

Technical Specification for Clinical Chemistry Auto Analyzer

It should be random access the analyzer should have close system with micro slide dry chemistry technology, but must be Truly Random Access system & must detect Clot & Bubble in the sample. It also must have liquid Level- sensing. (Pressure Transducer), Short – Sample Detection

It should be through put rate of upto 250 results per hour

It should have Barcode Sample Identification: Auto discriminates among all standard hymnologies, Including code 128,code 39,Interleaved 2 of 5, Codabar, and UPC, Barcodes can be of varying lengths.

Sample types:

It must process Serum, Plasma, Urine, and CSF with minimum 40 Samples loading at any point of time.

Sample Volume: 5-11ul max. Sample Containers:10ml,7ml,5ml,2-4ml.Collection Tubes,1ml Microtube Microsample cup and 5ml & 2ml cups.System must have Disposable Tips to minimize the Sample carry-over problems.

It must be ready to use reagents manufactured as per either IFCC or NCCLS recommendations. Reagent supply should have Bar-Code reading facility. At least 60 reagent packs must be loaded at any time. Should minimize the Hemolytic, Icteric & Lipemic interferences.

On board Storage Analyzer can store the reagents on-Board by controlling Humidity & Temperature of the reagents.

It should have inventory tracks methods, quantity, generation no, number of slides used, number of slides used for repeats, cal & QC.

On-Board Test Capacity:3600 Tests at any point of time.

It should be extended calibration (upto 6 months stability), Multiple Lots Supported.

The analyzer must have on-board Auto-Dilution facility.

It should have all routine some drugs & Electolytes (Direct ISE ONLY).It should also perform Conjugated & Un-Conjugated Bilirubin along with Delta Bilirubin and Direct HDL.

Reading & Result Management principles of Potentiometric (direct ISE), Colometric/rate, Immuno – rate
Time for Single result: 2.5-7 minutes Potentiometric 2.5 minutes Colometric 5 minutes Immuno rate
7 minutes_Quality Control Levy-Genic Plots

Operator Interface must be touch screen monitor, On Board User Guide

Automation Technology Field Upgradable, includes Automatic Tip loading and deep Tube sampling

Maintenance Minimal Daily, Weekly, Monthly & Periodic Maintenance.

Environment Management

Plumbing:

No Distilled water/ De-ionized water plant or drain required. Environment friendly Easy Waste deposal system.

Communications

RS 232 serial port. Should be able to interface with The computer (Uni & Bi-Directional).

Dry Chemistry

Quality:

1. Practically no external variables: Since the reagents are in ready to use slide form there are no external activities or variables that could effect the quality of results.
2. Daily standardization of reagents eliminated.
3. Calibration required once in 6 months only.
4. Repeatability is excellent and well proven.
5. Accuracy is very good. Most customers use dry chemistry as the bench mark for cross checking wet chemistry results that are suspect.
6. Physical and chemical interferences are eliminated by the spreading layer in the slide.
7. Heamolysis, Ictericity & Lipemia do not effect results even if sample is not pre-treated.

Turnaround Time:

8. Results within 2-5 minutes.
No programming for reagents required.
9. Negligible start up procedure Night work / Emergency samples can be done even by technician, with minimum training.

Sample Requirements:

10. Very less serum required. Standard 10 microlitres each for all tests. Thus less sample needs to be drawn. Ideal for pediatric and old patients. Need to redraw reduces.

Menu Breadth and usage:

11. Covers about 95% of the biochemistry menu which includes routine tests and some special tests like Lithium, Ammonia, Cholinesterase, lipase etc.

which are very difficult to perform on wet chemistry and can be done on dry with as much ease as a glucose test is done.

12. Electrolyte test can be done by direct ISE method. Thus there is no need for a separate electrolyte analyzer reducing the additional Capital cost .

Reagent & consumable cost:

13. High reagent efficiency. Very less wastage, which is accountable.

14. In the case of Rare Chemistries the cost per patient reportable result is less than wet Chemistry. This is because in wet chemistry the wastage due to open bottle stability, cost of frequent calibration, repeats, controls etc. is very high.

15. The consumables are very few, tips, sample cups and ERF fluid.

16. In the overall considering, reagents for routine tests, reagents for rare tests, consumables, wash buffers, detergents, electrodes, tubings spares etc dry chemistry & wet chemistry cost almost the same.

Maintenance:

17. Very low maintenance needs

Annexure-B

SL.NO	Product Description	Pack size
1	Albumin (ALB)	5*50
2	Albumin (ALB)	5*18
3	ALKP	5 *60
4	SGPT/ALTV	5*60
5	Amylase (AMYL)	5*60
6	Amylase (AMYL)	5*18
7	SGOT/AST	5*60
8	BUBC	5*60
9	BUBC	5*18
10	Calcium (CA)	5*60
11	Cholestrol (CHOL)	5*60
12	Cholinesteras (CHE)	5*60
13	Cholinesteras (CHE)	5*18
14	CK/CPK	5*50
15	CK/CPK	5*13
16	CKMB	5*60
17	CKMB	5*18
18	Chloride (CL)	5*50
19	Enzymatic CO2	5*60
20	Iron FE	5*60
21	Iron FE	5*18
22	GGT	5*50
23	Glucose (GLU)	5*60
24	Potassium(K+)	5*50
25	Lactate (LAC)	5*60
26	Lactate (LAC)	5*18
27	UPRO	5*18
28	LDH	5*50
29	Lithium (LI)	5*60
30	Lithium(LI)	5*18
31	Lipase (LIPA)	5*60
32	Lipase (LIPA)	5*18
33	Magnesium MG)	5*60
34	Magnesium MG)	5*18
35	Sodium(NA+)	5*50
36	Ammonia(NH3)	5*60
37	Ammonia(NH3)	5*18
38	Phosphorous (PHOS)	5*60
39	Single Slide Creatinine	5*60
40	Total Bilirubin (TBIL)	5*60

41	Theophylline (THEO)	5*60
42	Theophylline (THEO)	5*18
43	Total Protein (TP)	5*50
44	Triglycerides (TRIG)	5*60
45	Triglycerides (TRIG)	5*18
46	BUN	5*60
47	Uric Acid (URIC)	5*60
48	Acid Phosphatase	5*18
49	Alcohol (ALC)	5*18
50	CSF Protein	5*18
51	Digoxin	5*18
52	Phenytoin	5*18
53	Salicylate	5*18
54	Acetaminophen ACET	5*18
55	CRP	5*18
56	CRBM	5*18
57	D- HDL	5*60
58	PHBR	5*18
59	Urine Electrolyte Diluent	12*10ml
60	Micro Sample Cups	1Box-4000 cups
61	Humidity Pack	2 sets
62	Dessicant Pack	2 sets
63	CM Rate Box Liners	100 liners
64	E 750 Air Filters	6 filters
65	Electrolyte Reference Fluid	18 bottles
66	E 250 Air Filters	6 filters
67	Micro tube Adaptors (LightBlue)	10 Adaptors
68	Diluent Tray	BOX
69	Sample cup Adapter	1 UNIT
70	Pierceable Caps	SET
71	250 Tip Rack	1 UNIT
72	Micro Tips	1 Box of 250 tips
73	E250 Sample trays	1 UNIT
74	E250 Mixing Cup Arrays	BOX
75	Tips Disposal Boxes	100 Boxes
76	E250 Reference Fluid	30 vials
77	Immuowash Fluid	30 vials
78	Rate Lamp	1 lamps
79	PCS 11 Sampls	4QD
80	Citric Acid Solution	6 bottles
81	PM Box II Liners	1 UNIT
82	7% BSA solution	12*5 ml
83	PCS 10.25 MM Adaptors Magenta)	10 Adaptors
84	13 mm Adaptors white	10 Adaptors

85	PCS Micro Tu Adaptors(Light blue)	10 Adaptors
86	Cup Adaptors (ite)	10 Adaptors
87	75mm Short Adaptors (Black)	4 Adaptors
88	Disposable Sample tips PCS II	1000 Tips
89	Sample Tray Carrier	1 SET
90	Iron Reagent	50 Columns
91	Speciality Diluent	6 bottles
92	Calibrator Kit 1	1 Set each
93	Calibrator Kit 2	1 Set each
94	Calibrator Kit 3	1 Set each
95	Calibrator Kit 4	1 Set each
96	Calibrator Kit 5	1 Set each
97	Calibrator Kit 6	1 Set each
98	Calibrator Kit 7	1 Set each
99	Calibrator Kit 8	1 Set each
100	Calibrator Kit 9	1 Set each
101	Calibrator Kit 10	1 Set each
102	Calibrator Kit 25	1 Set each
103	Performance Verifier 1	1 set
104	Performance Verifier 2	1 set
105	Performance Verifier 1 (Liquid)	1 set
106	Performance Verifier 2 (Liquid)	1 set
107	Iso Enzyme Performance Verifier 1	1 set
108	Iso Enzyme Performance Verifier 2	1 set
109	CRP Performance Verifier 1	1 bottle
110	CRP Performance Verifier 2	1 bottle
111	TDM Performance Verifier 1(ACET)	6 bottles
112	TDM Performance Verifier 2 ACE	6 bottles
113	TDM Performance Verifier 3 ACET	6 bottles
114	UPRO Performance Verifier 1	6 bottles
115	UPRO Performance Verifier 2	6 bottles