Republic of the Philippines

Department of Health

REGION II TRAUMA AND MEDICAL CENTER

EVALUATION CRITERIA FOR EQUIPMENT AND REAGENTS IN THE CLINICAL LABORATORY

ANNEX A:

Name of Equipment: _____ Laboratory Section: _____

Company: _____ Start of Evaluation: _____

CRITERIA	RESULTS AND EVALUATION
Method/Principle of the test/throughput	
Accuracy of result (parallel testing or manual method if available)	
Frequency of Auto-shutdown/sleep	
Frequency of error flags	
NEQAS Results (Certificate of Evaluation from NRL)	
Sipping Volume if applicable	
Frequency of Preventive Maintenance (Monthly)	Conforme: _____
Availability of Technical person/Engineer to respond to calls anytime in case of emergency	Conforme: _____
Troubleshooting within 24-48 hours upon notice/call	Conforme: _____
Track record of the company in the timely and complete delivery of supplies/reagents including control, calibrators and consumables	C/O (Supplies and Materials office) No more than 25% late deliveries from previous awards.
User- friendliness of the machine. At least 75% total votes from end-users	
Ability to show quantitative and retrievable graphical QC. Provide sample print-out	
Reagent wastage during preventive maintenance, errors and trouble-shooting (to include dead volume) to be replaced.	Conforme:_____
Provision of all cleaning materials needed during preventive maintenance	Conforme:_____
Strict installation of interfaced computer and to provide consumables for the printer (barcode sticker, thermal paper) and ink/toner.	Conforme: _____
If winning bidder, Current model of machine shall be installed and at least 2 years in service will be installed and a back-up machine of not more than three (3) years of service	Conforme:_____
Agrees to pull-out machine within two (2) weeks after three (3) failed troubleshooting	Conforme: _____

Recommendations: _____

_____

Evaluated by: _____ Date: _____

Noted by: _____

Conforme: _____

Name of Company (in print)

_____

Name and Signature of Company Authorized Representative

_____

Date

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ANNEX-B	**AUTOMATED BLOOD COUNT TESTS**, Five (5) parts	
PURCHASER'S SPECIFICATIONS		SUPPLIER'S SPECIFICATIONS

A. ANALYTICAL OPERATION:
   1. Specimen: WB (whole blood) and other body fluids
   2. Mode: WB, Pre-dilution, and other body fluids or equivalent mode
   3. Employs flow cytometry principle (Capable of testing for volume, Nucleus/cytoplasm ratio via conductivity and granulocyte via light scatter)
   4. Other tests required: NRBC (Nucleated Red Blood Cell) count, Reticulocyte count and Immature Granulocytes
   5. Test Panels Available:
      a. Complete Blood Count (CBC): Hgb, HCT, WBC, diff Count (NE, LY, MO, EO, BA) APC, RBC, MCV, MCH, MCHC, RDW, MDW
      b. Complete Blood Count (CBC) and NRBC: Hgb, HCT, WBC, diff Count (NE, LY, MO, EO, BA) APC, RBC, MCV, MCH, MCHC, RDW, MDW, NRBC
      c. Complete Blood Count (CBC), NRBC and Reticulocyte Count: Hgb, HCT, WBC, diff Count (NE, LY, MO, EO, BA) APC, RBC, MCV, MCH, MCHC, RDW, MDW, NRBC, Reticulocyte Count
      d. Reticulocyte count only: Number in percent
      e. Body fluid count (CSF, Serous, Synovial): Total cell count, Total WBC count, Total RBC count, Diff. count in percent.

B. TIE-UP ANALYZER:
   1. Main Laboratory: Two (2) Current model and not more than two (2) years in service, with one (1) Interfaced work station computers with colored printer. To provide ink/toner for the whole duration of contract.
   2. OPD Laboratory: Two (2) Current model and not more than three (3) years in service. with two (2) Interfaced work station computer with colored printer. To provide ink/toner for the whole duration of contract.
   3. Provision of appropriate equipment table for the analyzer, work station computer unit and printer for the reports (to consult the end user for the fabrication of table)
   4. Provision of at least five (5) test-tube rack/ tray per analyzer for auto-loading of specimen
   5. Capable of barcoded entry of specimen by provision of two (2) barcode printers/scanners and supply of barcode stickers for the whole duration of contract.
   6. Counts comparable to manual methodology or parallel testing from other installed analyzers
   7. With on-board reagents and consumables inventory
   8. Stores results at least for 1 year
   9. Analyzers and work station computers should be interfaced together via middle wares for data management, delta checking and remote printing. LIS connectivity once available will be at no cost to the Procuring entity.
   10. Analyzer distributed and patented in G7 group of countries (Canada, France, Germany, Italy, Japan, the UK and the US)
   11. Power requirement:
      a. Provision of UPS (Uninterrupted Power Supply) with built-in AVR (Automatic voltage regulator) with a capacity of more than fifty percent (50%) compared to the normal consumption capacity of the machine.
      b. Machine and UPS must be compatible to the institution's power generator.
      c. All power cords should be three (3) prong.
   12. Availability of operation and troubleshooting manual
   13. Machine accessories that are not included in the bidding must be provided by the winning bidder.

14. Analyzer should be replaced after three (3) failed troubleshooting within three (3) working days

C. PREVENTIVE MAINTENANCE:
   1. Monthly preventive maintenance by trained personnel (to bring cleaning kits)
   2. Calibration should be done twice a year, new lot of reagent and after replacement of worn parts.

D. TROUBLESHOOTING:
   1. Provision of contact number/s for technical assistance available at all times
   2. Malfunction of machines shall be addressed immediately once informed within 24 to 48 hours (For strict compliance)

E. REAGENTS:
   1. To provide complete set of reagents with controls (compatible to the material used by EQAS provider) for daily QC assay, and consumables necessary to complete the test.
      a. Diluent
      b. Wash/rinse
      c. Lyse solution
      d. Diff Pack
      e. Control (High, Normal, Low) for daily use
      f. Cleaning solutions and other supplementary materials for daily preventive maintenance by end users.
   2. Strict compliance of the ten (10) days delivery period upon the receipt of Purchase Order (PO) following ordering agreement.
   3. Indicate the total number of items to be delivered in the Bid Proposals as to number of pcs, volume, bottles and set of reagents and consumables in compliance to the number of tests requested.
   4. To provide complete set of reagents for on-site demonstration
   5. All wasted reagents due to equipment malfunction must be replaced after documentation of both parties
   6. Near expiry reagents/consumables must be replaced three months before expiration with full coordination with the end user's consumption

F. REPORTING OF RESULTS:
   1. Counts from all the provided analyzers must automatically reflected in the interfaced computer unit/s and can be edited before printing the final report.
   2. Parameters Required:
      a. Hemoglobin
      b. Hematocrit
      c. WBC count
      d. Differential Count
      e. Absolute platelet count
      f. Blood Indices (MCV, MCH, MCHC, RDW)
      g. NRBC
      h. Reticulocytes count
      i. Mean distribution width
   3. Report format will follow the required ISO Hematology form
   4. Must provide colored printer with ink/toner available for the whole duration of contract

G. TRAINING:
   1. Availability of a Product Specialist to train at all Medical Technologist involved in the operation, troubleshooting and preventive maintenance of the analyzer.
   2. Product Specialist must have a certificate of Trainers training from the Manufacturer of the Machine
   3. To provide Certificate of Training duly signed by the Manufacturer representative and Product Specialist of the Company.

H. DEMONSTRATION FOR EVALUATION:

1. Demo unit and reagents for evaluation should pass the BAC for proper documentation 2. At least ten (10) days for evaluation purposes or until all demo reagents are consumed for the determination of the total number of tests per set. 3. On-site demonstration of the actual unit and reagents during the evaluation period shall be approved by the BAC (Bids and Awards Committee) 4. Actual report can be generated from the computer interfaced with the analyzer. **5.** Conforms with the **Evaluation Criteria for Machines and Reagents in the Clinical Laboratory. Annex A.** I. <u>DOCUMENTARY REQUIREMENTS:</u> 1. Certificate of Good Performance from the End-User (Previous winning bidder) or from other Level 3 Hospitals (First time Bidders) 2. Certificate of Product Registration issued by Philippine FDA-provide a copy during the first delivery together with compiled MSDS (Material Safety and Data Sheet) 3. Certificate of ISO compliance of the manufacturer 4. Certificate for the availability of supply and parts of the analyzer from the manufacturer within award period 5. Certificate of Distributor/Dealership agreement from the manufacturer 6. National External Quality Assurance Certificate from other Level III hospitals.	

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Annex C	**AUTOMATED BLOOD COUNT TESTS**, Three (3) parts	
PURCHASER'S SPECIFICATIONS		SUPPLIER'S SPECIFICATIONS

A. ANALYTICAL OPERATION:
   1. Specimen: WB (whole blood) and pre-diluted sample
   2. Mode: WB (whole blood) and pre-diluted sample mode
   3. Employs flow cytometry principle (Capable of testing for volume, Nucleus/cytoplasm ratio via conductivity and granulocyte via light scatter)

B. TIE-UP ANALYZER:
   1. Main Laboratory: two (2) Current model, one (1) for the Hematology section and one (1) for the blood bank donor screening. The machines should not be more than two (2) years in service.
   2. Provision of equipment table for the analyzer, computer unit and printer for the reports (to consult the end user for the fabrication of table).
   3. Counts comparable to manual methodology or parallel testing.
   4. With on-board reagents and consumables inventory
   5. Stores results at least for 1 year
   6. Interfaced together with all the hematology analyzers to a dedicated work station computer
   7. Analyzers should be LIS ready equipped with middle ware and to be connected to the Laboratory Information System at no cost to the procuring entity.
   8. Barcode reader for reagent and specimen entry
   9. Analyzer distributed and patented in G7 group of countries (Canada, France, Germany, Italy, Japan, the UK and the US)
   10. Power requirement:
      a. Provision of UPS (Uninterrupted Power Supply) with built-in AVR (Automatic voltage regulator) with a capacity of more than fifty percent (50%) compared to the normal consumption capacity of the machine.
      b. Machine and UPS must be compatible to the institution's power generator.
      c. All power cords should be three (3) prong.
   11. Availability of operation and troubleshooting manual
   12. Machine accessories that are not included in the bidding must be provided by the winning bidder.
   13. Analyzer should be replaced after three (3) failed troubleshooting within three (3) working days

C. PREVENTIVE MAINTENANCE:
   1. Monthly preventive maintenance by trained personnel (to bring cleaning kits)
   2. Calibration should be done twice a year, new lot of reagent and after replacement of worn parts.

D. TROUBLESHOOTING:
   1. Provision of contact number/s for technical assistance available at all times
   2. Malfunction of machines shall be addressed immediately once informed within 24 to 48 hours (For strict compliance)

E. REAGENTS:
   1. To provide complete set of reagents with control (compatible to the material used by EQAS provider) for daily QC assay, and consumables necessary to complete the test.
      a. Diluent
      b. Wash/rinse
      c. Lyse solution
      d. Diff Pack
      e. Control (High, Normal, Low) for daily use

f. Cleaning solutions and other supplementary materials for daily preventive maintenance by end users.

2. Strict compliance of the ten (10) days delivery period upon the receipt of Purchase Order (PO) following ordering agreement.
3. Indicate the total number of items to be delivered in the Bid Proposals as to number of pcs, volume, bottles and set of reagents and consumables in compliance to the number of tests requested.
4. To provide complete set of reagents for on-site demonstration
5. All wasted reagents due to equipment malfunction must be replaced

F. REPORTING OF RESULTS:

1. Counts from all the provided analyzers must automatically reflected in the interfaced computer unit/s and can be edited before printing the final report.
2. Parameters Required:
   a. Hemoglobin
   b. Hematocrit
   c. WBC count
   d. Differential Count (NE, LY and Mix cells)
   e. Absolute platelet count
   f. Blood Indices (MCV, MCH, MCHC, RDW)
   g. Mean distribution width
3. Report format will follow the required ISO Hematology form
4. Must provide colored printer with ink/toner available for the whole duration of contract

G. TRAINING:

1. Availability of a Product Specialist to train at all Medical Technologist involved in the operation, troubleshooting and preventive maintenance of the analyzer.
2. Product Specialist must have a certificate of Trainers training from the Manufacturer of the Machine
3. To provide Certificate of Training duly signed by the Manufacturer representative and Product Specialist of the Company.

H. DEMONSTRATION FOR EVALUATION:

1. Demo unit and reagents for evaluation should pass the BAC for proper documentation
2. At least ten (10) days for evaluation purposes
3. On-site demonstration of the actual unit and reagents during the evaluation period shall be approved by the BAC (Bids and Awards Committee)
4. Actual report can be generated from the computer interfaced with the analyzer.
5. Conforms with the **Evaluation Criteria for Machines and Reagents in the Clinical Laboratory. Annex A.**

I. DOCUMENTARY REQUIREMENTS:

1. Certificate of Good Performance from the End-User (Previous winning bidder) or from other Level 3 Hospitals (First time Bidders)
2. Certificate of Product Registration issued by Philippine FDA-provide copy of the CPR and Compiled copy of the MSDS (Material Safety and Data Sheet) during the first delivery.
3. Certificate of ISO compliance of the manufacturer
4. Certificate for the availability of supply and parts of the analyzer from the manufacturer within award period
5. Certificate of Distributor/Dealership agreement from the manufacturer
6. National External Quality Assurance Certificate from other Level III hospitals.

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TECHNICAL SPECIFICATIONS

ANNEX D	COAGULATION TEST, fully automated	
PURCHASER'S SPECIFICATIONS		SUPPLIER'S SPECIFICATIONS

A. ANALYTICAL OPERATION:
   1. Specimen: Plasma derived from 3.2% citrated tube
   2. Automation of manual coagulation procedure.

B. TIE-UP ANALYZER:
   1. Fully automated analyzer
   2. Main Laboratory: One (1) Current model of tie-up analyzer and not more than two years in service.
   3. Provision of equipment table for the analyzer, computer unit and printer for the reports (to consult the end user for the fabrication of table).
   4. Provision of test-tube rack/ tray for auto-loading of specimen as appropriate.
   5. Interfaced with a Work station computer via middle ware for delta checking and printing. Connected to the LIS at no cost to the Procuring entity.
   6. Analyzer distributed and patented in G7 group of countries (Canada, France, Germany, Italy, Japan, the UK and the US)
   7. Power requirement:
      a. Provision of UPS (Uninterrupted Power Supply) with built-in AVR (Automatic voltage regulator) with a capacity of more than fifty percent (50%) compared to the normal consumption capacity of the machine.
      b. Machine and UPS must be compatible to the institution's power generator.
      c. All power cords should be three (3) prong.
   8. Availability of operation and troubleshooting manual
   9. Machine accessories and consumables that are not included in the bidding must be provided by the winning bidder.
   10. Analyzer should be replaced after three (3) failed troubleshooting within three (3) working days

C. PREVENTIVE MAINTENANCE:
   1. Monthly preventive maintenance by trained personnel (to bring cleaning kits)
   2. Calibration should be done twice a year, new lot of reagent and after replacement of worn parts.

D. TROUBLESHOOTING:
   1. Provision of contact number/s for technical assistance available at all times
   2. Malfunction of machines shall be addressed immediately once informed within 24 to 48 hours (For strict compliance)

E. REAGENTS:
   1. To provide complete set of reagents with control (compatible to the material used by EQAS provider) for daily QC assay, and consumables necessary to complete the test.
      a. Prothrombin reagent
      b. Activated Partial Thromboplastin Time
      c. D-dimer
      d. Wash solutions
      e. Reaction vessels
      f. Control material appropriate to type and number of tests requested for use on a daily basis.
      g. Cleaning solutions and other supplementary materials for daily preventive maintenance by end users.
   2. Strict compliance of the ten (10) days delivery period upon the receipt of Purchase Order (PO) following ordering agreement.

3. Indicate the total number of items to be delivered in the Bid Proposals as to number of pcs, volume, bottles and set of reagents and consumables in compliance to the number of tests requested.
4. To provide complete set of reagents for on-site demonstration
5. All wasted reagents due to equipment malfunction must be replaced

F. REPORTING OF RESULTS:
1. Result from the analyzers must automatically reflected in the interfaced computer unit/s and can be edited before printing the final report.
2. Parameters Required:
   a. Result in number of seconds
   b. Activity in percent
   c. INR
   d. D-dimer
3. Report format will follow the required ISO Hematology form
4. Must provide colored printer with ink/toner available for the whole duration of contract

G. TRAINING:
1. Availability of a Product Specialist to train at all Medical Technologist involved in the operation, troubleshooting and preventive maintenance of the analyzer.
2. Product Specialist must have a certificate of Trainers training from the Manufacturer of the Machine
3. To provide Certificate of Training duly signed by the Manufacturer representative and Product Specialist of the Company.

H. DEMONSTRATION FOR EVALUATION:
1. Demo unit and reagents for evaluation should pass the BAC for proper documentation
2. At least ten (10) days for evaluation purposes
3. On-site demonstration of the actual unit and reagents during the evaluation period shall be approved by the BAC (Bids and Awards Committee)
4. Actual report can be generated from the computer interfaced with the analyzer.
5. Conforms with the **Evaluation Criteria for Machines and Reagents in the Clinical Laboratory.**

I. DOCUMENTARY REQUIREMENTS:
1. Certificate of Good Performance from the End-User (Previous winning bidder) or from other Level 3 Hospitals (First time Bidders)
2. Certificate of Product Registration issued by Philippine FDA-provide a copy during the first delivery together with compiled MSDS (Material Safety and Data Sheet)
3. Certificate of ISO compliance of the manufacturer
4. Certificate for the availability of supply and parts of the analyzer from the manufacturer within award period
5. Certificate of Distributor/Dealership agreement from the manufacturer
6. National External Quality Assurance Certificate from other Level III hospitals.

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Annex E	**IMMUNOHAEMATOLOGY TEST,** Column agglutination	
PURCHASER'S SPECIFICATIONS		SUPPLIER'S SPECIFICATIONS

A. ANALYTICAL OPERATION:
   1. Specimen:
      a. Serum
      b. Plasma derived from all types of anti-coagulants using test tubes and microtainers (to provide if purchased microtainers are compatible.
      c. Red Blood Cells
   2. PRINCIPLE: Column Agglutination Technology
   3. INTENDED USE:
      a. Forward Blood Typing with Rh (D)
      b. Reverse Blood Typing
      c. Direct Antiglobulin tests (DAT)
      d. Single (pooled cells) Panel Antibody Screening (Reagent cells compatible to Asian population)
      e. Three (Type I, II, III) Panel Antibody Screening (Reagent cell compatible to Asian population)
      f. Donor and Patient Compatibility Testing

B. TIE-UP ANALYZER:
   1. Main Analyzer: One (1) Current model of fully automated analyzer with less two (2) years in service, to provide equipment table as appropriate.
   2. Back-up Analyzer: One (1) set current model of semi-automated equipment (incubator and centrifuge with AVR) and complete set of Pipettes, Diluent dispenser and Tube racks.
   3. Real time release of report based on random access loading specially for stat request handling.
   4. Reaction cards can be retrieved from the analyzer for manual viewing of agglutination.
   5. On board inventory and stability monitoring of reagents and consumables.
   6. Analyzer distributed and patented in the G7 group of countries
   7. Barcoded entry for reagents and specimens. To provide barcode printer an stickers for the whole duration of the contract.
   8. Work list can be generated manually or by LIS.
   9. Machine should be connected to the Laboratory Information System of the Department once available without any expense.
   10. Analyzer interfaced computer with middle ware connection to LIS and NBB nets.
   11. Minimal sample needed for testing: Blood tubing sample volume (300 ul)
   12. Stores results at least for one (1) year
   13. Power requirement:
      a. Provision of UPS (Uninterrupted Power Supply Unit)
      b. Provision of AVR (Automatic Voltage Regulator) to compensate current fluctuations
      c. Compatible to the institution's power generator
      d. All power cords should be three (3) prongs
   14. Availability of operation manual and troubleshooting
   15. Machine accessories that are not included in the APP must be provided by the winning bidder in the performance of examinations.
   16. Analyzer should be replaced after three (3) failed troubleshooting within two (2) weeks

C. PREVENTIVE MAINTENANCE/CALIBRATION
   1. Quarterly or as the need arises preventive maintenance schedule by trained personnel (to bring cleaning kits)
   2. On-site calibration and validation with certification of conformity or equivalent.

D. TROUBLESHOOTING:
   1. Provision of contact number/s for technical assistance available at all times
   2. Malfunction of machines shall be addressed immediately once informed within 24 to 48 hours

E. REAGENTS:
   1. Column Agglutination medium containing materials that restricts passage of agglutinated cells after centrifugation
   2. Reagent cells
   3. Diluents and liquid reagents
   4. Applicable Antigens and Antibodies
   5. Strict compliance of the ten (10) days deliver period
   6. Indicate the total number of items to be delivered in the Bid Proposals as to number of pcs, volume, bottles and set of reagents and consumables in compliance to the total number of tests requested.
   7. To provide complete set of reagents for on-site demonstration
   8. All wasted reagents due to malfunctioning equipment must be replaced immediately and with proper documentation of both parties

F. REPORTING OF RESULTS:
   1. Results from the analyzer automatically transferred to the interfaced computer unit and printed automatically
   2. Provision of template for manual encoding of manually performed procedures.
   3. Report format will follow the approved ISO Report Form with reference values
   4. Must provide colored printer with ink/toner available for the whole duration of contract

G. TRAINING:
   1. Availability of a Product Specialist to train at all Medical Technologist involved in the operation, troubleshooting and preventive maintenance of the analyzer.
   2. Product Specialist must have a certificate of Trainers training from the Manufacturer of the Machine
   3. To provide Certificate of Training duly signed by the Manufacturer representative and Product Specialist of the Company.

H. DEMONSTRATION FOR EVALUATION:
   1. The BAC (Bids and Awards Committee) should be informed on the delivery of analyzer and reagents for evaluation
   2. The analyzer and reagents will be evaluated for at least ten (10) days or until evaluation is finished.
   3. Actual report can be generated with the analyzer interfaced with a desktop computer and printed an approved report
   4. Conforms with the attached Evaluation Criteria for Machines and Reagents in the Clinical Laboratory.

I. DOCUMENTARY REQUIREMENTS:
   1. Certificate of Good Service Performance from the End-User
   2. Certificate of Product Registration issued by Philippine FDA-provide a copy during the first delivery together with compiled MSDS (Material Safety and Data Sheet)
   3. Certificate of ISO compliance of the manufacturer
   4. Certificate for the availability of supply and parts of the analyzer
   5. Certificate of Distributor/Dealership agreement from the manufacturer

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TECHNICAL SPECIFICATIONS

ADDEX F.	DRY CLINICAL CHEMISTRY TESTS	
PURCHASER'S SPECIFICATIONS		SUPPLIER'S SPECIFICATIONS

A. ANALYTICAL OPERATION:
   1. Specimen: Serum, plasma, CSF and urine
   2. Volume: 5-12 microliter per test
   3. Employs Reflectance Spectrophotometry
   4. Assay type: Colorimetric and potentiometric
   5. Test panels availability:
      a. Renal Function tests
      b. Liver function tests
      c. Lipid profile tests
      d. Cardiac enzymes
      e. Inorganic ions
      f. Enzymes
      g. Special Chemistry

B. TIE-UP ANALYZER:
   1. Main Analyzer: One (1) current model analyzer with throughput of at least 800 tests per hour to be installed at the main lab.
   2. Back-up Analyzer: One (1) current model analyzer with throughput of at least 500 tests per hour to be installed at the main lab.
   3. OPD satellite lab Analyzer- One (1) current model analyzer with throughput of at least 500 tests per hour to be installed at the OPD
   4. Analyzer included in the G7 series of machines.
   5. Provision of individual work-stations for the three analyzers interfaced via middle ware for a single data management equipped with barcode reader and printer.
   6. Provision of a compatible table for the analyzer, computer unit and printers, reagents and other consumables
   7. All analyzers should be LIS ready and shall be connected once the institution availed a functional Laboratory Information System at no expense to procuring entity.
   8. Barcoded entry for specimens and reagents
   9. Employs single pipette tip sampling system
   10. With auto detection of clot, bubbles and viscosity
   11. Equipped with level detection to prevent bubbling in the slide
   12. Automatic dilution of sample with operator preferred ratio
   13. Sample rack automatically comes out after sampling allowing new specimens to be loaded
   14. Results comparable to parallel testing
   15. With on-board reagents and consumables inventory
   16. Stores results at least for 1 year
   17. Power requirement:
      a. Provision of UPS (Uninterrupted Power Supply Unit) that can support the machine for at least 30 minutes or until on board tests are completed.
      b. Provision of AVR (Automatic Voltage Regulator) to compensate current fluctuations and with a capacity of 50% higher than the actual consumption of the machine.
      c. Compatible to the institution's power generator
      d. All power cords should be three (3) prong
   18. Availability of operation manual and troubleshooting
   19. Machine accessories that are not included in the APP must be provided by the winning bidder.
   20. Analyzer should be replaced after three (3) failed troubleshooting within two (2) weeks

C. PREVENTIVE MAINTENANCE:

1. Quarterly or as needed preventive maintenance by trained personnel (to bring cleaning kits)
2. Certificate of Calibration valid for 1 year from date of installation up to time of decommissioning.

D. TROUBLESHOOTING:
   1. Provision of contact number/s for technical assistance available at all times
   2. Malfunction of machines shall be addressed immediately once informed within 24 to 48 hours

E. <u>REAGENTS AND CONSUMABLES:</u>
   1. To provide complete set of reagent, control, calibrators and consumables necessary to complete the required number of test available when needed:
      a. Reagents
      b. Specific controls for requested tests only
      c. Calibrator sets for requested tests only
      d. Reference fluids for electrolytes
      e. Reagent stability materials
   2. Minimal packaging of reagents (18-60 test)
   3. Strict compliance of the ten (10) days delivery period
   4. Indicate the total number of items to be delivered in the Bid Proposals as to number of pcs, volume, bottles and set of all reagents and consumables in compliance to the total number of tests requested
   5. To provide complete set of reagents for on-site demonstration and actual performance for at least one week
   6. All wasted reagents due to malfunctioning of equipment must be replaced immediately and with proper documentation of both parties.
   7. To provide enough supply of barcode stickers.

F. <u>REPORTING OF RESULTS:</u>
   1. Results from the analyzer automatically transferred to the interfaced computer unit and printed automatically.
   2. Provision of template for manual encoding of results from other devices which are not interfaced and from point of care devices.
   3. Report format will follow the approved ISO Report Form
   4. Must provide colored printer with ink/toner available for the whole duration of contract

G. TRAINING:
   1. Availability of a Product Specialist from the manufacturer to train all technical staff in the operation, troubleshooting and preventive maintenance of the analyzers.
   2. To provide certificate of training

H. DEMONSTRATION FOR EVALUATION:
   1. The BAC (Bids and Awards Committee) should be informed on the delivery of analyzers and reagents for evaluation.
   2. The analyzer and reagents will be evaluated for at least ten (10) days or until evaluation is finished.
   3. Actual report can be generated with the analyzer interfaced with a desktop computer and printed an approved report
   4. Conforms with the attached Evaluation Criteria for Equipment and Reagents in the Clinical Laboratory. Refer to Annex A.

I. DOCUMENTARY REQUIREMENTS:
   1. Certificate of Product Registration issued by PFDA. To provide a copy for the end user on the first delivery of reagents
   2. Certificate of ISO compliance of the manufacturer
   3. Certificate for the availability of supply and parts of the analyzer from the manufacturer
   4. Certificate of Distributor/Dealership agreement from the manufacturer

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TECHNICAL SPECIFICATIONS

Annex G Code:	AUTOMATED URINALYSIS TEST	QUANTITY:
		ABC:

PURCHASER'S SPECIFICATIONS	SUPPLIER'S SPECIFICATIONS

A. ANALYTICAL OPERATION:
   1. Specimen: URINE
   2. PRINCIPLE: Automation of traditional manual microscopy using digital imaging and real time microscopy
   3. INTENDED USE: Physical, chemical and microscopic evaluation of Urine specimen

B. TIE-UP ANALYZER:
   1. Main Lab Analyzer: One (1) Current model with less than 2 years in service, with stand-alone table for the Analyzer and one (1) Interfaced Work Station Computers.
   2. OPD Analyzer: One (1) Current model with less than 2 years in service, with stand-alone table for the analyzer and Interfaced work station. One (1) current model for back-up with less than 3 years in service, with stand-alone table for the analyzer and Interfaced work station
   3. Real time release of report based on random access loading specially for stat request handling.
   4. Allows double checking of results via real time microscopy and captured images
   5. On board inventory and stability monitoring of reagents and consumables.
   6. Analyzer distributed and patented in G7 group of countries
   7. Barcoded entry for reagents and specimen. To provide two (2) barcode printer and continues supply of barcode stickers.
   8. Interfaced work station computers connected to the analyzers should be capable of delta checking and printing.
   9. Analyzers should be LIS ready with middle ware and should be connected to the functional Laboratory information system without the expense of the department.
   10. Minimal sample needed for testing: at least three (3) ml of sample
   11. Stores results at least for one (1) year and the company is responsible in data migration as needed.
   12. Power requirement:
      a. Provision of UPS (Uninterrupted Power Supply Unit) that can support the machine for at least 30 minutes or until on board tests are completed.
      b. Provision of AVR (Automatic Voltage Regulator) to compensate current fluctuations and with a capacity of 50% higher than the actual consumption of the machine.
      c. Compatible to the institution's power generator
      d. All power cords should be three (3) prongs
   13. Availability of operational/troubleshooting manual and copy of MSDS.
   14. Machine accessories that are not included in the APP must be provided by the winning bidder.
   15. Analyzer should be replaced after three (3) failed troubleshooting within two (2) weeks

C. PREVENTIVE MAINTENANCE/CALIBRATION
   1. Monthly preventive maintenance or more often as needed. Service engineers should bring their own cleaning kits.
   2. On-site calibration and validation with certification of conformity or equivalent.

D. TROUBLESHOOTING:
   1. Provision of contact number/s for technical assistance available at all times for phone assisted trouble shooting.

2. Malfunction of machines shall be addressed immediately once informed within 24 to 48 hours

E. REAGENTS:
1. Reagent Strips (Single loading capacity) can be used manually and by using the automated analyzer.
2. Controls (third party type) for daily use
3. Calibrators
4. Appropriate consumables and cuvettes
5. Disposable test tubes equivalent to the number of tests requested. Provide tubes for minimal volume urine specimens.
6. Strict compliance of the ten (10) days deliver period
7. Indicate the total number of items to be delivered in the Bid Proposals as to number of pcs, volume, bottles or sets intended for the number of tests requested.
8. To provide complete set of reagents for on-site demonstration and dry-run for at least ten (10) days for the evaluation period.
9. All wasted reagents due to malfunctioning equipment must be replaced immediately and with proper documentation of both parties
10. Provision of appropriate volume of distilled water.

F. REPORTING OF RESULTS:
1. Three (3) physical parameters. (Specimen container should have calibration in ml.
2. Ten (10) Chemical parameters
3. Auto detection of particles with manual identification by end user
4. Results from the analyzer automatically transferred to the interfaced computer unit and printed automatically
5. Provision of template for manual encoding of manually performed procedures. (Pregnancy test, Stool analysis, body fluids, seminal, KOH etc.)
6. Report format will follow the approved ISO Report Form with reference values. Please refer to the previous forms.
7. Must provide colored printer with ink/toner available for the whole duration of contract

G. TRAINING:
1. Availability of a Product Specialist to train at least all technical staff in the operation, troubleshooting and preventive maintenance of the analyzer.
2. To provide certificate of training

H. DEMONSTRATION FOR EVALUATION:
1. The BAC (Bids and Awards Committee) should be informed on the delivery of analyzer and reagents for evaluation
2. The analyzer and reagents will be evaluated for at least ten (10) days or until evaluation is finished.
3. Actual report can be generated with the analyzer interfaced with a desktop computer and printed an approved report
4. Conforms with the attached Evaluation Criteria for Machines and Reagents in the Clinical Laboratory. Refer to Annex A.

I. DOCUMENTARY REQUIREMENTS:
1. Certificate of Good Service Performance from the End-User
2. Certificate of Product Registration issued by PFDA. Provide the end user a copy on the first delivery of reagent.
3. Certificate of ISO compliance of the manufacturer
4. Certificate for the availability of supply and parts of the analyzer
5. Certificate of Distributor/Dealership agreement from the manufacturer

Republic of the Philippines
Department of Health
REGION II TRAUMA AND MEDICAL CENTER
TECHNICAL SPECIFICATIONS

Annex H	**IMMUNO-SEROLOGICAL TESTS**	

PURCHASER'S SPECIFICATIONS	SUPPLIER'S SPECIFICATIONS

A. ANALYTICAL OPERATION:
   1. Specimen:
      a. Human serum
      b. Plasma derived from EDTA, Heparin, Sodium citrate and acid citrate dextrose anticoagulants
   2. Principle: Chemiluminescent Immunoassay (CLIA)
   3. Intended Use:
      a. This assay is intended for screening of Antigen and Antibodies of Transfusion Transmissible Infections (TTIs) from blood donations
      b. Thyroid Function Tests
      c. Hepatitis profile tests
      d. Tumor markers

B. TIE-UP ANALYZER:
   1. Main Analyzer: One (1) Current model and not more than two (2) years in service.
   2. Back-up Analyzer: One (1) Current model analyzer and not more than three (3) years in service.
   3. Throughput of not less than 80 test per hour
   4. On board inventory monitoring as to number of tests left and status of calibration/expiration.
   5. With random access for "stat" during routine processing
   6. At least 99% accuracy and specificity of all the results
   7. Analyzer should be used and distributed in G7 countries
   8. Barcoded entry of specimens and reagents
   9. Work list can be generated manually or by LIS
   10. Both analyzers should be interfaced for data management with individual computer unit provided with colored printer for results and barcode printer
   11. Provide equipment table for benchtop type analyzers
   12. With auto detection of clot and bubbles in the sample
   13. Results comparable to parallel testing
   14. With at least 30 days on-board stability of reagent once loaded in the machine
   15. Stores results at least for one (1) year
   16. Power requirement:
      a. Provision of UPS (Uninterrupted Power Supply Unit)
      b. Provision of AVR (Automatic Voltage Regulator) to compensate current fluctuations
      c. Compatible to the institution's power generator
      d. All power cords should be three (3) prong
   17. Availability of operation manual and troubleshooting
   18. Machine accessories and consumables must be provided by the winning bidder except A4 paper for result printing
   19. Analyzer should be replaced after three (3) failed repairs and troubleshooting

C. PREVENTIVE MAINTENANCE/CALIBRATION
   1. Quarterly preventive maintenance schedule by trained personnel (to bring cleaning kits)
   2. On-site calibration and validation with certification of conformity or equivalent. To provide sticker for calibrated analyzer.

D. TROUBLESHOOTING:
   1. Provision of contact number/s for technical assistance available at all times
   2. Malfunction of machines shall be addressed immediately once informed within 24 to 48 hours

E. REAGENTS AND CONSUMABLES:
   1. To provide complete set of reagents, controls, calibrators, reaction cuvettes, water needs necessary to complete the required number of test available when needed:
      a. Reagents sets, controls and calibrators
      b. Reaction tube/vessels or its equivalent enough to run the required number of tests
      c. Continuous supply of wash solutions
      d. Solutions used other than mentioned above will likewise be supplied
   2. Minimal packaging of reagents (at least 100 tests per set)
   3. Strict compliance of the ten (10) days delivery period
   4. Indicate the total number of items to be delivered in the Bid Proposals as to number of pcs, volume, bottles and set of reagents and consumables in compliance to the total number of tests requested
   5. To provide complete set of reagent for on-site demonstration
   6. All wasted reagents due to malfunctioning equipment must be replaced immediately after proper documentation by both parties.
   7. To provide barcode stickers for the whole duration of contract.

F. REPORTING OF RESULTS:
   1. Results from the analyzer automatically transferred to the interfaced computer unit and printed automatically
   2. Provision of template for manual encoding of result from other devices which are not interfaced and from point of care devices.
   3. Report format will follow the approved ISO Report Form with reference values
   4. Must provide colored printer with ink/toner available for the whole duration of contract

G. TRAINING:
   1. Availability of a Product Specialist from the manufacturer to train the technical staff in the operation, troubleshooting and preventive maintenance of the analyzer.
   2. To provide certificate of training

H. DEMONSTRATION FOR EVALUATION:
   1. The BAC (Bids and Awards Committee) should be informed on the delivery of analyzer and reagents for evaluation
   2. The analyzer and reagents will be evaluated for at least ten (10) days or until evaluation is finished.
   3. Barcoded entry of specimen and reagents shall be in place before the evaluation
   4. Actual report can be generated with the analyzer interface computer to be approved.

I. DOCUMENTARY REQUIREMENTS:
   1. Certificate of Product Registration issued by PFDA
   2. Certificate of ISO compliance of the manufacturer
   3. Certificate of Compliance to the National Council for Blood Services Technical Committee Recommendations for TTIs
   4. Certificate for the availability of supply and parts of the analyzer from the manufacturer
   5. Certificate of Distributor/Dealership agreement from the manufacturer