

Table 5 Analytical goals for haematology

Complete blood count	Units	Min	Max	X	Range	Std dev	Tonks	Aspen	6 Sigma	CLIA 2024	CLIA 2024
						Quartil	1 StD	1/2 StD	1/6 StD	Target Value ±	RCV=CLIA/Tonks
Erythrocyte count	m/uL	4.5	6.5	5.5	2.0	0.5	9.1%	4.5%	1.5%	6.0%	1.3
Hemoglobin	g/dL	13.5	18.0	15.8	4.5	1.1	7.1%	3.6%	1.2%	7.0%	1.0
Hematocrit	%	38.3	50.0	44.1	11.8	2.9	6.7%	3.3%	1.1%	6.0%	0.9
MCV	fL	85.0	97.5	91.3	12.5	3.1	3.4%	1.7%	0.6%		
MCH	pg	27.0	35.0	31.0	8.0	2.0	6.5%	3.2%	1.1%		
MCHC	g/dL	28.0	37.0	32.5	9.0	2.3	6.9%	3.5%	1.2%		
Leukocyte count	m/uL	4.0	11.0	7.5	7.0	1.8	23.3%	11.7%	3.9%	15.0%	0.6
Platelet count	m/uL	150	400	275	250	62.5	22.7%	11.4%	3.8%	25.0%	1.1
Coagulation	Units	Min	Max	X	Range	Std dev	Tonks	Aspen	6 Sigma	CLIA 2024	CLIA 2024
						Quartil	1 SD	1/2 SD	1/6 SD	TargetCLIA VALUE ±	RCV=CLIA/Tonks
Prothrombin time	Sec"	9	15	12	6.0	1.5	12.5%	6.3%	2.1%	15.0%	1.2
Prothrombin time	INR	0.5	1.5	1.0	1.0	0.3	25.0%	12.5%	4.2%	15.0%	0.6
Partial thromboplastin time	Sec"	15	45.0	30	30.0	7.5	25.0%	12.5%	4.2%	15.0%	0.6
Thrombin time	Sec"	5.0	15.0	10	10.0	2.5	25.0%	12.5%	4.2%		
AT III	%	75.0	125	100	50.0	12.5	12.5%	6.30%	2.1%		
Fibrinogen	mg/dL	200	400	300	200	50.0	16.7%	8.30%	2.8%	20.0%	1.2

Table 6 Analytical goals for biochemistry and blood gases

Biochemistry	Units	Min	Max	X	Range	Std Dev	Tonks	Aspen	6 Sigma	CLIA 2024	CLIA 2024 RCV
						Quartil	1 StD	1/2 StD	1/6 StD	Target value ±	CLIA/TONKS
Osmolality	mOsm/L	285.0	310.0	297.50	25.00	6.25	2.1%	1.1%	0.4%		
Glucose	mg/dL	70.0	110.0	90.00	40.00	10.00	11.1%	5.6%	1.9%	10.0%	0.9
BUN	mg/dL	6.0	20.0	13.00	14.00	3.50	26.9%	13.5%	4.5%	9.0%	0.3
Creatinine	mg/dL	0.5	1.2	0.85	0.70	0.18	20.6%	10.3%	3.4%	15.0%	0.7
Uric acid	mg/dL	2.4	7.0	4.70	4.60	1.15	24.5%	12.2%	4.1%	17.0%	0.7
Cholesterol Total	mg/dL	100.0	200.0	150.00	100.00	25.00	16.7%	8.3%	2.8%	10.0%	0.6
Cholesterol HDL	mg/dL	15.0	55.0	35.00	40.00	10.00	28.6%	14.3%	4.8%	30.0%	1.1
Cholesterol LDL	mg/dL	50.0	130.0	90.00	80.00	20.00	22.2%	11.1%	3.7%	20.0%	0.9
Tyiglycerides	mg/dL	50.0	150.0	100.00	100.00	25.00	25.0%	12.5%	4.2%	25.0%	1.0
Bilirubin Total	mg/dL	0.1	1.0	0.55	0.90	0.23	40.9%	20.5%	6.8%	20.0%	0.5
Bilirubin Direct	mg/dL	0.0	1.0	0.51	0.99	0.25	49.0%	24.5%	8.2%		
Bilirubin Indirecta	mg/dL	0.0	1.0	0.51	0.99	0.25	49.0%	24.5%	8.2%		
Protein Total	g/dL	6.4	8.8	7.60	2.40	0.60	7.9%	3.9%	1.3%	10.0%	1.3
Albumin	g/dL	3.4	4.8	4.10	1.40	0.35	8.5%	4.3%	1.4%	10.0%	1.2
ALT/SGPT	U/L	2.5	50.3	26.40	47.77	11.94	45.2%	22.6%	7.5%	20.0%	0.4
AST/SGOT)	U/L	2.2	43.7	22.95	41.53	10.38	45.2%	22.6%	7.5%	20.0%	0.4
LDH	U/L	17.8	356.9	187.35	339.01	84.75	45.2%	22.6%	7.5%	20.0%	0.4

Alkaline Phosphatase	U/L	5.8	116.4	61.13	110.61	27.65	45.2%	22.6%	7.5%	30.0%	0.7
GGT	U/L	2.8	56.4	29.63	53.61	13.40	45.2%	22.6%	7.5%	30.0%	0.7
Amylase	U/L	6.1	122.0	64.05	115.90	28.98	45.2%	22.6%	7.5%	30.0%	0.7
Lipase	U/L	9.0	180.3	94.65	171.27	42.82	45.2%	22.6%	7.5%		
CK	U/L	12.5	250.0	131.25	237.50	59.38	45.2%	22.6%	7.5%	30.0%	0.7
MB	U/L	1.0	20.0	10.50	19.00	4.75	45.2%	22.6%	7.5%		
Sodium	mEq/L	130.0	145.0	137.50	15.00	3.75	2.7%	1.4%	0.5%	2.9%	1.1
Potassium	mEq/L	3.3	5.5	4.40	2.20	0.55	12.5%	6.3%	2.1%	2.8%	0.2
Chloride	mEq/L	91.0	107.0	99.00	16.00	4.00	4.0%	2.0%	0.7%	5.0%	1.2
CO2	mEq/L	20.0	30.0	25.00	10.00	2.50	10.0%	5.0%	1.7%	20.0%	2.0
Calcium	mg/dL	8.2	10.2	9.20	2.00	0.50	5.4%	2.7%	0.9%	11.0%	2.0
Phosforus	mg/dL	2.7	4.5	3.60	1.80	0.45	12.5%	6.3%	2.1%	10.0%	0.8
Magnesium	mg/dL	1.5	3.0	2.25	1.50	0.38	16.7%	8.3%	2.8%	25.0%	1.5
Iron Total	ug/dL	37.0	158.0	97.50	121.00	30.25	31.0%	15.5%	5.2%	15.0%	0.5
Lactate	mmol/L	0.4	1.2	0.80	0.80	0.20	25.0%	12.5%	4.2%		
Calcium Ionic	mmol/L	1.0	2.5	1.75	1.50	0.38	21.4%	10.7%	3.6%		
Blood gases	Units	Min	Max	X	Range	Std Dev	Tonks	Aspen	6 Sigma	CLIA 2024	CLIA 2024
						Quartil	1 StD	1/2 StD	1/6 StD	Target value ±	RCV=CLIA/TONKS
PH	UI	7.35	7.45	7.4	0.100	0.025	0.3%	0.2%	0.1%	0.04%	0.1
PO2	mmHg	80.0	100.0	90.00	20.00	5.00	5.6%	2.8%	0.9%	15.0%	2.7
PCO2	mEq/L	35.0	45.0	40.00	10.00	2.50	6.3%	3.1%	1.0%	8.0%	1.3
HCO3	mEq/L	22.0	28.0	25.00	6.00	1.50	6.0%	3.0%	1.0%		
CO2 Total	mEq/L	23.0	30.0	26.48	7.04	1.76	6.6%	3.3%	1.1%		
Base Excess	mEq/L	-2.0	4.0	1.00	6.00	1.50	150.0%	75.0%	25.0%		
Saturation O2	%	80.0	100.0	90.00	20.00	5.00	5.6%	2.8%	0.9%		

Table 7 Analytical goals for immunoproteins, endocrinology, tumor markers

Immunoproteins	Units	Min	Max	X	Range	Std Dev	Tonks	Aspen	6 Sigma	CLIA 2024	CLIA 2024
						Quartil	1 StD	1/2 StD	1/6 StD	Targetvalue±	RCV=CLIA/TONKS
IGG	mg/dL	700.0	1600.0	1150.00	900.00	225.00	19.6%	9.8%	3.3%	20.0%	1.0
IGA	mg/dL	70.0	400.0	235.00	330.00	82.50	35.1%	17.6%	5.9%	20.0%	0.6
IGM	mg/dL	40.0	230.0	135.00	190.00	47.50	35.2%	17.6%	5.9%	20.0%	0.6
IGE	Ut/ml	1.0	100.0	50.50	99.00	24.75	49.0%	24.5%	8.2%	20.0%	0.4
C3	mg/dL	90.0	180.0	135.00	90.00	22.50	16.7%	8.3%	2.8%	15.0%	0.9
C4	mg/dL	10.0	40.0	25.00	30.00	7.50	30.0%	15.0%	5.0%	20.0%	0.7
AEL	UI/ml	1.0	200.0	100.50	199.00	49.75	49.5%	24.8%	8.3%		
FR	Ut/ml	1.0	30.0	15.50	29.00	7.25	46.8%	23.4%	7.8%		
PCR	mg/L	1.0	3.0	2.00	2.00	0.50	25.0%	12.5%	4.2%	30.0%	1.2
Endocrinology	Units	Min	Max	X	Range	Std Dev	Tonks	Aspen	6 Sigma	CLIA 2024	CLIA 2024
						Quartil	1 StD	1/2 StD	1/6 StD	Target value ±	RCV= CLIA/TONKS
Cortisol(matinal)	ug/dL	3.8	25.0	14.40	21.20	5.30	36.8%	18.4%	6.1%	25.0%	0.7
Insulin (basal)	uU/mil	2.6	24.9	13.75	22.30	5.58	40.5%	20.3%	6.8%		

FSH (mid cycle)	mU/mL	4.7	21.5	13.10	16.80	4.20	32.1%	16.0%	5.3%	18.0%	0.6
Prolactin(female)	ng/mL	6.0	29.9	17.95	23.90	5.98	33.3%	16.6%	5.5%	20.0%	0.6
LH mid cycle)	mU/mL	14.0	96.0	55.00	82.00	20.50	37.3%	18.6%	6.2%	20.0%	0.5
TSH	uU/mL	0.3	3.4	1.85	3.10	0.78	41.9%	20.9%	7.0%	30.0%	0.7
T3T	ng/dL	50.0	260.0	155.00	210.00	52.50	33.9%	16.9%	5.6%	20.0%	0.6
T4T	ug/dL	5.1	14.1	9.60	9.00	2.25	23.4%	11.7%	3.9%	20.0%	0.9
FT3	pg/mL	1.4	5.5	3.45	4.10	1.03	29.7%	14.9%	5.0%		
FT4	ng/dL	0.3	2.5	1.38	2.25	0.56	40.9%	20.5%	6.8%	15.0%	0.4
Estradiol(climaterium)	pg/mL	8.6	49.8	29.20	41.20	10.30	35.3%	17.6%	5.9%	30.0%	0.9
Progesterone(luteal phase)	ng/mL	0.7	27.0	13.85	26.30	6.58	47.5%	23.7%	7.9%	25.0%	0.5
Testosterone(adult male)	ng/dL	10.0	120.0	65.00	110.00	27.50	42.3%	21.2%	7.1%	30.0%	0.7
Tumoral markers	Units	Min	Max	X	Range	Std Dev	Tonks	Aspen	6 Sigma	CLIA 2024	CLIA 2024
						Quartil	1 SID	1/2 StD	1/6 SID	Target value±	CLIA/TONKS
AFP	ng/mL	0.1	7.0	3.55	6.90	1.73	48.6%	24.3%	8.1%	20.0%	0.4
BHGC	mUUmL	0.1	5.0	2.55	4.90	1.23	48.0%	24.0%	8.0%	18.0%	0.4
CA 125	U/mL	0.1	35.0	17.55	34.90	8.73	49.7%	24.9%	8.3%	20.0%	0.4
CA 15-3	U/mL	0.1	27.0	13.55	26.90	6.73	49.6%	24.8%	8.3%		
CA 19-9	UmL	0.1	37.0	18.55	36.90	9.23	49.7%	24.9%	8.3%		
CEA	ng/mL	0.1	3.4	1.75	3.30	0.83	47.1%	23.6%	7.9%	15.0%	0.3
PSA TOTAL	ng/mL	0.1	4.0	2.05	3.90	0.98	47.6%	23.8%	7.9%	20.0%	0.4
PSA LIBRE	ng/mL	0.1	1.0	0.55	0.90	0.23	40.9%	20.5%	6.8%		

Table 8 Analytical goals for therapeutic drug monitor and hematinics

Therapeutic drug monitor	Units	Min	Max	X	Range	Std Dev	Tonks	Aspen	6 Sigma	CLIA 2024	CLIA 2024
						Quartil	1 StD	1/2 StD	1/6 StD	Target value ±	RCV = CLIA/TONKS
Acetaminofen	ug/mL	0.1	12.5	6.30	12.40	3.10	49.2%	24.6%	8.2%	20.0%	0.4
Carbamacepin	ug/mL	0.1	2.2	1.15	2.10	0.53	45.7%	22.8%	7.6%	20.0%	0.4
Digoxin	ng/mL	0.1	1.1	0.60	1.00	0.25	41.7%	20.8%	6.9%	15.0%	0.4
Phenytoin	ug/mL	0.1	9.6	4.85	9.50	2.38	49.0%	24.5%	8.2%	15.0%	0.3
Phenobarbital	ug/mL	0.1	10.3	5.20	10.20	2.55	49.0%	24.5%	8.2%	15.0%	0.3
Gentamicin	ug/mL	0.1	1.4	0.75	1.30	0.33	43.3%	21.7%	7.2%	25.0%	0.6
Litium	mEq/L	0.1	0.5	0.30	0.40	0.10	33.3%	16.7%	5.6%	15.0%	0.5
Salicylates	mg/dL	0.1	6.5	3.30	6.40	1.60	48.5%	24.2%	8.1%	15.0%	0.3
Theophylline	ug/mL	0.1	7.2	3.65	7.10	1.78	48.6%	24.3%	8.1%	20.0%	0.4
Tobramicin	ug/mL	0.1	1.8	0.95	1.70	0.43	44.7%	22.4%	7.5%	20.0%	0.4
Valproic Acid	ug/mL	0.1	35.5	17.80	35.40	8.85	49.7%	24.9%	8.3%	20.0%	0.4
Vancomicin	ug/mL	0.1	6.4	3.25	6.30	1.58	48.5%	24.2%	8.1%	15.0%	0.3
Hematinic levels	Units	Min	Max	X	Range	Std Dev	Tonks	Aspen	6 Sigma	CLIA 2024	CLIA 2024
						Quartil	1 StD	1/2 StD	1/6 StD	Target value ±	RCV = CLIA/TONKS
Folic Acid	ug/L	2.0	20.0	11.00	18.00	4.50	40.9%	20.5%	6.8%	30.0%	0.7
Vitamin B12	ng/L	190.0	765.0	477.50	575.00	143.75	30.1%	15.1%	5.0%	30.0%	1.0

Ferritin	ug/L	20.0	120.0	70.00	100.00	25.00	35.7%	17.9%	6.0%	20.0%	0.6
Iron	ug/dL	37.0	158,0	97.50	121.00	30.25	31.0%	15.5%	5.2%	20.0%	0.6
Total Iron Binding Capacity	ug/dL	270.0	360.0	315.00	90.00	22.50	7.1%	3.6%	1.2%	20.0%	2.8

Table 9 Strategic plan: WWWWH

WHAT	Analytical performance specifications based on medical relevance, biological variability and technological evolution
WHO	Clinical Laboratories establish individual Analytical Goals for each test performed and evaluated through their Internal QC in order to approve CLIA's Proficiency Testing Requirements Proficiency Testing providers establish Analytical Goals in order to be evaluate participants on EQAS External Quality Assurance Surveys.
WHY	Medical Relevance is the fundamental premise. Mission in Clinical Laboratory is to provide reliable and timely information for decision making including diagnosis, prognosis, treatment and surveillance. In consequence, the necessity to establish proper goals for every test is evident, in order to guarantee that the information provides maximum benefit with least risk and best cost, avoiding false positive and false negative results. Analytical Performance Specifications APS also known as Analytical Goals AG can be set with several strategies depending on three different perspectives including: Medical Relevance, Biological Variation and Technology. In Clinical Laboratory these scopes are interdependent and have to be analyzed systematically as a whole in order to establish an inclusive strategy depending on the technological status of the facility
WHEN	According to Deming it is strongly recommended to approach the challenge in four stages: <ul style="list-style-type: none"> · PLAN · ORGANIZE · DEVELOP · CONTROL
WHERE	<ul style="list-style-type: none"> · IQC Internal Quality Control · EQAS External Quality Assessment
HOW	This procedure includes three steps: <ol style="list-style-type: none"> 1. Establish the coefficient of variation [CV%] in the Internal Quality Control Program IQCP of each and every test performed in the Laboratory 2. Calculate Tonks, Aspen and 6S levels which depend of the Reference Limits and Biological Variation of each measurand 3. Compare obtained data with the information provided in Tables 6,7,8,9 to assure CLIA's Proficiency Testing Requirements are accomplished.