

Discussed

①① PATHOLOGY & LAB MEDICINE

NIT 13277/6-12-16

To
The Director
RIMS, Ranchi

From:-

Prof. & Head
Department of Pathology

Sir,

Please find the list & Specification of Equipments require for Department of Pathology,

Sl	Name of Equipment
1	AUTO URINE SEDIMENT ANALYSER
2	Automated IHC Slide Stainer
3	Bone decalcifier
4	Coagulation Analyzer
5	Fully Automated IHC System
6	Sliding Microtome
7	Specification for immunoassay Analyzer
8	Specifications for Capillary electrophoresis
9	Thinprep

10 Auto analyser

Discussed

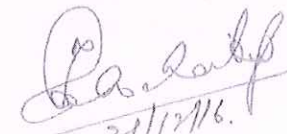
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Thanking you
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Prof. & Head
Department of Pathology
RIMS, Ranchi


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SPECIFICATIONS FOR FULLY AUTO URINE SEDIMENT ANALYSER

1. MUST BE A RANDOM ACCESS TOTALLY PATIENT ORIENTED SYSTEM FOR URINE INVESTIGATION,
2. MINIMUM 12-14 MEASURING PARAMETER WITH URINE BILIRUBIN, KETONES, BLOOD, PH, WBC, UROBILINOGEN, PROTEIN, NITRITE, GLUCOSE, MICROALBUMIN VITAMIN C, SPECIFIC GRAVITY, COLOR etc.
3. MUST HAVE A MINIMUM THROUGHPUT OF URINE CHEMISTRY AT LEAST 230 OR MORE SAMPLES PER HOUR.
4. SEDIMENT ANALYSER MUST HAVE A MINIMUM THROUGHPUT OF AT LEAST 60 SAMPLES/HOUR
5. IT MUST BE INBUILT MICROPROCESSOR BASED TOUCH SCREEN PC FOR OPERATION.
6. MUST BE 4 NOS WAVELENGTH FROM 520nm- 660nm.
7. IT SHOULD BE SAMPLE AUTOLOADER WITH SAMPLE RACK TYPE, WITH A MINIMUM SAMPLE LOADING CAPACITY OF 50 SAMPLES AT A TIME.
8. THE SEDIMENT ANALYSER MUST BE FLAT FLOW CELL TECHNOLOGY, HIGH SPEED IMAGING PROCESS . MINIMUM IMAGING CAPACITY SHOULD BE MORE THAN 800 FRAME.
9. THE SYSTEM SHOULD HAVE FACILITY FOR EACH FORMED ELEMENT IMAGE DISPLAYED ON THE SCREEN IS SEPARATED INTO EACH FRAME.
10. URINE & SEDIMENT ANALYSER, BOTH SHOULD HAVE CONNECTED WITH THE CONNECTOR FOR FAST PROCESSING.
11. INSTRUMENT SHOULD HAVE FACILITY FOR COMBINED RESULT PRINTING.
12. THE SYSTEM MUST HAVE BAR CODE IDENTIFICATION FOR SAMPLE & REAGENTS.
13. SYSTEM SHOULD HAVE DATA STORAGE CAPACITY OF 10000 OR MORE.
14. LASER PRINTER AND COMPUTER SHOULD BE SUPPLIED WITH THE INSTRUMENT.
15. THE URINE STRIP MUST HAVE US FDA APPROVED & CERTIFICATE SHOULD BE ATTACHED.
16. POWER SUPPLY- MUST BE OPERATABLE WITH 220-240 V.


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Automated IHC Slide Stainer		
1	System Capability	Process FFPE and Frozen Sections; Process IHC, SS and ISH
2	System Throughput	Process upto 60 Slides in a Single Run and 200 Slides in a Eight Hour Shift
3	System Software	Diagnostic Software on Windows XP Platform
4	Application Support	System Supports Routine Diagnostic IHC Application.
5	Slide Processing Options	Continuous and STAT Access; STAT for Priority Slide Processing, while Continuous to allow addition of new slides during the run
6	Real Time Slide Map	Display Current Step and remaining Incubation time for each slide
7	Audio and Visual Alerts	Run completion/ system error alerts; custom color selection- visual prompts
8	Reagent dispense capacity	From 100 micro litre to 900 ul.
9	Slide Capacity	Should have 5 independent horizontal platforms with 12 slides per platform
10	Reagents Capacity	60 Reagent Vials in two racks of 30 vials each
11	Run Parameters Control	Reagent Volume, incubation time and washing and blowing steps
12	Reagents Racks	Removable reagent racks offer ease of loading and storage of vials. Reagent tracking should be possible with RFID tracking on the reagent vials.
13	Disposable Pipette Tips	Eliminates On-board reagent cross contamination
14	High Precision Robotic Arm	Precise and accurate staining operations and includes Barcode Scanner, Pipettor, Wash Reagent Dispenser and Slide Blower with instrument head following non contamination path
15	Reagent dead volume	Reagent dead volume in the system should be less than 600 ul
16	User Convenience	Real time slide map indicates dispensing pattern and displays the current step and remaining incubation time for each slide; delayed overnight run to receive the ready slides next day morning. Instrument has built in compressor and air blower.
17	Slide Processing Options	Random access to allow placement of slide anywhere; Continuous access for adding new slides to an on-going run and STAT access to add and prioritize slides; batching of the slides to allow quick STAT in continuous mode
18	User Friendly Software	Color Coded GUI; Easy to learn and operate and protocol customization and flexibility to edit and save protocols; edit individual slide function and audio and visual alerts.
19	Reporting Capabilities	Support multiple reports with details like case #, physician name, specimen type and reagents usage; regulatory compliance with run parameters, test protocols and reagent lot information
20	Reagents and Consumable	Bar coded reagent vials for IHC Primary antibodies, IHC detection systems and Ancillary reagents and Consumables include barrier slides, empty Bar Coded reagent vials and pipette tips. Reagent dispensing with disposable pipettes only.
21	Reagent Container capacity	Reagent container capacity should be 10ml / 20 ml
22	Certifications	Should be CE and TUV approved


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Specifications for Bone Decalcifier.

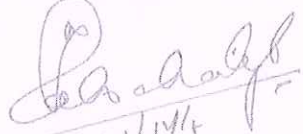
- Capacity Up to 30 cassettes
- Dimensions
 - W x D x H Bench System 30 x 21 x 11 cm
 - Solution Reservoir 16 x 12.5 x 6 cm
- Weight 3 kg
- Solution Volume Up to 750 mL
- Bone Section can be processed in just 15 minutes.

Slide Drying Hot Plate

Variable temperature control up to 70°C. Non-reflecting aluminium matt black surface and coated housing. The Hot Plate control panel consists of a main power switch, push buttons for adjusting the settings and a Liquid Crystal Display (LCD). The Hot Plate comes with a Overheating Protection set at 90°C. Temperature > 60°C, Voltage 230 V or 115 V, Power 75 VA, Material Aluminium, Inside & dry edges Matt black.

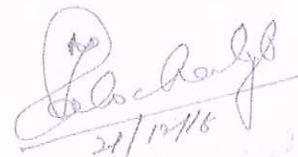
Water Bath Square

Variable temperature control up to 80°C. Inside surface and dry edges are aluminium lacquered matt black. The Water Bath control panel consists of a main power switch, a light switch, a pilot lamp when heating occurs and buttons for adjusting and setting the temperature with an overheat protection at 90°C. The temperature and settings are on display on the LCD. Dimensions inside 250 x 250 mm Dimensions outside 320 x 440 mm Height 50 - 70 mm Water volume max 2.5 L. Water depth 40 mm, Temperature 30 - 80°C, Voltage 230 V or 115 V, Material Aluminium

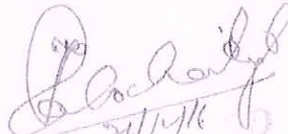

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Specification of Coagulation Analyser

1. It should have fully automated Random access, Floor model coagulation analyser.
2. The throughput of analyser should be 300 or more per Hr.
3. It must be able to perform clotting assay PT, APTT, Fbg, Chromomeric assay AT,PLG, Heprin and latex Turbidimetry assay i.e FDP,D Dimer,etc.
4. Measuring wavelength must be between 405- 730 nm.
5. Minimum 50 sample should be placed at a time
6. Minimum test parameter for each sample can be analysed.
7. It must have separate and large (15" monitor) computer control unit. Easy operation by touch panel is preferable, with latest window software XP/ window 7 for easy operation.
8. Barcode reader must be there to read the sample and reagents information.
9. It should store the reagent inventory details, i.e reagent exchange info, etc.
10. Reaction profile can be displayed and printed to analyse any data error.
11. It should have automated calibration switching function.
12. Preference will be given for "OPEN REAGENTS" analyser, which will eliminate our dependability due to late/ non supply of reagents.


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Sr.No	Specification for Fully Automated IHC/ISH staining system
1	System should be complete automation for Baking-DeWaxing-Antigen Retrieval-Staining-Counterstaining-Dehydration & Clearing-Permanent Mounting-Coverslip-all in one system
2	It should have application modes for IHC, ISH, SS
3	System should allow random access with STAT facility
4	System should be preferably a floor model with top loading of slides
5	It should have individual slide stations
6	It should accommodate minimum 40 slides
7	Upgradation to perform FISH should be possible
8	It should perform tests from baking to final cover slipping with 40 slides in 8 hours shift.
9	It should have Reagent vials minimum 30 for FISH and 49 for IHC with volume capacity not more than 17ml
10	Reagent tracking should be possible with RFID tagging on the reagent Vials
11	Slides should posses Barcoded lable for ID and protocol information
12	Reagents dispense volume should start from 80 µl to 200 µl.
13	Reagent Dispensing should be through Disposable pipette tips only
14	System should have 7 Bulk Reagent Carboys with capacity of 4L
15	Slide Processing temperature should allow temperature from 25°C to 105°C
16	Instrument should have built in compressor and air blower
17	There should be individual slide temperature control with active heating cooling < 2 mins
18	System should have built in Cover-slipping mechanism of sizes 25x40 mm, 25x25 mm and 18x18 mm which should allow Coverslip placing and removing from individual slides
19	Instrument should have oil sealing mechanism
20	System should have minimum 2 waste management carboys inside the instrument.
21	Precise and accurate staining with instrument head following non contamination path
22	System should support to run Multiple protocols simultaneously
23	System should allow Operating Temperature 15-30°C and Humidity 15%-55% RH
24	It should have 4 removable slide carriers with 10 slides per carrier.
25	It should have Disposable pipette tips quantity of 96X2 for dispensing Microreagents & Reagents
26	It should have 2 cover slip box
27	Staining operation should have the facility of simultaneous ruuning of multiple protocols with multiple parameters in single run


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Sledge Microtome

With universal cassette clamp with knife holder SN for reusable knives or blade rails Stable instrument construction. Totally enclosed micrometer feeding systems prevents debris from entering the roller bearings. Ergonomically positioned object head. Smooth running sledge, lockable in 11 positions by using easily accessible sledge brake. Individually adjustable Ergogrip, selection of 3 ergonomically designed grips. Precise 8° XY specimen orientation with defined zero position and click stops every turn. Section thickness selection between 0 and 60 µm. Manual feed by either pushing or pulling the coarse feed lever. Clockwise or counter clockwise operation of smooth running coarse feed wheel, depending on personal preference. Automatic feeding up to 30 µm. Adjustable cutting window avoids unnecessary long sledge movements and speeds up the sectioning process. Quick release system for specimen clamps. Large volume antistatic waste tray with collection container. Universal cassette clamp with adapter to be used with quick release system for specimen clamps. Knife holder SN for reusable knives or disposable blade rails. Knife holder declination with indicator for reproducible setting up to 45°C. Two clamping screws for fast and stable cutting tool clamping. Safe and precise lateral displacement function allows use of entire cutting tool. Integrated, space saving safety guard in signal color.

Technical specifications:

Section thickness adjustable between 0.5 and 60 µm

Section thickness selection:

- 0.5 to 5 µm in 0.5 µm steps
 - 5 to 10 µm in 1 µm steps
 - 10 to 20 µm in 2 µm steps
 - 20 to 60 µm in 5 µm steps
- Automatic advance between 0 and 30 µm Total specimen feed range: 50 mm / 1.96 inches Clearance angle adjustment: -3° to 10° Specimen orientation in cutting direction: +/- 8° Specimen orientation opposite of cutting direction: +/- 8° Declination: 0° to 45° in sectioning direction

Technical Data:

Width (incl. coarse feed wheel and Ergogrip): 390 mm

Width (base plate): 256 mm

Depth: 430 mm

Height (total/with blade holder): 343 mm

Working height (knife edge/measured from the table): 255 mm

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Specification for Random Access Chemiluminescence System for Immunoassay
FULLY AUTOMATED ENHANCED CHEMILUMINESCENCE with Chemiflex Technology

Must have clot & bubble detection both for Samples & reagents

Throughput

Minimum throughput of more than 200 Tests/hr

Assay Technology

Should be Direct Enhanced Chemiluminescence with chemiflex Technology.

Quality Control LJ plots & Westgard rules

Assay Specifications:-

Must have HIV Ag/Ab combo kit...should detect upto 18pg/MI

Should detect all subtypes of HIV such as M(A-K), N & O
HBsAg with Mutant Detection

STAT/ Time

STAT within 15 mins

Assay time less than 30 minutes

Calibration stability

Should be Lot to Lot

The samples & reagents should have continuous access through
Robotic sample handler

Should have PC based data management with
bi directional connection with host computer,
storage of events & patient data for atleast 3
months,for atleast 3 months std & control files
storage & process control mechanism to
monitor all functions of machine

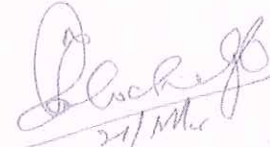

Reagent

Barcode identification of reagent & Calibrators
preferred. Flash alarm should be automatically
displayed in cases of expired; low volume or
contaminated reagents. Instrument should
monitor vol.verifications during operation fo each
test& provide the user with all the activities of
the sample.

Carry over

Should be less than 0.01 ppm & must have separate probe for samples
& Reagents.

Should prioritise Urgent Requests with the help of Robotic sample handler

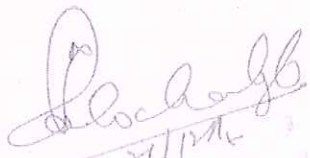

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Specifications for Capillary Electrophoresis System

- Fully automated bench-top analyzer, complete walk away system with no manual intervention platform intended for serum electrophoresis and Immuno displacement/ Immuno typing, urine electrophoresis and Immuno displacement/ Immuno typing.
- At least 8 silica capillary based system for electrophoresis in liquid flow, which should be loaded in Peltier temperature controlled capillary chamber
- Diameter of capillary should not be less than 40µm to avoid any clog during sample run – to increase efficiency of system and avoid loss of reagents.
- Throughput : Atleast 70 samples /hour for proteins
- System should be able to process minimum 32 samples/hour for Haemoglobin electrophoresis.
- System should have onboard quality control with option of Levy Jennings and statistical reports.
- System should have minimum six on-board buffer system containers, up to four open user- defined assay buffer positions to run different test- parameters simultaneously for ease of functioning and time saving in daily operation.
- System should have bar coded buffer and reagent containers with dynamic buffer level monitoring to have better visibility of reagent status in the system during functioning.
- System should position for antisera, e.g. Anti -IgG, IgA, IgM, Kappa, Lambda for optimized utilization of antisera and cost saving in reagent consumption.
- System should have minimum 8 temperature controlled reagent position for on board assay flexibility for addition anti sera like IgD and IgE
- System should have automatic reflex testing option based on the user defined criteria with no manual intervention.
- System should have option for Agarose gel integration facility to have wider options for analysis of critical samples in single go. No need of processing samples separately for confirmation.
- System should work at 230V±10% and input frequency 50-60HZ
- System should have audible and different color light indication for system status (error messages, running status and maintenance status)

Test menu Available

- Serum Protein,
- Urine Protein,
- Immunodisplacement (IgG, IgA, IgM, Kappa, Lambda)
- Serum Protein High Resolution
- Carbohydrate Deficient Transferrin (CDT)
- Haemoglobin IEF


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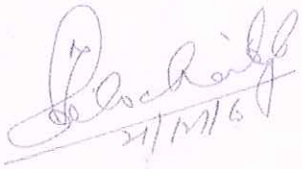
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Optics

- Deuterium lamp
- Gradient system
- Optical fibres for emission and reception
- UV lenses
- C-MOS diode detector system

Programs and software

- Detection of abnormal values (flagging)
- Statistics: 3QC levels per analysis program (Levey- Jennings)
- Compressed print-outs results and curves
- Storage capacity of at least 5,00,000 patients database
- System should be compatible for integration into the Laboratory Information System (LIS) with bi-directional compatibility
- Both pre-programmed and manual entry of comments
- Selection of pre-programmed identification table for fraction identification
- Overlay of reference pattern, control or patient curve
- Data display: Equipment should be compatible with printer and provide output via built-in digital display.
- Remote maintenance & software upgradation facility should be available with system.
- Instrument should be equipped supplied along with online UPS with a power backup of atleast 30 minutes
- Standards and certification: System and reagent should be CE/IVD (for Invitro diagnostic) certified.
- Quotations should include all necessary accessories to run the equipment.
- Installation of the equipment and all the necessary accessories such as UPS(back up of half an hour), desktop PC, LaserPrinter (black and white) compatible with the existing power supply and back up should be included.
- The rates of consumables shall be frozen for one year from the date of supply order.
- Any specific necessary pre installation conditions required should be mentioned and budget to incorporate the same should be included in the quote.
- Supplier shall provide onsite comprehensive training to the lab staff & support services till the familiarity and confidence in using the system, free of cost
- Installation : free of cost
- Quotation should include 5 year warranty from the date of installation with all the spares.
- CMC: For five years after expiry of warranty period as per policy of the institution


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Specifications for LBC


1. Automated system for processing of Gyn and non- gyn cytology samples for liquid based cytology.
2. Ability to make single slides from a single cytology sample which is uniform and reproducible.
3. Approved for use with either broom type or end cervical brush/spatula collection device.
4. Simplifies borderline smear management with HPV testing.
5. Pap Test should approved for use with the digene hybrid capture 2 assay for HPV DNA Testing.
6. Technology should be demonstrated as significantly more effective than the conventional Pap Smear.
7. System should allow residual material to be used for ancillary testing such as HPV, CT/NG, Immunocytochemistry, Special Stains, etc..
8. FDA approved system.
9. Improved detection of endocervical and endometrial adenocarcinoma.,
10. Controlled Membrane transfer Technology, automated provides consistent sample to slide preparation.
11. Cells limited to smaller 20mm diameter.
12. 1 KVA UPS along with machine.

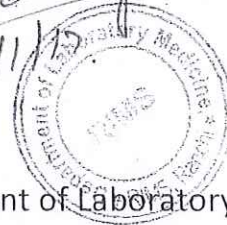

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Department of Pathology
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Specification for Auto analyzer is attached with this letter.

Thanking You,

Your faithfully,


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Department of Laboratory Medicine,

RIMS Ranchi

SPECIFICATION FOR AUTO ANALYZER

1. MUST BE A FLOOR MODEL, OPEN REAGENTS SYSTEM, DISCRETE, PATIENT ORIENTED SYSTEM FOR BIOCHEMICAL INVESTIGATION ENZYMES SUBSTRATES ELECTROLYTES, IMMUNOTURBIDIMETRIC TEST, TDM'S & DAU'S.
2. MUST HAVE A MINIMUM THROUGHPUT OF AT LEAST 800 PHOTOMETRIC TEST PER HOUR, USING UP TO TWO STEP REAGENTS & 1200 TEST/HR WITH ISE.
3. ANY ORDINARY COMPUTER, (COMMERCIALY AVAILBLE IN THE LOCAL MARKET) CONFIRMING TO THE ABOVE SPECIFICATION SHOULD BE CAPABLE OF WORKING AS A CONTROL UNIT: SO AS TO AVOID DEPENDENCE ON SPARES/CONSUMABLES OF PROPRIETARY NATURE & OF IMPORTED ORIGIN.
4. MORE THAN 86 TEST PROGRAMMES IN MEMORY.
5. TYPE OF ASSAYS POSSIBLE COLORIMETRIC, TURBIDITY, LATEX AGGLUTINATION, HOMOGENIOUS IMMUNOASSAYS, ISE.
6. SHOULD PERMIT ON BOARD PLACEMENT OF 45 OR MORE REAGENTS/TEST AT ONE TIME. ALL THE REAGENT POSITION SHOULD BE REFRIGERATED.
7. PHOTOMETRIC RANGE 0-3.0 OD.
8. MINIMUM REACTION VOLUME NOT MORE THAN 120UL.
9. SAMPLE POSITION MUST BE 140 OR MORE WITH CONTINUOUS LOADING FACILITY.
10. PHOTOMETRIC SYSTEM WITH AT LEAST 12 WAVELENGTHS FROM 340-800nm.
11. MINIMUM SAMPLE VOLUME SHOULD BE 1.6UL.
12. SYSTEM SHOULD HAVE REMOTE MAINTENANCE (OPTIONAL) AND DATA MANAGEMENT CAPACITY THROUGH MODEM CONNECTION.
13. THE SYSTEM SHOULD HAVE AUTOMATIC DIGITAL LIQUID LEVEL DETECTION CLOT DETECTION AND COLLISION PROTECTION.

14. THE SYSTEM SHOULD HAVE 3 STAND – ALONE PROBES, ONE FOR SAMPLE, TWO PROBES FOR REAGENT;THE PROBES AREPOLISHED WITH NANO PROCESSING TECHNOLOGY, WHICH REDUCE CROSS –CONTAMINATION EFFECTIVELY.

15.THE SYSTEM SHOULD HAVE DEGASSING TECHNOLOGY : THE ANALYSER HAS SPECIAL DEGASSING DEVICE TO REMOVE THE AIR DISSOLVED IN THE TUBE SYSTEM, WHICH ENSURE QUICK, ACCURATE AND SMALL VOLUME PIPETING.

16. SYSTEM SHOULD BE SUPLLED WITH ONLINE UPS & DEIONISER.

17. SYTEM SHOULD BE SUPPLIED WITH VEIN IMAGING DEVICE (2 UNITS) BASED ON NEAR INFRA RED (NIR) TECHNOLOGY.

18. THE VEIN IMAGING DEVICE SHOULD HAVE THE ABILITY TO VISUALIZE VESSELS UPTO 10 mm DEEP.

19. BIDDER SHOULD PROVIDE MANPOWER (MINIMUM 2 PERSON) FOR MINIMUM PERIOD OF THREE YEAR FROM THE DATE OF INSTALLATION FOR OPERATIONAL & RUOTINE MAINTENANCE OF THE INSTRUMENT.

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