(September 2021)

PERFORMANCE CRITERIA
FOR

SECTION 11 53 00

LABORATORY EQUIPMENT
09/21

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GENERAL
This Performance Criteria specifies the requirements for laboratory equipment.

1.1 REFERENCE

1.1.1 Unified Facilities Criteria (UFC)
Contractor must comply with the following:
- **A.** UFC 1-200-01 General Building Requirements
- **B.** UFC 1-200-02 High Performance and Sustainable Building Requirements
- **C.** UFC 4-510-01 Military Medical Facilities
- **D.** UFC 3-120-10 Interior Design

1.1.2 Military Standard
- **A.** MIL-STD 1691 Construction and Material Schedule for Medical, Dental, Veterinary and Medical Research Laboratories

1.1.3 National Fire Protection Association (NFPA)
- **A.** NFPA 99 Healthcare Facilities Code
- **B.** NFPA 101 Life Safety Code
- **C.** NFPA 260 Standard Methods of Tests and Classification System for Cigarette Ignition Resistance of Components of Upholstered Furniture
- **D.** NFPA 701 Standard Methods of Fire Tests for Flame Propagation of Textiles and Films

1.1.4 Military Health System Standards
- **A.** Reserved for future

1.1.5 American Society for Testing and Materials (ASTM)
- **A.** ASTM E84 Standard Test Method for Surface Burning Characteristics of Building Materials
- **B.** ASTM D4157 Standard Test Method for Abrasion Resistance of Textile Fabrics (Oscillatory Cylinder Method)

1.1.6 American National Standards Institute (ANSI)

A. ANSI/ASHRAE 110 Method of Testing Performance of Laboratory Fume Hoods

1.1.7 Underwriters Laboratories (UL)

A. UL 60601-1 Medical and Electrical Equipment, Part 1: General Requirements for Safety

B. UL 1805 Standard for Laboratory Hoods and Cabinets

1.1.8 [International Electrotechnical Commission (IEC)

A. IEC 60601 Medical Electrical Equipment and Systems]

1.1.9 Food and Drug Administration

A. CFR Title 21, Chapter I

B. FDA Compressed Medical Gases Guideline

1.1.10 NSF International Standard (NSF)

A. NSF/ANSI 49 Biosafety Cabinetry: Design, Construction, Performance, and Field Certification

1.1.11 International Organization for Standardization (ISO)

A. ISO 9001 Quality Management Systems - Requirements

B. ISO 13485 Quality Management System for Medical Devices

1.1.12 Other Standards

A. CAL-117 (California Technical Bulletin 117-2013)

B. Reserved for future

2.1 DESCRIPTION & MATERIALS

All requirements within the MIL-STD 1691 JSN descriptions must be met as well as the performance guidelines listed in the following descriptions.

2.1.1 All JSN'S

A. Paints, fabrics, and finishes will be selected from the manufacturer's standard options for the specified model unless noted otherwise.

B. All fabrics (upholstery or drapery) must meet the appropriate fire test associated with each type of fabric as outlined by testing within the reference standards.

C. All fabrics (upholstery) must meet the appropriate resistance to abrasion test associated with each type of fabric as outlined by testing within the reference standards.

D. All product finishes and fabrics (upholstery or drapery) must meet industry standards for infection control and performance.

E. All product finishes must be capable of maintaining sheen and color through warranty period when using industry standard cleaning and disinfection solutions.

F. All display panel surfaces must maintain clarity through warranty period when using industry standard cleaning and disinfection solutions.

G. All equipment that have components that are meant for reuse must be autoclavable or able to withstand industry standard cleaning and disinfection processes.

H. Electrified equipment must be 115 Volt 15 amp maximum unless noted otherwise.

I. Casters provided must be designed for use on the installed floor finish.

J. All products that have interoperability capable hardware (i.e. internal storage, data transmission via wireless, Ethernet, LAN, or USB to PC or server connectivity) must meet Cybersecurity requirements in accordance with DoDI 8510.01 Risk Management Framework.

K. DoDI 8510.01 applies to all DoD IT (medical devices included) that receive, process, store, display, or transmit DoD information. These technologies are broadly grouped as DoD IS, platform IT (PIT), IT services, and IT products. This includes IT supporting research, development, test and evaluation (T&E), and DoD-controlled IT operated by a contractor or other entity on behalf of the DoD.

2.1.2 Analyzers – Blood Gas

L1930 – Analyzer, pH/Blood Gas

L1931 – Analyzer, Blood Gas

A. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.

B. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

C. Analyzer must have capability to connect to hospital electronic health record and/or laboratory information systems.

D. [System must be bench top, portable bench top, floor mounted, hand held or point of care.]

E. [Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission.]

F. [System must auto calibrate before every sample is inserted.]

G. Provide hardware that includes internal memory of [500 GB] to store a minimum of [1000 patient] tests data.

H. [Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission.]

I. [Provide a barcode reader [wired or wireless with battery charger] and internal or external printer.]

J. [System must be upgradeable to future parameters/testing capabilities.]

2.1.3 Chemistry Equipment

A. Chemistry Analyzers

L1025 – Analyzer, Chemistry, Drug Screening

L1030 – Analyzer, Chemistry, Stat, High Capacity

L1035 – Analyzer, Chemistry, Stat

L1080 – Analyzer, Chemistry, Multichannel

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. [Must be able to process serum, plasma, urine, cerebrospinal fluid (CSF), supernatant, and/or whole blood.]
4. [Provide hardware that includes internal memory of [500 GB] to store a minimum of [1000 patient] tests data.]
5. Analyzer must have capability to connect to hospital electronic health record and/or laboratory information systems.
6. Must accept sample tube sizes [13 x75 mm, 13 x 100mm, 16 x 75mm, 16 x100mm, Hitachi standard cup 2.5mL, cobas sample cup 2.5mL, Hitachi Micro cup 1.5mL 11-16 x 63-102mm.]
7. [Assay menu must include anemia, bone markers, tumor markers, diabetes, fertility/hormones, thyroid function, cardiac markers, specific proteins, hepatitis, growth hormones, infectious disease, Sepsis/Inflammation, Rheumatoid Arthritis, STAT, or Immunosuppressant drugs.]
8. [Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission.]
9. [Provide a barcode reader and internal or external printer.]

B. Electrophoresis Analyzers

L1120 – Electrophoresis, General

L1125 – Electrophoresis, Thin Layer

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. [System must be routine, high resolution (HRES), polyacrylamide gel, capillary, isoelectric, immunochemical fixation, two-dimensional (2D), pulsed field.]
4. [Provide gel box/capillary array, power supply, buffer receptacle.]
4. [Provide hardware that includes internal memory of [500 GB] to store a minimum of [1000 patient] tests data.]
5. [Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission.]
6. [Provide a barcode reader and internal or external printer.]

2.1.4 E.I.A. Analysis Equipment

A. E.I.A. Analyzers

L0205 – E.I.A. Analysis System, Advanced

L0210 – E.I.A. Analysis System, Basic

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. [Analyzer must have capability to connect to hospital electronic health record and/or laboratory information systems.]
4. [Must be able to run [80] tests per hour.]
5. [Must be able to process serum, plasma, urine, amniotic fluid, and/or whole blood.]
6. [Onboard reagent storage must be able to hold [50] reagent packs.]
7. [Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission.]

B. Microplate Washers

L0211 – E.I.A. Plate Washer System

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. [Must be able to adjust parameters of the number of wash cycles, soaking time, shaking speed, dispense and aspiration height, and/or aspiration speed.]
3. Plate washing system must be [automatic] [manual].
4. Washing configuration must be [plate or strip.]
5. System must have [aerosol shield, integral shaker, and/or x-y-z positioning.]
5. System must be [96-well] [384-well] [1536-well] plate compatible.
6. [Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission.]
7. [Hardware attachments to process different microplate styles - Microplate nests & robot grippers- Internal or remote computer interface.]

2.1.5 Analyzers - Hematology

L0215 – Hemoglobin Analysis System
L0220 – Analyzer, Hemoglobin, Portable, Hand Held
L0221 – Analyzer, Blood, Portable, Hand Held
L1000 – Analyzer, Blood Chem, Auto, 60 Samples/Hour
L1085 – Analyzer, Coagulation, Automatic
L1115 – Analyzer, Hematology, Differential, Automatic
L2655 – Apparatus, Culture, Anaerobic
L2657 – Analyzer, Blood Culture

A. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
B. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
C. Analyzer must have capability to connect to hospital electronic health record and/or laboratory information systems.
D. Provide hardware that includes internal memory of [500 GB] to store a minimum of [1000 patient] tests data.
E. [Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission.]
F. [Provide a barcode reader and internal or external printer.]

2.1.6 Analyzers - Other

L0200 – Protein Analysis System
L0895 – Analyzer, Sperm Motility
L1050 – Cytometer, Flow, Clinical Laboratory
L1055 – Cytometer, Flow, Advanced Laboratory
L1060 – Screening Device, Cystic Fibrosis
L1065 – Analyzer, Fetal Fibronectin
L1070 – Analyzer, BUN, Discrete
L1105 – Co-Oximeter
L1185 – Analyzer, Glucose
L1925 – Analyzer, Sedimentary Rate
L1940 – Analyzer, Lead

L4350 – Bilirubinometer

A. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.

B. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

C. Analyzer must have capability to test very small sample volumes.

D. Analyzer must have capability to connect to hospital electronic health record and/or laboratory information systems.

E. Provide hardware that includes internal memory of [500 GB] to store a minimum of [1000 patient] tests data.

F. [Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission.]

G. [Provide a barcode reader and internal or external printer.]

2.1.7 Analyzers - Urinalysis

L0990 – Analyzer, Urine, Basic

L0995 – Analyzer, Urine, Advanced

A. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.

B. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

C. Analyzer must have capability to test very small sample volumes.

D. Analyzer must have capability to connect to hospital electronic health record and/or laboratory information systems.

E. Provide hardware that includes internal memory of [500 GB] to store a minimum of [1000 patient] tests data.

F. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]

G. [Provide a barcode reader and internal or external printer.]

2.1.8 Weighing Equipment

A. Balances

M1205 – Balance, Analytical, Laboratory/Pharmacy

M1210 – Balance, Electronic, Laboratory/Pharmacy

M1215 – Balance, Prescription, 10 mg Sensitivity

M1225 – Balance, Trip, 2 Beam, 2kg Capacity, .1gm Division

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. Balances must have a readability of 0.01 to 0.1 mg and a reproducibility of 0.1mg or better.
3. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]

B. Calibration Sets

M1230 – Weight Set, Calibration, 100 gm to 1 kg

M1235 – Weight Set, Calibration, 1 mg to 100 gm

1. Weights must be constructed of stainless steel.
2. Weight sets must have Class I certification and a certificate must be provided.

C. Balance Table

M1240 – Table, Balance, Marble

1. Worksurface must be non-porous so it will not stain.
2. Worksurface and legs must be a minimum of 3 inches [76 mm] thick marble slabs with all edges rounded level and smooth
3. Table frame must be reinforced with metal crossbeam coated for corrosion resistance**.**

2.1.9 Centrifuges

L1300 – Centrifuge, Small, Blood Typing, Variable Speed

L1350 – Centrifuge, Table, Small, 3200 RPM, 6 Place

L1400 – Centrifuge, Microhematocrit, 24 Tube

L1500 – Centrifuge, Medium Duty, Refrigerated, Floor Model

L1502 – Centrifuge, Tabletop

L1660 – Cell Washer/Centrifuge

L1670 – Centrifuge, Refrigerated, Floor Model

L1680 – Centrifuge, Refrigerated, Benchtop

L1690 – Centrifuge, Serological, Multi Speed, Benchtop

L1750 – Centrifuge, Heavy Duty, Floor Model, Refrigerated

L1770 – Ultracentrifuge
L1780 – Centrifuge, Cytology

A. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
B. Provide functions that allow for variation of the speed and duration of operation.
C. Lid must include gasket seal, auto lock during operation, and emergency lock release functions. Provide a viewing window for the measuring of the rotor speed without opening the lid.
D. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

2.1.10 Chromatographs

L1005 – Chromatograph, Gas, General
L1010 – Chromatograph, Gas, Mass Spectrometer
L1015 – Chromatograph, Liquid
L1020 – Chromatograph, Ion

A. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
B. Provide user modifiable program modes. Include parameters for instrument control, injection speed, temperature, and time of operation. All parameters must be shown on the display.
C. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
D. Provide hardware that includes internal memory of [500 GB] to store a minimum of [1000 patient] tests data.
F. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]

2.1.11 Counters

L2600 – Counter, Cell, Auto
L2630 – Counter/Timer, Digital
L2650 – Counter, Bacteria
L9835 – Counter, Radioimmunoassay, Multichannel
L9836 – Counter, Radioimmunoassay, Single Channel
L9840 – Counter, Gamma, RIA, Manual

A. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
B. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
C. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]

2.1.12 Drying Ovens

L8275 – Oven, Drying, Small, w/Timer
L8280 – Oven, Drying, Medium, 2 Cubic Foot
L8285 – Oven, Drying, Medium, 3 Cubic Foot
L8290 – Oven, Drying, Large, 2 Door

A. Display must be LCD high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
B. User must be able to vary time and temperature of operation.
C. Door must be gasketed with full view tempered safety glass.
D. Provide safety features that include internal monitor and safety controller to prevent overheating.
E. Temperature accuracy must be within 2% of set temperature.
F. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
G. [Provide connections for constant external temperature monitoring/recording.]

2.1.13 Microscopy

A. Microscopes
L0075 – Microscope, Stereo, Photographic, Desk Top
L0080 – Microscope, Inverted, Tissue Culture
L0085 – Microscope, Karyotyping, Digital Image

L0100 – Microscope, Binocular
L0105 – Microscope, Binocular, Phase Contrast
L0110 – Microscope, Trinocular
L0115 – Microscope, Photographic
L0125 – Microscope, Projection / Video System
L0140 – Microscope, Fluorescence
L0142 – Microscope, Fluorescent, Photographic
L0145 – Microscope, Teaching, Multiple Head
L0147 – Microscope, Teaching, Multiple Head (18)

1. Provide variable magnification lens selection for high resolution imaging over entire magnification range (including photographic where applicable) and fine focus adjustments on eyepiece and all focusing attachments for clarity of imaging capture and viewing.
2. Provide LED or halogen light sources with variable light intensity controller. Light sources must be appropriate for research and routine examinations and have lighting, filtering and exposure controls suitable for photo-microscopy when required.
3. Provide a rotating nosepiece to accommodate varying users.
4. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
5. Provide a dust cover and hard box with each microscope.
6. [Hardware must include port for input and output data transmission using the manufacturers standard software interface.]

B. Microscope Tables
L0090 – Table, Microscope, 1-2 Person
L0095 – Table, Microscope, Teaching, 3-5 Person

1. Work surface material and top must be epoxy resin or stainless steel. Surface top must be pressure, scratch, heat and chemical resistant.
2. Provide four leg supports with nonskid adjustable glides and rubber boots. Material must be sturdy [include corner braces option for extra support]. [Legs to include casters with locking brakes.]
3. Table design must be available in a variety of lengths and widths.
4. [Table must allow height and tilt/incline adjustments.]

C. Stainers
L8580 – Stainer, Slide, Automatic, Hematology
L8585 – Stainer, Slide, Batch, Histological
L8590 – Stainer, Immunostaining System

1. Display must be LCD high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. Twelve slide minimum capacity.
3. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
4. [Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission.]

D. Slide Printers
L8300 – Printer, Cassette Label, Laboratory
L8305 – Printer, Slide, Laboratory

1. Labels and ink must be durable, resistant to rubbing, impervious to liquids and able to withstand temperature variations.
2. Provide different printer label sizes to be selected based on intended use.

E. Miscellaneous Slide Equipment
L4360 – Warmer, Slide
L8307 – Scanner, Slide, Telepathology
L8570 – Cabinet, Microscope Slide
L8600 – Slide Cover, Automated

1. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

2.1.14 Hematology/Blood Bank
L1090 – Cell Washer, Frozen Blood Deglycerolizer
L1095 – Cell Saver, Autologous Blood Recovery

L1075 – Bath, Cryoprecipitate Thawing (+4 Deg C)
L1076 – Bath, Water, Plasma Thawing, Rapid
L1097 – Irradiator, Blood
L1110 – Pheresis Unit
L1112 – Welder, PVC Blood Tubing, Sterile Process
L1160 – Densitometer, Blood
L1170 – Viewer, Agglutination
L1180 – Dilutor, 1:25,000 Dilution
L2690 – Computer, Mean Cell Volume
L2691 – Hematocrit Accessory, Automatic
M1450 – Sealer, Electronic, Blood Bag

A. Display must be LCD high contrast with continuous display of measured parameters. Display must be readable in any ambient light level.
B. System must include sample management system.
C. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

2.1.15 Hoods/Biological Safety Cabinets

L2280 – Hood, Laminar Flow, Horizontal, Free Standing, 6ft
L2290 – Hood, Laminar Flow, Horizontal, Bench Top, 4ft

A. All surfaces that could come in contact with liquids or gasses must be corrosion resistant and easily cleanable. All glass within equipment must be tempered.
B. On-board lighting must be provided and deliver uniform foot-candles at the work area.
C. All vented air must pass through HEPA filtration before leaving equipment.
D. Hood must be mounted on adjustable leveling legs [casters] [base stand with toe kick].
E. Hood designs must be available in a variety of lengths and widths.
F. Provide an [automatic/manual] telescoping base stand to adjust the work surface height to accommodate technicians of various heights and promote proper ergonomics.

2.1.16 Microbiology Equipment

A. Microbial Identification
L2660 – Microbiological Identification System
L2665 – Microbiological Susceptibility/ID System

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. Unit must have continuous fill and flushing cycle**.**
4. Analyzer must have capability to connect to hospital electronic health record and/or laboratory information systems.
5. Provide hardware that includes internal memory of [500 GB] to store a minimum of [1000 patient] tests data.
6. [Provide a barcode reader and internal or external printer].
7. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission].

B. Media Dispensing Equipment
L3190 – Washer, Pipette, Automatic
L5610 – Pipettor, Micro, 3 Range
L5630 – Pipettor, 20-100 Micro Liter

1. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

2.1.17 Histology Equipment

A. Solvent Recovery/Recycling
L1945 – Distilling Apparatus, Xylene Recovery
L1946 – Recycling System, Formalin

1. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

2. Provide a spill containment and leak prevention design.
3. Systems must bring solvent types back to its original purity of 99.9%.
4. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]

B. Specimen Storage

L8575 – Cabinet, Paraffin Block

1. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

2.1.18 Incubators

L2550 – Incubator, Bacteriological
L2570 – Incubator, Bacteriological, Single
L2575 – Incubator, Platelet, Freestanding, w/Rotator
L3570 – Incubator, Bacteriological, Dry Block
L4215 – Incubator, Multipurpose, Dry Block
L8000 – Incubator, Anaerobic, Vacuum
L8005 – Incubator, Blood Bank, Tabletop
L8130 – Incubator, Bacteriological, 2 Compartment
L8150 – Incubator, Paraffin, +/- 10 Cubic Foot
L8155 – Incubator, Gel & Centrifuge Combination

A. Display must be LCD high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.

B. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All glass within equipment must be tempered.

C. [Temperature chart recorder must be included.]

D. [Incubators must have an external data connection for the monitoring of temperature from a remote location and the signaling of alarms.]

E. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]

2.1.19 Tissue Processing Equipment

A. Microtomes

L3400 – Microtome, Rotary, Tilt, Bench Mounted
L3430 – Microtome, Rotary, Tilt, Refrigerated

1. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
2. Display must be LCD high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
3. Section thickness settings must be in [1 micron] increments.
4. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]

B. Tissue Processors

L0160 – Tissue Processor, Vacuum
L3575 – Processor, Cell Block System
L3580 – Processor, Pap Smear Slide, Countertop
L3581 – Processor, Image, w/Server and Interface
L3582 – Processor, Pap Smear Slide, Automated
L9020 – Tissue Processor, Automatic, 2 Level
L9022 – Tissue Processor, Electron Microscopy

1. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
2. Display must be LCD high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
3. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]

C. Tissue Processing Support Equipment

L9000 – Embedder, Tissue
L9010 – Homogenizer, Tissue
L9015 – Sharpener, Blade, Microtome
L9025 – Freeze-Dryer, Tissue

L9026 – Cabinet, Tissue Storage, Ventilated

1. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
2. Display must be LCD high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
3. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]

2.1.20 Laboratory Information Management System

L1022 – Automation System, Laboratory

A. System must be able to interface with DoD approved electronic health record (EHR).

B. System must provide advanced security with single control point for multiple analyzers and provide for auto-verification.

2.1.21 Laboratory Pumps

L7200 – Dispenser, Reagent, Phenolic

L9030 – Pump, Vacuum, Laboratory Oven

L9740 – Pump, Embalming

A. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

B. Pumps must have anti-suck back mechanism and thermal overload protection.

C. Pumps must have explosion proof motor.

2.1.22 Miscellaneous

A. Water Treatment

L1950 – Demineralizer, Water, Floor Mounted,1/2-3 GPM

L2000 – Purification System, Water

1. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
2. Display must be LCD high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
3. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]

B. Air Purifiers

L2192 – Purifier, Air

1. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
2. Display must be LCD high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
3. Filter must be able to remove 99.97% of dust, pollen, mold, bacteria, and any airborne particles with a size of 0.3 microns.

C. Other Equipment

L1130 – Densitometer, Scanning

L2191 – Calibrator, Radioisotope

L5218 – Scale, Autopsy

L6000 – Detector, Mercury

L7400 – Burner, Safety, Bunsen

A. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

2.1.23 Fluid Measurement Devices

A. Turbidity Measurement

L7095 – Nephelometer, Fluorescence

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. Must have an accuracy of +/- 2% of reading plus 0.01 Nephelometric Turbidity Units (NTU).
3. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
4. [Hardware to include port for input and output data transmission using the manufacturers standard

software interface.]

B. Viscosity Measurement

L7500 – Viscometer

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. Must have an accuracy of +/- 1% of the measuring range.
4. Must have a repeatability of +/- 0.2%.
5. [Hardware to include port for input and output data transmission using the manufacturers standard software interface.]

C. Other Fluid Measurement Devices

L1100 – Meter, pH

L1182 – Refractometer

L1190 – Osmometer

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

2.1.24 Mixing and Blending Equipment

A. Shakers

L8500 – Shaker, Reciprocating

L8510 – Shaker, Platform, Frozen Blood Processing

L8520 – Shaker, Rotating, 12 Standard Tubes

L8540 – Shaker, Rotating, 15 Slides

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. Provide functions that allow for variation of the speed and duration of operation.
4. [Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission and data logging.]

B. Mixers

L7300 – Stirrer, Hot Plate, Magnetic

L7305 – Mixer, Vortex, Test Tube

L7330 – Rotator, Mixer

L7335 – Mixer, Blood Collection

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. Provide functions that allow for variation of the speed and duration of operation.
4. [Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission and data logging.]

2.1.25 Photometers

L1040 – Spectrometer, Infrared, Single Beam

L4080 – Photometer, Flame

L7050 – Spectrophotometer, Infrared, Two Beam

L7060 – Spectrometer, Atomic Absorption, Double Beam

L7070 – Spectrophotometer, Atomic Absorption

L7080 – Spectrophotometer, Atomic Absorption, Computerized

L7085 – Spectrophotometer, Fluorescence

L7090 – Spectrophotometer, UV/Vis, Basic

A. Display must be LCD high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.

B. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
D. Provide hardware that includes internal memory of [500 GB] to store a minimum of [1000 patient] tests data.
E. [Barcode reader accessory must be included.]
F. [Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission.]

2.1.26 Water Bath

L4200 – Bath, Water, Serology, Electric
L4205 – Bath, Water, Tissue Processing
L4210 – Bath, Water, Refrigerated, Circulating

A. Display must be LCD high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
B. Provide user programmable temperature settings with +-1 deg. C. accuracy unless noted otherwise.
C. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

3.1 SUBMITTALS

3.1.1 Submittals required for government review

A. Submittal requirements are outlined in [Division 01] [PWS SOW] [___]
B. [Product Information must include manufacturer's installation instructions, sizing (including required clearance for access and maintenance), utility requirements, isometric drawings, tagged floorplans showing placement for count accountability and accessories/options/consumables lists.]
C. All submittals require Government approval prior to procurement. Submit all listed items herein, with information sufficient to show full compliance with the criteria. Submit all product selections for review and approval, including but not limited to: materials, finishes, colors, options, accessories, and complimentary products. Provide for review all warranties and service contracts and any available extended warranty or service options.
D. Samples: Furnish material samples and full range of color selection options for all items that offer material and color selections.
E. Submit and highlight all applicable options for Government review for all items which optional accessories are provided.
F. [Joint Interoperability Test Command (JTIC) Approval Documentation.]

3.2 QUALITY ASSURANCE

3.2.1 Materials and Equipment

A. Materials and equipment must be standard products of a manufacturer regularly engaged in the manufacture of products which are of a similar material, design, and workmanship and are offered for sale on the commercial market through advertisements, manufacturer's catalogs, or sales brochures. The products must have been in commercial or industrial use under similar circumstances and of similar size for 2 years prior to selection for approval/procurement. Products must be supportable for at least three years after government acceptance.

3.2.2 Alternative Service Record

A. Products having less than a 2-year field service record will be acceptable if a certified record of the manufacturer's factory or laboratory tests demonstrating performance compliance is provided to the Contracting Officer.

3.2.3 Service Support

A. Equipment items must be supported by service organizations located near the equipment installation, able to service the equipment on a regular basis and respond to emergency calls throughout the warranty period.

3.2.4 Manufacturer's Nameplate

A. Each item of equipment must have an attached nameplate that is securely affixed in a conspicuous space. A nameplate listing only the name of the distributing agent is not acceptable. The nameplate must contain the following fields in English:

1. Manufacturer's name and address

2. Model and Serial Number
3. Item's utility ranges and/or capacities
4. Voltage, amperage, and applicable Underwriters Laboratory (UL) or Conformitè Europëenne (CE) rating if electrically powered
5. Date of manufacture

3.2.5 Factory Inspection

A. Arrange and perform all quality control and quality assurance inspections required by the technical sections of the criteria, unless otherwise specified. Report these inspections in the daily report to the Government inspector.

3.2.6 Product Qualifications

A. The products specified in the technical sections of this criteria establish standards for each item.

3.2.7 Design Parameters

A. It is not the intention of this Criteria to limit consideration to products of specific manufacturers. The product standards establish the characteristics for which submitted items of equipment will be reviewed and approved by the Government. Equipment furnished must meet each of the following parameters specified in the technical sections:

1. Size of equipment
2. Function of equipment
3. Standard and listed accessories and options
4. Equipment controls and performance of equipment
5. Construction of equipment
6. Finish

3.3 STANDARDS DEVIATIONS

3.3.1 Reporting and Submission for Approval

A. Submit for approval a record of deviations from the standards listed in section (3.2.7.A.) established for each specified product, before ordering equipment.

3.4 DELIVERY, STORAGE AND PROTECTION

3.4.1 Packaging and Transporting

A. Each unit of equipment must be placed in a substantial shipping container or crate for safe transportation to final destination. The shipping container or crate for heavy equipment must be on skid construction to facilitate handling by lift equipment.

3.4.2 Packing List

A. Clearly and legibly indicate on exterior of each container or crate the shipping address and a brief description of contents. Fasten to outside of container a packing list and complete instructions for uncrating equipment and setting it in place. Protect such information in a weatherproof envelope.

3.4.3 Protection

A. Properly protect all materials and equipment from injury and damage during storage, installation, and acceptance.

3.5 INSTALLATION, VERIFICATION AND ACCEPTANCE TESTING

3.5.1 Qualifications of Installers and Inspectors

A. If required by product warranty, use installers that are approved and licensed by the manufacturer. When required to complete installation, all electricians and plumbers used must be bonded and licensed in the project's jurisdiction.

B. [Company specializing in installing the products specified in this section must have a minimum 5 years of documented experience.]

C. [Company specializing in installing the products specified in this section must be within 200 miles or 4 hours travel time.]

3.5.2 Installation, Operation, Testing and Certification

A. Products must be delivered in manufacturer's original packaging with manufacturer's installation instructions. Include clearly marked project reference.

B. Prior to installation, thoroughly examine the equipment, materials, and components for both visual defects and conformance with criteria.

C. Install all equipment in compliance with manufacturer's written instructions and installation procedures.

D. After installation, the equipment must be inspected and tested under operating conditions. If the equipment fails an inspection or test, such defects/failures must be corrected. Upon correction of defects/failures, inspect and retest all affected functions related directly and indirectly to the defect or failure. Corrections, replacement, and retesting must be made at no additional expense to the Government.

E. Provide all items necessary to make equipment fully functional.

F. Provide appropriately trained personnel to energize, commission, inspect, electrical safety check, calibrate, certify, and provide all required technical testing for equipment and systems. Contractor must provide documentation, test reports and certification documentation attesting that the equipment is properly installed, functional, safe, calibrated, and ready for its intended use.

G. An equipment item will be considered defective if it cannot be made to meet all established criteria consistent with the activities listed in section (F).

H. Provide two sets of special tools, software, and any other item/s for each equipment [item] [item type] if required for maintenance and/or future reconfiguration of the item.

I. Contractor to supply all start-up supplies for medical equipment for a fully operational installation. Contractor must supply to the Government a listing of all needed supplies for ongoing equipment operation for each item of equipment requiring additional supplies for operation.

J. Engage a factory-authorized service representative to train Government's staff and maintenance personnel to adjust, operate, and maintain medical equipment.

K. [Confirm functionality of required interfaces to other systems and networks.]

3.6 WARRANTY

3.6.1 Minimum Requirements

A. Warranty requirements are outlined in [Division 01] [PWS SOW] [___].

B. [Provide manufacturer's written warranty for all items listed. Provide warranty for a minimum of (1) year against defects in materials and workmanship. Warranty must provide for material, labor and all associated replacement and/or repair costs required to provide for a fully operational equipment replacement or repair. Submit manufacturers and installers standard service contract beyond the warranty period for Government review. Warranty must be transferrable to the final owner without risk of being voided. All warranty certification and documentation must be provided to the final owner after date of acceptance.]

C. Provide routine warranty service in accordance with manufacturer's warranty requirements, for a period of [12 months (minimum)] [___] after the open for business date. Perform work during regular working hours. Perform service only by factory trained personnel. Maintain a maintenance log of all service orders performed during the warranty period.

3.7 OPERATIONS AND MAINTENANCE (O & M)

3.7.1 Provide the following to the final owner

A. Provide O & M data for all FFE-LVS as outlined in [Division 01] [PWS SOW] [___].

B. Upon completion of equipment installation, furnish [two (2)] copies of operators/service/maintenance manuals for each type of equipment which will require service or maintenance

C. Each manual must contain operating instructions and information required for performing periodic maintenance on the equipment. Each service manual must include an illustrated parts breakdown which identifies each part of the unit with manufacturer's part number, wiring diagrams, and a list of necessary service parts, tools, and equipment needed to support maintenance requirements.

D. Accessory Catalogs: Upon completion of the Project, furnish two copies of the manufacturer's catalogs containing optional accessory items available for all equipment relative to the procured equipment/system delivered herein.

E. Provide instruction video for cleaning and maintenance, when available.

F. Provide cleaning requirements for all items to prevent void of warranty.

G. [Provide contact information for Repair Technician or Emergency Repair Company]

H. Provide contact information to [Logistics, Pharmacy, Laboratory, and Biomedical Equipment Services.]

I. Train designated staff in the operation and maintenance of the provided equipment/system. Provide two training sessions for equipment/system users and two training sessions for maintenance personnel scheduled to accommodate shift work. [Provide training certificates that can be executed up to eleven months after the system is installed, in order to provide a refresher course for each group of trainees.] Provide DVD copy of the training with the O & M data.

--End of Section--