Specification for Chemiluminescence Analyzer (CLIA) Machine

- A diagnostic equipment based on the highly specific interaction between an antibody and an antigen. Chemiluminescence Immunoassay analyzer is used to perform serological and immunological tests to detect or measure specific proteins or other substances through their properties as antigens or antibodies.
- Fully automated analyzer, bench top analyzer to perform the immunoassays from serum, plasma, & other body fluids.
- Chemiluminescence Immunoassay analyzer, complete unit with complete accessories, reagents.
- System shall be based on "Flash-Chemiluminescence label/ Direct Chemiluminescence/E-CLIA technology for measuring the assays.
- System shall have batch, random or continuous random access.
- System shall have provision of emergency/STAT samples with continuous loading facilities without stoppage.
- Onboard reagent stability of minimum 28 days which should be mentioned in each reagent of Kit Insert.
- System must have throughput of minimum 200 tests/hr or more and 24 hours ready to use.
- Should have RFID/Barcode recognition system for reagent and sample.
- System should have at least 50 test can be incubate at the same time, and incubator temperature must be 36.8 ±0.5 °C.
- No daily calibration required. Depends on assay parameter. Calibration stability at least 7 days to 28 days.
- Shall have system to detect clot and liquid level detection.
- Shall have automatic sample dilution and auto reflex testing available.
- Inbuilt refrigeration system with controlled temperature for Reagent to maintain temperature of reagents.
- Reagent assays must be ready to use, liquid, and include calibrator and control in each reagent kit, FOC calibrator and control.
- The reagent should come with 50 Test or 100 Test pack size.
- Must have single disposable cuvette system.
- System should have inventory track, flag, calibration validate, reagent inventory and expiry.
- Shall have the features of QC management within run control program includes Levy-jennings histograms, Mean X and Westergard rules etc. to monitor the quality of result with company provided QC material.
- Shall have LIS facilities.
- Following tests should be available:
  Virus and markers: TORCH IgG and IgM markers (Toxo, Rubella, CMV, HSV), Anti HCV (IgM), HBsAg, Anti-HBs, HBeAg, Anti -HBe, Anti-HBc, Anti-HAV, HAV IgM, HIV Ag/Ab combine, H.Pylori(IgG, IgM, IgA), Syphilis, EBV, Dengue Virus (IgG, NS1), Monkeypox virus Ag etc.
  Autoimmune: ANA screen, ENA Screen, Anti-dsDNA,IgG, Anti-SmIgG, Anti-Rib-P IgG, Anti-nRNP/SmIgG, Anti-SS-A Igg, Anti-SS-B IgG, Anti-scl-70 IgG, Anti-Jo1 IgG, Anti-Histones IgG, Anti-Centromeres IgG

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Inflammation Monitoring: IL-6, SAA, TNF alpha, PCT, HsCRP.
Immunoglobulin: Total IgE, IgA, IgG

- Must submit ISO13485 for Medical Devices.
- Must have USFDA approved certificate for the instrument
- Must Submit European CE certification for HBsAg, HIV Ag/Ab combine and Anti HCV (IgM)
- Must provide user training (including how to use and maintain the equipment).
- Warranty for 2 years of instrument and AMC/CMC policy in details
- The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.
- List of important spare parts and accessories with their part numbers and costing.
- More than 10 units of similar model already must be installed in Nepal with proper functioning with list.
- The company must have factory trained engineer with 24 X 7 availability
- During warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required.
- The ownership of the machine will be transferred to Dhulikhel Hospital after 5 years of service on reagent rental basis.

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