Module 6: Quality Assurance

Key Message …

My lab assures accurate and reliable testing processes.

Desired Outcome

Consistently accurate and reliable test processes

- Pre-analytical
- Analytical
- Post analytical

Tasks

- Ensure the Quality Manual with quality assurance policies and procedures is accessible to and reviewed by all staff
  - Module 10: Why Was the Outdated Version Used?
- Validate new equipment, reagents, and supplies
  - Module 3: Did You Receive What You Ordered?
  - Module 8: Validation of Test Results
- Review discordant rates and determine appropriate action
  - Cross-cutting: Workstation Set-up

Tasks

- Review occurrence log for patterns/trends and take corrective action
  - Module 2: Safety Incident Role Plays
- Periodically observe/assess accuracy of personnel's work and take corrective action
  - Module 1: Competency Assessment

Bonus Question

- Which section - Key Area of Work – in the Framework has three tasks that refer to SOPs?

- Answer
  - Section or Key area of Work 6
  - Note tasks 6.2, 6.10 & 6.11
  - Additional related tasks – 1.4, 1.6, 1.7, 7.3, 8.1, 10.1

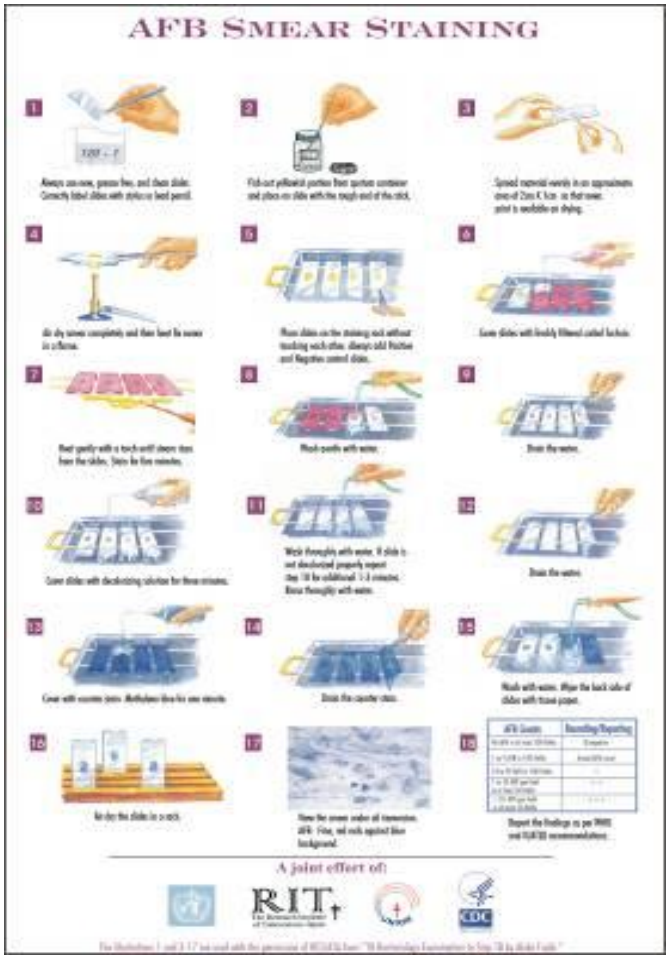
Tasks

- 6.2 - Ensure the QC material is tested according to SOP
- 6.10 - Customize site-specific SOPs as needed
- 6.11 - Ensure that SOPs are read and understood by staff

Using Standard Operating Procedures

Standardizing Best Laboratory Practices

Job Aid depicting a Standard Operating Procedures - SOP



Activity:
Using Standard Operating Procedures

Purpose

To write and follow a simple SOP on handwashing

What will you need?

Handout 1: Hand Washing Article

Job Aid 1: SOP Template

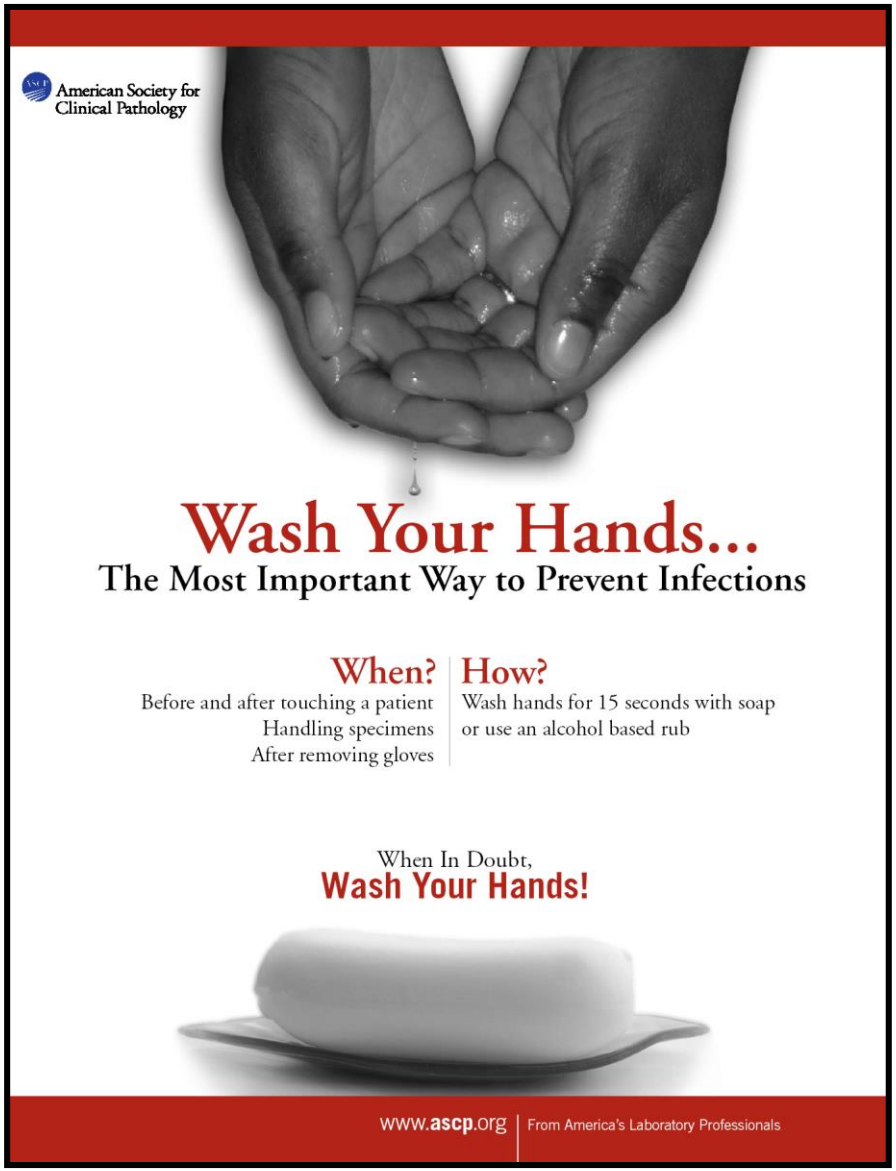
Job Aid 2: Annotated SOP

Flipchart pages & markers

What will you do?

- Read Handout 1 for OVERNIGHT HOMEWORK
- Use Handout 1 and Job Aid 1 & 2 as needed to write a simple 7-step SOP on hand washing
- Record the SOP on the flipchart pages
- One group to demonstrate the SOP written by another group
- Participate in the classroom discussion

20 minutes for writing


American Society for Clinical Pathology
Wash Your Hands...
The Most Important Way to Prevent Infections
When?
Before and after touching a patient
Handling specimens
After removing gloves
How?
Wash hands for 15 seconds with soap
or use an alcohol based rub
When In Doubt,
Wash Your Hands!
www.ascp.org
From America's Laboratory Professionals

Demonstration Time

- Let's see if these SOPs are -
  - Complete
  - Easy to follow
  - Yield Accurate & Consistently Reliable Results

Another Bonus Question

- Name one Checklist Item that defines how to use SOPs?

- Checklist Items
  - 1.5, 1.6, 1.7, 1.8, 3.4, 3.7, and 8.7

Tasks

- Establish acceptable ranges for control material
- Track test performance (e.g. Levey-Jennings chart) for trends
- Review records of environmental checks and QC trends to assess impact on testing and take corrective action
- Monitor reagent performance
- Enroll in EQA program, monitor results, and take corrective action

Activity: Is QC That Important

Purpose

To voice and examine the behavior and attitude applied at the worksite regarding quality control.

What will you need?

Worksheet: QC Program Questions

What will you do?

- Complete the Worksheet as homework the evening before this activity
- Participate in the classroom discussion for each question on the Worksheet
- Share your viewpoints openly and respectfully throughout the discussion and listen to others in the same manner.

40 minutes

Knowing where you are and where you want to be starts with creating the right graph.

Is There More to QC Than Just Plotting the Data?

Wrong Patient Results Can:

- Endanger patient lives.
- Prolong suffering.
- Add significant cost (money and time) to patient treatment.

The right QC approach will detect and prevent errors.

Categories of QC

- Quantitative
  - Measures the quantity of an analyte
  - Numeric
  - 5.2 mmol/L
- Semi-quantitative
  - Measures the quantity of an analyte
  - Estimate
  - trace, moderate, +1, +3
- Qualitative
  - Presence or absence
  - Positive, negative, growth, no growth, reactive, non-reactive

Statistical QC

- Mean ($\bar{x}$)
  - the average of a set of values
  - primary indicator of accuracy
  - measure of systematic error (error in a given direction)
- Standard deviation (SD)
  - used to measure dispersion/scattering of a group of values around a mean
  - primary indicator of precision
  - measure of random error (error in any direction)

Mean

$$\bar{X} = \frac{\sum x_i}{N}$$

X_i = individual value
N = number of individual values

Standard Deviation

$$SD = \sqrt{\frac{\Sigma (x_i - \bar{x})^2}{N-1}}$$

Σ = sum (of the differences)

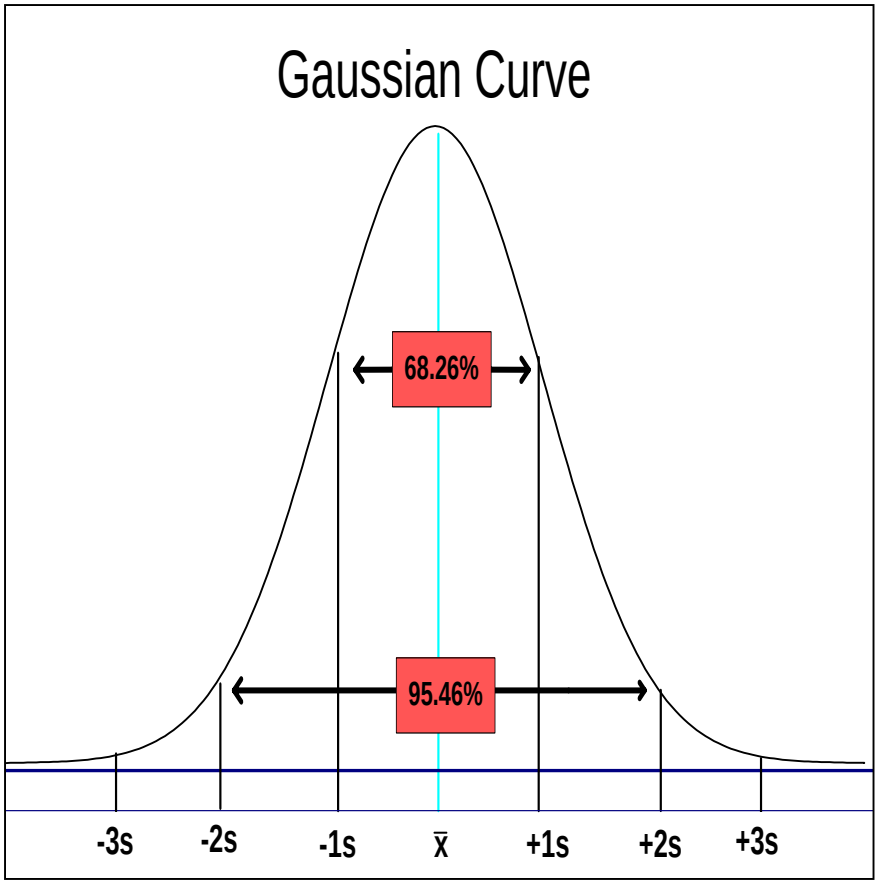
X_i = individual value

$\bar{X}$ = mean of individual values

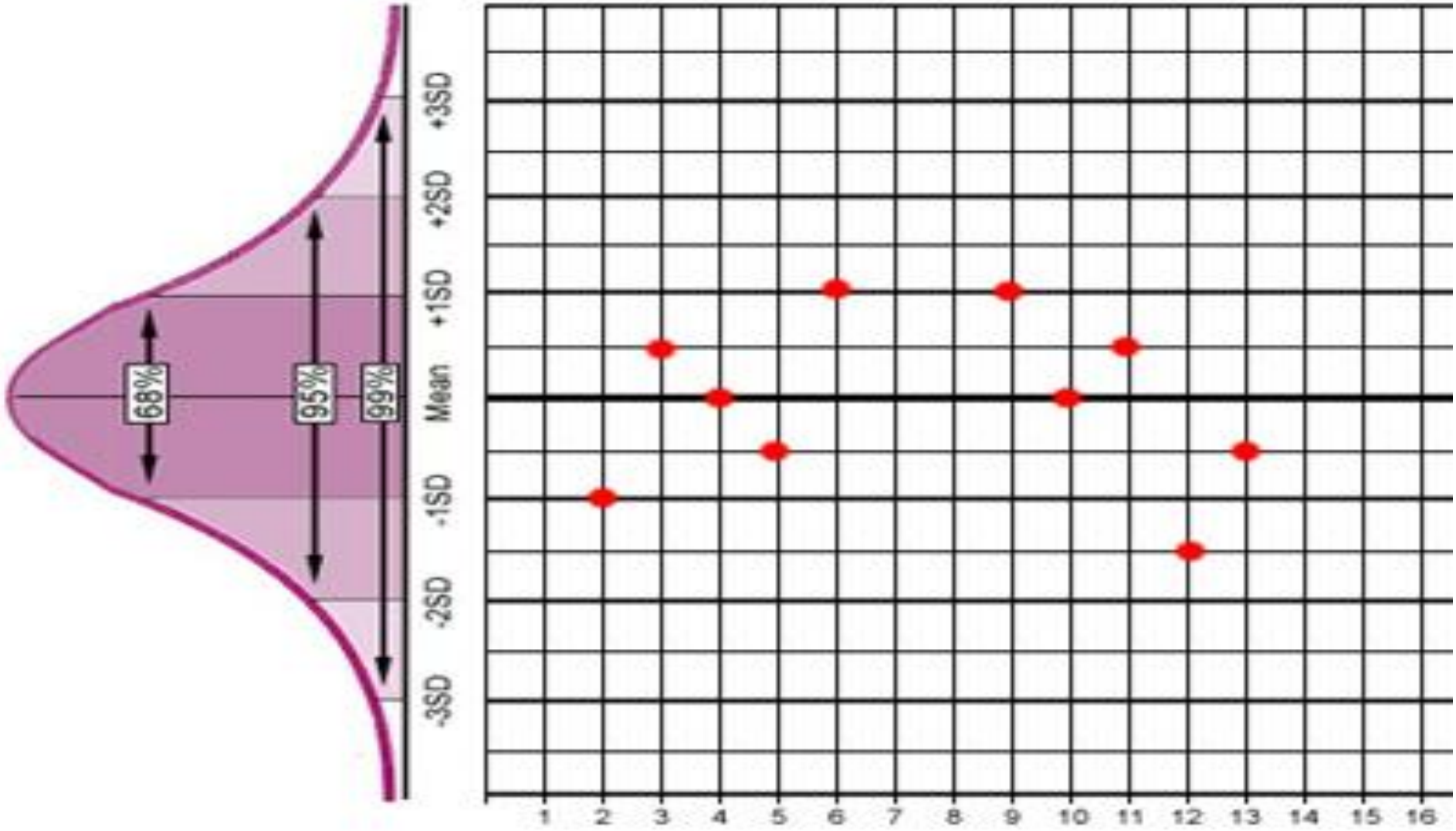
N = number of individual values

Confidence Limits

- Based on normal distribution of results (a bell-shaped frequency curve) a control result will have the following confidence limits:
- 68% will be 1 standard dev. above and below the mean
- 95% will be 2 SD above and below the mean
- 99% will be 3 SD above and below the mean
- 95% confidence limits are the most important limits used.



Levey-Jennings Chart



Activity: Is There More to QC than Just Plotting the Data?

Purpose

To demonstrate control range and rule selection's effect on the error detection level of a QC system.

What will you need?

Worksheet 1: Normal Control

Worksheet 2: Data Points

Worksheet 3: L-J Charts

What will you do?

Work individually during the first part of the activity to complete Worksheet 1

For the second half, work with a partner (pairs) to chart data points using Worksheet 1, 2 & 3

- Simple arithmetic used in the worksheets
- Apply different rules and assess level of error detection

25 minutes

Establishing Quality Control Range

Step 1:

- Run new control daily for 20-30 data pts. Run in parallel with current control material

- All new controls must be within the manufacturer's product package insert range

Step 2:

- Calculate from the 20-30 data points of the new control:

  - the mean

  - the standard deviation (1 S.D.)

- From the mean and standard deviation, calculate:

  +/- 1 S.D.; +/- 2 S.D.; and =/- 3 S.D.

The following information was included in the control's package insert:

Chemistry Normal Control Lot # 13427N Expiration Date 15/04/XX		
Analyte	**Mean ($\bar{x}$)**	**SD**
Creatinine	80 umol/L	10 umol/L

You analyzed 30 control samples on your chemistry analyzer, the Illustra 200, and calculated the following values based upon your instrument's control results:

Chemistry Normal Control Lot # 13427N Expiration Date 15/04/XX		
Analyte	**Mean ($\bar{x}$)**	**SD**
Creatinine	81 umol/L	4 umol/L

Complete the following table using the information above

	Values Using the Package Insert's $\bar{x}$ and SD	**Values Using Your Instrument's $\bar{x}$ and SD**
$\bar{x}$	80	81
+ 1 SD	90	85
+2 SD	100	89
+3 SD	110	93
- 1 SD	70	77
- 2 SD	60	73
-3 SD	50	69
68% of the data will fall between (± 1SD)	70 - 90	77 - 85
95% of the data will fall between (± 2SD)	60 - 100	73 - 89
99% of the data will fall between (± 3SD)	50 - 110	69 - 93

Cape Clinic Laboratory

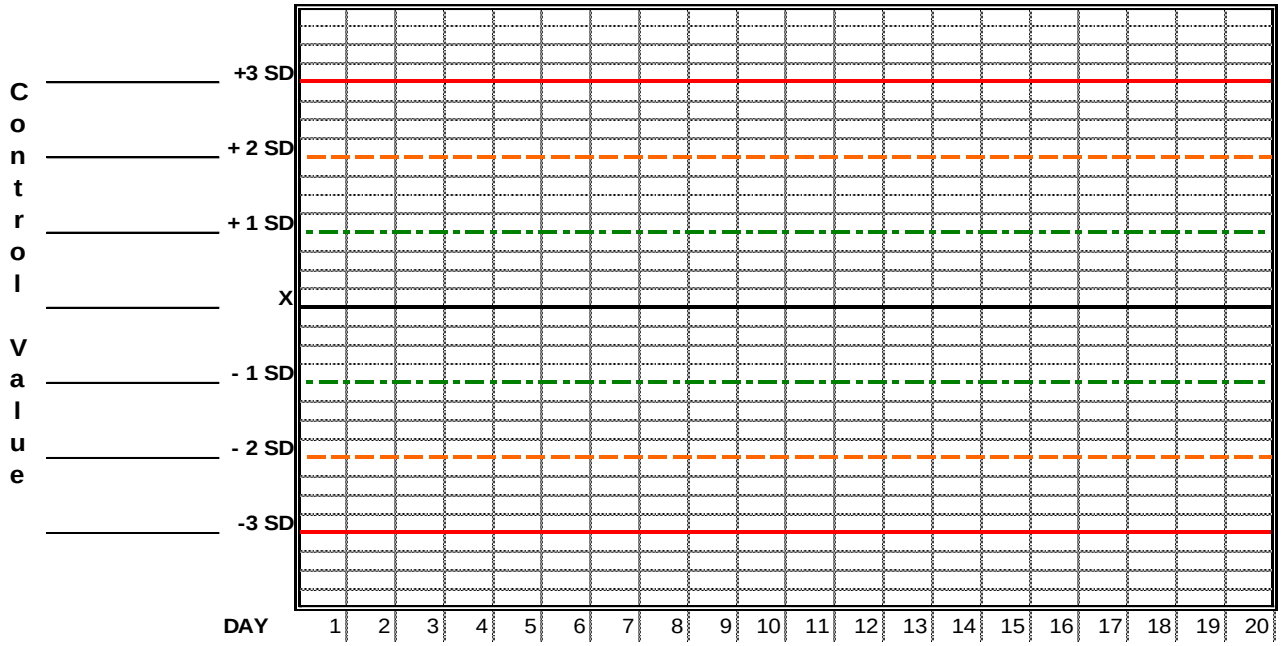
L-J Chart for Illustra 200 Chemistry Analyzer

Analyte: *Creatinine* **Control Material:** *Normal* **Units:** _____

Lot #: _____ **Exp Date:** _____ **$\bar{x}$** _____ **SD** _____

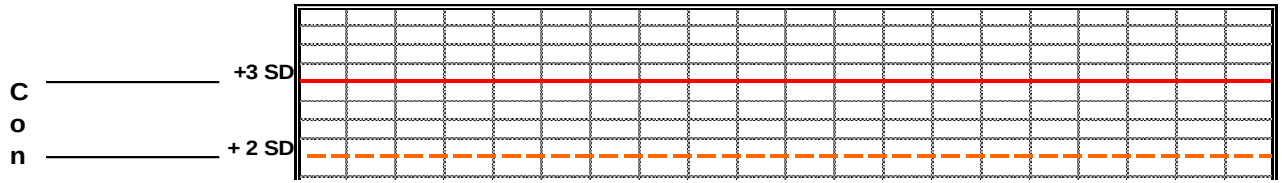
From: *May 1, 20XX* **Through:** *May 20, 20XX*

Use This Graph to Create and Plot the Package Insert Values



Use This Graph to Create and Plot the Instument's Calculated Values

$\bar{x}$ _____ **SD** _____



Cape Clinic Laboratory

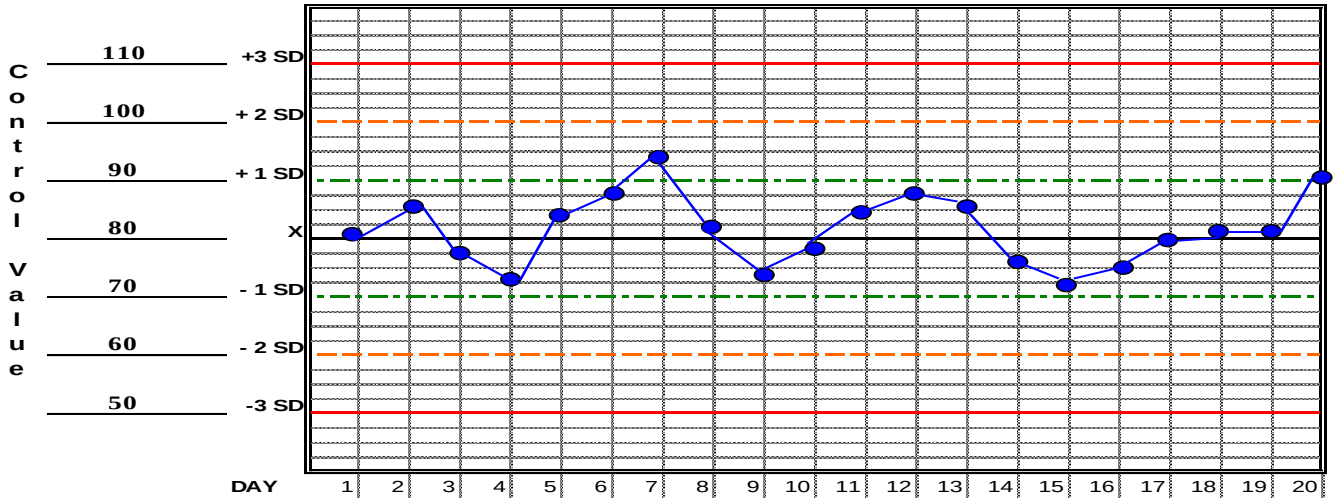
L-J Chart for Illustra 200 Chemistry Analyzer

Analyte: *Creatinine* **Control Material:** *Normal* **Units:** *umol/L*

Lot #: 13427N **Exp Date:** 4/15/XX $\bar{x}$ 80 **SD** 10

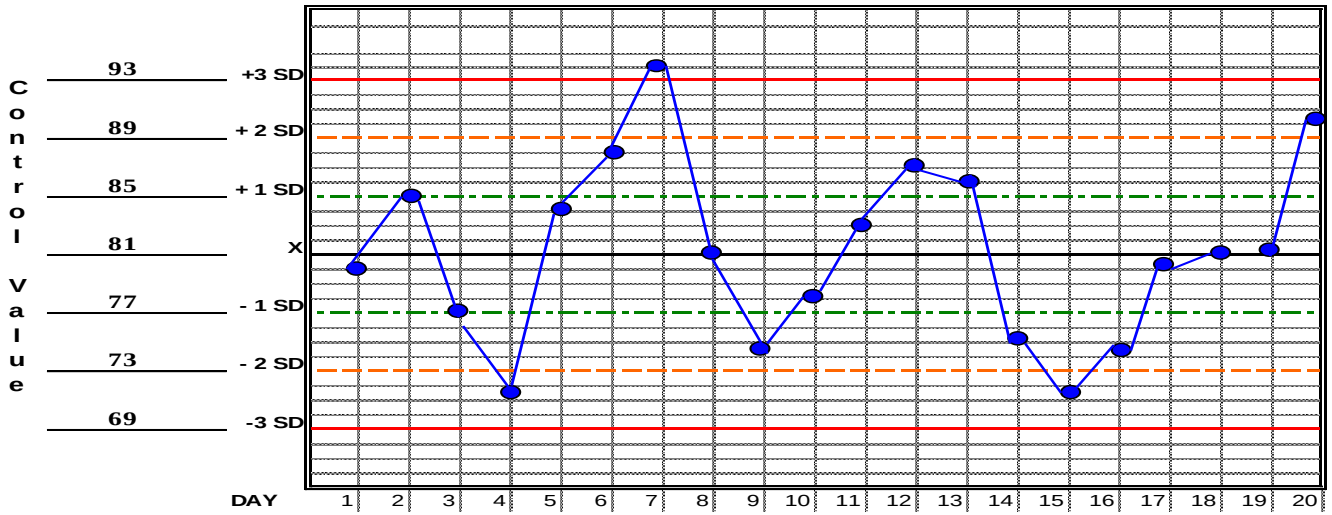
From: *May 1, 20XX* **Through:** *May 20, 20XX*

Package Insert Values



Instument's Calculated Values

$\bar{x}$ 81 **SD** 4



1_{2s} rule and 1_{3s} rule violations using the instrument's mean and SD chart values.

Day	Normal Control Value	1_{2s} Violation	1_{3s} Violation
1	80		
2	85		
3	77		
4	72	√	
5	84		
6	88		
7	94	√	√
8	81		
9	74		
10	78		
11	83		
12	87		
13	86		
14	75		
15	71	√	
16	74		
17	80		
18	81		
19	81		
20	90	√	
		4	**1**

It makes a difference what control rule(s) is/are applied to accept or reject a run. 4 rejections using the 1_{2S} rule versus 1 rejection using the 1_{3S} rule .

Common QC Terms

- Control Rule - a decision criteria to assess whether an analytical run is in-control or out-of-control.
  - Single-rule uses a single criterion or a single set of control limits such as 1_{3s} or 1_{2s}.
  - Multirule uses a combination of decision criteria such as $1_{3s}/2_{2s}/R_{4s}$.
- Analytical Run - the interval (time or a group of samples) for which a decision on acceptability (in-control or out-of-control) is made.

Choice of Quality Control Rules

- Control rules should be carefully selected to **maximize error detection** and **minimize false rejection**
- The best set of control rules will **vary from method to method** and will be based upon:
  - the allowable error required by the test
  - the imprecision and inaccuracy of your method

How QC Works for You

- Calculate the mean and SD of the control material for a single data population.
- Use the calculated mean and SD on the QC chart.
- Use the right QC rules for your method
- Plot the control values versus time on a control chart.
- If a significant change occurs in accuracy or precision, then the QC rule failures alert you to the change.
- Investigate, resolve, and document the rule failure before patient results are reported.

Periodic Review

- **Daily** review of control values and control charts by the technologist before accepting or rejecting the analytical run.
- **Weekly** review of QC data and charts by the supervisor
- **Monthly** review of QC data and charts by the director of the laboratory
- **Periodic** quality audits by the quality assurance department

Cape Clinic Laboratory

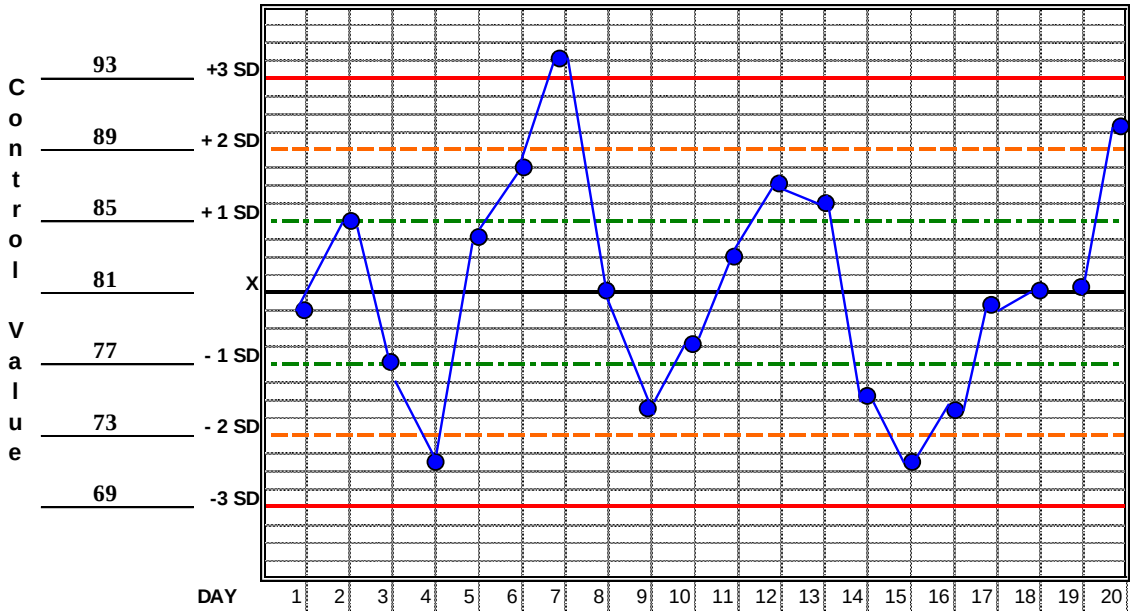
L-J Chart for Illustra 200 Chemistry Analyzer

Analyte: Creatinine **Control Material:** Normal **Units:** umol/L

Lot #: 13427N **Exp Date:** 15/04/XX $\bar{x}$ 81 **SD** 4

From: May 1, 20XX **Through:** May 20, 20XX

Reviewed 3/5/XX AM
Reviewed 10/5/XX AM
No documentation found for Day 4, will discuss with tech
Reviewed 17/5/XX AM



Internal and External

- Internal QC- detecting problems during routine laboratory operations.
- External Quality Assessment (EQA)
  - A group of laboratories analyze the same specimens and submit their results to an external facility.
  - Compares your laboratory to a peer group with regard to accuracy and precision of your method.
  - Types of EQA
    - Peer Comparison
    - Proficiency Testing

Activity: Workstation Set-up

Purpose

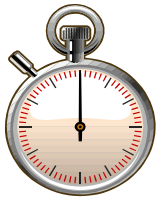
To create and organize an efficient and productive workstation using elements developed from each module.

What will you do?

- Participate in the classroom's discussion
- Integrate key concepts from earlier activities

What will you need?

Laboratory Accreditation Preparedness Checklist



15 minutes

URINALYSIS DAILY Q.C. LOG AND MAINTENANCE

Multistix 10 SG:

lot #: *SG101*

exp. date 11/11/XX

Chek-Stix Combo Pak:

Positive Control lot # *P83* exp. date *1/15/XX*

Negative Control lot # *N83* exp. date *1/15/XX*

EXPECTED RESULTS	*negative*	neg	neg	neg	1.010 - 1.025	6.0 - 7.0	neg	0.2 - 1	neg	neg	neg
	positive	trace - 250	pos	trace - 80	1.000 - 1.015	8.0 - 9.0	trace- 100	2.0 - 8.0	pos	mod - large	trace-moderate

Date	Clean	Cal	*units*	mg/dl		mg/dl			mg/dl	EU/dl				
			Control	**Glu**	**Bili**	**Ket**	**S.G.**	**pH**	**Prot**	**Urobili**	**Nit**	**Blood**	**Leuk**	**Initials**
2/03/XX	✓		**negative**	*neg*	*neg*	*neg*	**1.0** *20*	*6.5*	*neg*	*0.2*	*neg*	*neg*	*neg*	*LLC*
		✓	**positive**	*250*	*pos*	*40*	**1.0** *05*	*8.5*	*30*	*8.0*	*pos*	*large*	*mod*	
3/03/XX	✓		**negative**	*neg*	*neg*	*neg*	**1.0** *20*	*6.5*	*neg*	*0.2*	*neg*	*neg*	*neg*	*LLC*
		✓	**positive**	*250*	*pos*	*40*	**1.0** *05*	*8.5*	*30*	*8.0*	*pos*	*mod*	*mod*	
3/03/XX *New bottle opened; same lot#*			**negative**	*neg*	*neg*	*neg*	**1.0** *20*	*6.5*	*neg*	*0.2*	*neg*	*neg*	*neg*	*LLC*
			positive	*250*	*pos*	*80*	**1.0** *15*	*8.5*	*30*	*8.0*	*pos*	*large*	*mod*	
			negative				**1.0**							
			positive				**1.0**							
			negative				**1.0**							
			positive				**1.0**							

AFB Stain Log

Manufacturer: Microtrek, Inc

ZN Carbolfuchsin	Decolorizer	Methylene Blue	Results	Initials	Date
1Z	1D	1M	1S - A	LLC	7/8/XX
1Z	1D	1M	2S - A	LLC	7/8/XX
1Z	1D	1M	1S - A	AT	9/8/XX
1Z	1D	1M	2S- A	AT	9/8/XX
1Z	2D	1M	1S - A	LLC	13/8/XX
1Z	2D	1M	2S - A	LLC	13/8/XX

Reagent	Reagent Code	Lot Number	Expiration Date	Code	Lot Number	Expiration Date
TB Ziehl Neelsen Carbolfuchsin	1Z	C837	2/11/XX	2Z		
TB Decolorizer (3% acid alchohol)	1D	D837	2/11/XX	2D	D954	15/12/XX
TB Methylene Blue	1M	B837	2/11/XX	2M		

QC Slide			
Manufacturer	Reagent Code	Lot Number	Expiration Date
Microtrek Positive (M. gordonae)	1S	QC-589P	4/7/XX
Microtrek Negative (E.coli)	2S	QC-589N	4/7/XX

Positive control expected result: red bacilli **Negative control expected result: blue bacilli**

Interpretation: **A** = Acceptable control results
F = Control results are **Not** acceptable

Complete an Occurrence Report Form if results are not acceptable.

Comments:

Supervisor Review: Theresa Rhinehardt Date: 31/08/XX

Reviewed by / date:
AM 4/6/XX

Glucometer QC Maintenance and QC Log

Calibration /Test Strip:

Lot Number #654 / # 977

Expiration Date 7/06/XX / 12/12/XX

Glucometer #2: Outpatients SN #2875S

Daily:
Verify test strip matches with display
Run three control levels each day of use & plot

With New Lot# of Strips:
Change code chip
Run three control levels

As Needed:
Change Battery
Clean Glucometer with a damp cloth

Control Level	LOW	NORMAL	HIGH
Lot Number	L835	N721	H854
Expiration Date	2/1/XX	2/1/XX	2/1/XX
Opened Date	10/04/XX	13/04/XX	08/04/XX
Expected Range (mmol/L)	2.5 - 3.5	4.5-5.5	21.0 - 23.0
Opened Expiration Date of Vial (90 days)	9/07/XX	12/07/XX	07/07/XX

Date	Display Lot # matches Test Strip Lot #?	Control Level	Control Result (mg/dl)	QC Plotted	Initials
30/05/XX	✓	Low	2.7	✓	RSM
		Normal	4.9	✓	
		High	22.1	✓	
3/06/XX	✓	Low	3.0	✓	ABL
		Normal	5.0	✓	
		High	22.4	✓	
5/06/XX	✓	Low	2.8	✓	RSM
		Normal	4.6	✓	
		High	21.7	✓	
		Low			
		Normal			
		High			
		Low			
		Normal			
		High			

Action Log

Date	Action Item	Initials
30/05/XX	New batteries installed, notified supervisor - one set of batteries available	RSM
5/06/XX	New Lot number of test strips in use; code chip inserted	RSM

Reviewed by / date:
AM 3/6/XX
AM 11/6/XX

u HCG QUALITY CONTROL LOG

Date	Kit Lot Number	Kit Expiration Date	QC Lot Number	QC Expiration Date	Control	Results	Control Line Present	Initials
11/06/XX	SA 721	15/12/XX	SA 721 N	15/12/XX	negative	+ / (-)	(Y) / N	LLC
			SA 721 P	15/12/XX	positive	(+) / -	(Y) / N	
12/06/XX	SA 721	15/12/XX	SA 721 N	15/12/XX	negative	+ / (-)	(Y) / N	TY
			SA 721 P	15/12/XX	positive	(+) / -	(Y) / N	
					negative	+ / -	Y / N	
					positive	+ / -	Y / N	

Corrective Action:
Date: Initials:

RESULT LOG BOOK (example)

Date	Patient Name	uHCG	Control Line Present	Initials
11/06/XX	Ramos, Lucinda	positive	✓	LLC
	Martek, Elizabeth	negative	✓	LLC
	Caspella, Janice	negative	✓	LLC
12/06/XX	King, Mary	negative	✓	TY

Excerpts from Workstation's SOP

Quality Control:

Built-in Control

The appearance of a control line in the "C" region must appear on the membrane for a test to be valid and for a result to be reported. Document the control line result on the …..

If the colored line fails to appear in the "C" region, then ……

Qualitative Quality Control:

A positive and negative quality control material must be performed and recorded in the 'uHCG Quality Control Log' for the following instances:

A. each day ….

B. when opening a new ……

If either the positive or negative Q.C. is unacceptable, then …….

Activity: What Would You Do?

Purpose

To integrate the module's lessons and apply them to the case scenario.

What will you need?

Handout: Case Study Scenarios

What will you do?

Divide into groups of 4-5

- Select a spokesperson for your group
- Formulate specific action steps to address the scenario from the Handout.
- The group's spokesperson presents the proposed steps during the 2 minute class report.

5 minutes

What Would You Do?

You notice that only one staff member performs testing on EQA (External Quality Assurance) samples. In fact, the EQA survey was not performed last week because that staff member was on holiday. When you questioned the other staff members they explained they are uncomfortable performing EQA tests. During the same discussion, you discover that the staff member who usually performs the tests has been running the samples 5 times to make certain he has the correct result. You know patients' samples are not to be handled in this manner, and it does not reflect your testing process.

How should you handle EQA surveys at your facility?

Tasks

- Ensure the Quality Manual with quality assurance policies and procedures is accessible to and reviewed by all staff
- Validate new equipment, reagents, and supplies
- Review discordant rates and determine appropriate action
- Review occurrence log for patterns/trends and take corrective action

Tasks

- Periodically observe/assess accuracy of personnel's work and take corrective action
- Ensure the QC material is tested according to SOP
- Customize site-specific SOPs as needed
- Ensure that SOPs are read and understood by staff

Tasks

- Establish acceptable ranges for control material
- Track test performance (e.g. Levey-Jennings chart) for trends
- Review records of environmental checks and QC trends to assess impact on testing and take corrective action
- Monitor reagent performance
- Enroll in EQA program, monitor results, and take corrective action