FRENCH MEDICAL INSTITUTE FOR MOTHERS AND CHILDREN (FMIC)
Request for Information (RFI) – Laboratory Analyzers
Technical Specifications

1- Fully Automated Biochemistry Analyzer

Fully automatic biochemistry analyzer with the following capabilities:

Technology: Fully automated, random-access clinical chemistry analyzer with photometric and turbidimetric measurement capabilities and an Ion-Selective Electrode (ISE) module
Throughput: Minimum 200 photometric tests per hour, excluding ISE tests.
Sample Handling: Continuous sample loading, STAT priority, barcode identification, and automatic sample dilution and rerun capabilities.
Reagent Management: Refrigerated onboard reagent storage, automatic reagent monitoring, and adequate onboard reagent positions.
Connectivity: Bidirectional LIS/LIMS connectivity.
Analytical Performance: High precision, accuracy, linearity, and minimal sample and reagent consumption.
Market Presence and Installed Base: Bidders must provide the total number of installed and operational analyzers of the proposed model.
Certification: Appropriate international regulatory approvals and quality certifications.

2- Fully Automated Immunoassay Analyzer

Technology: Fully automated, random-access CLIA, CMIA, ECLIA, or equivalent technology.
Throughput: High Throughput.
Sample Capacity: Minimum 100 sample positions with continuous loading, STAT priority, and barcode identification.
Reagent Capacity: Minimum 25 onboard refrigerated reagent positions with continuous reagent loading and automatic reagent monitoring.
Test Menu: Comprehensive menu covering thyroid, fertility, tumor markers, cardiac markers, infectious diseases, autoimmune disorders, vitamins, hormones, and specialized immunoassays, including TB-IGRA and other advanced parameters.
Automation: Automatic sample dilution, clot detection, liquid-level sensing, reagent monitoring, and continuous loading of consumables.
Analytical Performance: High precision, accuracy, sensitivity, and specificity, with minimal sample carryover and documented analytical performance.
Quality Control: Automated calibration, internal quality control management, and error detection.

Connectivity: Bidirectional LIS/LIMS connectivity compatible with the existing laboratory information system.
Market Presence and Installed Base: Bidders must provide the total number of installed and operational analyzers of the proposed model.
Certification: Appropriate international regulatory approvals and quality certifications.

3- Fully Automated Hemoglobin Electrophoresis / HPLC Analyzer

Technology: Fully automated High-Performance Liquid Chromatography (HPLC) system using ion-exchange chromatography for hemoglobin fraction separation and quantification.
Test Menu: Quantitative measurement of HbA, HbA2, and HbF, with detection and identification support for common hemoglobin variants, including HbS, HbC, HbD, and HbE.
Throughput: Minimum 10 samples per hour.
Sample Handling: Automated sample aspiration, barcode identification, and continuous or batch sample loading.
Analytical Performance: High accuracy, precision, reproducibility, and resolution for hemoglobin fraction separation, particularly HbA2 and HbF quantification.
Result Interpretation: Automatic generation of chromatograms, hemoglobin fraction percentages, retention times, and abnormal hemoglobin variant flags.
Quality Control: Built-in calibration, internal quality control monitoring, and automated error detection.
Reagent Management: Adequate reagent stability, minimal reagent wastage, and automatic monitoring of reagent levels.
Market Presence and Installed Base: Bidders must provide the number of installed and operational analyzers of the proposed model.

4- Semi-Automated Coagulation Analyzer

Technology: Semi-automated coagulation analyzer utilizing optical, mechanical, or equivalent reliable clot detection technology.
Test Menu: Capable of performing PT, INR, APTT, Fibrinogen, Thrombin Time (TT), and other routine coagulation assays.
Testing Channels: Minimum 4 independent testing channels with simultaneous or parallel sample processing.
Sample Handling: Compatible with citrated plasma samples, with low sample and reagent volume requirements.
Analytical Performance: High accuracy, precision, reproducibility, and reliable clot detection, including in abnormal coagulation samples.
Reagent Management: Compatibility with commercially available coagulation reagents, with adequate reagent stability and minimal wastage.

User Interface: User-friendly software with a display, result storage, and automated calculation of INR and fibrinogen concentration.
Connectivity: LIS/LIMS connectivity, preferably bidirectional, compatible with the existing laboratory information system.
Market Presence and Installed Base: Bidders must provide the number of installed and operational analyzers of the proposed model.

5- Immunoassay Analyzer (multi-channels with Random Access option) to Perform the H. Pylori Antigen Quantitative Test

Analyzer Compatibility and Performance

- Must support human feces sample as a validated input for H. pylori testing.
- Must allow quantitative result output.
- Must provide accuracy ≥98% sensitivity and 98% specificity, and CV ≤10%.

Multi-Channel and Throughput Capabilities

- Minimum 10 independent channels for sample loading.
- Random access to test slots is a must.

User Interface & Software

- Intuitive and user-friendly software interface.
- Integrated or external thermal printer support.
- Direct LIS/HIS connectivity (standard HL7 support is a plus).
- Auto reading and storing of ID chip batch numbers and calibration data.

Sample and Reagent Requirements

- Compatible with whole blood, serum, plasma, urine, and stool.
- Pre-filled cartridges or ID chips must contain all calibration and test information.
- All reagents and kits should support room temperature storage.
- Shelf life of reagents/kits good to be ≥12 months (ideally 24 months).

Maintenance and Calibration

- Must include calibration features.
- It must have scheduled preventative maintenance.

Regulatory and Certification

- Device and kits must be CE marked, IFCC approved, or ISO13485 certified.
- Manufacturer must comply with international quality standards.