QUALITY CONTROL PROCESS IN HEMATOLOGY DEPARTMENT

Safety Message

All Quality Control reagent products contain biological source materials from human, avian, reptile and ungulate. Always use appropriate universal precautions while using them to perform a test.

Policy

- All unacceptable control results are resolved before testing patient specimens.
- When controls are out of range, a step by step approach must be taken to resolve the out of control results on commercial controls.
- It is the responsibility of the Clinical Laboratory Scientist assigned in the department to ensure that quality controls are run and meet the acceptable criteria prior to releasing patient results as outlined in this policy.

Purpose

- To provide a general summary of the quality control process in Hematology Department. Please refer to each specific policy and procedure for testing quality controls mentioned in this policy.

Definition

"**Out-of-Control"** - If a result outside of these limits is obtained.

"Acceptable limit of error" - the permissible range by which the obtained results may vary from the specified result. Repeated analysis of the control or an unknown specimen should give results within this limit.

"Abbreviated parallel testing"- When reagents are not available or adequate to complete parallel testing, test the new lot number and verify its range with the manufacturer's range provided. For parallel testing that requires more than one (1) result, run at least (five) 5 samples.
Note: Abbreviated parallel testing must only be practiced in the event old or current lot numbers are unavailable and must not be routinely applied.

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Interpreting results and course of action:

New lot numbers/shipments of reagents and controls must be verified before placed in operation for patient testing. Packet inserts (if applicable) must be reviewed for any changes. New reagents are tested in parallel with the current reagents in use and results for both must be within the established acceptable range.

If values are outside the acceptable range, the data must be carefully evaluated and resolved before any patient results are reported.

If the source of error cannot be found, a new control specimen and/or with several of the unknowns chosen at random is re-assayed. If the new control gives an appropriate value and the unknowns check with the previous tests performed the same day, the values are reported; if not, the data is held back and the reagents procedure and instrument are checked one by one until the problem is found and resolved.

Equipment And Reagents

A. Sysmen XN-550
1. XN Check Tri-level control

B. iSED ESR
1. Seditrol: ESR- bi-level control

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Control Run Table:

Control	Instrument	Frequency	Performed by:	Reviewed
Sysmex XN 550				
XN-L Check Control	Sysmex XN 550	Run daily, three levels of XN Check controls are run once per shift.	CLS	Monthly by a supervisor/ designee.
XBarM	Sysmex XN 550	Each shift, Xm charts reviewed after daily QC run	CLS	Monthly by a supervisor/ designee.
Instrument Correlation	Sysmex XN 550	• Biannual evaluation is performed.	CLS	Biannually by supervisor.
iSED-ESR				
Seditrol ESR I &II	iSED	• Daily by AM shift	CLS	Monthly by supervisor/designee.

Procedures:

I. DAILY

AM Shift:

Control	Instrument or Equipment
XN-L Check (Level I, Level II, Level III)	Sysmex XN 550
Seditrol ESR I & II	iSED

PM Shift Daily QC:

Control	Instrument
XN-L Check (Level I, Level II, Level III)	Sysmex XN 550

a. Bring controls to room temperature and gently mix before use.
b. Record reagent lot #s and expiration dates in QC log.
c. Perform test using the control material.
d. Record results in designated area of QC log.
e. Evaluate control results and resolve out of control runs before proceeding with patient testing. (see section III of this procedure)

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II. UNSCHEDULED:

A. Parallel Testing: New Lot # or Shipment vs Current Lot #.

New Lot#	Instrument/Equipment	Required Number of Test
XN-L Check (Level I, Level II, Level III)	Sysmex XN 550	at least 5-10 runs to establish/verify range
Seditrol ESR QC	iSED	

Parallel testing is required for both **new lot and new shipment.

Note: Ideally to establish/verify new lot number control range, parallel testing is conducted over several days. i.e. 5-10 days. Verification run must be within assay range of insert. If reagents are not available to parallel test or if the new control material arrives late, perform ***abbreviated parallel testing***. Test the new lot # and use the manufacturer's range to establish/verify range. Please see definition of abbreviated parallel testing at the Definition section of this policy.

Instrument Bi Annual Correlation

	Analytes	Policy	Reviewed
Auto Diff vs Manual Diff	Neutrophils Lymphocytes Monocytes Eosinophils Basophil	Run minimum of 10 samples	Bi annual by supervisor/designee

Rumke's Table: 95% Confidence Limits for various percentages of blood cells of a given type as determined by differential count.

RUMKE DISTRIBUTION TABLE					
n	a=100	n	a=100	n	a=100
1	0-2	34	27-42	67	60-74
2	0-4	35	28-43	68	61-75
3	0-6	36	29-44	69	62-76
4	1-8	37	30-45	70	63-77
5	2-10	38	31-46	71	64-77
6	3-11	39	32-47	72	65-78
7	3-12	40	33-48	73	66-79
8	4-13	41	33-49	74	67-80
9	5-14	42	34-50	75	68-81
10	6-15	43	35-51	76	69-82
11	6-16	44	36-52	77	70-83
12	7-17	45	37-53	78	71-84
13	8-18	46	38-54	79	72-85
14	9-20	47	39-55	80	73-89
15	10-21	48	40-56	81	75-86
16	10-22	49	41-57	82	76-87
17	11-23	50	42-58	83	77-88
18	12-24	51	43-59	84	78-89
19	13-25	52	44-60	85	79-90
20	14-27	53	45-61	86	80-90
21	15-28	54	46-62	87	81-91
22	16-29	55	47-63	88	82-92
23	17-30	56	48-63	89	83-93
24	18-31	57	49-64	90	84-94
25	19-32	58	50-65	91	86-95
26	19-33	59	51-66	92	87-96
27	20-34	60	52-67	93	88-97
28	21-35	61	53-68	94	89-97
29	22-36	62	54-69	95	90-98
30	23-37	63	55-70	96	92-99
31	24-38	64	56-71	97	93-99
32	25-39	65	57-72	98	94-100
33	26-40	66	59-73	99	96-100
				100	98-100

n is the total number of cells counted.
a the observed percentage of cells of the given type

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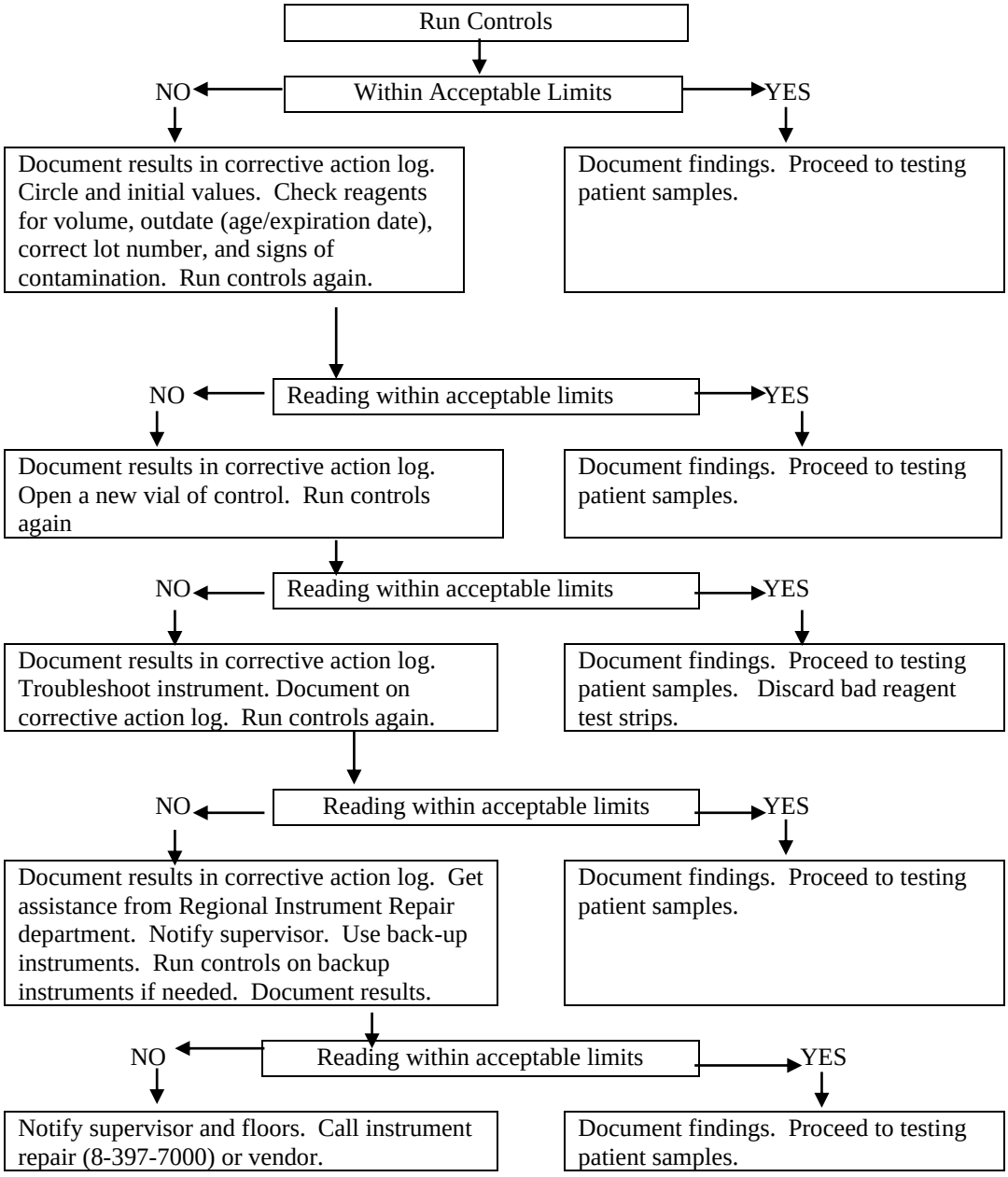
III. Evaluating/Troubleshooting Control Run:



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Troubleshooting Controls Use the following table to determine who is responsible for evaluating quality control results and correcting problems.

Stage	What Happens	Who is responsible
XN- L Check Control	Evaluate the results of the XN Check control. If the results are not within the assigned values and expected ranges, then troubleshoot and document the steps taken to resolve the problem.	Clinical Laboratory Scientist
XBarM	Evaluate the X_m chart and if the results are drifting, troubleshoot the analyzer and document the steps taken to resolve the problem	Clinical Laboratory Scientist
Seditrol ESR QC- Level I & II	Evaluate results. If results are not within the designated limits, then troubleshoot and document the steps taken to resolve the problem.	Clinical Laboratory Scientist

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Procedural Notes

- All control testing is performed according to specific test procedure.

References

College of American Pathologists: Laboratory Accreditation Manual 2007
July Edition by Francis Sharkey, MD, FCAP

Differential Leukocyte Counting: CAP Conference Aspen 1977
Koepke, John A