Enabled
LEVEL: Level 1
N: 128
MEAN: 3.98500
SD: 0.11250
CONTROL RANGE: 3.76000 - 4.21000
COMPARISON MEAN:
COMPARISON SD:
VISIBLE DATE RANGE
20.11.2019
30.11.2019
+3 SD
+2 SD
+1 SD
MEAN
-1 SD
-2 SD
-3 SD
LEVEL: Level 2
N: 133
MEAN: 2.65000
SD: 0.11000
CONTROL RANGE: 2.43000 - 2.87000
COMPARISON MEAN:
COMPARISON SD:
VISIBLE DATE RANGE
23.11.2019
30.11.2019
Date range:
01.10.2019 - 30.11.2019
Graph
Point
Time completed: 30.11.2019 / 22:41
Value: 4.1 g/dL
Exit
F1
QC selection
F2
QC summary
F3
Print
F4
Details...
F5
F6
F7
F8


Overview
Orders
QC-Cal
Reagents
Supplies
System
Levey-Jennings graph
Assay: CaC
Control lot: 26440
Comparison type: None
Control: BIORAD CC
Exp. date: 30.11.2020
Module: 1
Status: Enabled
LEVEL Level 1
N 100
MEAN 10.17500
SD 0.31250
CONTROL RANGE 9.55000 - 10.80000
COMPARISON MEAN
COMPARISON SD
VISIBLE DATE RANGE
12.11.2019
30.11.2019
+3 SD
+2 SD
+1 SD
MEAN
-1 SD
-2 SD
-3 SD
LEVEL Level 2
N 97
MEAN 11.70000
SD 0.35000
CONTROL RANGE 11.00000 - 12.40000
COMPARISON MEAN
COMPARISON SD
VISIBLE DATE RANGE
15.11.2019
30.11.2019
+3 SD
+2 SD
+1 SD
MEAN
-1 SD
-2 SD
-3 SD
Date range:
01.10.2019 - 30.11.2019
Graph
Point
Time completed: 30.11.2019 / 22:43
Value: 10.5 mg/dL
Exit
F1
QC selection
F2
QC summary
F3
Print
F4
Details...
F5

ANALYTICAL ERROR (EXAMINATION)

EXAMPLE OF FRACAS

Steps/Type of error in which failure occurs	Failure/Incident	Cause/RCA	Effect	Risk			CAPA
	Sample Quality Compromised			*Probability*	*Severity*	*Criticality*	
Analytical Errors (Examination)	Multiple analyte QC failures (1/39688)	• Poor feed water quality ? TDS250 • RO Filtration failed • Post filter TDS:7 • VERY HIGH • Acceptable Limits TDS <1	• All WORK HALTED!!! • Wrong report released of one patient report • UA 6.8, Chol 341, HDL-C 63, LDL-C 106, TG 892 • *Risk !!!*	1	4	4	• All reports reviewed • One report which was released was recalled • Entire water pipeline of water supply to equipment was cleaned • Equipment daily maintenance, • QC rerun – ok • Patient sample reanalyzed: • UA - 7.3, CHOL 195,HDL-C 29, LDL-C 79,TG 531 • Amended Report issued • Internal protocol for feed water to lab - revised • Water systems –Pipeline changed

EXAMPLE OF FRACAS

ANALYTICAL ERROR (EXAMINATION)							
Steps/Type of error in which failure occurs	**Failure/Incident**	**Cause/RCA**	**Effect**	**Risk**			**CAPA**
Analytical Errors (Examination)	**Sample Quality Compromised**			***Probability***	***Severity***	***Criticality***	
	Ca value is 17.5 ***Not acceptable!!!***	• **Fibrin picked by machine and error given was ignored by technician.** • **Equipment Flagged 3375 missed by technician**	**Mitigated -discussed with Clinician**	**3**	**4**	**12**	• **Serum defibrinized** • **Same sample rerun** • **rerun** • **Ca 8.5** • **CAPA: retraining of technical staff on error codes** • **Lab protocol to inform supervisor/HOD/clinician**

EXAMPLE OF FRACAS

POSTANALYTICAL ERROR (POSTEXAMINATION)							
Steps/Type of error in which failure occurs	**Failure/Incident**	**Cause/RCA**	**Effect**	**Risk**			**CAPA**
Postanalytical Errors (Post-examination)	**Sample Quality Compromised**			***Probability***	***Severity***	***Criticality***	
	•Wrong typed Vitamin B12 value 21.2 released	**•Typographical error (Post dispatch error)**	**•Mitigated**	**3**	**2**	**6**	• **Report recalled** • **Vit B12 115 retyped correctly** • **Amended report issued**

EXAMPLE OF FRACAS

POSTANALYTICAL ERROR (POSTEXAMINATION)

Steps/Type of error in which failure occurs	Failure/Incident	Cause/RCA	Effect	Risk			CAPA
Postanalytical Errors (Post-examination)	Sample Quality Compromised			*Probability*	*Severity*	*Criticality*	
	• Wrong value of HbA1C typed 0.34 by typist	•Typographical error (Pre dispatch error)	•Mitigated	3	2	6	• HbA1C value 6.0, corrected during authentication
	• Report typed without comments of Biological reference interval	•Typographical error (Pre dispatch error)	•Mitigated	3	1	3	• Report corrected during authentication • Re raining of typist

A Note on What Are and Are Not Failures

- Some failures occur at interfaces between the clinical laboratory and the clinician
- If a clinician makes an incorrect medical decision, but benefits from better information provided in a laboratory report, errors can be minimized
- Case 1
- 40 year male patient CKD, regular visitor for dialysis unit
- Lab Investigations: Urea : 109; Cr: 4.0; iPTH : 5250 pg/ml – vv high
- Lab advisory: Hyperparathyroidism , need for further evaluation to rule out PTH tumor
- Case discussed with Nephrologist: candidate for surgical parathyroidectomy!!!

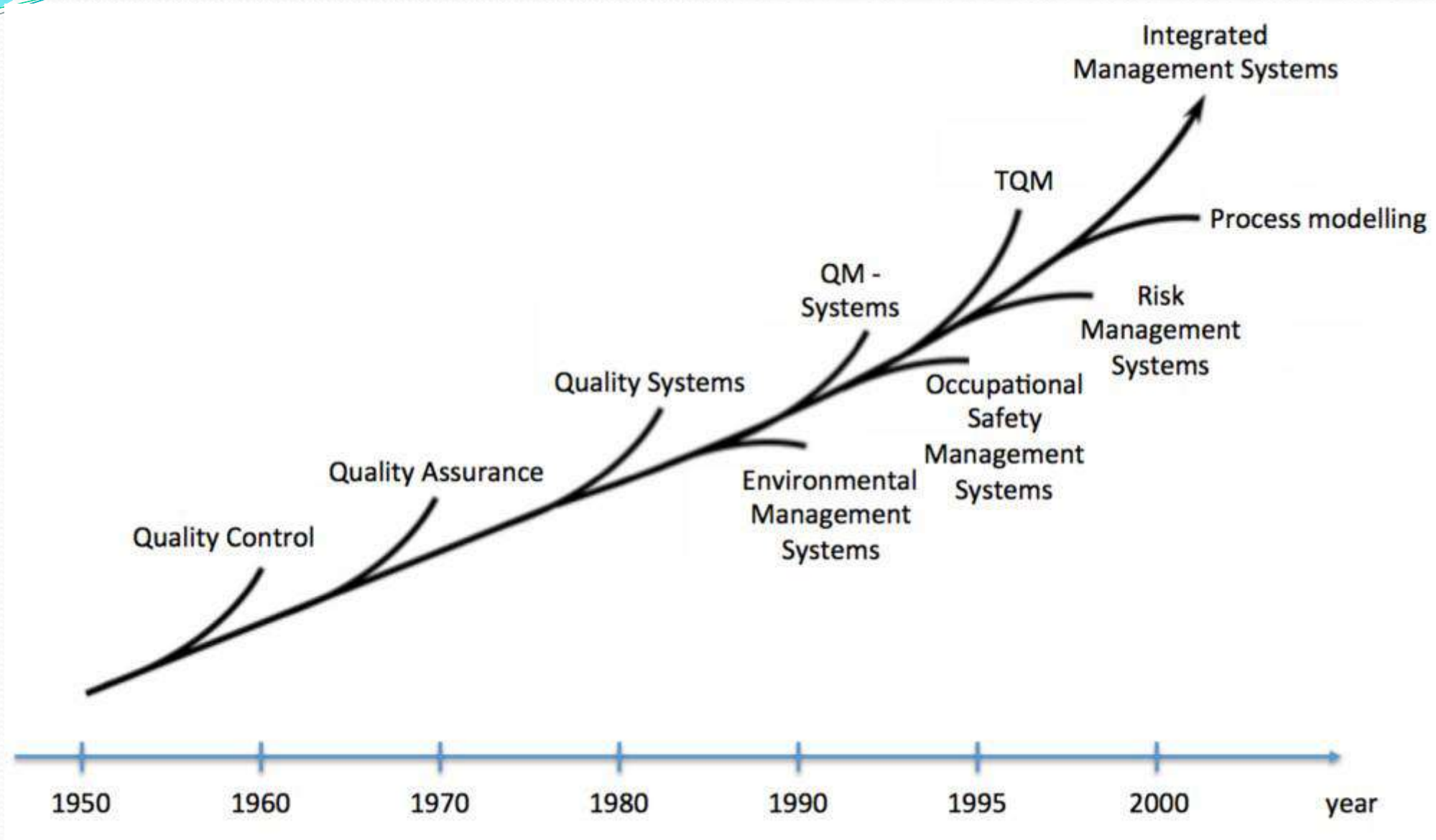
A Note on What Are and Are Not Failures

- Case 2
  - Specimen: Pancreatic Juice/Fluid: For CEA, CA19.9, Amylase
  - CEA <0.5ng/ml; CA 19.9 < 2.0 U/ml; Amylase: 3.0 U/L
  - Cytology - acellular findings
  - D/D : Psuedocyst, Mucinocyst
  - So probable diagnosis by Lab report is Simple Hydatid Cyst

IQCPANIC?


IQCP


Failure Modes
Severity
Detection
"Equivalent QC"
Occurrence
EQC
CMS
ISO 14971
EP23™
CLSI
Process Map
CLIA
Defect Rate
ISO 15189
FMEA
Residual Risk
Six Sigma
Risk Metric
QC Frequency
Sigma-metrics
SIMPLIFY
YOUR
IQCP


Integrated Management Systems
TQM
Process modelling
QM - Systems
Risk Management Systems
Quality Systems
Occupational Safety Management Systems
Quality Assurance
Environmental Management Systems
Quality Control
1950
1960
1970
1980
1990
1995
2000
year

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THE UNSUNG LAB HEROS!!!

Acknowledgements!!!


THANK YOU


Thank You
Any Questions pls…