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USING TOTAL ALLOWABLE ERROR TO QUALIFY REAGENTS AND CALIBRATORS

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American Association for
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44th National Meeting
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Chicago

METHODS

1. LABORATORY STUDIES

- TOTAL ALLOWABLE ERROR LIMITS WERE BASED ON CLINICAL REQUIREMENTS

RETROSPECTIVELY

- TOTAL ERROR (te) FROM SIX HOSPITALS' MONTHLY DATA WAS COMPARED TO TOTAL ALLOWABLE ERROR (TEa).

- WHEN TE > TEa THE RESULTS WERE INVESTIGATED USING 'PSF'

PROSPECTIVELY

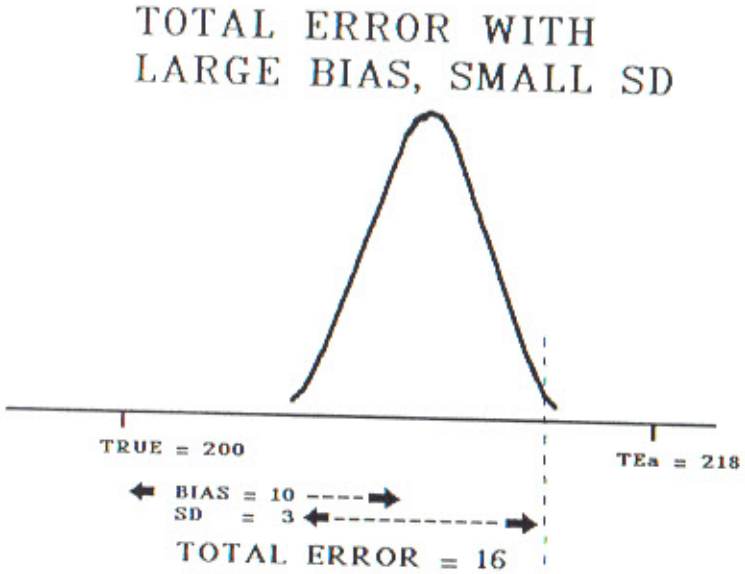
- PRIOR TO IMPLEMENTING THE USE OF A NEW LOT OF REAGENT(S), LABORATORY TESTED PATIENT SAMPLES AND QC MATERIALS USING BOTH CURRENT AND TRIAL LOTS ON 3-5 RUNS.

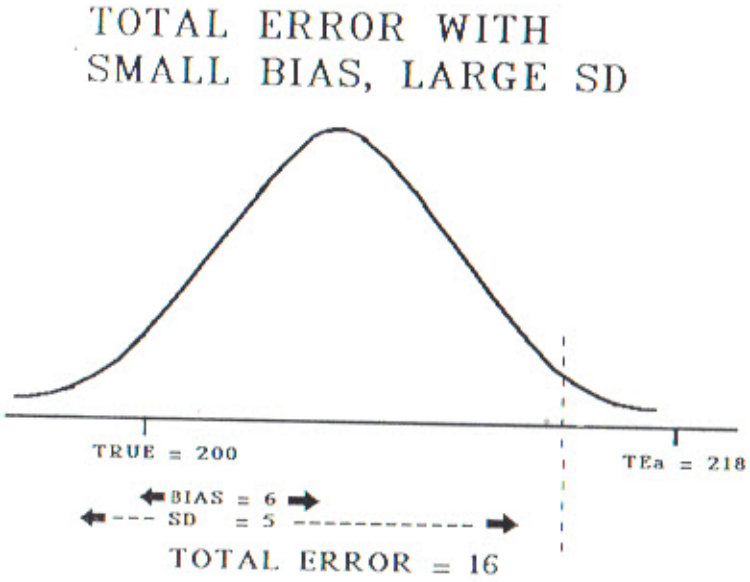
THE PROJECTED TE OF THE NEW LOT WAS COMPARED TO THE TEa

WHEN TE > TEa THE NEW LOT WAS REJECTED

2. COMPUTER SIMULATIONS

SIMULATIONS WERE USED TO ANALYZE THE EFFICACY THE TE CRITERIA AND TO COMPARE TE ASSESSMENT TO THE CHANGES IN SEc, REc AND SHIFTS IN THE MEAN GREATER THAN 1 SD.





CHEM XLS-529, XPS-629 JUNE 15, 1992

Albumin

CONTROL CODE: CH1

LAB	N	MEAN	SD	BIAS	TEa	TE	RATIO TO TEa TE	SD	BIAS	ERROR TYPE
503	35	40.30	1.20	-3.00	5.00	5.35	1.07	.24	.60	SYSTEMATIC
506	46	27.60	.70	1.70	3.00	3.07	1.02	.23	.57	SYSTEMATIC

CONTROL CODE: CH2

LAB	N	MEAN	SD	BIAS	TEa	TE	RATIO TO TEa TE	SD	BIAS	ERROR TYPE
503	35	30.30	1.20	-2.00	3.00	4.35	1.45	.40	.67	RANDOM SYSTEMATIC

ALT (SGPT)

CONTROL CODE: CH1

LAB	N	MEAN	SD	BIAS	TEa	TE	RATIO TO TEa TE	SD	BIAS	ERROR TYPE
503	31	27.50	2.70	.40	5.42	5.69	1.05	.50	.07	RANDOM
505	61	18.51	1.25	-1.69	4.04	4.14	1.02	.31	.42	SYSTEMATIC
504	20	29.20	2.20	-3.40	6.52	7.71	1.18	.34	.52	RANDOM SYSTEMATIC

Amylase

CONTROL CODE: CH1

LAB	N	MEAN	SD	BIAS	TEa	TE	RATIO TO TEa TE	SD	BIAS	ERROR TYPE
502	17	28.80	3.20	.70	5.62	6.97	1.24	.57	.12	RANDOM
501	21	78.60	5.20	6.10	14.50	16.29	1.12	.36	.42	RANDOM SYSTEMATIC
504	20	54.50	5.00	-2.80	11.46	12.60	1.10	.44	.24	RANDOM SYSTEMATIC

Calcium

CONTROL CODE: CH2

LAB	N	MEAN	SD	BIAS	TEa	TE	RATIO TO TEa TE	SD	BIAS	ERROR TYPE
503	26	2.97	.07	-.08	.20	.21	1.06	.33	.42	SYSTEMATIC

Cholesterol

CONTROL CODE: CH1

LAB	N	MEAN	SD	BIAS	TEa	TE	RATIO TO TEa TE	SD	BIAS	ERROR TYPE

ASSESSMENT CRITERIA:

The following values were calculated for each time period (month) of Q.C. data and for prospective lot changes:

INDICATOR	FORMULA	PASS CRITERIA
TE	$\|Bc\| + (SDc * 1.96)$	$TE < TEa$
ΔSE	$(\bar{X}c - \bar{X}i)/SDc$	$\Delta SE < \Delta SEc$
ΔRE	SDc/SDi	$\Delta RE < \Delta REc$
$\Delta \bar{X}$	$[\bar{X}c - \bar{X}(n-1)]/SDc$	$\Delta \bar{X} < 1.0$

STATISTICAL DATA:

Quality Control Analysis:

- Initial Mean ($\bar{X}i$) = value set during first period of use with current control lot.
- Initial Bias (Bi) = bias established by comparison of patient data to a reference laboratory over a 3-day study.
- Current Mean ($\bar{X}c$) = mean from routine daily QC data.
- Current SD (SDc) = standard deviation from routine daily QC data.
- Current Bias (Bc) = $(\bar{X}c - \bar{X}i + Bi)$
- TEa = Total Error Allowable
- TE = $|Bc| + (1.96 \times SDc)$
- $\Delta SEc = ([TEa - |Bi|]/SDi) - 1.65$
- $\Delta REc = TEa/(SDi \times 1.96)$
- $\Delta \bar{X} = ((\bar{X}c - \bar{X}(n-1))/SDc$

TEST NAME: EXAMPLE 1 - INCREASED SYSTEMATIC ERROR

ASSESSMENT CRITERIA FOR THIS CONTROL:

TEa	18.0	Measurement Units
^SEc	2.9	SD (Current Standard Deviations)
^REc	2.3	SD (Current Standard Deviations)
^X	1.0	SD (Shift in mean from previous month)

Q.C. DATA:	UNITS	TIME 0	TIME 1	TIME 2	TIME 3	TIME 4	TIME 5	TIME 6
MEAN	Units	200	204	208	212	196	192	188
SD	Units	4	4	4	4	4	4	4
BIAS	Units	0	4	8	12	-4	-8	-12

INDICATORS:

TE	Units		11.8	15.8	19.8	11.8	15.8	19.8
^SE	SD		1.0	2.0	3.0	-1.0	-2.0	-3.0
^RE	SD		1.0	1.0	1.0	1.0	1.0	1.0
^X	SD		1.0	1.0	1.0	-4.0	-1.0	-1.0

ASSESSMENT:

TE < TEa		PASS	PASS	FAIL	PASS	PASS	FAIL
^SE < ^SEc		PASS	PASS	FAIL	PASS	PASS	FAIL
^RE < ^REc		PASS	PASS	PASS	PASS	PASS	PASS
^X < 1.0		PASS	PASS	PASS	FAIL	PASS	PASS

TEST NAME: EXAMPLE 2 - INCREASED RANDOM ERROR

ASSESSMENT CRITERIA FOR THIS CONTROL:

TEa	18.0	Measurement Units
^SEc	2.9	SD (Current Standard Deviations)
^REc	2.3	SD (Current Standard Deviations)
^X	1.0	SD (Shift in mean from previous month)

Q.C. DATA:	UNITS	TIME 0	TIME 1	TIME 2	TIME 3	TIME 4	TIME 5	TIME 6
MEAN	Units	200	200	200	200	200	200	200
SD	Units	4	6	8	10	12	14	16
BIAS	Units	0	0	0	0	0	0	0

INDICATORS:

TE	Units		11.8	15.7	19.6	23.5	27.4	31.4
^SE	SD		0.0	0.0	0.0	0.0	0.0	0.0
^RE	SD		1.5	2.0	2.5	3.0	3.5	4.0
^X	SD		0.0	0.0	0.0	0.0	0.0	0.0

ASSESSMENT:

TE < TEa		PASS	PASS	FAIL	FAIL	FAIL	FAIL
^SE < ^SEc		PASS	PASS	PASS	PASS	PASS	PASS
^RE < ^REc		PASS	PASS	FAIL	FAIL	FAIL	FAIL
^X < 1.0		PASS	PASS	PASS	PASS	PASS	PASS

TEST NAME: EXAMPLE 3 - INCREASED SYSTEMATIC AND RANDOM ERROR

ASSESSMENT CRITERIA FOR THIS CONTROL:

TEa	18.0	Measurement Units
^SEc	2.9	SD (Current Standard Deviations)
^REc	2.3	SD (Current Standard Deviations)
^X	1.0	SD (Shift in mean from previous month)

Q.C. DATA:	UNITS	TIME 0	TIME 1	TIME 2	TIME 3	TIME 4	TIME 5	TIME 6
MEAN	Units	200	204	204	204	196	196	196
SD	Units	4	4	6	8	4	6	8
BIAS	Units	0	4	4	4	-4	-4	-4

INDICATORS:

TE	Units		11.8	15.8	19.7	11.8	15.8	19.7
^SE	SD		1.0	0.7	0.5	-1.0	-0.7	-0.5
^RE	SD		1.0	1.5	2.0	1.0	1.5	2.0
^X	SD		1.0	0.0	0.0	-2.0	0.0	0.0

ASSESSMENT:

TE < TEa		PASS	PASS	FAIL	PASS	PASS	FAIL
^SE < ^SEc		PASS	PASS	PASS	PASS	PASS	PASS
^RE < ^REc		PASS	PASS	PASS	PASS	PASS	PASS
^X < 1.0		PASS	PASS	PASS	FAIL	PASS	PASS

TEST NAME: EXAMPLE 4 - INCREASED SYSTEMATIC AND RANDOM ERROR

ASSESSMENT CRITERIA FOR THIS CONTROL:

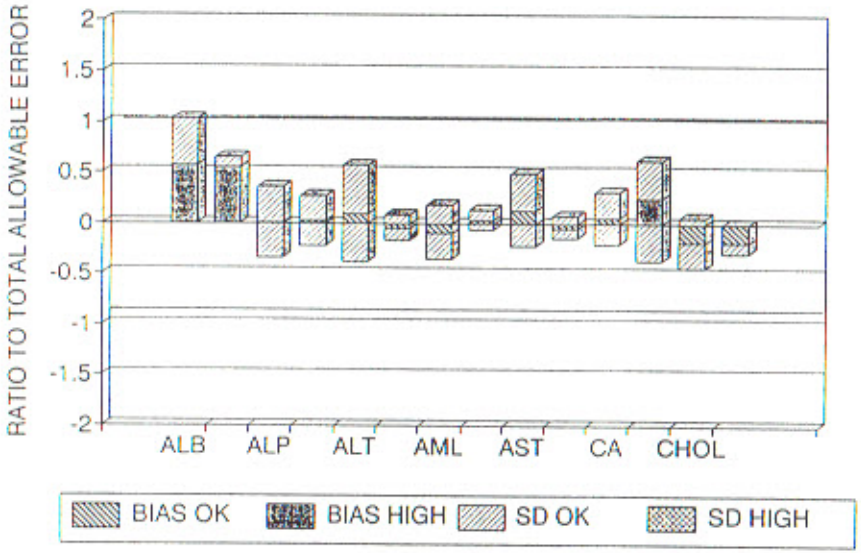
TEa	18.0	Measurement Units
^SEc	2.9	SD (Current Standard Deviations)
^REc	2.3	SD (Current Standard Deviations)
^X	1.0	SD (Shift in mean from previous month)

	UNITS	TIME 0	TIME 1	TIME 2	TIME 3	TIME 4	TIME 5	TIME 6
MEAN	Units	200	208	208	208	212	212	212
SD	Units	4	4	6	8	4	6	8
BIAS	Units	0	8	8	8	12	12	12

TE	Units		15.8	19.8	23.7	19.8	23.8	27.7
^SE	SD		2.0	1.3	1.0	3.0	2.0	1.5
^RE	SD		1.0	1.5	2.0	1.0	1.5	2.0
^X	SD		2.0	0.0	0.0	1.0	0.0	0.0

TE < TEa		PASS	FAIL	FAIL	FAIL	FAIL	FAIL
^SE < ^SEc		PASS	PASS	PASS	FAIL	PASS	PASS
^RE < ^REc		PASS	PASS	PASS	PASS	PASS	PASS
^X < 1.0		FAIL	PASS	PASS	PASS	PASS	PASS

TOTAL ERROR QC REPORT
[LAB E] [CHEMISTRY] [JUNE 1992]



CONTROL LOT No'S: XLS-529, XPS-629 MONTH-ENDING: JUNE 15, 1992

INITIAL USE DATE: 8/14/91 PREVIOUS MONTH-END: MAY 14, 1992

****

Creatinine (QC CODE: CRE)

CONTROL CODE: CH1 TOTAL ALLOWABLE ERROR: 15.00

	N	MEAN	SD	CV	BIAS	TE	TE/TEa	FLAG
CURRENT	60	97.80	3.00	3.1%	-2.10	7.98	.53	
PREVIOUS	75	98.90	3.30	3.3%	-1.00	7.47	.50	
INITIAL	105	99.90	3.80	3.8%	0.00	7.45	.50	
LOT-TO-DATE	661	100.70	3.80	3.8%	.80	8.25	.55	

CONTROL CODE: CH2 TOTAL ALLOWABLE ERROR: 50.00

	N	MEAN	SD	CV	BIAS	TE	TE/TEa	FLAG
CURRENT	59	506.70	6.70	1.3%	-4.10	17.23	.34	
PREVIOUS	76	514.30	10.90	2.1%	3.50	24.86	.50	
INITIAL	105	510.80	9.60	1.9%	0.00	18.82	.38	
LOT-TO-DATE	659	521.10	11.70	2.2%	10.30	33.23	.66	

Gamma-GT (QC CODE: GGT)

CONTROL CODE: CH1 TOTAL ALLOWABLE ERROR: 3.76

	N	MEAN	SD	CV	BIAS	TE	TE/TEa	FLAG
CURRENT	45	20.90	1.40	6.7%	2.10	4.84	1.29	TE > MAX
PREVIOUS	51	19.80	1.60	8.1%	1.00	4.14	1.10	
INITIAL	66	18.80	1.30	6.9%	0.00	2.55	.68	
LOT-TO-DATE	447	19.20	1.50	7.8%	.40	3.34	.89	

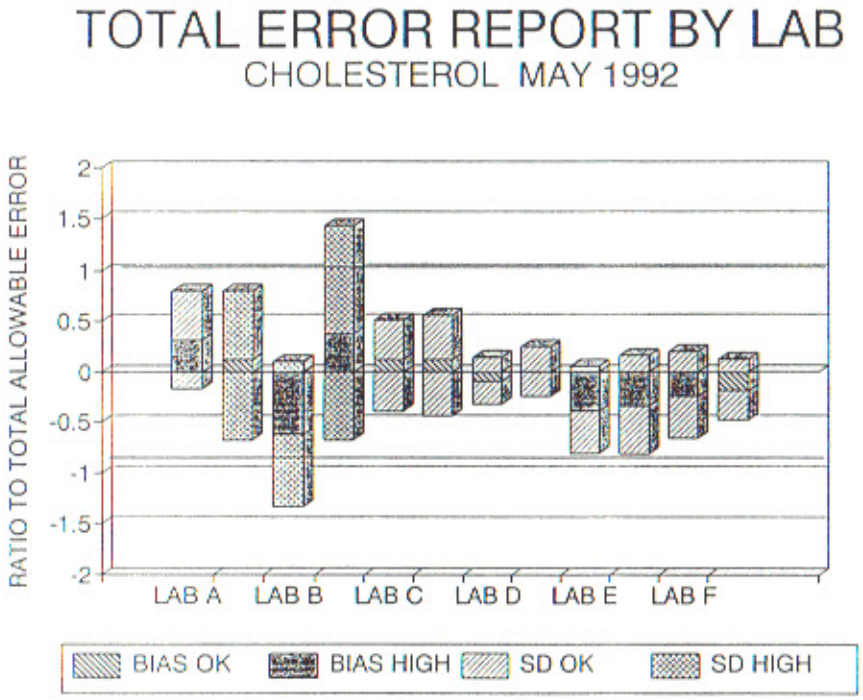
CONTROL CODE: CH2 TOTAL ALLOWABLE ERROR: 22.96

	N	MEAN	SD	CV	BIAS	TE	TE/TEa	FLAG
CURRENT	45	112.90	2.10	1.9%	-1.90	6.02	.26	
PREVIOUS	50	112.40	2.40	2.1%	-2.40	7.10	.31	
INITIAL	66	114.80	2.90	2.5%	0.00	5.68	.25	
LOT-TO-DATE	446	113.10	2.70	2.4%	-1.70	6.99	.30	

Glucose - Fasting (QC CODE: GLU)

CONTROL CODE: CH1 TOTAL ALLOWABLE ERROR: .60

	N	MEAN	SD	CV	BIAS	TE	TE/TEa	FLAG
CURRENT	60	4.41	.06	1.4%	-.10	.22	.36	
PREVIOUS	74	4.46	.09	2.0%	-.05	.23	.38	
INITIAL	99	4.51	.08	1.8%	0.00	.16	.26	
LOT-TO-DATE	638	4.51	.08	1.8%	0.00	.16	.26	



Cholesterol

CONTROL: CH1

LAB	N	MEAN	SD	CV	BIAS	TE	TEa	TE/TEa	FLAG
503	29	4.79	.16	3.3%	.22	.53	.41	1.30	TE > MAX
502	21	4.50	.10	2.2%	-.51	.71	.45	1.57	TE > MAX
501	22	4.74	.12	2.5%	-.02	.26	.43	.60	
506	37	4.64	.06	1.3%	-.10	.22	.43	.51	
505	25	4.72	.12	%	-.09	.32	.43	.73	
504	18	4.46	.14	3.1%	.03	.30	.40	.76	

CONTROL: CH2

LAB	N	MEAN	SD	CV	BIAS	TE	TEa	TE/TEa	FLAG
503	29	3.65	.11	3.0%	.11	.33	.32	1.02	TE > MAX
502	21	3.37	.07	2.1%	-.09	.23	.31	.73	
501	22	3.55	.10	2.8%	-.02	.22	.32	.67	
506	39	3.36	.02	.6%	-.06	.10	.31	.32	
505	25	3.55	.11	%	-.05	.26	.32	.80	
504	18	3.42	.12	3.5%	-.05	.29	.31	.91	

Creatinine

CONTROL: CH1

LAB	N	MEAN	SD	CV	BIAS	TE	TEa	TE/TEa	FLAG
503	53	98.70	4.00	4.1%	-1.10	8.94	15.00	.60	
502	33	100.00	4.00	4.0%	2.90	10.74	15.00	.72	
501	49	106.30	3.00	2.8%	2.00	7.88	15.00	.53	
506	60	97.80	3.00	3.1%	-2.10	7.98	15.00	.53	
505	59	105.54	4.82	%	-1.46	10.91	15.00	.73	
504	22	100.00	3.30	3.3%	5.20	11.67	15.00	.78	

CONTROL: CH2

LAB	N	MEAN	SD	CV	BIAS	TE	TEa	TE/TEa	FLAG
503	53	540.50	16.40	3.0%	-18.50	50.64	50.00	1.01	TE > MAX
502	33	548.20	12.20	2.2%	-11.70	35.61	50.00	.71	
501	50	536.40	10.80	2.0%	3.70	24.87	50.00	.50	
506	59	506.70	6.70	1.3%	-4.10	17.23	50.00	.34	
505	53	543.68	11.66	%	-7.22	30.07	50.00	.60	
504	22	554.90	23.00	4.1%	-2.00	47.08	50.00	.94	

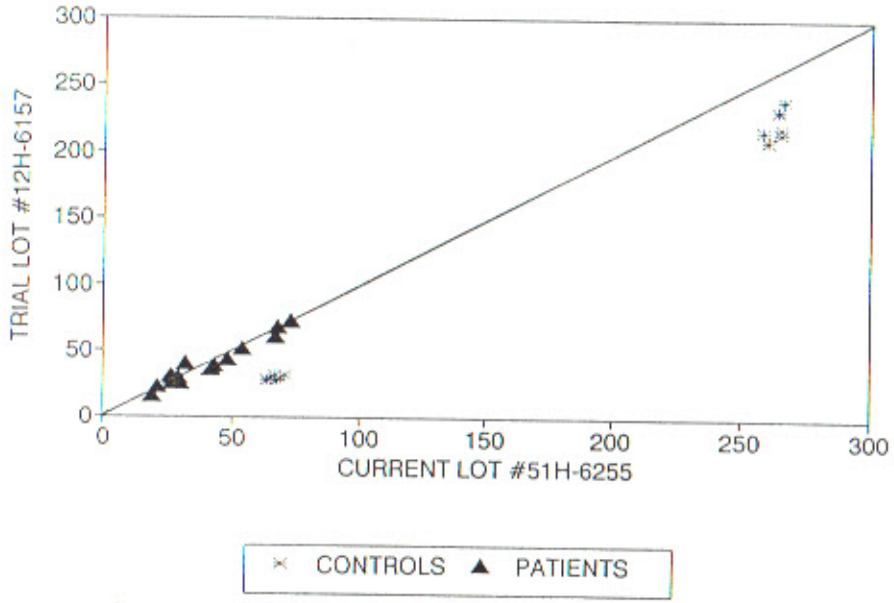
Direct Bilirubin

CONTROL: CH1

LAB	N	MEAN	SD	CV	BIAS	TE	TEa	TE/TEa	FLAG
505	27	3.85	.36	%	3.85	4.56		0.00	N/A

AMYLASE REAGENT LOT CHANGE

A.G.H. APRIL 1992



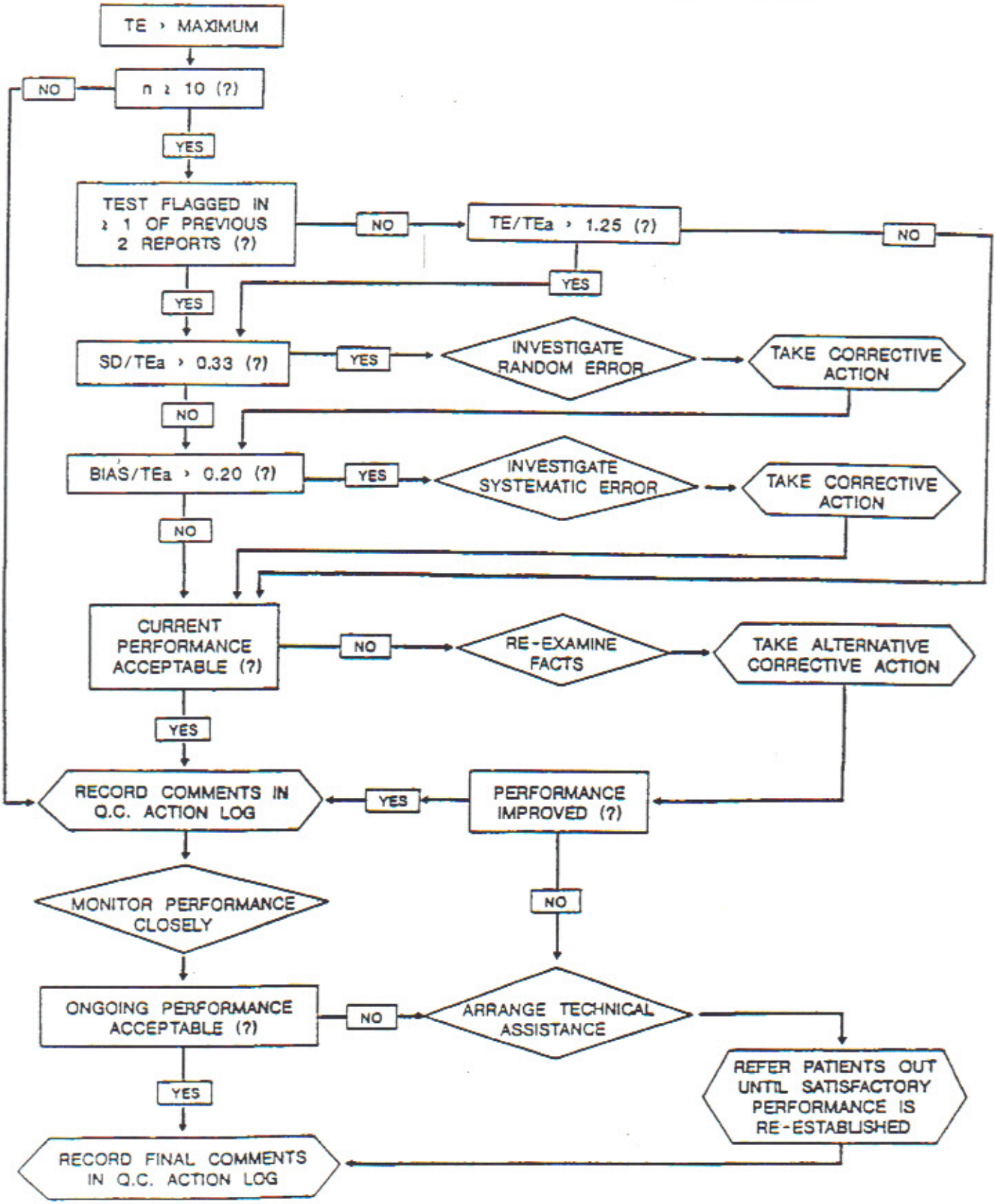
C.R.L.P. COMPARISON OF REAGENT OR CALIBRATOR LOTS

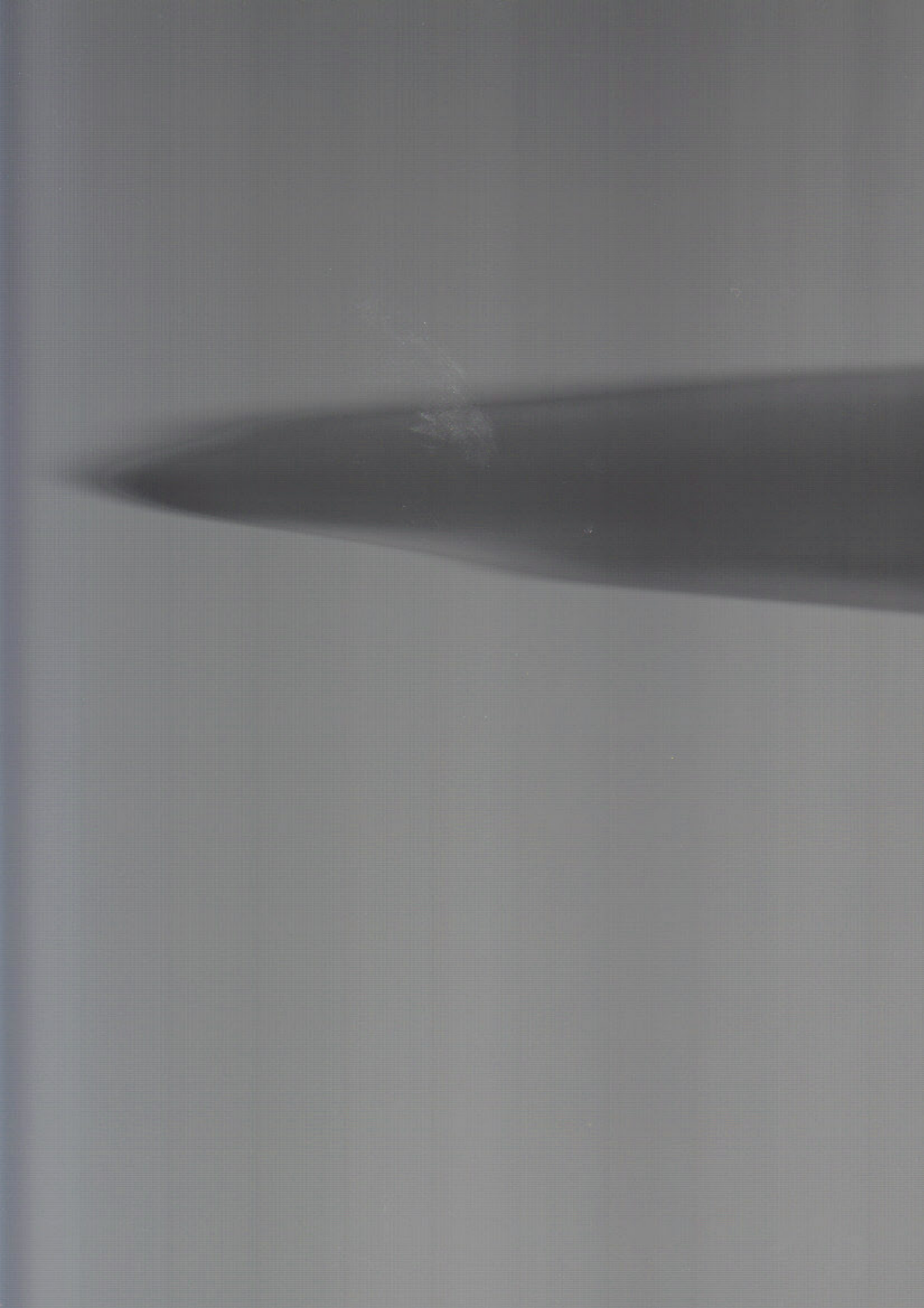
*** TEST CONTROLS IN DUPLICATE AND 5 PATIENTS SPANNING THE
*** ANALYTICAL RANGE BY CURRENT AND TRIAL LOTS FOR 3 - 5 DAYS

LAB: AG TEST: AMYLASE INSTR MIRA

	CURRENT REAGENT/CAL	TRIAL REAGENT/CAL
SOURCE:	516 MA	516 MA
LOT No:	51H-6255	12H-6157
EXP DATE	MAY/92	JAN/93
DATE:	92/5/6 KC	
CTRL 1	68	28
CTRL 2	264	232
PT 1	19	16
PT 2	54	52
PT 3	68	68
PT 4	27	26
PT 5	48	44
CTRL 1	69	29
CTRL 2	260	209
DATE:	92/5/8 CG	
CTRL 1	65	29
CTRL 2	258	217
PT 1	27	30
PT 2	29	30
PT 3	32	41
PT 4	73	73
PT 5	21	23
CTRL 1	64	28
CTRL 2	265	215
DATE:	92/5/8 CG	
CTRL 1	67	32
CTRL 2	266	139
PT 1	26	31
PT 2	43	39
PT 3	67	61
PT 4	30	26
PT 5	42	36
CTRL 1	71	32
CTRL 2	265	219

TOTAL ERROR PROBLEM-SOLVING FLOW CHART





CONCLUSIONS

- TE CRITERIA IS AS EFFECTIVE AS SEc AND REC WHEN INDEPENDENT CHANGES OCCUR IN SYSTEMATIC AND RANDOM ERROR
- TE IS MORE SENSITIVE THAN SEc AND REc TO SIMULTANEOUS CHANGES IN SYSTEMATIC AND RANDOM ERROR
- ACCEPTING SHIFTS IN MEAN VALUES WHEN THEY ARE LESS THAN 1 SD IS NOT A VALID PRACTICE
- COMPARISON OF TE TO TEa IS A SIMPLE AND EFFECTIVE WAY TO MONITOR CHANGES IN QC PERFORMANCE AND TO PREDICT ACCEPTABILITY OF NEW LOTS OF REAGENTS OR CALIBRATORS

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